

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

**Amendment No. 1
To
Form 10**

**GENERAL FORM FOR REGISTRATION OF SECURITIES
Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934**

Aptevo Therapeutics Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

81-1567056
(I.R.S. employer
Identification number)

2401 4th Avenue, Suite 1050
Seattle, Washington
(Address of principal executive offices)

98121
(Zip Code)

(206) 838-0500
(Registrant's telephone number, including area code)

Securities to be registered pursuant to Section 12(b) of the Act:

**Title of Each Class
to be so Registered**
Common Stock, par value \$0.001 per share

**Name of Each Exchange on which
Each Class is to be Registered**
The NASDAQ Stock Market LLC

Securities to be registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

**INFORMATION REQUIRED IN REGISTRATION STATEMENT
CROSS-REFERENCE SHEET BETWEEN INFORMATION STATEMENT
AND ITEMS OF FORM 10**

Certain information required to be included herein is incorporated by reference to specifically identified portions of the body of the information statement filed herewith as Exhibit 99. None of the information contained in the information statement shall be incorporated by reference herein or deemed to be a part hereof unless such information is specifically incorporated by reference.

Item 1. Business.

The information required by this item is contained under the sections of the information statement entitled “Information Statement Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business,” “Certain Relationships and Related Party Transactions,” and “Where You Can Find More Information.” Those sections are incorporated herein by reference.

Item 1A. Risk Factors.

The information required by this item is contained under the section of the information statement entitled “Risk Factors.” That section is incorporated herein by reference.

Item 2. Financial Information.

The information required by this item is contained under the sections of the information statement entitled “Capitalization,” “Unaudited Pro Forma Combined Balance Sheet,” “Selected Historical Combined Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Index to Financial Statements” and the financial statements referenced therein. Those sections are incorporated herein by reference.

Item 3. Properties.

The information required by this item is contained under the section of the information statement entitled “Business—Properties.” That section is incorporated herein by reference.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

The information required by this item is contained under the section of the information statement entitled “Security Ownership of Certain Beneficial Owners and Management.” That section is incorporated herein by reference.

Item 5. Directors and Executive Officers.

The information required by this item is contained under the section of the information statement entitled “Management.” That section is incorporated herein by reference.

Item 6. Executive Compensation.

The information required by this item is contained under the sections of the information statement entitled “Compensation Discussion and Analysis” and “Executive Compensation.” Those sections are incorporated herein by reference.

Item 7. *Certain Relationships and Related Transactions.*

The information required by this item is contained under the sections of the information statement entitled “Management” and “Certain Relationships and Related Party Transactions.” Those sections are incorporated herein by reference.

Item 8. *Legal Proceedings.*

The information required by this item is contained under the section of the information statement entitled “Business—Legal Proceedings.” That section is incorporated herein by reference.

Item 9. *Market Price of, and Dividends on, the Registrant’s Common Equity and Related Stockholder Matters.*

The information required by this item is contained under the sections of the information statement entitled “Dividend Policy,” “Capitalization,” “The Separation and Distribution,” and “Description of Aptevo’s Capital Stock.” Those sections are incorporated herein by reference.

Item 10. *Recent Sales of Unregistered Securities.*

The information required by this item is contained under the section of the information statement entitled “Description of Aptevo’s Capital Stock—Sale of Unregistered Securities.” That section is incorporated herein by reference.

Item 11. *Description of Registrant’s Securities to be Registered.*

The information required by this item is contained under the sections of the information statement entitled “Dividend Policy,” “The Separation and Distribution,” and “Description of Aptevo’s Capital Stock.” Those sections are incorporated herein by reference.

Item 12. *Indemnification of Directors and Officers.*

The information required by this item is contained under the section of the information statement entitled “Description of Aptevo’s Capital Stock—Limitation of Liability and Indemnification of Officers and Directors.” That section is incorporated herein by reference.

Item 13. *Financial Statements and Supplementary Data.*

The information required by this item is contained under the section of the information statement entitled “Index to Financial Statements” and the financial statements referenced therein. That section is incorporated herein by reference.

Item 14. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.*

None.

Item 15. *Financial Statements and Exhibits.*

(a) *Financial Statements*

The information required by this item is contained under the sections of the information statement entitled “Unaudited Pro Forma Combined Balance Sheet” and “Index to Financial Statements” and the financial statements referenced therein. Those sections are incorporated herein by reference.

(b) Exhibits

See below.

<u>Exhibit Number</u>	<u>Exhibit Description</u>
2**	Form of Separation and Distribution Agreement by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc. (schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The company hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the Securities and Exchange Commission.)
3.1**	Form of Restated Certificate of Incorporation of Aptevo Therapeutics Inc.
3.2**	Form of Amended and Restated By-Laws of Aptevo Therapeutics Inc.
4***	Form of Registration Rights Agreement by and among Aptevo Therapeutics Inc. and the stockholders parties thereto
10.1***	Form of Transition Services Agreement by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.
10.2**	Form of Tax Matters Agreement by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.
10.3***	Form of Employee Matters Agreement by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.
10.4***	Form of Manufacturing Services Agreement by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.
10.5***	Form of Canadian Wholesaler Agreement by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.
10.6**	Form of Trademark License Agreement by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.
10.7**	Form of Product License Agreement by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.
10.8*	Form of Promissory Note made by Emergent BioSolutions Inc. in favor of Aptevo Therapeutics Inc.
C 10.9**	Form of Indemnity Agreement for directors and senior officers
C 10.10***	Form of Aptevo Therapeutics Inc. 2016 Stock Incentive Plan
C 10.11***	Form of Aptevo Therapeutics Inc. Senior Management Severance Plan
10.12**	Fourth and Battery Office Lease, dated as of April 28, 2003, by and between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc. and Genecraft, Inc.) and Selig Real Estate Holdings Eight L.L.C. (the "Seattle Office Lease")
10.13**	Seattle Office Lease Amendment, dated December 8, 2004
10.14**	Seattle Office Lease Amendment, dated February 1, 2006
10.15**	Seattle Office Lease Amendment, dated February 2, 2007
10.16**	Seattle Office Lease Amendment, dated June 7, 2010
10.17**	Seattle Office Lease Amendment, dated December 21, 2010
10.18**	Seattle Office Lease Amendment, dated July 17, 2012
10.19**	Seventh Amendment to Seattle Office Lease, dated December 5, 2014

10.20†**	License and Co-Development Agreement, dated as of August 19, 2014, by and between Emergent Product Development Seattle, LLC and MorphoSys AG (the “MorphoSys Collaboration Agreement”)
10.21†**	First Amendment to MorphoSys Collaboration Agreement, dated June 19, 2015
10.22†**	Second Amendment to MorphoSys Collaboration Agreement, dated December 7, 2015
10.23†**	Amended and Restated License Agreement, dated as of November 28, 2008, by and between Cangene Corporation (as successor-in-interest to Inspiration Biopharmaceuticals, Inc.) and The University of North Carolina at Chapel Hill, as amended on June 14, 2012
10.24†*	CMC Commercial Supply (Manufacturing Services) Agreement, dated June 17, 2011, between CMC ICOS Biologics, Inc. and Aptevo BioTherapeutics LLC (as successor-in-interest to Inspiration Biopharmaceuticals, Inc.)
10.25†*	Settlement and Amendment, dated November 20, 2012, Concerning a Manufacturing Agreement dated December 2, 2005 and a Commercial Supply Agreement dated June 20, 2011 between CMC ICOS Biologics, Inc. and Aptevo BioTherapeutics LLC (as successor-in-interest to Inspiration Biopharmaceuticals, Inc.)
10.26†*	Supply Agreement, dated April 29, 2014, between Aptevo BioTherapeutics LLC and Rovi Contract Manufacturing, S.L.
10.27†*	Manufacturing Services Agreement, dated May 27, 2015, Aptevo BioTherapeutics LLC and Patheon UK Limited
21***	Subsidiaries of Aptevo Therapeutics Inc.
99*	Information Statement of Aptevo Therapeutics Inc., preliminary and subject to completion, dated May 31, 2016

* Filed herewith.

** Previously Filed.

*** To be filed by amendment.

C Management contract or compensatory plan or arrangement.

† Confidential treatment requested from the Securities and Exchange Commission as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to Registration Statement on Form 10 to be signed on its behalf by the undersigned, thereunto duly authorized.

APTEVO THERAPEUTICS INC.

By: /s/ Robert G. Kramer

Name: Robert G. Kramer

Title: President

Date: May 31, 2016

NON-NEGOTIABLE PROMISSORY NOTE

[•], 2016

\$20,000,000

Rockville, Maryland

FOR VALUE RECEIVED, Emergent BioSolutions Inc., a Delaware corporation (“Maker”), promises to pay to Aptevo Therapeutics Inc., a Delaware corporation (“Holder”), by wire transfer of immediately available funds to an account designated in writing by Holder at least two Business Days prior to the Payment Date (as defined below), the principal sum of \$20,000,000, payable on the Payment Date. “Payment Date” means a date specified in a written notice delivered by Holder to Maker that is (a) at least 60 days after the date of delivery of such written notice and (b) between the date that is six (6) months after the Distribution Date and the first (1st) anniversary of the Distribution Date. Capitalized terms used herein and not otherwise defined herein shall have the respective meanings ascribed to such terms in the Separation Agreement (as defined below).

No interest shall accrue on this Note.

This Note shall become immediately due and payable without notice or demand upon the occurrence at any time of any of the following events of default (individually, “an Event of Default” and collectively, “Events of Default”):

- (1) default in the payment when due of any amounts owing under this Note which default continues for a period of three (3) Business Days;
- (2) the liquidation or dissolution of Maker;
- (3) the institution against Maker of any proceedings under the United States Bankruptcy Code or any other federal or state bankruptcy, reorganization, receivership, insolvency or other similar law affecting the rights of creditors generally, which proceeding is not dismissed within 90 days of filing; or
- (4) the institution by Maker of any proceedings under the United States Bankruptcy Code or any other federal or state bankruptcy, reorganization, receivership, insolvency or other similar law affecting the rights of creditors generally or the making by Maker of a composition or an assignment or trust mortgage for the benefit of creditors.

This Note may be prepaid in whole or in part at any time or from time to time. Any such prepayment shall be without premium or penalty.

The provisions of Article VIII and Article XI (except Section 11.3) of the Separation and Distribution Agreement entered into or to be entered into between Maker and Holder (the “Separation Agreement”) are incorporated herein by this reference, as if set forth in full herein, *mutatis mutandis*. This Note constitutes an Ancillary Agreement, and the remedies expressly set forth in the Separation Agreement shall be the sole and exclusive remedies of the parties with respect to this Note. If the Distribution Date does not occur by December 31, 2016, this Note shall be null and void *ab initio*.

Holder may not assign or transfer this Note (or any interest herein). Subject to the preceding sentence, this Note will be binding upon and inure to the benefit of the parties hereto and their respective successors.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have executed this Note as of the date first written above.

EMERGENT BIOSOLUTIONS INC., as Maker

By: _____
Name:
Title:

APTEVO THERAPEUTICS INC., as Holder

By: _____
Name:
Title:

[Signature Page to Promissory Note]



Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

CONFIDENTIAL

**COMMERCIAL SUPPLY
(MANUFACTURING SERVICES) AGREEMENT**

BETWEEN

CMC ICOS Biologics, Inc. and

Inspiration Biopharmaceuticals, Inc.

EXECUTION COPY

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THIS AGREEMENT is made as of June 17 2011 (“**Effective Date**”)

BETWEEN

- (1) **CMC ICOS BIOLOGICS, INC.**, duly incorporated under the laws of the State of Washington and having its principal place of business at 22021 20th Avenue SE, Bothell, WA, 98021, United States of America (hereinafter referred to as “**CMC**”); and,
- (2) **INSPIRATION BIOPHARMACEUTICALS, INC.**, duly incorporated under the laws of the State of Delaware and having its principal place of business at 28202 Cabot Road, Suite 300, Laguna Niguel, CA 92677 (hereinafter referred to as “**Customer**”).
- CMC and Customer may each be referred to herein as a “**Party**” and collectively as the “**Parties**.”

RECITALS

- (A) Customer is engaged in the discovery and development of new pharmaceutical candidates, including recombinant factor IX product as described in BB-IND 13551 (known as “**IB-1001**”) and factor VIIa product for hemophilia A and other bleeding disorders (the “**IB-1007**”);
- (B) CMC and Customer have previously worked together in the development and manufacture (for clinical evaluation) of IB-1001 which is anticipated shortly to be approved by the Regulatory Authorities;
- (C) In addition to development and scale-up activities CMC also provides commercial manufacturing activities for biological products to pharmaceutical and biotechnology companies;
- (D) Customer has discussed certain areas of interest with CMC and is familiar with CMC’s facilities and expertise and, as a result, wishes to retain CMC to provide certain services associated with development and validation of manufacturing Processes and use of such processes to manufacture and/or supply certain quantities of IB-1001 and CMC is willing to so perform, subject to the terms of this Agreement;
- (E) The Parties have entered into a Letter of Agreement (as defined below) pursuant to which, among other things, the Parties agreed to use best efforts to negotiate in good faith and execute this Agreement by April 15, 2011;
- (F) Customer exercised its option under the non-exclusive license agreement dated 29 November 2005 (the “**Clinical License Agreement**”) to obtain a non-exclusive, worldwide, sublicenseable license within the Field (as defined in the Clinical License Agreement) to the Patent Rights (as defined in the Clinical License Agreement) in accordance with the terms and conditions set forth in the Clinical License Agreement (as amended, the “**Existing License Agreement**”);

- (G) Customer wishes to contract with CMC for the provision of the commercial supply of Product as more clearly defined by the Services (as defined below); and
- (H) CMC is willing to provide the Services to the Customer on the terms and conditions set out in this Agreement in exchange for the Price plus any Additional Charges, which the Customer agrees to pay.

NOW THEREFORE, THE PARTIES AGREE as follows:

1. **DEFINITIONS AND INTERPRETATION**

- “Act”** the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 et seq.) and related U.S. regulations including 21 Code of Federal Regulations (Chapters 210 and 211 and 610), as amended from time to time;
- “Additional Charges”** means those additional costs and charges agreed by the Parties in writing or, in default of agreement as otherwise determined pursuant to clause 7.5 of this Agreement to be payable by Customer in addition to the Price in respect of any part of the Services from time to time;
- “Additional Country”** means any one of Canada, Brazil, Russia, India, China, Poland, Israel, Taiwan, Australia, Turkey, Argentina, Mexico, Switzerland, South Korea, Thailand, Sweden and South Africa and **“Additional Countries”** means all of the foregoing;
- “Additional Order”** has the meaning set out in **Clause 5.9**;
- “Additional Term”** has the meaning set out in **Clause 14.1**;
- “Affiliate”** any company, partnership or other entity which directly or indirectly through one or more intermediaries controls or is controlled by, or is under common control with the applicable party, company, partnership, person or entity. For the purpose of this definition control means the direct or indirect beneficial ownership of more than 50% of the voting share capital in such company, partnership or entity or the legal power to control the general management and policies of such party, company, partnership, person or entity;
- “Agreement”** this Agreement including all Appendices and any amendments to the foregoing made in accordance with this Agreement;
- “Alternative Site”** has the meaning set out in **Clause 6.10**;

“Allowed Adjustment”	has the meaning set out in Clause 5.7.2 ;
“Appendix” or “Appendices”	one or more of the Appendices to this Agreement;
“Applicable Laws”	any law, statute, ordinance, regulation, judgment, order, injunction, decree, declaration, license, permit or rule of (i) the United States of America, (ii) the European Union (including all member countries) and (iii) any other country which, pursuant to Clause 2.6, the Parties agree this Agreement shall cover, and in each case to which any Party is subject, including without limitation the Act;
“Auditors”	has the meaning set out in Clause 8.3 ;
“Authority Submission”	has the meaning set out in Clause 8.8 ;
“Batch”	one fermentation run using the Cell Line at 3000L (being approximately 2400L working volume) fermenter scale, and such purification, analytical and further processing steps applicable to the Drug Substance harvested from that run according to the approved Process and cGMP documentation;
“Batch Price”	the price payable for each Batch as initially described in Appendix Three and as may be amended by agreement between the Parties or by operation of Clause 7 ;
“Business Day”	any day which is not a Saturday, a Sunday or a U.S. public holiday;
“Calendar Quarter”	the three calendar month periods commencing 1 January, 1 April, 1 July and 1 October;
“Cell Line”	the mammalian cell line described in Appendix One which is currently held by CMC or derived from a master cell bank of the same strain as that held by CMC and any progeny clone of the foregoing cell line(s);
“Certificate of Analysis”	CMC’s standard form certificate of analysis confirming that Product to which the certificate relates meets the Specification and such other criteria as identified on the certificate;
“Clinical License Agreement”	has the meaning set out in the Recitals above;

“current Good Manufacturing Practice” or “cGMP”	current Good Manufacturing Practices as promulgated under each of the following as in effect on the Effective Date and as amended or revised after the Effective Date: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 et seq.) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210 and 211, 600 and 610) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; (b) Eudralex Volume 4, Medicinal Product for Human and Veterinary Use: Good Manufacturing Practice and (c) the ICH guide Q7a “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients” as applied to investigational drugs (Section 19); (d) all additional U. S. Regulatory Authority documents that replace, amend, modify, supplant or complement any of the foregoing; and (e) any national regulatory cGMP or agency requirements applicable to any Additional Country which, pursuant to Clause 2.6, the Parties agree this Agreement shall cover;
“Commercially Reasonable Endeavours” or “CRE”	the application of efforts and resources (including those in relation to timely performance) that would be typically and ordinarily expended, in accordance with generally accepted biological manufacturing industry standards, by a prudent and experienced biological contract manufacturing services company of a size and experience equal to, and having similar financial resources to that of CMC, and having regard to the same or similar Services to be provided hereunder, the profit earned under this Agreement and the strategic value of the Agreement to the business of CMC;
“Competitor Change of Control Event”	has the meaning set out in Clause 14.5 ;
“CHEF1 Property”	has the meaning set out in Clause 11.2 ;
“CHEF1 Technology”	the Chinese Hamster EF-1 alpha regulatory DNA (“CHEF1”) as further described in US Patent Number 5,888,809 and the technology described in US Patent Number 5,888,809;
“CMC”	has the meaning set out in the preamble above;
“CMC Facility”	CMC’s then current facility at Bothell, Washington, United States of America;

“CMC Intellectual Property Rights”	Intellectual Property rights and CMC Know-How (excluding CHEF1 Technology) owned by or licensed to (and freely sub-licenseable by) CMC and used in the performance of the Services;
“CMC IPR”	has the meaning set out in Clause 11.6 ;
“CMC Know-How”	all information, techniques and technical information known to CMC or developed during the Services (excluding the CHEF1 Technology or improvements thereto) which is not Customer Know-How or of general public knowledge;
“CMC Manufacturing Failure”	has the meaning set out in Clause 13.3 ;
“CMC Parties”	has the meaning set out in Clause 12.1 ;
“Commercial Quality Agreement” (QAg)	the agreement between the Parties defining the quality responsibilities, including cGMP standards, regarding the performance of the Services;
“Committee Member”	has the meaning set out in Clause 4.10 ;
“Confidential Information”	any business or technical information, trade secrets, know-how, techniques, data, proposals, capacity, pricing or other information of a confidential nature and in any form (oral, written or otherwise) the use of which is governed according to the provisions of Clause 10 ;
“Customer”	has the meaning set out in the preamble above;
“Customer Audit”	has the meaning set out in Clause 8.1 ;
“Customer Failure”	has the meaning set out in Clause 13.3 ;
“Customer Intellectual Property Rights”	Intellectual Property rights and Customer Know-How owned by Customer or licensed to Customer by a third party covering any aspect of the Services or materials, techniques or processes used in the Services;
“Customer IPR”	has the meaning set out in Clause 11.5 ;

“Customer Know- How”	all information, techniques and technical information known to Customer as of the Effective Date or developed by Customer pursuant to the Services in connection with the Cell Line, Customer Materials or Process which is not known to CMC or of general public knowledge;
“Customer Materials”	the Cell Line, vectors, plasmids and all other materials supplied by Customer, its Affiliate or agent to CMC or made available to CMC by Customer including, without limitation, those described in Appendix One;
“Customer Parties”	has the meaning set out in Clause 12.2 ;
“Defaulting Party”	has the meaning set out in Clause 14.2 ;
“Deliverables”	for each Batch undertaken for the purpose of commercial supply, the Drug History Record and Product relevant to and derived from that Batch
“Delivery” or “Delivered”	has the meaning set out in Clause 6.3 ;
“Defect” or “Defective”	has the meaning set out in Clause 6.12 ;
“Defect Notice”	has the meaning set out in Clause 6.12 ;
“Disclosing Party”	has the meaning set out in Clause 10.1 ;
“Dispute”	has the meaning set out in Clause 17.2 ;
“Disputed Deliverable”	has the meaning set out in Clause 6.17 ;
“Dispute Notice”	has the meaning set out in Clause 17.2 ;
“Drug History Record”	all lot disposition documentation relevant to a Batch to be provided to Customer with the Product from that Batch, including but not limited to a Certificate of Analysis;
“Drug Substance”	the active pharmaceutical ingredient of IB-1001 described or classified in Appendix One expressed by the Cell Line and harvested in bulk from a fermentation run pursuant to the applicable Process;

“Effective Date”	has the meaning set out in the preamble above;
“EMA”	the European Medicines Agency;
“Existing License Agreement”	has the meaning set out in the Recitals above;
“FDA”	means the United States Food and Drug Administration, or its successor agency;
“Firm Order”	has the meaning set out in Clause 5.3.1 ;
“First Payment”	means the sum of [**] Dollars paid to CMC on 18 August 2010;
“First Priority Basis”	means at each issuance of Customer’s rolling Forecast, CMC will schedule capacity in the Line 1 Suite and Line 2 Expansion for new capacity requested by any third party received after the Forecast only after having first scheduled the maximum capacity allowable to Customer subject to the provisions of Clause 5.7 and the then current Forecast subject to the Maximum Values;
“FIX Product”	means the native FIX protein or a recombinant FIX protein, including, but not limited to truncated, conjugated, pegylated and fused protein forms, in each case when such forms have at least 50% homology with the native FIX protein as part of their primary amino acid structure;
“Force Majeure Event”	has the meaning set out in Clause 16.1 ;
“Forecast”	has the meaning set out in Clause 5.1 ;
“Fund”	has the meaning set out in Clause 7.2 ;
“Fund Payment”	has the meaning set out in Clause 7.2 ;
“Group”	in respect of the relevant Party, its Affiliates and holding companies and the Affiliates of those holding companies;
“IB-1001”	has the meaning set out in the Recitals above;
“Indemnitee”	has the meaning set out in Clause 12.3 ;
“Indemnitor”	has the meaning set out in Clause 12.3.1 ;

“Initial Term”	has the meaning set out in Clause 14.1 ;
“Intellectual Property”	all intellectual property rights, including (without limitation) patents, supplementary protection certificates, petty patents, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know-how, techniques and confidential information and other proprietary knowledge and information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the World, in each case for their full term and together with any renewals or extensions;
“Joint Steering Committee”	has the meaning set out in Clause 4.10 ;
“Letter of Agreement”	the Binding Term Sheet executed by CMC and Customer dated 18 August 2010, as amended from time to time;
“Line 1 Suite”	CMC’s 3,000 litre manufacturing capacity at Bothell as of the Effective Date excluding the Line 2 Expansion;
“Line 2 Expansion”	the expansion of CMC’s manufacturing capacity at the CMC Facility to incorporate a further 3,000 litre manufacturing suite;
“Manifest Error”	means an error in assessment or judgment that is clear or obvious to a reasonable person skilled in the relevant subject matter;
“Material Change”	has the meaning set out in Clause 4.6 ;
“Maximum Values”	the number of Batches defined in Clause 5.5 (to be pro-rated quarterly for the first Year);
“Milestone Event”	Individually each event defined in Appendix Two as a milestone and collectively all the milestones defined in Appendix Two;
“Milestone Payment”	the sum defined in Appendix Two that is payable upon the achievement of the corresponding Milestone as set out in Appendix Two,
“Minimum Values”	the number of Batches defined in Clause 5.6 (to be pro rated quarterly for the first Year);

“Non-Defaulting Party”	has the meaning set out in Clause 14.2 ;
“Non-Fault Delays”	has the meaning set out in Clause 4.1 ;
“Parent”	has meaning set out in Clause 19.13 ;
“Party” or “Parties”	has the meaning set out in the preamble above;
“Permitted Recipients”	the directors, officers, employees, Testing Laboratories or professional advisers who are required, on a strict need to know basis, in the course of their duties to receive and consider the Confidential Information for the purpose of enabling the relevant Party to perform its obligations under this Agreement provided that such persons are under obligations of confidence no less onerous than those set out in Clause 10 imposed on the recipient party;
“PIP”	has the meaning set out in Clause 8.5 ;
“Pre-Existing IPR”	has the meaning set out in Clause 11.1 ;
“Process”	the method for manufacture, harvesting and purification of the Product;
“Product”	the Drug Substance derived from a Batch;
“Project Manager”	has the meaning set out in Clause 4.10 ;
“Project Team”	those Representatives of both Parties responsible for the day to day performance of the Services as set out in Clause 4.11 ;
“Purchase Order”	has the meaning set out in Clause 5.10 ;
“Raw Materials”	media, resins, catalysts, raw materials, solvents, filters, membranes, disposable analytical test kits, disposable bags, and other items consumed as well as any subcontracted analytical testing performed by Testing Laboratories during the performance of the Services;
“Recall”	any action to withdraw from supply or distribution or to recover title to or possession of quantities of Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market or correction) or the detention or destruction of any Product by any Regulatory Authorities;

“Recipient Party”	has the meaning set out in Clause 10.1 ;
“Regulatory Authority”	any governmental entity having jurisdiction in the USA or the European Union (or any Additional Country which, pursuant to Clause 2.6, the Parties agree this Agreement shall cover) including, without limitation, the FDA and the EMA, that is responsible for issuing approvals, licenses, registrations or authorizations necessary for the manufacture, use, storage, import, transport or sale of Product in such country;
“Regulatory Inspection”	has the meaning set out in Clause 8.6 ;
“Regulatory Obligations”	those mandatory regulatory requirements applicable in the European Union, the United States and any Additional Country which, pursuant to Clause 2.6, the Parties agree this Agreement shall cover, to the manufacture of Product for human use that is intended for commercial supply;
“Release For Further Processing”	has the meaning set out in Clause 6.6 ;
“Representatives”	has the meaning set out in Clause 4.11 ;
“Semi-Binding Order”	has the meaning set out in Clause 5.3.2 ;
“Services”	the manufacture of Batch(es) of Product that are the subject of a Firm Order in accordance with the terms of this Agreement and those additional services to be performed hereunder in exchange for Additional Charges;
“Shipping Company”	has the meaning set out in Clause 6.8 ;
“Shipping Guidelines”	storage and transport guidelines issued by CMC in relation to the Product;
“Slot”	in respect of CMC’s cGMP manufacturing suite the period of time the suite is reserved in preparation for and the performance of a Batch;
“Specification”	the specification for the Product as defined in cGMP documentation QST-F90A02-06 or as may otherwise be agreed between the Parties or modified in accordance with Clause 4.8 which includes

(i) specifications for Drug Substance and Raw Materials, (ii) manufacturing, testing and packaging instructions and specifications for Product, (iii) storage and shipping requirements, and (iv) any other technical information necessary to manufacture a Batch;

“Standard”	has the meaning described in Clause 2.3 ;
“Standard Operating Procedures” or “SOPs”	the standard operating procedures of CMC in place from time to time which define CMC’s methods of performing activities applicable to the Services;
“Supply Failure”	has the meaning set out in Clause 5.17 ;
“Technology Transfer”	has the meaning set out in Clause 15.1 ;
“Term”	the Initial Term (as defined in Clause 14.1) and any Additional Terms (as defined in Clause 14.1)
“Testing Laboratories”	any third party instructed by CMC to carry out tests on the Cell Line, Customer Materials, Drug Substance and/or Product pursuant to the performance of the Services;
“Third Party CMO”	has the meaning set out in Clause 5.17.2 ;
“Timeline”	the timeline for the manufacture of and preferred delivery dates for each Batch of Product that is the subject of a Firm Order;
“Year”	the period commencing with the Effective Date until 31 December of that same calendar year and thereafter the 12 calendar month period commencing on 1 January.

1.1 For the purposes of this Agreement, the terms defined in this **Clause 1.1** shall have the respective meanings set forth below:

1.2 In this Agreement (except where the context otherwise requires):

1.2.1 any reference to a recital, clause or appendix is to the relevant recital, clause or appendix of or to this Agreement and any reference to a sub-clause or paragraph is to the relevant sub-clause or paragraph of the clause or appendix in which it appears;

- 1.2.2 the table of contents and clause headings are included for convenience only and shall not affect the interpretation of this Agreement;
- 1.2.3 use of the singular includes the plural and vice versa and use of any gender includes the other genders;
- 1.2.4 any reference to “persons” includes natural persons, firms, partnerships, companies, corporations, associations, organizations, governments, states, governmental or state agencies, foundations and trusts (in each case whether or not having separate legal personality and irrespective of the jurisdiction in or under the law of which it was incorporated or exists);
- 1.2.5 a reference to a “Party” is a reference to a party to this Agreement and a reference to a “Party” includes a reference to that Party’s successors in title, permitted assignees and transferees (if any) and in the case of an individual, to his or her estate and personal representatives;
- 1.2.6 a reference to “writing” does not include email;
- 1.2.7 any phrase introduced by the terms “including”, “include”, “in particular” or an similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

- 1.3 The Appendices form an integral part of this Agreement shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the Appendices.
- 1.4 Where there is any inconsistency between the Appendices and the main body of this Agreement, the conflicting terms of the main body of this Agreement shall, unless expressly specified to the contrary, prevail.

2. MANUFACTURING SUPPLY AND APPLICABLE STANDARDS

- 2.1 During the Term CMC shall manufacture and deliver Product in the quantity of Batches that are the subject of a Firm Order pursuant to the forecast mechanism set out in Clause 5 and in accordance with the standards and requirements set out herein.
- 2.2 Customer shall purchase all quantities of Product ordered from CMC and which are the subject of a Firm Order on the terms of this Agreement for the Batch Price per Batch plus any Additional Charges for the Batch. During the Term, Customer shall, and where it or its Affiliates are obliged to supply any of their partners’ and their Affiliates’ requirements for Product it shall ensure that it and its Affiliates only source and obtain such Product from CMC other than where otherwise permitted under **Clause 5.17.4** in the event of a Supply Failure. Customer shall use reasonable efforts to procure that its partners, and their respective Affiliates shall only source and obtain FIX Product from CMC.

Performance Standards

- 2.3 CMC shall act diligently and shall apply its reasonable professional standards and use its Commercially Reasonable Endeavors (the “Standard”) in its performance of the Services and discharge of its obligations under this Agreement to:
- 2.3.1 undertake the Services in accordance with the Forecast and projected Delivery dates; and
 - 2.3.2 manufacture, in compliance with the Specification and cGMP, the Commercial Quality Agreement and all Applicable Laws, those quantities of Batches of Product that are the subject of a Firm Order using the same Process that has previously been used by CMC to manufacture the Product in accordance with the Specification.
- 2.4 CMC shall retain and store samples of all Product released by CMC’s quality department with a Certificate of Analysis under this Agreement for such period as may be required by applicable Regulatory Obligations, which in the absence of a definitive time period shall be fifteen (15) years from the date of release or Delivery (whichever is the earlier). If the Parties agree, CMC shall retain such samples for a longer period at the Customer’s expense and CMC’s then current rates.

Third Party Testing Laboratories

- 2.5 CMC may subcontract:
- 2.5.1 to Testing Laboratories proposed by CMC (and approved by Customer, such approval not to be unreasonably withheld or delayed) only those parts of the Services identified in Appendix One or such other part(s) of the Services approved by Customer (such approval not to be unreasonably withheld or delayed); or
 - 2.5.2 to any other third party, any part(s) of the Services with the prior written consent of Customer (such consent not to be unreasonably withheld, delayed or conditioned);

provided that, in any case CMC shall remain responsible for the activities of the party to whom that part(s) of the Services is subcontracted and for compliance of its subcontractors with the requirements of this Agreement, and all Applicable Laws to the same extent that CMC would be responsible if CMC were doing such work directly. Nothing herein shall constitute any contractual relationship between Customer and any subcontractor of CMC or any direct obligation between Customer and such subcontractor to pay, or be responsible for the payment of, any sums to any such subcontractors but Customer shall remain responsible to CMC for payment of the Price plus any Additional Charges.

Totality of Services

- 2.6 The manufacture of those Batches which are the subject of a Firm Order in accordance with Clause 5 are, subject to any written agreement or amendment to the contrary, the only Services to be performed by CMC under this Agreement. In the event of any changes to the Services or Customer requests CMC to perform reasonable services beyond the scope of Services specifically stated in a Firm Order, the Parties shall agree in writing on a description of such supplemental services whereupon CMC shall accommodate Customer's reasonable requests for such supplemental services and the Additional Charges for those supplemental services shall be determined in accordance with Clause 7.5. If at any time during the Term of this Agreement Customer requests and CMC agreed to perform Services to meet regulatory and legal compliance within any of the Additional Countries or any other countries other than the US and the EU, then CMC shall be responsible for the Services meeting regulatory and legal compliance in those identified countries outside of the US and EU regulations and shall invoice Customer for any Additional Charges associated with such Services in accordance with Clause 7.5.
- 2.7 CMC shall manufacture and supply such amounts of Factor VIIa (IB1007 for hemophilia A and other bleeding disorders) as requested by Customer:

Exclusivity in the Field

- 2.8 During the Term of this Agreement:
- 2.8.1 Customer shall, and shall procure that its Affiliates shall, only source FIX Product for the treatment of hemophilia from CMC unless and until a Supply Failure occurs following which Customer shall be permitted to manufacture for itself or by its Affiliate and/or source FIX Product in accordance with Clause 5.17; and
- 2.8.2 provided that (i) CMC is the sole manufacturer and supplier of FIX Product for Customer (other than where Customer is permitted to source FIX Product under **Clause 5.17**), and where Customer or its Affiliates are obligated to supply to its partners, and their respective Affiliates, CMC is the sole supplier to such partners and their respective Affiliates and (ii) provided the Customer is in material compliance with its obligations under the terms of this Agreement, and is not in material breach of the Agreement, then CMC agrees it shall not, without the prior written consent of Customer in its sole reasonable discretion, engage in any activity for its own development or a third party knowingly directed to the process development, manufacture, supply, or commercialization of FIX Products (other than with respect to the Services and capacity supplied to the Customer, its partners, and their respective Affiliates pursuant to this Agreement).

3. RAW MATERIALS

- 3.1 All Raw Materials purchased by CMC for the Services will be the property of the Customer and deemed Customer Materials. If Customer fails to pay for the Raw Materials then such Raw Materials shall remain CMC property and CMC shall be entitled to use the same for third party services without any compensation or liability to Customer.

4. TIMELINE, SPECIFICATION AND PROJECT MANAGEMENT

Timeline

- 4.1 CMC shall use its Standard to Deliver the Firm Orders and meet the Delivery dates with respect to a Firm Order. Notwithstanding that obligation the Parties acknowledge and agree that the Timeline may not be met or may be varied in order to accommodate delays or changes caused by or contributed to by (i) actions or omissions of the Customer (or its agents); and/or (ii) additional activities added to or amendments to the Services; and/or (iii) Force Majeure Events and/or other circumstances beyond CMC's reasonable control ("Non-Fault Delays").
- 4.2 In the event of any Non-Fault Delays, CMC and Customer shall update the Forecast and Timeline and, applying the Standard, CMC shall keep the revised Timeline as close as possible to the Timeline in its form as it existed immediately prior to the Non-Fault Delays.
- 4.3 Notwithstanding Clauses 19.1 and 19.2, the Timeline may be amended by agreement between CMC and Customer provided that the revised Timeline is set out in writing and agreed by the Project Team.
- 4.4 Where the Timeline has been amended in accordance with this Clause 4, it shall be automatically binding upon the Parties. CMC shall keep Customer updated as to the current Timeline on a reasonable frequency. Customer may at any time on a reasonable basis request an update on the current Timeline.

Specification & Quantities

- 4.5 CMC shall manufacture Product to meet the Specification. Where the Specification, Process or Raw Materials are modified or changed or a Material Change (as defined in Clause 4.6 below) is introduced, CMC shall continue to be obliged to use its Standard to manufacture Product to meet Specification. Notwithstanding the foregoing, CMC shall not be in breach of any obligation of this Agreement in respect of the manufacture of a Batch that does not meet Specification following the change or revision to the Specification, Process and/or Raw Materials or introduction of a Material Change until the changed or revised Process has been validated to manufacture Product to Specification by CMC.
- 4.6 At no time will CMC implement any Material Change to the Process without Customer's prior written approval (such approval not to be unreasonably withheld or delayed) of such Material Change or other than in accordance with the applicable provisions of the

Commercial Quality Agreement. A “Material Change” is any variation in the written procedures then currently in place that (i) has a material impact on the regulatory commitments or filings for the Product, (ii) is reasonably expected to materially affect the quality, purity, identity, stability or strength of the Product, or (iii) would necessarily result in a material change, alteration or modification to the Specification. Any changes to the Specification will be managed in accordance with the terms of the Commercial Quality Agreement provided that outside of the terms of the Commercial Quality Agreement the Specifications may be amended from time to time as described in Clause 4.8 or as dictated by the FDA or other applicable Regulatory Authority or Applicable Laws. With respect to (i) changes dictated by the FDA or other applicable Regulatory Authority or Applicable Laws that, at the time, are raised specifically in respect of the Product or Process rather than a deficiency in the CMC Facility or equipment generally and (ii) the implementation of any Material Changes that are approved by Customer, in each case Customer shall be responsible for the Additional Charges in making such changes and/or in validating the Process after such change(s), which Additional Charges shall be calculated in accordance with Clause 7.5. The foregoing shall not allow an automatic increase to the agreed upon Batch pricing set forth in Appendix 3 other than annual increases in accordance with the PPI-C Index or as otherwise agreed to by the parties in writing.

- 4.7 CMC shall manufacture, package, label, store, transport and handle the Product in compliance with the Specification for the validated manufacturing Process and validated analytical methods, the Commercial Quality Agreement, cGMPs, the Act and all other Applicable Laws.
- 4.8 The Parties agree that the Specification may be modified and updated by the Parties if agreed to by the Project Team in writing and signed by an authorized Quality Representative of both Parties. In the event that a modification or update to the Specification requires additional services or work and/or the payment by Customer of Additional Charges, the Additional Charges shall be calculated in accordance with Clause 7.5.
- 4.9 The Parties acknowledge that all quantities of Product derived from a Batch are estimated only and that CMC shall not be liable for any low or unexpected yield of Product from a Batch; provided that CMC used its Standard for the manufacture of the Product during that Batch. Notwithstanding the foregoing, the Parties shall seek to establish and agree upon yield limits (the “**Yield**”) which shall be calculated according to the average yield of Product derived from twenty-five (25) consecutive Batches (excluding any that fail to meet Specification or cGMP) inclusive of the conformance campaign. These Batches shall be manufactured by CMC using the same Process, fermentation scale, suppliers and specifications of Raw Materials and facilities at the CMC Facility, subject to no Material Change. Upon completion of the 25 consecutive Batches, the Parties shall set upper and lower performance limits (calculated by reference to the average +/- 3 standard deviations) to be used as part of Batch disposition, which limits shall be updated by the Parties at least annually thereafter. In the event that actual Yield is below or above the then-current performance limits established by the Parties, (i) the appropriate representatives from both

Parties shall, as soon as commercially practicable, meet to discuss and evaluate the situation, and (ii) such fact shall not, of itself, be automatically demonstrative of a breach or failure by CMC.

Project Manager, Joint Steering Committee and Project Team

- 4.10 Each Party shall, within thirty (30) days of the Effective Date, appoint an individual as a project leader (“Project Manager”) who shall be responsible for leading and coordinating the day to day operation of the Services. In addition, within thirty (30) days of the Effective Date, each Party shall select three of their senior executives (each a “Committee Member”), one of whom (for each Party) may be a Project Manager, to form the steering committee who shall have responsibility for providing leadership and strategic oversight of the Services governed by this Agreement (“Joint Steering Committee”). For the avoidance of doubt, the Joint Steering Committee referenced in this Clause 4.10 will undertake the role of and replace the Steering Committee referenced in Work Statement #8 to the Existing Supply Agreement in respect of the Product.
- 4.11 Separate from the Joint Steering Committee, the Parties shall each name and notify the other of representatives (“Representatives”) who shall form the Project Team and will be responsible for the day to day performance of the Services including planning, executing and discussing issues regarding the Forecasts, the Timeline, the Services and communicating between the Parties. Any disputes or issues that cannot be readily resolved by the Project Team (it being recognised that each Party has an equal vote in the Project Team irrespective of the number of Representatives) shall be referred to the Joint Steering Committee for resolution. Each Party’s Representatives may, upon written notification to the other Party, change from time to time.
- 4.12 Each Party’s Project Manager shall, subject to the oversight of the Joint Steering Committee, (i) manage the relationship between the Parties, (ii) oversee the performance of the Services and the activities of the Project Team, (iii) undertake actions delegated to them by the Joint Steering Committee and (iv) be the principal point of contact for the Services. The Project Leaders shall meet upon reasonable request of either Party, but in any event at least monthly, either in person or by telephone or video conference and each Party shall bear its own costs for attending such meetings.
- 4.13 The Joint Steering Committee shall be responsible for (i) making decisions regarding issues outside the scope of the Project Team or Project Managers, (ii) reviewing the decisions of the Project Team and/or Project Managers, (iii) providing a forum for the Parties to exchange information and coordinate their respective activities regarding the Services, and, (iv) providing a forum to discuss any technical difficulties, Additional Charges or changes to Services or Price triggered by a change to the Services or in accordance with Clause 7.4 as well as resolving any disputes or disagreements before escalation to the dispute resolution provided for in Clause 17. The Joint Steering Committee shall meet on a reasonably regular basis, being no less than twice a year, during the Term and each Party shall have a single vote in the Joint Steering Committee

irrespective of the number of members present and all decisions must be unanimous. Any dispute that cannot be resolved by the Joint Steering Committee within twenty (20) Business Days shall be referred to the CEOs of the Parties for resolution within ten (10) Business Days.

- 4.14 At regular intervals the Representatives shall schedule Project Team meetings for the purpose of overcoming any issues with Forecasts, delivery of Product or the performance of all other aspects of the Services and providing an initial forum for discussing and resolving any difficulties or hurdles encountered in the performance of the Services. Such meetings shall be conducted by telephone conference or, if necessary, by face-to-face meetings at an agreed upon frequency unless particular difficulties arise which dictate the need for more frequent meetings. Each Party shall be responsible for their own costs in attending and conducting the Project Team meetings.
- 4.15 Any decision by the Project Team, the Project Managers or Joint Steering Committee which has the effect of amending the Services in any way must, before it becomes binding, be recorded in writing and signed by both Parties in accordance with Clauses 19.1 and 19.2. None of the Joint Steering Committee, Project Team or the Project Managers shall have the right to amend this Agreement.

5. FORECASTS, ORDERS, MANUFACTURING CAPACITY AND FAILURE TO SUPPLY

Forecasts

- 5.1 Commencing with the first week of July 2011, and thereafter at least one (1) week prior to the beginning of each Calendar Quarter, Customer shall, subject to the provisions of this Clause 5, deliver to CMC a written rolling forecast of Customer's requirements for Product ("**Forecast**"). Customer shall ensure that its Forecasts shall spread the number of Batches such that a maximum of eight (8) Batches may be requested for any Calendar Quarter, being four (4) per each of the Line 1 Suite or Line 2 Expansion per Calendar Quarter, exclusive of any Additional Orders ordered by Customer pursuant to Clause 5.9). For the avoidance of doubt: (i) Customer shall order Product pursuant to the Forecasts by production line; (ii) the first Firm Order under this Agreement shall not be placed before Quarter 2 of 2012; (iii) following qualification of the Line 2 Expansion by CMC, the use of the production lines by CMC in respect of Forecasts shall be interchangeable by CMC with respect to the Product destined for those territories where it is approved; and (iv) the Line 2 Expansion is expected but not guaranteed to be qualified by CMC within the fourth Calendar Quarter of Year 2011.

- 5.2 Each Forecast shall set out the number of Batches of Product required by Customer during each Calendar Quarter covered by the Forecast together with the delivery dates for Product in each Calendar Quarter covered by the Forecast. In preparing a Forecast Customer shall:
- 5.2.1 Forecast numbers of Batches defined by the Minimum Value and Maximum Value for each Year within the applicable time limits and in accordance with Clause 5.1;
 - 5.2.2 use its commercially reasonable efforts to provide a Forecast that accurately reflects its genuine and anticipated requirements for the period covered by the Forecast; and
 - 5.2.3 notify CMC within ten (10) Business Days of each of the FDA and the EMA issuing a marketing authorization for the Product.
- 5.3 In respect of each Forecast due to be delivered prior to each of the EMA and FDA granting a marketing approval/authorization for the Product (“Pre-Approval Forecasts”), the Forecast shall be for six consecutive Calendar Quarters as follows:
- 5.3.1 the first four (4) Calendar Quarter periods covered by the Forecast shall be a definitive and binding order on Customer (a “Firm Order”); and
 - 5.3.2 the fifth (5th) and sixth (6th) Calendar Quarter period covered by the Forecast shall be a semi-binding order on Customer (“Semi-Binding Order”).
- 5.4 In respect of each Forecast due to be delivered after each of the EMA and FDA granting a marketing approval/authorization for the Product (“Post-Approval Forecasts”), the Forecast shall be for eight consecutive Calendar Quarters as follows:
- 5.4.1 the first four (4) Calendar Quarter periods covered by the Forecast shall be a definitive and binding order on Customer (a “Firm Order”); and
 - 5.4.2 the fifth (5th) to eighth (8th) Calendar Quarter periods shall be a semi-binding order on Customer (“Semi-Binding Order”).
- 5.5 Without affecting Clause 5.9, the maximum number of Batches that may be included in any given Year in a Forecast without the prior written consent of CMC shall subject to clause 5.1 be the Maximum Value. If CMC gives its prior written consent the Parties can agree to increase the number of Batches for a particular Calendar Quarter for the Line 1 Suite and/or the Line 2 Expansion. The Maximum Value shall be thirty-two (32) Batches for a full Year.
- 5.6 The minimum number of Batches to be included in any given Year in a Forecast, without the prior written consent of CMC, shall be the Minimum Value. The Minimum Value shall be eight (8) Batches for a full Year (subject to adjustment for a Supply Failure as set forth in Clause 5.17).
- 5.7 The Forecasts are prepared for and intended to provide CMC with clarity as to the Customer’s requirements for Product. Forecasts shall be provided by Customer on a rolling quarterly basis as provided above and each subsequent Forecast shall reflect the

previous relevant Forecasts provided by Customer such that (i) in the case of Pre-Approval Forecasts the last five Calendar Quarters of the immediately preceding Pre-Approval Forecast shall become the first five Calendar Quarters of the next Forecast and (ii) in the case of Post-Approval Forecasts the last seven Calendar Quarters of the immediately preceding Forecast shall become the first seven Calendar Quarters of the next Forecast; and in each case:

- 5.7.1 the quantity of Product in a Calendar Quarter (other than the first Calendar Quarter) that is a Firm Order in the immediately preceding Forecast shall, in the next Forecast, continue to be a Firm Order and may not be varied (other than with CMC's prior written consent);
- 5.7.2 the quantity of Product in a Calendar Quarter that was a Semi-Binding Order in the immediately preceding Forecast shall, in the next Forecast, either become a Firm Order or continue to be a Semi Binding Order (subject to Clause 5.3 or 5.4, as applicable) in the next Forecast but in each case may be varied by Customer (subject to Clause 5.1, the Maximum Value and Minimum Value) by a maximum of twenty percent (20%), rounded to the nearest whole Batch (each an "Allowed Adjustment"); and,
- 5.7.3 Customer shall provide a new projection for the sixth or eighth (or where the preceding forecast was a Pre-Approval Forecast and the next forecast due is a Post-Approval Forecast, the sixth, seventh and eighth) Calendar Quarter, as applicable, in accordance with the principles set out in Clauses 5.3 and 5.4.

5.8 Should Customer fail to submit a Forecast in accordance with the preceding provisions of this Clause 5, a Forecast shall automatically be deemed to be served under this Clause 5 by Customer, subject to Maximum Values and Minimum Values where:

- 5.8.1 in respect of a Pre-Approval Forecast:
 - 5.8.1.1 the first five Calendar Quarters of such new Forecast shall be identical to the last five Calendar Quarters of the immediately preceding Forecast; and,
 - 5.8.1.2 the sixth Calendar Quarter of the new Forecast shall be identical in terms of the quantity of Batches identified in the last Calendar Quarter of the immediately preceding Forecast; and,
 - 5.8.1.3 the preferred delivery dates for the sixth Calendar Quarter of the new deemed Forecast shall be the preferred delivery dates set out for the last Calendar Quarter of the immediately preceding Forecast each extended by a 3 month period.

5.8.2 in respect of a Post-Approval Forecast:

- 5.8.2.1 the first seven Calendar Quarters of such new Forecast shall be identical to the last seven Calendar Quarters of the immediately preceding Forecast; and,
- 5.8.2.2 the eighth Calendar Quarter of the new Forecast shall be identical in terms of the quantity of Batches identified in the last Calendar Quarter of the immediately preceding Forecast and the preferred delivery dates for the eighth Calendar Quarter of the new deemed Forecast shall be the preferred delivery dates set out for the last Calendar Quarter of the immediately preceding Forecast, each extended by a three (3) month period; and,
- 5.8.2.3 where it is the first Post-Approval Forecast due, the sixth, seventh and eighth Calendar Quarters of the new Forecast shall be identical in terms of the quantity of Batches identified in the last Calendar Quarter of the immediately preceding Forecast and the preferred delivery dates for each of the sixth, seventh and eighth Calendar Quarter of the new deemed Forecast shall be the preferred delivery dates set out for the last Calendar Quarter of the immediately preceding Forecast, each extended respectively by a three (3) month, six (6) month and nine (9) month period.

5.9 Customer may in addition to the Batches in a Forecast request additional Batches to be manufactured in a given Calendar Quarter beyond the quantity in a Firm Order or beyond the maximum quantity that may be added under an Allowed Adjustment (each, an “Additional Order”). CMC shall use its Commercially Reasonable Endeavours to supply such Additional Order, taking into account its then available resources and commitments. CMC shall reply in writing within thirty (30) Business Days of a request for an Additional Order identifying (i) how much (if any) of the Additional Order can be filled, (ii) a time estimate for Delivery of the Additional Order (or portion thereof) which can be filled, and (iii) the price for each Batch (excluding Raw Materials, external costs, shipping costs as described in Clause 7.1 and payable in addition to the Price). Batches requested as Additional Orders shall not count against the Allowed Adjustment for any Calendar Quarter. The discounted pricing defined in Appendix 3 hereto will not apply to any Additional Orders which shall be chargeable at a non-discounted rate at CMC’s then regular price (which shall not be deemed Additional Charges or calculated pursuant to Clause 7.5). For clarity, an Additional Order is not binding on Customer unless Customer and CMC agree in writing on the quantities of the Additional Order, the time estimate for delivery of the Additional Order and the price for each Batch.

Orders

5.10 The first Calendar Quarter of the latest Forecast, when delivered with requested delivery dates, shall serve as the written or electronic purchase order for the Firm Order of that first Calendar Quarter (each, a “Purchase Order”) and CMC shall confirm receipt within ten

(10) Business Days. Requested delivery dates shall be consistent with the lead times described in Appendix 3 (as may be modified from time to time by the Joint Steering Committee). CMC shall have the right to notify Customer of any amendment to the requested delivery date at the time it confirms receipt of the Purchase Order where, due to the scale of Firm Orders, it anticipates or knows that it will be unable to meet the requested delivery dates. No terms contained in any Purchase Order, order acknowledgment or similar document shall be construed to amend or modify the terms of this Agreement and in the event of any conflict, this Agreement shall prevail and control, unless the Parties otherwise expressly agree in writing by making reference to both this Agreement and the alternative terms.

- 5.11 All Batches that are the subject of a Firm Order submitted in accordance with the provisions of this Clause 5 shall be binding upon Customer and, subject to Clause 5.10, CMC, and may not, other than subject to the terms or exceptions in this Agreement, be delayed or cancelled by Customer or CMC. All Batches that are the subject of a Semi-Binding Order submitted in accordance with the provisions of this Clause 5 shall be binding upon Customer and, subject to Clause 5.10, CMC, and may not, other than subject to the terms or exceptions in this Agreement, be delayed or cancelled by Customer or CMC except to provide for an Allowed Adjustment as set forth in Clause 5.7.
- 5.12 Notwithstanding the foregoing, Customer shall strive to order in each relevant Year at least twelve (12) Batches. Should the total number of Firm Orders being the subject of a Purchase Order placed in any given Year be less than twelve (12) Batches, then the price for each Batch ordered in that Year shall be adjusted upwards as set forth in Appendix 3 (and where less than eight (8) Batches are ordered (i) in 2012 and 2013 the price for each Batch ordered in either of those Years shall be the price in Appendix 3 for that Year as if eight (8) Batches are ordered (ii) in 2014 and beyond, the price for each Batch ordered shall be determined by the unit price terms in Schedule 3) and CMC shall invoice Customer for such adjustment and Customer shall pay such invoice in accordance with the provisions of Clause 7.13. Should the total number of Firm Orders being the subject of a Purchase Order placed in any given Year be less than eight (8), such circumstance shall not, in and of itself, be deemed a breach by Customer but Customer shall nevertheless be responsible for payment to CMC, in addition to those sums due for batches ordered (in accordance with the foregoing provisions of this clause), a further sum due at the end of the Year calculated by reference to the number of batches short of eight (8) Batches per Year multiplied by (i) US\$[**] for 2012 or (ii) US\$[**] from 2013 onwards for the remainder of the Term.
- 5.13 Subject to Customer's compliance with this Agreement, CMC shall pursuant to Clause 2.3 be obliged to manufacture the quantity of Batches identified in a Firm Order up to the Maximum Value and shall use its Standard to meet the Delivery dates for those Batches subject to the provisions of Clauses 4.1-4.4 (inclusive), 5.10 and 5.17.
- 5.14 Subject to Clause 4.1, CMC shall use the Forecasts to plan for, have Delivered and, as appropriate, reserve Slots in its cGMP manufacturing suite for those Batches to be manufactured under a Firm Order according to the then current Forecast and Delivery

dates. Without prejudice to Clause 2.3, upon the reasonable request of CMC, the Parties shall cooperate to seek an agreement in good faith to vary or amend any part of a Forecast (including the Firm Orders, Semi-Binding Orders and Timeline for delivery) to accommodate lead times or other reasonable requirements of CMC and/or its suppliers.

- 5.15 Where the Timeline is amended and such amendment affects the scheduled Slot(s) for those Batches which are the subject of a Firm Order, CMC shall update its manufacturing schedule and reserve a new Slot for each affected Batch which, subject to reserved slots under CMC's existing manufacturing schedule for its whole facility, shall be reserved as near in time to the existing vacated Slots as CMC's then current schedule will permit.

Inventory

- 5.16 CMC shall upon request by Customer and subject to CMC's scheduling to enable it to manufacture such additional Batches beyond those in a Forecast, hold a maximum inventory capacity of five (5) Batches of Product for Customer provided that Customer shall pay for the manufacture of such inventory Batches on the basis of 100% of Price in Appendix 3 upon thaw of a vial of the Cell Line and CMC will inventory Product at CMC's Facility for a period not to exceed 90 days, provided that full title and responsibility for loss of such Product shall transfer to Customer on the date of Delivery or expiry of the 90 day period (whichever is the earlier).

Failure to Supply

- 5.17 CMC shall inform Customer as soon as practicable of any events that prevent CMC from providing timely deliveries of Product to Customer. Should CMC, when subject to a Firm Order, become aware that it will be unable to meet the Timeline for Delivery of a Batch of Product or to manufacture a Batch of Product in accordance with a Firm Order, as applicable, then CMC shall as soon as reasonably practicable notify Customer of such circumstances and explain what efforts CMC is taking to address such delay. Commencing no earlier than the end of the second Calendar Quarter of 2012 and at the end of each subsequent six (6) month period thereafter, Customer shall conduct a rolling 12 month "look-back" at the preceding four Calendar Quarters of Firm Orders and if less than seventy-five percent (75%) of Batches that were the subject of those Firm Orders were Delivered to Customer (of which the total Batches delivered does include inventory stock) in that rolling 12 month period due solely to CMC's breach of its obligations (including, but not limited to, those concerning its personnel or equipment, procedural errors of CMC, the materials planning, procurement, testing and qualification CMC is obliged to procure, CMC's operations in the production facility during manufacture and its general workmanship in accordance with cGMP), and provided that the percentage of those undelivered Batches that were the subject of Firm Orders is measured over a period of at least two (2) Calendar Quarters in that 12 month period such that, for clarity, the number of undelivered Batches for purposes of calculating the percentage of Delivered Batches cannot be attributable solely to failed Batches that are the subject of a Firm Order within a single Calendar Quarter (a "Supply Failure") then the following shall apply:

- 5.17.1 CMC and Customer shall work collaboratively to discuss and find ways to promptly overcome the Supply Failure and re-establish supply of Product as soon as practicable in accordance with the Firm Orders and Semi-Binding Orders of the most recent Forecast;

- 5.17.2 provided that Customer is not in material or continuous breach of this Agreement, and a Supply Failure is not due to or contributed to by Customer's actions or omissions or breach, the exclusivity provisions in Clause 2.8 shall no longer apply with respect to Customer and Customer shall, notwithstanding the provisions of clauses 2.2 and 2.8, have the right, at its option, to itself manufacture, or have manufactured for it by one third party contract manufacturer ("Third Party CMO") of its choosing, in each case, up to fifty percent (50%) of Forecasted demand of Product (or up to one hundred percent (100%) of Forecasted demand of Product less that which CMC can supply until Supply Reinstatement), in such circumstances:
- 5.17.2.1 the Minimum Value for the period from the date of the Supply Failure arising until the Supply Reinstatement shall automatically be adjusted downward by one (1) Batch for each complete Calendar Quarter (or two (2) Batches where no Batches have been Delivered during the 12 month period by CMC) during which there continues to be a Supply Failure from the date of the Supply Failure until the Supply Reinstatement (such adjusted Minimum Value hereinafter, the "Adjusted Minimum Value")
 - 5.17.2.2 CMC shall enter into a commercially reasonable license with Customer or the Third Party CMO, as applicable, to license the Intellectual Property Rights licensed to Customer under Clause 11.7 solely for the manufacture of Product during any period allowed by this Agreement, provided that the Third Party CMO enters into appropriate confidentiality obligations and use restrictions with respect to CMC's Intellectual Property Rights, Know-How and Confidential Information on terms no less onerous than those on Customer under this Agreement;
 - 5.17.2.3 CMC shall provide its reasonable assistance in accordance with Clause 15 to Customer or the Third Party CMO, as applicable, to facilitate technology transfer to Customer or the Third Party CMO of information in CMC's possession that it can disclose to the Customer or the Third Party CMO, as applicable, regarding the Process and manufacture of Product, solely for the purpose of manufacturing Product;
 - 5.17.2.4 Customer shall be responsible for payment of CMC's then standard license fees due through Customer's or its third party CMO's use of the CHEF1 Technology, provided CMC shall not charge for time incurred by its own personnel in providing technology transfer in accordance with Clause 15;

- 5.17.3 Customer shall continue to submit Forecasts (in accordance with the principles of this **Clause 5**) prior to and during any Supply Failure and CMC will use its Standard to meet the supply of Batches in accordance with the Forecast but shall not be in breach of its obligations to supply Product during the Supply Failure until Supply Reinstatement if it is unable to meet any or all of the Forecast;
- 5.17.4 where CMC is able to successfully Deliver to Customer (i) at least seventy-five percent (75%) of conforming Batches of Product in accordance with the most recent four (4) Firm Orders submitted in accordance with this Clause 5, and (ii) one hundred percent (100%) of the backlog of Firm Orders (less the total number of Batches (a) manufactured by Customer and (b) supplied by the Third Party CMO) not successfully Delivered to Customer in accordance with the Forecasts submitted up to the date of Supply Failure (“Supply Reinstatement”) thereafter :
- 5.17.4.1 Customer shall promptly submit a Forecast (which shall be prepared in accordance with the principles in this **Clause 5**) which shall be (i) for no less than 50% of Customer’s requirements for Product (subject to the Maximum Value) and (ii) no less than half of the Minimum Value in such Year; and
- 5.17.4.2 Customer may, at its discretion, continue to fulfil any then-existing contractual commitments, including without limitation commercial supply of the Product by Customer through self-manufacture or through its Third Party CMO that exists under any binding orders placed with the Third Party CMO prior to the Supply Reinstatement and in respect of all future orders thereafter Customer shall only be entitled to place a maximum of fifty (50%) percent of their annual requirements with the Third Party CMO (or with itself or its Affiliates, as applicable) with the other fifty (50%) percent placed with CMC and;
- 5.17.4.3 for the remainder of the Term of this Agreement, regardless of whether a Supply Reinstatement occurs, Customer shall be entitled to dual source Product from its Third Party CMO (or from itself through self-manufacture, as applicable) and CMC provided that the Third Party CMO (or Customer, as applicable) delivers no more than 50% of Customer’s requirements.

For the purpose of this **Clause 5.17** the commencement of the Supply Failure shall be the date of the “look-back” giving rise to the Supply Failure. Furthermore, notwithstanding any other provision in this Agreement, CMC shall not, whilst it is seeking to remedy a Supply Failure and achieve a Supply Reinstatement, be deemed in breach of its obligations under this Agreement with respect to the supply of Product.

6. PACKAGING, DELIVERY, STORAGE AND EXAMINATION

Packaging

- 6.1 Product and perishable Deliverables to be Delivered shall be packaged by CMC in accordance with its obligations under the Commercial Quality Agreement, the applicable packaging SOPs (as approved by CMC) and Regulatory Obligations.

Delivery

- 6.2 CMC shall provide Customer with advance notice of the anticipated date of Delivery and, in any event, shall provide at least 5 (five) Business Days advance notice of the date CMC is to Deliver Product to Customer or Customer's shipping company.
- 6.3 Except as set out in the Specifications, all Product that CMC manufactures pursuant to this Agreement shall be released to Customer Ex Works (Incoterms 2000) at CMC's Facilities at 9.00am on the date specified on CMC's notification to Customer (under clause 6.2) that the Deliverables are available for collection. Product will be deemed to have been delivered upon the date Product is so released ("Delivery" or "Delivered"). Collection may be arranged at any time thereafter during normal business hours on Business Days or such other time as may be agreed by the Parties.
- 6.4 CMC shall not be responsible for or have an obligation to clear for export or import any Deliverables that CMC (or its sub-contractors) generates or manufactures pursuant to this Agreement nor be obliged to obtain, or assist Customer in obtaining, relevant and applicable export and import licenses, consents or permissions. Upon Delivery to Customer, subject to the shelf life approved by the applicable Regulatory Authority, the expiration dating on each lot of Product shall be no less than seventy-five percent (75%) of the licensed shelf life or "hold time" (namely the allowable period for which Drug Substance may be stored from the date of release until it expires) for the Product or one (1) year, whichever is shorter, such shelf life or hold time to be specified in the Commercial Quality Agreement and/or Specification.
- 6.5 Data, results, deviation reports, Batch records and Drug History Records shall be delivered by mail or electronic mail.

Release For Further Processing

- 6.6 Subject to Regulatory Obligations and cGMP compliance, Customer may, by written notice, request that CMC Deliver Product to Customer prior to CMC issuing a Certificate of Analysis ("Release For Further Processing"). Any Product that is the subject of Release For Further Processing shall until the applicable Certificate of Analysis is issued by CMC:
- 6.6.1 be handled by Customer with utmost care and attention and treated with caution as if it were an unknown substance;

- 6.6.2 be accepted at Customer's sole risk and liability and CMC shall not be liable for any loss or damage caused by Product which is the subject of Release For Further Processing other than for death or personal injury caused by CMC's gross negligence or willful misconduct; and
- 6.6.3 not be administered to any living organism.

Title and Risk

- 6.7 Subject to Clause 5.16, title and risk in the Deliverables shall pass to Customer on Delivery, regardless of whether a Product Batch has been dispositioned and released with a Certificate of Analysis or Released For Further Processing and the Payment for the Batch will, subject to it not being Defective (due to CMC's default) at the time of Delivery, become due and payable in accordance with Clause 7.

Storage and Transport

- 6.8 Where Customer elects to have a shipping company or other agent ("Shipping Company") collect and transport the Product upon Delivery, Customer shall, prior to the collection of the Deliverables, inform CMC of its designated Shipping Company. Customer shall coordinate with such Shipping Company for the collection and shipment of the Product and CMC shall not be responsible for any shipping costs of the Shipping Company. CMC shall ensure that the Deliverables are packaged in accordance with Clause 6.1 and Customer shall ensure that the Deliverables are stored and transported in accordance with the Shipping Guidelines.
- 6.9 If Customer or Customer's Shipping Company is unable to collect Deliverables (including the Product and/or Drug Substance) at the time of Delivery, CMC shall, upon the Customer's request, store at its Facility (or ship to an Alternative Site, as hereinafter defined) such Deliverables for a period of 20 (twenty) Business Days after Delivery on behalf of Customer. Storage of Deliverables at CMC's premises after Delivery shall be at Customer's sole risk and liability except that CMC shall only be responsible for damage to the Deliverables to the extent that the damage is attributable to and caused during such storage by an act or omission which constitutes CMC's gross negligence or wilful misconduct. If Deliverables and API have not been collected by Customer or Customer's Shipping Company 20 (twenty) Business Days after Delivery CMC shall notify Customer of the outstanding collection and with effect from the twenty-first (21st) Business Day after Delivery CMC shall continue to store the Deliverables at a cost to Customer of \$US1,500 per day after the 20 (twenty) Business Days (which Customer shall pay) but such storage shall be entirely at Customer's risk and liability and CMC shall be entitled to dispose of such Deliverables, at Customer's cost, if not collected following a written notice from CMC.

- 6.10 Customer may, if not itself collecting the Deliverables, prior to their Delivery, request that CMC arrange for of the Deliverables to a location specified by Customer (“Alternative Site”) subsequent to their Delivery. Where CMC agrees to such a request CMC shall provide reasonable assistance for shipment and:
- 6.10.1 Customer shall provide CMC with all reasonable assistance for shipment, including without limitation all the necessary export and import clearances, consents, permits and licenses to allow CMC to arrange transport of the Deliverables to the Alternative Site; and,
 - 6.10.2 transport and storage organized by CMC shall be at the Customer’s sole cost, risk and liability except that during storage at CMC’s Facility, pursuant to this Clause 6.10, CMC shall only be liable to Customer to the extent any damage is attributable to and caused to Deliverables due to an act of CMC’s gross negligence or wilful misconduct; and,
 - 6.10.3 CMC shall, in the Customer’s name and at the Customer’s cost, insure the Deliverables until such time as they are transported to the Alternative Site; and,
 - 6.10.4 Customer shall indemnify and keep indemnified CMC from and against any liability incurred in arranging or undertaking such shipment in accordance with this **Clause 6.10**.
- 6.11 If Customer shall or intends to examine or test Deliverables and wishes to reserve its right to make a claim against CMC in respect of Defective Deliverables, Customer undertakes to ensure that the Deliverables since collection from CMC’s Facility or transport to the Alternative Site are always stored and transported strictly in accordance with the Shipping Guidelines. Failure to comply with such Shipping Guidelines before or after serving a Defect Notice (as defined below) will invalidate Customer’s right to make any claim under this Agreement in respect of such Deliverables.
- Examination of Deliverables for Defects etc.
- 6.12 Following their Delivery, Customer shall promptly examine and test the Deliverables for any defect or non-conformity, including in the case of Product or Drug Substance non-conformity with the Specifications, any applicable Certificate of Analysis (unless Delivery is subject to Clause 6.6) and cGMP standards which Deliverables are specified to meet (a “Defect” or “Defective”). Where any alleged Defect (other than a Latent Defect) is identified, Customer shall notify CMC by written notice (“Defect Notice”) within forty-five (45) Business Days of Customer’s or its agent’s receipt of the Deliverables.
- 6.13 A Defect Notice must identify (i) the Deliverable and, in the case of Product, the Batch from which the Product was derived, (ii) the date(s) of Delivery and collection (or where the Deliverables are transported to the Alternative Site the date received at the Alternative Site), (iii) reasonable detail, including test results if applicable, of the Defect, (iv) where applicable, full disclosure of the methodology of all analytical tests performed on the

Deliverables and the results of those tests, (v) evidence demonstrating that the Deliverables have been stored and transported in accordance with the applicable Shipping Guidelines, (vi) where the Customer asserts that the Defect is due to CMC's default, the reasons why the Customer makes that assertion. Customer shall arrange with CMC to return the Deliverables which are the subject of the Defect Notice in accordance with the Shipping Guidelines to CMC within 15 (fifteen) Business Days. If a Defect in any Deliverable is not notified to CMC in accordance with the provisions and time limits stipulated in Clauses 6.12, 6.13 and 6.15 the Deliverable shall be deemed accepted and free of Defect and Customer shall have no further remedy against CMC in respect of that Deliverable.

- 6.14 Upon receipt of the Defect Notice CMC shall promptly investigate whether or not the Defect is due to CMC's negligence or failure to comply with its obligations hereunder and shall report to Customer within twenty-five (25) Business Days of receipt of the Deliverables whether it accepts responsibility for the Defect in full, in part or not.

Latent Defects

- 6.15 If after accepting a shipment of Product, Customer subsequently discovers a Defect within twenty-four (24) months of Delivery and such Defect could not have been identified by testing and analysis of the Deliverables during the period between Delivery and the subsequent identification and the Product is still within its approved shelf life (a "Latent Defect"), Customer shall notify CMC of such Latent Defect within ten (10) Business Days of such identification whereupon the provisions of Clause 6.13 and 6.14 shall apply. If CMC accepts or it is reasonably proven that the Latent Defect was caused by CMC's breach of its obligations hereunder then the provisions of Clause 6.16 to 6.18 (inclusive) shall apply with respect to the Latent Defect, otherwise Customer shall have no further remedy against CMC in respect of that Deliverable.

Consequences of Defective Product

- 6.16 If CMC accepts or, subject to Clause 6.17, it is reasonably proven that the Defect was caused by CMC's breach of its obligations hereunder and not as a consequence of third party or Customer action or inaction and Customer has notified the Defect to CMC in accordance with Clause 6 then (i) Customer shall, at CMC's election, either return such Product to CMC or destroy or dispose of such Product in the least expensive and most environmentally sound manner; and (ii) at Customer's option, (a) CMC shall be relieved of any obligation to deliver any replacement Batch with respect to the Defective Product and will refund Customer the full Price of those Batch(es) that were the subject of the Defect Notice, or (b) CMC shall, at no additional cost to Customer beyond the Price for the Defective Product, use its Standard to promptly replace the Defective Product with non-Defective Product or, to the extent permitted under Regulatory Obligations, rework the affected Deliverables to overcome the Defect. If Customer elects to receive a refund in accordance with subsection (a) above, the Defective Batches at issue shall not be considered for purposes of determining whether a Supply Failure has occurred. In the situation described in subsection (ii)(b) of this Clause 6.16, CMC shall be responsible for

the costs of Raw Materials that may be incurred by it in replacing the Defective Product with non-Defective Product or reworking the affected Deliverables to overcome the Defect, as applicable.

- 6.17 If there is a dispute regarding whether or not a Deliverable is Defective or who is liable and/or responsible for the Defect (“Disputed Deliverable”), then (a) analysts from both parties will directly communicate to determine the Parties’ respective validated methods of analysis are the same and are being executed in the same manner, and to attempt to determine whether any non-compliance may have been caused during the shipment of the sample from CMC’s Facility, and (b) carefully controlled and split samples as agreed should be sent from one site to another for testing in an attempt to reach agreement (which may involve Customer sending a representative and a sample of the Disputed Deliverable to CMC, and the parties conducting jointly agreed upon tests on the Customer sample of the Disputed Deliverable and a sample of the Disputed Deliverable retained by CMC). The Parties will use good faith efforts for a period of twenty-five (25) Business Days after completing such tests to resolve whether the Disputed Deliverable is Defective and/or whether it was Defective due to CMC’s failure to manufacture in accordance with its obligations under this Agreement or the Commercial Quality Agreement. In the event the parties cannot resolve their dispute in the manner described, a mutually agreed-upon independent laboratory shall be asked to test the Disputed Deliverable. The costs of such independent laboratory shall be borne by the Parties equally; provided, however, the Party that is determined to be incorrect in the dispute shall be responsible for all such reasonable costs and shall reimburse the correct Party for its share of such reasonable costs incurred. The decision of such independent laboratory shall be in writing and shall be binding on both CMC and Customer unless there has been a Manifest Error on the face of the decision whereupon the Parties shall revert to this Clause 6.17 to the extent retesting at another independent laboratory is possible or otherwise, to the dispute resolution procedures in Clause 17. With respect to all Product that Customer properly rejects, Customer shall destroy all remaining unused Product as soon as reasonably possible after CMC’s request. In no event may Customer use any of the rejected Product for any human clinical testing or trials after it becomes aware of the basis for such rejection (and Company shall indemnify CMC for all liabilities, costs and damages incurred by CMC resulting from Customer’s breach of this limitation on use).
- 6.18 The remedies and obligations under Clauses 6.16 and, 6.17 shall be Customer’s sole remedy for Defective Deliverables but this Clause does not seek to exclude any Parties’ liability for death or personal injury including, without limitation, with respect to CMC’s indemnity obligations under Clause 12.2.6.

7. **PRICE, PREPAYMENTS, PAYMENT TERMS AND MILESTONE PAYMENTS**

Price

- 7.1 The Price in Appendix Three is stipulated in U.S. Dollars and is exclusive of all taxes, duties, or other fees of whatever nature imposed by or under the authority of any State,

government or public authority (other than taxes on CMC's income), or any Additional Charges, external costs required to manufacture or release the Product (e.g. external testing), Raw Materials, consumables or shipping costs that CMC incurs to provide the Services, which Customer shall pay in addition to the Price in accordance with Clause 7 of this Agreement. In respect of shipping costs and external costs, CMC shall give Customer advance notice of the estimated amount of such costs. If Customer does not dispute those costs within five (5) Business Days of receipt of notification they shall be irrevocably deemed acceptable to Customer. Where Customer disputes the costs within five (5) Business Days of notification, the Project Team shall first meet to discuss the costs and explore ways to mitigate them, and in the absence of agreement the matter shall then be referred to the Joint Steering Committee for resolution within five (5) Business Days of notification from the Project Team that an agreement cannot be reached. If the Joint Steering Committee is unable to reach agreement within such time period, the matter shall then be referred for resolution by the Parties CEOs. If (i) the dispute is not settled by agreement in writing between the Parties' CEOs or (ii) the Parties have failed to discuss the dispute or use good faith negotiations, the matter shall be referred, first, to mediation and then, if necessary, to binding arbitration in accordance with Clause 17. Pending resolution of the dispute, Customer shall pay to CMC the costs in dispute in accordance with the payment terms set out in this Clause 7 and once the dispute has been resolved if Customer has overpaid for the additional services or work CMC shall make a refund or credit of such overpayment or if Customer has underpaid Customer shall make a payment in a sum equal to the amount of the underpayment, in either case within 30 days of the decision. In no event shall CMC be permitted to suspend or cease performing Services where a dispute under this Clause is raised unless Customer withholds payment therefor.

Prepayments

7.2 Customer and CMC shall establish a fund to part finance the performance of the Services as follows:

7.2.1 Customer shall pay to CMC, by wire transfer of immediately available U.S. funds to an account designated by CMC, the following payments, to build the Fund to an aggregate value of not more than [**] Dollars (\$[**]) (the "Fund"):

- 7.2.1.1 [**] Dollars (\$[**]) on the Effective Date;
- 7.2.1.2 [**] Dollars (\$[**]) on October 1, 2011;
- 7.2.1.3 [**] Dollars on January 1, 2012;
- 7.2.1.4 [**] Dollars on April 1, 2012; and
- 7.2.1.5 [**] Dollars on July 1, 2012;

(each, a "Fund Payment" and together, the "Fund Payments"); provided, however, that Customer shall not be required to remit a Fund Payment to CMC if such Fund

Payment would otherwise be payable on a date (i) on which CMC is in material (and unremedied) default with the terms of this Agreement, or (ii) where a Supply Failure is ongoing and has not been remedied in accordance with Clause 5.17.4, unless and until the default is remedied or a Supply Reinstatement occurs whereupon the withheld Fund Payment shall be paid to CMC. For the purpose of this Clause 7.2, the Threshold Value shall be the aggregate value of the Fund having regard to the total of the Fund Payments at a relevant date, such that, by way of example, the Threshold Value on 1 January 2012 shall be US\$[**] and on 1 April 2012 shall be US\$[**]. For the avoidance of doubt, the Fund is not a prepayment in respect of Batches, save for where the Fund is set off against sums due to CMC in accordance with Clause 7.2.2.

7.2.2 Upon the expiration of the Term or the earlier termination of this Agreement (other than for a termination by CMC in accordance with Clause 14.2, in which case CMC shall be entitled to retain the entire sum of the remaining Fund in addition to any other sums properly due and payable to CMC by Customer), then, at Customer's option, (i) CMC shall apply all or any specified portion of the remaining Fund to amounts due to CMC from Customer for any outstanding sums properly due and payable to CMC and any costs payable to CMC associated with Technology Transfer in accordance with Clause 15, or (ii) CMC shall promptly refund, and in any event within thirty (30) days of such expiration or termination of this Agreement, any portion of the Fund Payment not applied in accordance with this **Clause 7.2** as of such date in respect any sums due for Services undertaken by CMC under this Agreement.

7.3 The Price stipulated in Appendix Three shall, together with those Additional Charges incurred where there are changes to the Services, the Process or otherwise as required by CMC to, at Customer's request in accordance with Clause 2.6, extend its obligations to meet Applicable Laws and/or Regulatory Obligations of any Additional Countries or other countries beyond US and EU under this Agreement, automatically increase on an annual basis, commencing with the first anniversary of the Effective Date and thereafter on each anniversary of the Effective Date during the Term in accordance with the PPI-C (or any index substituted therefor) announced by the US Department of Labor (or its successor or replacement body) that is applicable on the date of the anniversary of the Effective Date. The increase to the Price (and any Additional Charges incurred where there are changes to the Services, the Process or otherwise as required by CMC to extend its obligations to meet Applicable Laws and/or Regulatory Obligations of any Additional Countries or other countries beyond US and EU under this Agreement, as applicable) shall be a compound increase based on the immediately preceding Price (and any such Additional Charges, as applicable).

- 7.4 If there are any material and unforeseen changes in cGMP or manufacturing regulations promulgated pursuant to enabling legislation under a statute that:
- 7.4.1 are specific to the Product and not of general requirement for biologics contract manufacturing services; and
 - 7.4.2 require capital investment by CMC for the performance of the Services in excess of the total Price of the Services, or
 - 7.4.3 which result in the financial returns under this Agreement being substantially affected to CMC's detriment, then the Parties shall in good faith discuss ways to continue the Services overcoming any such financial investment or detriment. If no agreement can be reached and CMC's financial returns under the agreement will be so affected,
 - 7.4.4 then the Parties shall in good faith negotiate any Additional Charges in respect of the Services to neutralise any financial investment or detriment incurred by such changes, or in the absence of agreement the Additional Charges shall be calculated in accordance with Clause 7.5 below.

Additional Charges

- 7.5 The charges set forth in Appendix Three are based on the scope of work CMC plans to undertake under this Agreement in the ordinary course of manufacture of the Product in accordance with the terms and conditions of this Agreement, the Process and the Specifications existing as of the Effective Date. Unless otherwise provided elsewhere in this Agreement:
- 7.5.1 any costs of CMC associated with additional or different work shall, subject to the proviso in this Clause 7.5 be:
 - 7.5.1.1 to the extent concerned with CMC accepting legal or regulatory compliance within any Additional Countries or countries other than the US or EU shall be borne by Customer;
 - 7.5.1.2 borne by CMC to the extent any such changes are made primarily for CMC's benefit rather than for any technical or regulatory requirements or to have any advantageous benefit to the Product, the Process or the Services including, without limitation, to improve the Yield, purity or stability of the Product, whereupon Customer shall be responsible in accordance with subsection 7.5.1.3, or
 - 7.5.1.3 borne by Customer to the extent any such changes are recommended by CMC and agreed to by Customer for any technical requirements or to have any advantageous benefit to the Product, the Process or the Services including, without limitation, to improve the yield, purity or stability of the Product, or

- 7.5.1.4 borne by Customer to the extent any such changes are requested by Customer or result from requirement of a Regulatory Authority, change in any Applicable Law or other requirement which is specific to the Product or
- 7.5.1.5 shared equally by CMC and Customer to the extent any such changes result from changes in any Applicable Law which are not primarily applicable to the Product but apply more generally to biologics manufacture.
- 7.5.2 subject to any costs due under Clause 8 for audits:
 - 7.5.2.1 all costs and expenses relating to CMC's cGMP compliance readiness and Regulatory Inspection preparation with respect to the Facility for the purposes of FDA and EMA approval and manufacturing and testing operations performed thereon that are not specific to the Product, including without limitation those costs associated with FDA and EMA responses to regulatory requirements relating to the Facility and Regulatory Inspection observations with respect to its Facility and manufacturing and testing operations conducted thereon that in each case are not specific to the Product, shall be borne by CMC;
 - 7.5.2.2 all costs and expenses relating to cGMP compliance readiness and Regulatory Inspection Readiness preparation for territories outside the FDA or EMA jurisdiction at Customer's request or specific to Customer's Product shall be borne by Customer;
- 7.5.3 The Additional Charges payable for each set of additional services or work proposed or requested shall be:
 - 7.5.3.1 calculated on a "cost plus" basis such that the costs and expenses (both internal and external) incurred by CMC for those additional services shall be payable by Customer together with a profit element which shall be calculated as a value in addition to the costs and expenses to ensure that the profit margin in respect of the Services prior to CMC taking on the additional services or work shall continue to be the same profit margin earned by CMC by taking on the additional services or work;
 - 7.5.3.2 payable on 30 days of issuance of invoice;
 - 7.5.3.3 notified by CMC to Customer once calculated in accordance with Clause 7.5.3.1 and, subject to Clause 7.5.4 below, shall be payable by Customer in addition to the Price if CMC undertakes or commences performance of the additional services or work;

- 7.5.4 upon notification by CMC of the Additional Charges pursuant to Clause 7.5.3.3, Customer shall within thirty (30) days notify CMC whether it still wishes for CMC to undertake the additional services or work connected with such Additional Charges and:
- 7.5.4.1 should Customer elect not to have such additional services or work undertaken, then notwithstanding any other provision in this Agreement CMC shall not be obliged to undertake such additional services or work and Customer shall not be obliged to pay such Additional Charges; or
- 7.5.4.2 should Customer elect to have such additional services or work undertaken then CMC shall perform the additional services or work and Customer shall be responsible for and pay the Additional Charges associated therewith which shall be deemed agreed between the Parties unless Customer notifies CMC in writing at the same time of its election to have the services undertaken that it disputes the value of the Additional Charges for that set of specific additional services or work whereupon (i) Customer shall explain the basis for its dispute; and (ii) until that dispute is resolved, either through agreement or pursuant to Clause 17, Customer shall continue to be obliged pay such Additional Charges in accordance with Clause 7.5.3.2 and (iii) once the dispute has been resolved if Customer has overpaid for the additional services or work CMC shall make a refund or credit of such overpayment or if Customer has underpaid Customer shall make a payment in a sum equal to the amount of the underpayment;
- 7.5.4.3 until Customer makes its election pursuant to Clauses 7.5.4.1 or 7.5.4.1, CMC shall not be obliged to commence any such additional services or work.

Milestones and Milestone Payments

- 7.6 Customer shall pay to CMC each individual Milestone Payment upon the achievement or occurrence of the Milestone Event applicable to the Milestone Payment. Each Milestone Event and its respective Milestone Payment is independent of achievement or occurrence of any of the other Milestones or payment of the other Milestone Payments CMC shall inform Customer upon the achievement of a Milestone as soon as practicable. Customer shall remit each Milestone Payment in immediately available funds to an account designated by CMC in accordance with the payment terms set out in Appendix 2. CMC shall be solely responsible for any and all taxes it incurs with respect to the Milestone Payments.

Further Covenants

- 7.7 CMC shall keep accurate records pertaining to the expenditures it incurs for the Line 2 Expansion in sufficient detail to verify the accuracy of such expenditures and the use of the First Payment to offset them. In addition, CMC shall provide Customer with a final project financial summary indicating total incurred expenses for the Line 2 Expansion on or about August 30, 2011.
- 7.8 The Parties agree that on the date that Customer's Forecast for Batches of Product reach 50% of CMC's 3,000L scale capacity on an annual basis (which for clarity includes the Line 1 Suite and the Line 2 Expansion), (i) the Parties shall in good faith reassess the exclusivity obligations on each of them as to whether they continue to bind them, it being recognised that if the Parties are to agree any change in exclusivity then it must be a reciprocal change; and (ii) the Parties will in good faith commence planning and negotiations for further expansion of CMC's manufacturing capacity in the CMC Facility.
- 7.9 CMC shall grant Customer the right, at Customer's option and subject to prior agreements between CMC and Third Parties, to reserve and negotiate manufacturing capacity on a First Priority Basis in the Line 1 Suite and the Line 2 Expansion, upon thirty (30) days written notice from Customer to CMC of its intent to exercise such right(s).

Invoicing & Payment Terms

- 7.10 All invoices will be raised in U.S. Dollars and Customer agrees to pay all sums due hereunder in U.S. Dollars.
- 7.11 All Milestone Payments that become due during the term of this Agreement shall be paid by Customer to CMC in accordance with the payment terms stipulated in Appendix 2.
- 7.12 CMC will issue invoices in accordance with Clause 5.16, clause 7.5.3.2 or the provisions of Appendix Three (as applicable) save that:
- 7.12.1 in respect of all Batches where the thaw date is prior to July 2, 2012 the Price shall be invoiced as of the thaw date; and
- 7.12.2 in respect of all Batches where the thaw date is on or after July 2, 2012 the Price shall be invoiced as of the date of Delivery.
- 7.13 All invoices shall be paid by wire transfer to the following account:
- [**] Bank
[**]
Routing & Transit #: [**]
Account #: [**]

Unless expressly stated in this Agreement or on an invoice to the contrary, all invoices are issued net and will, unless disputed in good faith and in writing according to **Clause 7.17**, be paid in full without any deductions, deferment or set off by Customer within thirty (30) Calendar Days of issue by CMC.

- 7.14 Customer shall pay to CMC, in addition to the Price, Additional Charges and the charges for the Raw Materials, a sum in respect of CMC's storage of Raw Materials purchased by CMC for the Services ("Storage Cost"). CMC shall invoice Customer on a monthly basis for the Storage Cost incurred during the Services. The Storage Cost shall be, unless stipulated in Appendix One, calculated at the daily rate of \$US\$[**] per pallet per month.
- 7.15 Raw Materials costs for all Services may be invoiced to Customer up to sixty (60) calendar days in advance of the commencement of the applicable stage of the Services. The majority of incidental Raw Material costs will be estimates, either as associated with the scope of work to which they are relevant or as otherwise set out in Appendix Three. Customer acknowledges that the prices for Raw Materials will vary during the Term of this Agreement and the estimates in Appendix Three are non-binding. Raw Material costs for resins, media, filters, and assay kits will be invoiced on an item by item basis. Such invoices will be reconciled in a timely fashion, but at least once per Calendar Quarter.
- 7.16 Raw Materials may be invoiced to Customer up to sixty (60) calendar days in advance of the commencement of the applicable Stage of the Services. Such invoices will be reconciled in a timely manner, but at least once per Calendar Quarter.
- 7.17 All invoice disputes will be notified by Customer to CMC in good faith and in writing within ten (10) Business Days of the receipt of the invoice in question. Any such notification must include an adequately detailed explanation of the reasons why the invoice is disputed and the amount of the invoice disputed. To the extent that only part of the invoice is disputed, the undisputed portion shall be paid by Customer in accordance with Clause 7.10. Upon receipt of notice of a dispute, the Parties shall negotiate in good faith and seek to overcome the dispute in accordance with Clause 4.13. To the extent that the dispute is not resolved by the Parties within sixty (60) calendar days of original notification by Customer of the dispute, and only if Customer has withheld payment, then CMC shall be entitled to suspend the Services until such time as the dispute is finally resolved in accordance with Clause 17 and CMC shall have no liability to Customer for such suspension or delay in the Timeline and the Price (including any Additional Charges) for any Batches that are the subject of a Firm Order or a Semi-Binding Order which are delayed or cancelled as a result of the suspension shall become due and payable by Customer. For the purposes of this clause a dispute as to the amount of Additional Charges proposed by CMC under Clause 7.5 shall be governed by the terms of that Clause save that if Customer has withheld payment of Additional Charges, then CMC shall be entitled to suspend the Services until such time as the dispute is finally resolved in accordance with Clause 17 and CMC shall have no liability to Customer for such suspension or delay in the

Timeline and the Price (including any Additional Charges) for any Batches that are the subject of a Firm Order or a Semi-Binding Order which are delayed or cancelled as a result of the suspension shall become due and payable by Customer.

- 7.18 CMC will invoice Customer \$[**] for each domestic shipping event. CMC will invoice Customer \$[**] for packaging and labeling of shipments for each international shipping event such sum increasing on an annual basis to reflect any increase in costs for such shipping event incurred by CMC in the preceding 12 month period and as may be notified to CMC for the future 12 month period.

Late Payments

- 7.19 If an undisputed invoice is not settled by Customer in full in accordance with this Agreement, CMC may, at its discretion, charge Customer, which Customer will pay, interest at a monthly rate of [**]% ([**] percent).

Payments due to Customer

- 7.20 Where any payment, credit or refund is properly due to the Customer under this Agreement, the Customer can elect to either:
- 7.20.1 have that amount refunded to it by CMC on 30 (thirty) calendar days notice; or
 - 7.20.2 have that amount set-off against any further amount payable by the Customer under this Agreement or any future agreement the Parties enter into.
- 7.21 Where Customer elects to have an amount set-off against any further amount payable by the Customer under this Agreement and, subsequent to that credit, the Customer remains entitled to a payment, credit or refund, CMC shall refund that amount to the Customer within 30 (thirty) calendar days of CMC receiving notice from the Customer requesting CMC refund that amount.

8. CUSTOMER AUDITS, REGULATORY INSPECTIONS & MATTERS

Customer Audits

- 8.1 Customer shall be entitled, without charge, to conduct one audit (a "Customer Audit") of CMC's Facility annually in respect of Product manufacture. A Customer Audit shall be arranged upon no less than 20 (twenty) Business Days notice. For clarity, a Regulatory Inspection (hereinafter defined) shall not be deemed a Customer Audit hereunder and shall not count against the annual cap permitted under this Clause 8.1.

- 8.2 Additional Customer Audits may be conducted:
- 8.2.1 other than in accordance with Clause 8.2.2 on no less than 20 (twenty) Business Days' notice subject to CMC's consent and at a cost of \$1500 (U.S. Dollars one thousand five hundred) per calendar day; and
 - 8.2.2 for cause as soon as is reasonably practicable for the Parties each time the performance of the Services has encountered a serious and material difficulty, failure or obstacle, provided that Customer shall bear the costs of any such "for cause" audit unless such difficulty, failure or obstacle, as applicable, was due to CMC's default or CMC's breach of this Agreement or the Commercial Quality Agreement.
- 8.3 A Customer Audit shall last no longer than 2 (two) Business Days and may only be conducted during regular business hours. A maximum of 3 (three) named employees or consultants of Customer (the "Auditors"), all of whom must be subject to an enforceable confidentiality agreement with CMC no less stringent than the confidentiality obligations hereunder, may attend the Audit. During the Audit, the Auditors may under appropriate escort enter those permitted areas of CMC's facility concerned with the Services for the sole purpose of observing and inspecting the performance of the Services and those records of CMC specific to or otherwise relevant for the Services (including qualification systems, water systems and environmental monitoring) subject to the following:
- 8.3.1 the Auditors will obey and adhere to the rules and regulations in place at CMC concerning health and safety, cGMP and customer confidentiality; and
 - 8.3.2 the Auditors may not enter any prohibited parts of the CMC Facility.
 - 8.3.3 Customer indemnifying CMC for the Auditor's actions or omissions in accordance with Clause 12.
- 8.4 Customer will itself and shall ensure that (i) Customer's Auditors conduct a Customer Audit efficiently and (ii) its Auditors will not take advantage of or use any information obtained or observed (by error or otherwise) during a Customer Audit which does not relate to the Services.
- 8.5 Customer may elect, at Customer's expense, to have up to two persons in plant ("PIP") during the performance of the Services subject to:
- 8.5.1 Customer reimbursing CMC at a rate of US\$[**] per month for two PIP;
 - 8.5.2 the PIP will obey and adhere to all rules, regulations and directions of CMC during their attendance at the CMC Facility including, but not limited to those concerning health and safety, cGMP and customer confidentiality and such PIP shall only have access to those areas of the CMC Facility actually concerned with the Services where acceptable under Applicable Laws and cGMP and while escorted by CMC personnel;

- 8.5.3 the PIP may not enter any prohibited parts of the CMC Facility.
- 8.5.4 Customer indemnifying CMC for the PIP's actions or omissions in accordance with Clause 12; and,
- 8.5.5 the other commercially reasonable conditions set out in any notice served by CMC; and,

CMC shall provide PIP with an appropriate workspace during the regular hours of operation. CMC shall, to the extent it does not disrupt or interfere in the timely provision of the Services, allow the PIP personnel to verify that all documentation and records solely applicable to the Product are complete and accurate, including that, but not limited to, raw materials and components are released, equipment is within calibration, and the final training has occurred with appropriate manufacturing personnel. CMC shall provide training and, where applicable, documented guidance to the PIP personnel as needed to comply with any specialized safety requirements of CMC. Generally, it is anticipated that each PIP will have access, as reasonably necessary, to all IB-1001 product data, records, meetings, and other information as necessary to fulfill his onsite responsibilities. CMC shall promptly respond in writing to Customer regarding any items of non-compliance identified by Customer, and shall develop a plan with Customer, reasonably satisfactory to Customer to promptly remedy such items of non-compliance, all in accordance with the Commercial Quality Agreement.

Regulatory Inspections

- 8.6 In addition to Customer Audits, CMC shall permit, upon reasonable notice and during reasonable times, a competent governmental or Regulatory Authority body to enter those areas of CMC's Facility concerned with the Services for the sole purpose of observing and inspecting the performance of the cGMP Services and those records of CMC specific to the cGMP Services (each, a "Regulatory Inspection"). Such Regulatory Inspections are subject to:
 - 8.6.1 the individuals representing such governmental or Regulatory Authority body obeying and adhering to the rules and regulations in place at CMC concerning health and safety, cGMP and confidentiality. To the extent it is able and permitted to, CMC will give Customer prompt notice of any impending Regulatory Inspection and provide copies of all responses and explanations relating thereto to the extent concerning the Product. CMC agrees to permit a Customer representative (a "Quality Representative") to accompany the Regulatory Authority representative(s) during any Regulatory Inspection, provided that (i) Quality Representative obeys and abides by the rules and regulations in place at CMC concerning health and safety, cGMP and customer confidentiality; (ii) does not enter any prohibited parts of the CMC Facility; (iii) Customer indemnifies CMC for the Quality Representatives' actions or omissions in accordance with Clause 12 and (iv) the Quality Representative shall only participate as an observer and be present only during those portions of the Regulatory Inspection that pertain to the Services.

8.6.2 CMC being entitled to charge Customer for such visits at CMC's then standard rates, other than where such visits are being conducted due to the fault of or breach by CMC (e.g., upon the issuance to CMC of a 483 warning letter in respect of its facility), in which case CMC shall not make any charge for the inspection.

8.7 During any Regulatory Inspections CMC shall provide reasonable assistance as requested by the relevant government or Regulatory Authority and shall promptly permit access to and (at Customer's expense, if the Regulatory Inspection being conducted is Product-related) copy and verify records and reports in CMC's possession, custody or control relating to the cGMP Stages of the Services.

Regulatory Filings and Standards

8.8 During the preparation for filing with any Regulatory Authority of any documentation which is or is equivalent to the Regulatory Authority's Chemistry and Manufacturing Controls ("Authority Submission") portion of applicable approval application, including any New Drug Application, Abbreviated New Drug Application (ANDA), Marketing Approval Application (MAA) or other approval, as the case may be, Customer shall provide CMC with a copy of the relevant Authority Submission portion as well as all supporting documents which have been relied upon to prepare the Authority Submission portion so as to permit CMC to verify that the Authority Submission portion accurately describes the work that CMC has performed and the manufacturing processes that CMC will perform pursuant to this Agreement. CMC shall provide Customer with its comments as soon as reasonably possible (and ideally within fifteen (15) Business Days (except with respect to Customer's initial MAA submission, in which case CMC shall comment as soon as possible)) from receipt of the documents and thereafter shall provide any further comments as CMC discovers other relevant matters in the performance of the Services.

8.9 For clarity, the Parties agree that in reviewing the documents referred to in Clause 8.8 above, CMC's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by CMC. As such, CMC shall not assume any responsibility or liability for the accuracy of the filings with Regulatory Authorities; provided, that the foregoing shall not relieve CMC of its obligations to Customer with respect to the performance of the Services including delivery of accurate data (it generates) and reports. For clarity, the Parties agree that CMC shall at all times be responsible and liable for the accuracy of its own data that it generates and provides to Customer but shall not be responsible or liable for any interpretations it makes or for any conclusions derived by Customer or any Regulatory Authority in the application or use of such data. The sole responsibility of the preparation and filing of all regulatory documents with the Regulatory Authorities shall be borne by Customer. CMC shall promptly furnish Customer with a copy of all pertinent portions of all Regulatory Inspection reports issued by a Regulatory Authority and related correspondence to the extent the same relates to the manufacture of the Product.

- 8.10 Customer shall provide to CMC:
- 8.10.1 all documents reasonably necessary or requested by CMC relating to any Regulatory Authority's pre-approval inspection of CMC's Facility, including but not limited to, development reports, Chemistry and Manufacturing Controls documentation and stability data; and,
 - 8.10.2 at least twenty (20) Business Days prior to filing any documents with any Regulatory Authority that incorporate data generated by CMC, Customer shall provide CMC with a copy of the documents incorporating such data so as to permit CMC to verify the accuracy and regulatory validity of such documents as it relates to the CMC-generated data; and,
 - 8.10.3 all Regulatory Inspection reports issued by a Regulatory Authority and related correspondence to the extent the same relates to CMC's manufacture of the Product.
- 8.11 Customer shall ensure that all critical analytical methods supplied by or on behalf of Customer and used by CMC to accept Raw Materials from any source or to release Product from the CMC Facility (i) are certified by Customer to be appropriate for the intended use (e.g., cleaning verification, product release, in-process testing, and stability testing); (ii) are validated per current regulatory guidelines, Regulatory Obligations and laws; and (iii) are made available to CMC personnel. Periodic re-certification of methods of validation may be required in accordance with cGMP and shall be certified in accordance with this Clause 8.11 and be provided free of charge at Customer's expense to CMC by Customer.

9. **WARRANTIES**

Customer Warranties

- 9.1 Customer warrants and represents to CMC that:
- 9.1.1 to the best of its knowledge, Customer has the right to supply and deliver to CMC the Customer Materials (including the Cell Line provided by or on behalf of Customer where applicable) and the Customer Intellectual Property Rights and CMC has the right to use the same for the Services and the manufacture of Product;
 - 9.1.2 any information provided by Customer to CMC regarding the Customer Materials and Cell Line is materially accurate and, to the best of Customer's knowledge, the Cell Line provided by or on behalf of Customer and any Customer Materials are free from all contaminants (including without limitation virus, bacteria or other vectors) and if handled and used in strict

accordance with the recommendations and guidelines provided by Customer to CMC in advance of receipt of the Customer Materials and Cell Line will not cause a health hazard or biohazard;

- 9.1.3 to the best of Customer's knowledge, the use of any of the Cell Line, Customer Materials, and Customer Intellectual Property Rights, the Process and the manufacture of Product does not infringe any Intellectual Property rights of third parties;
- 9.1.4 the license of Customer Intellectual Property Rights to CMC for the Services is lawfully granted; and
- 9.1.5 to the best of its knowledge the Cell Line and Process provided by or on behalf of the Customer and Customer Materials are viable, adequate and suitable for the effective performance of the Services and manufacture of Product according to Specification and it knows of no reason (suspected or otherwise) why the Objective cannot be achieved or the Services successfully performed and the information supplied to CMC regarding the Cell Line provided by or on behalf of the Customer and Process is full and true in all reasonable and material respects; and
- 9.1.6 to the knowledge of Customer there is no claim, suit, proceeding or investigation pending or threatened against Customer or its Affiliates which might prevent or interfere with Customer's or CMC's performance under this Agreement.

CMC Warranties

9.2 CMC warrants and represents to Customer that:

- 9.2.1 to the best of its knowledge it has the necessary permits, facilities, third party contractors and skilled personnel that may be reasonably anticipated to be necessary of a biologics contract manufacturer for the provision of the Services to be provided hereunder;
- 9.2.2 all Deliverables shall be Delivered free of encumbrances or liens but for the avoidance of doubt no warranty is given in this Clause 9.2.2 in respect (i) non-infringement of third party Intellectual Property Rights, or (ii) freedom to use;
- 9.2.3 to the best of its knowledge, the CMC Intellectual Property Rights used in the Services do not infringe third party Intellectual Property rights except that no warranty is given to the extent that infringement arises due to the combination of CMC Intellectual Property Rights used together with the Cell Line, Process, Customer Materials and Customer Intellectual Property Rights but that CMC shall promptly notify Customer if it receives notice that its manufacture of Product infringes a third party Intellectual Property right;

- 9.2.4 where Services are to be performed according to cGMP, CMC shall apply cGMP standards to the performance of those Services and perform the Services in accordance with the Commercial Quality Agreement;
- 9.2.5 the Product, when Delivered to Customer and released with a Certificate of Analysis by CMC, will conform to the Specification and cGMPs applicable to the Product;
- 9.2.6 to the knowledge of CMC there is no claim, suit, proceeding or investigation pending or threatened against CMC which might prevent or interfere with CMC's performance under this Agreement;
- 9.2.7 no Product Delivered and released with a Certificate of Analysis by CMC pursuant to this Agreement will, at the time of such Delivery, be adulterated within the meaning of the Act;
- 9.2.8 Product Delivered and released with a Certificate of Analysis by CMC will have been stored, shipped or prepared for shipment by CMC up to the point of Delivery in accordance with all applicable cGMPs; and
- 9.2.9 CMC has a valid license to the CHEF1 Technology.

Mutual Warranties

- 9.3 Each Party warrants and represents to the other that:
 - 9.3.1 it has the right and corporate authority to enter into this Agreement;
 - 9.3.2 it shall obtain and during the Term maintain in force all appropriate permits and regulatory licenses required in connection with the handling, transport and storage of the Cell Line and Product;
 - 9.3.3 it will promptly (and within 5 (five) Business Days if permissible under applicable law or stock exchange rules) notify the other Party in writing of any allegation of or misuse of or infringement of any third party Intellectual Property rights due to the handling, storage or use of the Cell Line, Customer Materials, Customer Intellectual Property Rights, CMC Intellectual Property Rights or manufacture of Product;
 - 9.3.4 It is not debarred and has not and will not knowingly use in any capacity the services of any person debarred in subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992 or any comparable law of any foreign jurisdiction, as each may be amended from time to time and that each Party will notify the other immediately in the event of a change in such status known to the Party;

- 9.3.5 Neither Party nor any of its Affiliates nor any member of their staff have been charged with or convicted under federal Laws, or other Applicable Laws, for conduct relating to the development or approval, or otherwise relating to the regulation of any drug product under the Generic Drug Enforcement Act of 1992 or any and all other relevant statutes, laws or regulations; and
- 9.3.6 Neither the execution and delivery of this Agreement nor the performance of the transactions contemplated hereby, nor compliance by the Parties with the provisions hereof, shall (i) conflict with or result in a material breach of any provision of the certificate of incorporation or bylaws of a Party, (ii) violate any material order, writ, injunction, decree, statute, rule or regulation applicable to a Party, or (iii) conflict with any material obligations or agreements of a Party to any person, contractual or otherwise.

Warranty Disclaimer

- 9.4 To the maximum extent permitted by the applicable law of this Agreement, except for those express warranties set out above, the Parties neither make nor give any other express or implied (whether by statute, custom or otherwise) warranties in relation to each of their respective obligations, duties or activities owed or performed under this Agreement and hereby exclude any other such express or implied warranty in respect of that subject matter.

10. **CONFIDENTIAL INFORMATION**

- 10.1 In consideration of one Party (the “Disclosing Party”) making available its Confidential Information to the other (the “Recipient Party”), the Recipient Party hereby undertakes that it shall, and shall procure that each of its Permitted Recipients, shall:
- 10.1.1 treat and safeguard as private and confidential all the Confidential Information;
- 10.1.2 use the Confidential Information only during the Term for those purposes reasonably necessary for or anticipated under this Agreement and without prejudice to the generality of the foregoing, not use any Confidential Information to obtain any commercial advantage over the Disclosing Party;
- 10.1.3 ensure the proper and secure storage of all Confidential Information applying standards of care reasonably expected and no less stringent than standards applied to protection of Recipient Party’s own confidential information;
- 10.1.4 not at any time without the Disclosing Party’s prior written consent disclose or reveal, whether directly or indirectly, any of the Confidential Information to any person whatsoever except its Permitted Recipients, and then only on a limited need to know basis, who shall be informed by it of the confidential

nature of the Confidential Information and of the confidentiality terms of this Agreement and for whom it hereby accepts full responsibility in the event that any such person shall breach the duty of confidence imposed upon them; and

10.1.5 not at any time have any discussion, correspondence or contact with any third party concerning the Confidential Information without the prior written consent of the Disclosing Party.

10.2 The obligations in this Agreement regarding Confidential Information do not apply to information:

10.2.1 which, at the time of its disclosure by the Disclosing Party, was wholly available to the public and could be obtained without reference to the Confidential Information by any person with no more than reasonable diligence;

10.2.2 which becomes generally available to the public after such disclosure otherwise than by reason of a breach of any of the undertakings in this Agreement or any breaches of confidence by the Recipient Party or its Permitted Recipients;

10.2.3 which is, at the time of such disclosure and as evidenced by the Recipient Party's written records, lawfully already within its possession; or

10.2.4 to the extent that the Recipient Party or any of its Permitted Recipients is compelled to disclose the Confidential Information by law or by any stock exchange or other Regulatory Authority having jurisdiction over it or them (but, for the avoidance of doubt, only to that extent).

10.3 Other than the limited and restricted rights of use set out in this Clause 10 nothing in this Agreement intends to or has the effect of granting any right, title, license or interest in or to the Recipient Party or Permitted Recipients in respect of the Disclosing Party's Confidential Information. All data directly generated in the performance of the Services that is not CMC IPR or does not incorporate any Intellectual Property of CMC shall be deemed Confidential Information of Customer and all other data shall be CMC Confidential Information, in each case subject to the provisions of Clause 10.2.

10.4 If the Recipient Party or any of its Permitted Recipients becomes aware of any misuse of the Confidential Information, compelled to disclose any Confidential Information in the circumstances described in Clause 10.2.4 of this Agreement or a breach or threatened breach of this Clause 10 occurs or becomes apparent, the Recipient Party shall inform the Disclosing Party in writing of such obligation or fact as soon as possible after it is informed, or becomes aware, of it and if possible, before any Confidential Information is disclosed, so that (if the Disclosing Party in its absolute discretion shall see fit) a protective order or other appropriate remedy may be sought. The Recipient Party agrees to assist and co-operate (and shall procure that each of its Permitted Recipients shall, as appropriate, assist and co-operate) in any action which the Disclosing Party may decide to take. The

Recipient Party shall notify the Disclosing Party prior to each disclosure of Confidential Information if it is under any obligation which would or might compel it to disclose any Confidential Information and subsequent to such disclosure it shall not voluntarily assume any such obligation.

- 10.5 Except as otherwise provided for in this Agreement or otherwise required by law or administrative authorities, neither Customer nor CMC shall disclose any terms or conditions of the Agreement to any third party without the prior written consent of the other Party.
- 10.6 Upon termination or expiry of this Agreement or at the request of the Disclosing Party, the Recipient Party shall promptly return to the Disclosing Party any and all Confidential Information (including copies of documents, computer records and records on all other media) then in its possession or under its control except where such Confidential Information is covered under surviving license rights between the Parties. Notwithstanding the foregoing, the Parties may retain a single copy of any document contained the Disclosing Party's Confidential Information solely for the purpose of determining the scope of the obligations under this Agreement.
- 10.7 The Parties acknowledge that they have received Confidential Information under other agreements between each other including [define agreements]. The Parties hereby agree that Confidential Information received under those earlier agreements may be used for the purposes of performing the Services under this Agreement.
- 10.8 The Parties acknowledge that each Party may make use of the other Party's Confidential Information in any filing or response (whether oral or written) to a Regulatory Authority provided that each Party shall use its reasonable endeavours to seek confidential treatment of such Confidential Information by the applicable Regulatory Authority, including, without limitation, in the case of Customer filing any CMC Confidential Information concerning its regulatory dossier, the Customer filing such information under the confidential portion of that dossier.
- 10.9 The provisions of this Clause 10 shall survive termination or expiry of the Agreement.

11. **INTELLECTUAL PROPERTY**

Pre-Existing Intellectual Property

- 11.1 Any Intellectual Property owned by a Party or licensed by a third party to a Party as of the Effective Date or before the commencement of the Services ("Pre-Existing IPR") shall remain the sole and absolute property of the Party that owned or was licensed to use such PreExisting IPR. Except as otherwise expressly set forth in this Agreement, nothing in this Agreement shall act as any assignment, license, or other transfer of the Pre-Existing IPR. The Pre-Existing IPR shall not be licensed to the other Party under this Agreement unless an express license is granted hereunder. Nothing in this Agreement affects the terms of the license granted by CMC to Customer under the Existing License Agreement.

CHEF1 Technology

- 11.2 Notwithstanding anything to the contrary and without prejudice to the scope of the license granted under the Existing License Agreement, CMC shall own all right, title and interest in and to (a) the CHEF1 Technology; (b) any polynucleotides or vectors comprising all or part of CHEF1 Technology and any host cells transfected with such polynucleotides or vectors; and (c) all Intellectual Property Rights which are or become owned by, licensed to or otherwise controlled by CMC in any of (a) or (b); and (d) all improvements, developments or modifications to any of (a), (b) or (c) (collectively, "CHEF1 Property").
- 11.3 For the avoidance of doubt, nothing in this Agreement grants, shall be deemed to grant or obligates or shall obligate CMC to grant, transfer or license, save in the case of licensing as required by Clause 5.17.2, any right, title or interest in the CHEF1 Technology or any Intellectual Property Rights in the CHEF1 Property or any parts thereof.

Customer's grant of Intellectual Property License for the Services

- 11.4 The Customer hereby grants to CMC for the Term of this Agreement a non-exclusive, royalty-free, sub-licensable (but only to those persons permitted with Customer's prior approval under Clause 2.5), limited license in respect of Customer Intellectual Property Rights and Customer IPR solely to the extent the same is required and necessary for the proper performance of the Services. This license:
- 11.4.1 does not prevent the Customer from granting a license to or making any use of its Pre-Existing IPR; and
- 11.4.2 terminates automatically upon the expiry or termination of this Agreement, whichever is the earlier.

Intellectual Property created in the course of the Services

- 11.5 Without affecting Clauses 11.1 and 11.2, all data, information and Intellectual Property newly generated by CMC exclusively in its performance of the Services and which is specifically related to the Product and not useful for general biologics manufacturing activities shall be owned by the Customer ("Customer IPR"). Notwithstanding anything to the contrary in the Letter of Agreement, this provision shall control the ownership of any Customer IPR developed during the term of the Letter of Agreement. CMC shall, provided Customer has paid all sums properly due and payable hereunder, assign to Customer, without the payment of additional compensation to CMC, the entire right, title and interest for the entire world in and to all Customer IPR, including without limitation all joint inventions with respect thereto.
- 11.6 All Intellectual Property other than Customer IPR generated under the Services shall be owned by CMC ("CMC IPR").

License to CMC IPR

- 11.7 CMC hereby grants to Customer a general, royalty free, sub-licensable, worldwide license to use CMC Intellectual Property Rights and CMC IPR (excluding any CHEF1 Property, which is governed by the Existing License Agreement) to the extent that the same is used for the exploitation of the Product or use of the Cell Line or Process to manufacture Product. Nothing in the foregoing shall permit Customer to make any disclosure of Confidential Information or CMC's Know-How to a third party without the express prior written consent of CMC. This license does not prevent CMC granting a license to or making any use of CMC Intellectual Property Rights or CMC IPR.

Right to file for protection

- 11.8 Each Party may file patent protection on any Intellectual Property it owns in accordance with this Clause 11 and the other Party shall promptly upon request co-operate at the requesting Party's reasonable expense, with any requests to assist or enable the Party's protection including but not limited to signing and delivering documents and other information necessary for the valid application and prosecution of any such patent.

Party's Names & Press Release

- 11.9 Except as otherwise provided for in this Agreement or required by any applicable law, regulation or order of an administrative agency or court of competent jurisdiction, neither Party shall use the name of the other Party or of the other Party's Affiliates, directors, officers or employees in any advertising, news release or other publication except that CMC may identify Customer by name as a customer of CMC. The Parties will within 90 days of the Effective Date prepare a joint press release to announce the collaboration arising under this Agreement and any amendment to the text of any such press release shall require the prior written approval of the other Party, which shall not be unreasonably withheld.

12. INDEMNITIES AND LIABILITYCMC's Indemnity

- 12.1 Except to the extent any of the following Claims (defined herein) are caused as a direct result of CMC's material breach of this Agreement, negligence, or willful misconduct, Customer shall promptly indemnify and hold harmless CMC and each of its directors, officers, permitted subcontractors and Testing Laboratories and those employees and contractors of CMC introduced to Customer by CMC and involved in the manufacture and quality of the Product (the "CMC Parties") against any and all losses, demands, claims, liabilities, damages, costs and expenses (including but not limited to, court costs and

reasonable documented attorney's fees and expenses together with any applicable taxes thereon) (collectively, "Claims") that any of the CMC Parties may or have suffered as a result of the following:

- 12.1.1 any third party claim of infringement or alleged infringement or breach of any third party rights including Intellectual Property rights in CMC's use of the Cell Line, Process, Customer Intellectual Property Rights, Customer Materials or the performance of the Services or manufacture of Product, except to the extent such infringement or breach is due to CMC Intellectual Property Rights and/or CMC IPR;
- 12.1.2 Customer's material breach of any of its covenants, representations, or warranties under **Clause 9.1** of this Agreement;
- 12.1.3 any third party claims resulting from the use, handling, distribution, marketing, safety or sale of the Product or Drug Substance including any derivative, conjugated form or formulation of the same;
- 12.1.4 any Recall other than one for which CMC is responsible pursuant to **Clause 13.3**;
- 12.1.5 any contamination or damage to CMC's operations or Facility caused by the Cell Line or Customer Materials except to the extent such Cell Line and Customer Materials were not handled materially in accordance with the guidelines provided by Customer to CMC in advance of receipt of the relevant Cell Line and/or Customer Materials;
- 12.1.6 any use, handling, distribution, marketing, safety or sale of Product by a third party which was the subject of a Release for Further Processing in accordance with Clause 6.6;
- 12.1.7 Customer's gross negligence, recklessness or willful misconduct in the performance of its obligations under this Agreement; or,
- 12.1.8 any acts or omissions of an Auditor, PIP or Quality Representative.

Customer's Indemnity

12.2 Except to the extent any of the following Claims in this clause 12.2 are as a direct result of Customer's material breach of this Agreement, negligence or willful misconduct, CMC shall promptly indemnify and hold harmless Customer and each of its directors and officers and those employees and contractors of Customer introduced to CMC by Customer and involved in the manufacture and quality of the Product (the "Customer Parties") against any Claims that any of the Customer Parties may or have suffered as a result of the following:

- 12.2.1 third party claims caused due to Product at the time of Delivery failing to meet Specification where such Product was certified by CMC at the time to meet Specification;

- 12.2.2 third party claims to the extent caused by CMC's failure to manufacture Product according to cGMP (where such Product is released at the time of Delivery as meeting cGMP);
- 12.2.3 any third party claim of infringement or alleged infringement or breach of any third party rights including Intellectual Property rights by CMC to the extent such infringement is due to CMC's use of the CMC Intellectual Property Rights in the performance of the Services;
- 12.2.4 CMC's material breach of any of its covenants, representations, or warranties under Clause 9.2 of this Agreement;
- 12.2.5 CMC's gross negligence, recklessness or willful and intentional misconduct in the performance of its obligations under this Agreement; or
- 12.2.6 third party claims of personal injury or property damage actually incurred by a third party caused by the use of Product Delivered and released by CMC under this Agreement with a Certificate of Analysis where such Product at the time of Delivery did not comply with the Certificate of Analysis, Specification or cGMP.

Indemnification Procedure

- 12.3 The Party (the "Indemnitee") that intends to claim indemnification under this Clause 12 shall:
 - 12.3.1 promptly, and in any event within fifteen (15) Business Days of it receiving notice of the Claim, threat or action, notify the other Party (the "Indemnitor") in writing in general terms of the Claim, threat or action which has or has the potential to give rise to the Indemnitee seeking to rely on and claim the benefit of the indemnification together with notification of the Indemnitee's intention to rely on such indemnity, provided that failure to give such notice shall not relieve the Indemnitor of its indemnification obligations except and only to the extent such failure actually and materially prejudices the ability of the Indemnitor to defend against such relevant Claims;
 - 12.3.2 not prejudice any defense to the Claim or attempt to settle or compromise such claim;
 - 12.3.3 shall comply with the procedure in Clause 12.3.1 except that nothing shall prevent it from complying with the procedural requirement of any proceedings which have been commenced;
 - 12.3.4 subject to its other rights and obligations and compliance with the procedures set out in this Clause 12 permit the Indemnitor to have overall control of the conduct of the negotiations and the proceedings including any counterclaim;

- 12.3.5 cooperate as reasonably requested by the Indemnitor, at the Indemnitor's expense, in the conduct of such Claim (and any counterclaim); and
- 12.3.6 have the right (at the Indemnitor's expense) to instruct independent counsel and participate in all proceedings and negotiations whether named or not as a party in the Claim or proceedings.
- 12.4 The Indemnitor shall promptly after notification of a Claim, appoint experienced and professional attorneys who will professionally and thoroughly defend and prosecute any Claim that gives rise to an indemnity claim under this Clause 12. If the Indemnitor does not act in accordance with its obligation under this Clause 12.4 the Indemnitee may, at the Indemnitor's sole cost and expense, appoint its own experienced and professional attorneys to defend and prosecute such Claim and notwithstanding Clause 12.3.4, the Indemnitee will have full control and conduct of defending and prosecuting such Claim.
- 12.5 Notwithstanding any other provision in this Clause 12, the Indemnitor shall not settle or consent to an adverse judgement in any such Claim, demand, action or other proceeding that adversely affects the rights or interests of any Indemnitee or imposes additional obligations (financial or otherwise) on such Indemnitee, without the prior express written consent of such Indemnitee (such consent to be at the Indemnitee's sole discretion).
- 12.6 The Parties shall promptly and in good faith discuss ways, whether by modifications to the Services or Product, licensing or otherwise to settle or overcome a Claim under the indemnities. In the event that formal legal proceedings are commenced the Parties shall use their best endeavours to conduct such discussions expeditiously. Notwithstanding the foregoing, if a Claim under an indemnity under Clause 12.1.1, 12.1.5 (but only if the claim includes Customer Materials) or 12.2.3 is made and the Parties do not reach a plan to settle or overcome the Claim or reasonably satisfy the concerns of the Indemnitee within 120 days (or such other period as may be reasonably agreed by the Parties to assess the situation) of notification under Clause 12.3.1, the Party to whom the indemnity claim has been made may, on 20 (twenty) Business Day's notice in writing suspend or terminate the Services where a failure to do so could continue to increase that Party's liability.

Insurance

- 12.7 Customer shall procure from a financially strong insurance carrier commercial general liability insurance including coverage for products and completed operations and contractual liability (including coverage for advertising and personal injury) with a combined single limit of no less than twenty million dollars (\$20,000,000) per occurrence and twenty million dollars (\$20,000,000) in the aggregate. Customer will maintain such insurance during the Term of this Agreement and for three (3) years after the last sale of Product. Upon reasonable request, Customer will deliver a certificate of insurance evidencing such coverage.

- 12.8 CMC shall maintain, at its expense comprehensive general liability insurance and workers compensation insurance, including product liability insurance, in the amount of twenty million dollars (\$20,000,000) per occurrence and twenty million dollars (\$20,000,000) in the aggregate. All insurance required under this Agreement shall be maintained during the Term, and CMC shall from time to time provide copies of certificates of such insurance to Company upon reasonable request. Notwithstanding the preceding sentence, CMC shall be obligated to maintain product liability insurance obtained by it pursuant to this Clause 12.8 during the Term and after expiration or termination of this Agreement for a period three (3) years following the expiration date for the last lot of Product delivered hereunder. Upon reasonable request, CMC will deliver a certificate of insurance evidencing such coverage.
- 12.9 Each Party will provide the other Party with at least 30 calendar days' written notice prior to non-renewal, termination or modification of their respective insurance coverage as described above.

Limitation of Liability

- 12.10 The parties represent and acknowledge that they have negotiated the terms of this Agreement and have reached agreement on the terms based on their own assessment of their own risks, liabilities and rewards in connection with this Agreement and the Product in addition to having had the benefit of professional legal advice and accordingly the Parties agree that without prejudice to the terms of Clauses 6.16 and 6.17, CMC's aggregate liability to Customer for any loss or damage suffered by Customer, as a result of breach of this Agreement or of any other liability (including but not limited to negligence, misrepresentation or claim under the indemnities) in respect to any claim arising under this Agreement or in connection with the Services in a particular calendar year shall be limited to (a) at all times prior to Customer securing FDA and EMA approval of the Product, an amount equal to the greater of One Million US Dollars (\$US1,000,000) or an amount equal to 1.1 times the total Price of the Services performed to date since the Effective Date subject to a maximum of thirty (30) million US Dollars, and (b) following Customer securing both FDA and EMA approval for the Product, an amount equal to the greater of (i) the total Price of the Services performed in the twenty-four (24) month period immediately preceding the event giving rise to liability subject to a maximum of thirty (30) million US Dollars or (ii) the amount recovered from CMC's insurers under CMC's insurance policy in respect of the loss to Customer so claimed but excluding any excess payable by CMC or sums recovered from CMC by or on behalf of the insurer. Customer shall be entitled to request CMC to increase its insurance premium to a reasonable sum in excess of CMC's then current coverage provided that Customer shall, in advance, pay to CMC's insurer in respect of CMC's increase in coverage the premium associated with such increased insurance coverage. Notwithstanding the foregoing, CMC's obligation to repay the Fund in accordance with Clause 7.2.2 shall not be subject to the limitation of liability set out above.

- 12.11 Without prejudice to Clause 12.12, neither CMC nor Customer shall be liable for any loss or damage howsoever caused (even if foreseeable or in the contemplation of CMC or Customer) in respect of indirect, special or consequential damages or losses.
- 12.12 Nothing in this Agreement shall purport or attempt or serve to exclude or restrict any liability for (i) death or personal injury resulting directly from either Party's negligence; (ii) liability for fraud or fraudulent misrepresentation; or (iii) any liability for breach of implied undertakings which cannot be excluded by contract such as, and without limitation, warranties as to title, or strict product liability.
13. **PRODUCT RECALL**
- 13.1 Except as otherwise set forth in Clause 13.3 below, the costs and obligations with respect to any Recall of Product and handling enquiries and contacts from any Regulatory Authority relating to any Recall of Product shall be the responsibility of Customer. Customer shall notify all Regulatory Authorities having jurisdiction over Product (whether or not the issue arose in the jurisdiction controlled by the Regulatory Authority) of any Recall, and shall be responsible for coordinating all necessary activities regarding the action taken; provided, however, that nothing in the foregoing shall prevent CMC from making any notification to a Regulatory Authority with respect to the Product or a Recall. CMC shall, at Customer's expense, provide all reasonable assistance to Customer in connection with any Recall. The Parties agree to keep each other advised of any Recall, the progress of undertaking any Recall, and to exchange copies of such documentation as may be reasonably required, to assure regulatory compliance with a Recall.
- 13.2 If either Party has reason to believe that any Product (whether the Product itself or particular batch(es)) should be Recalled, such Party shall promptly inform the other in writing, to also include the reasons and explanations for the Recall, prior to taking any such action. In addition, Customer shall give CMC prompt written notice of any Recalls that Customer believes were caused by or may have been caused by CMC's failure to comply with its obligations under this Agreement.
- 13.3 If any Product is Recalled for safety reasons or due to a mandatory notification from a Regulatory Authority dictating the Recall and, in either case, such reasons are solely attributable to CMC's failure to manufacture Product in accordance with cGMP and the terms of this Agreement ("CMC's Manufacturing Failure"), then CMC shall, subject to Clause 12.10, reimburse Customer for all reasonable documented expenses actually and reasonably incurred by Customer in undertaking the Recall of those specific Products which are the subject of a Manufacturing Failure. Such payment shall be made within forty-five (45) Business Days of Customer providing CMC with an adequately detailed breakdown of such costs and responses to all requests for clarification by CMC with respect thereto. If such Recall is solely attributable to Customer's actions or omissions, then Customer shall be responsible for all costs and expenses concerned with the Recall ("Customer Failure"). If the Recall is contributed to by both CMC's Manufacturing Failure and Customer Failure then CMC shall be liable for a proportion of the reasonable

documented expenses actually and reasonably incurred by Customer in undertaking the Recall of those specific Products to the extent caused by CMC's Manufacturing Failure subject to the provisions of Clause 12.10. If either Party, acting in good faith, disputes that the Recall is:

- 13.3.1 due to safety reasons or mandatory notification from a Regulatory Authority dictating the Recall then the Parties shall mutually select a regulatory expert to evaluate whether the Recall was appropriate to address the safety reason or comply with the Regulatory Authority's notice (as applicable); and/or
- 13.3.2 due to CMC's Manufacturing Failure or Customer Failure (as applicable), then the Parties shall mutually select an independent laboratory to evaluate whether the Product is defective due to CMC's Manufacturing Failure and/or Customer Failure; and, the evaluation(s) by the regulatory expert and/or independent laboratory shall be binding on the Parties (other than where such decision is a Manifest Error) although the regulatory expert and/or independent laboratory shall not be empowered to determine the percentage of contribution, which percentage shall be determined by the Parties or, in the absence of agreement, pursuant to the dispute resolution mechanism under Clause 17. Any payment by CMC under this Clause 13.3 shall be Customer's sole remedy for the Recall and Customer shall not be entitled to make any further claim against CMC in respect of Product that was the subject of the Recall under Clause 6. This clause is subject to the provisions of Clause 12.12.

13.4 In all circumstances other than those explicitly identified under Clause 13.3 Customer shall be responsible for all costs and expenses in undertaking any Recall.

14. **TERM AND TERMINATION**

14.1 This Agreement shall commence on and have effect as of the Effective Date and will, subject to earlier termination in accordance with this Clause 14 or otherwise, continue for an initial term of six (6) years (the "Initial Term"). The term of this Agreement may be extended beyond the then current term for (a) further one-year periods (up to a maximum of four (4) years) provided the first notice is served during the Assignment Option Period in the event of an assignment in accordance with Clause 19.5 below, and (b) for a further two year period ("Additional Term") provided that with respect to this subsection (b) only (i) Customer has at all times complied with all of its material obligations under this Agreement and (ii) Customer provides CMC with written notice to extend the current Term no less than twenty-four (24) months before the expiry of the Initial Term or more than thirty-six (36) months before the expiry of the Initial Term.

Events of Termination

- 14.2 Either Party (“Non-Defaulting Party”) may terminate this Agreement before expiry of the Term with immediate effect upon prior written notice to the other Party (“Defaulting Party”) if:
- 14.2.1 the Defaulting Party fails to pay any sum properly due and payable under this Agreement within ten (10) Business Days of notice demanding payment served after expiry of the original payment term stipulated in **Clause 7**;
 - 14.2.2 the Defaulting Party commits a material breach of its obligations under this Agreement and (i) if the breach is capable of remedy, fails to remedy it during a period of 20 (twenty) Business Days starting on the date of receipt of notice from the Non-Defaulting Party generally identifying the breach and requiring it to be remedied (ii) if the breach is CMC’s breach in the manufacture or performance of a Batch, CMC fails to commence manufacture of a replacement Batch within ninety (90) calendar days of receipt of notice from Non-Defaulting Party generally identifying the breach and requiring it to be remedied; or
 - 14.2.3 the Defaulting Party is (i) generally unable to pay its debts as they become due; or (ii) has an administrator appointed or administration order made against it or an order for winding-up or dissolution made (otherwise than in the course of a bona fide reorganisation previously approved in writing by the Non-Defaulting Party) or liquidator appointed and such step is not withdrawn within sixty (60) calendar days.
- it being recognised that for the purposes of this Agreement and, without limitation, the assessment of a material breach under Clause 14.2.2 or otherwise, the failure to manufacture Batches by CMC from time to time (including during a Supply Failure) shall not be deemed a material breach provided that CMC shall have during the Term with reasonable consistency (but for the occasional default) Delivered non-Defective Product to Customer in material compliance with its obligations hereunder, provided, that nothing in this **Clause 14.2.3** shall serve to limit or in any way affect the determination of a Supply Failure in accordance with **Clause 5.17**.
- 14.3 Customer may terminate this Agreement for any reason and without breach upon the greater of (i) twelve (12) months written notice or (ii) the duration (in months) of all Firm Orders and Semi-Binding Orders then on order by Customer and in effect at the time of written notice to terminate.
- 14.4 Customer shall have the right to terminate this Agreement without breach in the event that CMC has any material permit or regulatory license permanently revoked thereby preventing the performance of the Services by CMC, which termination shall become effective on the date that is fifteen (15) calendar days from the termination notice.

- 14.5 Customer shall have the right to terminate this Agreement without breach upon written notice served on CMC within fifteen (15) Business Days of the earlier of notice by CMC of an intended Competitor Change of Control Event or the occurrence of a Competitor Change of Control Event. For purposes of this Agreement, a “Competitor Change of Control Event” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events: (i) a sale or other disposition of all or substantially all of the assets (including this Agreement) of the CMC Facility to a Competitor; (ii) a merger or consolidation of CMC into a Competitor, such that the Competitor shall be the surviving entity that owns or operates the CMC Facility, and in which the stockholders of the Competitor immediately prior to such transaction own, immediately after the transaction, more than fifty percent (50%) of the voting power of the surviving entity or its parent; (iii) a reverse merger in which a Competitor that owns or operates the CMC Facility is the surviving entity and the stockholders of such entity immediately prior to such reverse merger own less than fifty percent (50%) of the voting power of such entity or its parent immediately after the transaction; or (iv) an acquisition by a Competitor within the meaning of Section 13(d) or 14(d) of the Exchange Act of the beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of securities of any entity that owns or operates the CMC Facility representing at least fifty percent (50%) of the voting power entitled to vote in the election of directors. A “Competitor” shall be those companies set forth in Appendix Four, which list shall be updated no more frequently than once annually on or before each anniversary of the Effective Date by the Joint Steering Committee acting in good faith and which list may not exceed more than five (5) companies. For clarity, this termination right does not apply to any other change of control event or for then unnamed competitors. Upon termination under this clause and provided that Customer is not in material breach of its obligations hereunder, CMC (or the surviving entity in the case of a merger) will not charge Customer for its personnel time in respect of Technology Transfer to a Third Party in accordance with Clause 15.
- 14.6 Customer shall have the right to terminate this Agreement for a Supply Failure by serving written notice prior to a Supply Reinstatement where there is no Supply Reinstatement within 12 months of the declaration of a Supply Failure.

Effect of Termination

- 14.7 Upon termination of this Agreement and subject to Clause 7.2.2, Customer shall pay to CMC:
- 14.7.1 payments due by Customer to CMC in respect of Services performed in accordance with the terms and conditions of this Agreement up to and including the day of such termination in full for all completed Services and for partially completed Services a sum calculated on a pro-rata basis having regard to the Price and any Additional Charges agreed for the cancelled Stages (fairly determined by the Project Team having regard to man hours, materials, profit element and irreversible commitments incurred by CMC), it being understood that any amounts payable by Customer hereunder shall either be made by Customer or reduced in accordance with those provisions set forth in **Clause 7.2.2**;

- 14.7.2 other than where termination is by Customer pursuant to **Clause 14.2.2** (for material breach by CMC), **Clause 14.6** (Failure to Supply), a sum by way of liquidated damages:
- 14.7.2.1 in respect of Firm Orders and Semi-Binding Orders in existence at the date of termination, a payment calculated as the total Price (plus any Additional Charges agreed) in respect of all pending, outstanding and undelivered Batches that have not been Delivered at the time of termination, which Deliverables shall be Delivered to Customer in accordance with **Clause 14.8**; and
- 14.7.3 payments properly due and payable at the time of termination pursuant to **Clauses 7.2, 7.11, 7.12, 7.14** and/or **7.19** and/or in accordance with the payment terms in Appendix Three.

14.8 Upon termination of this Agreement for any reason, provided the Customer has paid all sums outstanding and which are properly due and payable under this Agreement, CMC shall provide the Customer with all Deliverables then manufactured or generated and all transferable work in progress and all Product then manufactured. CMC shall not be obliged to transfer any materials pursuant to this Clause 14.8 until Customer has paid CMC all sums properly due and payable to CMC as of the date of termination of this Agreement. Batches that are in the process of being manufactured as of the effective date of termination under this Clause 14 shall not be cancelled without the mutual agreement of the Parties (unless termination is by CMC or Customer is in material breach of its obligations whereupon CMC can cancel such Batches), and this Agreement shall continue to survive with respect to those in-process runs.

14.9 By no later than the date on which the termination of this Agreement becomes effective, each Party will return to the other all Confidential Information in association therewith which it possesses or controls that belongs to the other, except that each may retain a copy in its law department solely for record keeping purposes to enable it to monitor compliance with its obligations hereunder and for no other purpose.

Survival

14.10 Termination or expiry of this Agreement for whatever reason shall not affect the accrued rights of either CMC or Customer arising under or out of this Agreement and all provisions which are expressed to survive this Agreement and the provisions of Clauses 6.6 (Product released for further processing), 6.12 to 6.18 (defects and latent defect handling), 7.9.4 (exclusion of warranties), 10 (Confidential Information), 11 (Intellectual Property, excluding clause 11.4 and, subject to 14.11 below, clause 11.7), 12 (indemnities and

liability), 13 (Product Recall), 14.7 through to 14.11 (Consequences of Termination); 15 (Technology Transfer); 17 (Applicable law & jurisdiction) and 19 (General) shall survive termination or expiry and remain in full force and effect.

14.11 Provided that this Agreement has not been terminated for Customer's breach or insolvency and Customer has paid all sums properly due and payable hereunder the license granted by CMC to Customer pursuant to clause 11.7 in respect of the CMC Intellectual Property Rights and CMC IPR shall survive the termination or expiry of this Agreement.

15. **TECHNOLOGY TRANSFER**

15.1 Upon (i) termination or during the notice period regarding termination of this Agreement or the Services other than where termination is due to material breach by Customer, (ii) the occurrence of a Supply Failure, (iii) the occurrence of a Competitor Change of Control Event, (iv) the service of written notice during the Assignment Option Period in accordance with Clause 19.5 below or (v) on expiry of this Agreement, in each case provided that Customer is in material compliance with its obligations hereunder, Customer may by written notice to CMC seek assistance from CMC, and CMC shall provide reasonable assistance to Customer, with respect to the transfer to Customer or to another manufacturer of the then-current Process, as applicable, solely for the purpose of manufacturing Product ("Technology Transfer"). Following CMC's receipt of such notice, the Parties will establish, in good faith, a schedule and plan for effecting such Technology Transfer and CMC will thereafter co-operate with Customer in implementing such plan subject to the provisions of Clause 15.2. As part of the Technology Transfer, CMC will, subject to Clause 15.2, make available for collection, subject to any applicable Regulatory Obligations, all Customer Materials, Cell Line and one copy of relevant documentation in CMC's possession and (to the extent not previously delivered to Customer) generated pursuant to the Services up to the date of termination or expiry including Batch records, development reports and Process documentation.

15.2 The obligations on CMC in respect of the Technology Transfer shall (subject to Clause 7.2.2):

15.2.1 where triggered due to termination for a Supply Failure:

15.2.1.1 be exercisable by Customer within 12 months of the Supply Failure and once exercised for so long as necessary for Customer's Third Party CMO to become licensed by the FDA and EMA; and,

15.2.1.2 require CMC to support the Technology Transfer by providing personnel on a reasonable basis for the 36 months following notice with the total FTE hours to be committed by CMC during that period to be determined in good faith (it being acknowledged that CMC will not be obliged to make available its personnel on full time secondments); and,

- 15.2.1.3 not be charged by CMC other than for external costs incurred by CMC which shall be charged at cost; or
- 15.2.2 where triggered due to termination for a Competitor Change of Control Event:
 - 15.2.2.1 be exercisable by Customer within 12 months of the Competitor Change of Control Event and once exercised for so long as necessary for Customer's Third Party CMO to become licensed by the FDA and EMA; and,
 - 15.2.2.2 require CMC to make a lump sum payment to IBI of \$[**] USD; and,
 - 15.2.2.3 require CMC to support the Technology Transfer by providing personnel on a reasonable basis for the 48 months following notice with the total FTE hours to be committed by CMC during that period to be determined in good faith (it being acknowledged that CMC will not be obliged to make available its personnel on full time secondments); and,
 - 15.2.2.4 not be charged by CMC other than for external costs incurred by CMC which shall be charged at cost; or,
- 15.2.3 where triggered due to any circumstance other than under Clause 15.2.1 or Clause 15.2.2:
 - 15.2.3.1 be exercisable by Customer for a maximum of 18 months from the date the Technology Transfer becomes operable according to Clause 15.1 above;
 - 15.2.3.2 require CMC to support the Technology Transfer by providing personnel on a reasonable basis for the 36 months following notice with the total FTE hours to be committed by CMC during that period to be determined in good faith (it being acknowledged that CMC will not be obliged to make available its personnel on full time secondments); and
 - 15.2.3.3 the Customer shall pay, in addition to all sums due hereunder (less any portion of the remaining Fund, if any, elected by Customer to be applied to CMC's costs associated with Technology Transfer in accordance with **Clause 7.2.2**), CMC's costs of co-operating with and providing Technology Transfer at a daily FTE rate of US\$[**] (such rate to increase annually on the anniversary of the Effective Date in accordance with the published PPI C rate of inflation) and all costs incurred by CMC (other than personnel time) shall be charged at cost plus [**] handling fee.
- 15.2.4 require CMC to provide reasonable support to Customer and/or its Third Party CMO and respond to reasonable enquiries raised by the Customer and/or its Third Party CMO concerning a transfer of the actual technology used for the manufacture of the Product by CMC; and,

- 15.2.5 not oblige CMC to transfer any CMC Know-How pursuant to this Technology Transfer until the Third Party CMO/Customer enters into a limited license and confidentiality agreement acceptable to and with CMC in order to protect CMC's Know-How and Confidential Information at CMC's reasonable discretion. Following the execution of such license and confidentiality agreement by such Third Party CMO/Customer, CMC shall promptly transfer the CMC Know-How to such Third Party CMO/Customer.

16. **FORCE MAJEURE**

- 16.1 CMC shall not be held liable or responsible to Customer nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement or the Services to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of CMC or its permitted subcontractors including but not limited to fires, earthquakes, floods, embargoes, wars, acts of war (whether war is declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labour disturbances, other substantial similar acts of nature, omissions or delays in acting by any administrative authority, government agency or other party (each, a "Force Majeure Event"). For the avoidance of doubt, a Force Majeure Event shall not include a lack of funds, bankruptcy or other financial cause or disadvantage.
- 16.2 CMC shall notify Customer in writing of any Force Majeure Event which prevents CMC from performing the Services, which notice shall contain CMC's estimate of the duration of such condition and a description of the steps being taken or proposed to be taken to overcome such Force Majeure Event. Upon cessation of the Force Majeure Event, and provided that this Agreement shall not have been terminated in accordance with this Clause 16.2, the Parties shall promptly resume performance under this Agreement as soon as it is commercially reasonable for to do so. If a Force Majeure Event continues for more than three (3) months after notice is served, and is adversely affecting the performance of this Agreement, each Party will have the right, on 30 (thirty) calendar days advance written notice not to expire before the three (3) month period, to terminate this Agreement. In the case of such termination, Customer will not have a right to reimbursement for any sums paid under this Agreement or any claim for damages as a result of the termination of the Agreement or non-performance of the Services. Customer shall account to CMC for any sums due under this Agreement in respect of Services performed up to and including the day of the first day of the Force Majeure Event giving rise to the termination when CMC has been unable to undertake the Services or any part thereof from that date, or from the date or termination where CMC has been able to undertake the Services or parts thereof notwithstanding the Force Majeure Event.

17. **APPLICABLE LAW, JURISDICTION AND DISPUTE RESOLUTION**

Applicable Law

17.1 This Agreement shall be interpreted and governed, and all rights and obligations of the Parties shall be determined, in accordance with the laws of the State of Delaware (regardless of choice of law provisions). The Parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.

17.2 Before resorting to litigation, unless emergency relief is required by either party when either party shall be free to resort to litigation in accordance with Clause 17.4 below, the parties shall use their reasonable efforts to negotiate in good faith and settle amicably any dispute that may arise out of or relate to this Agreement (or its construction, validity or termination) (a "Dispute"). If a Dispute cannot be settled through negotiations by appropriate representatives of each of the parties, either party may give to the other a notice in writing (a "Dispute Notice"). Within seven (7) calendar days of the Dispute Notice being given the parties shall each refer the Dispute to their respective Quality Representatives who shall meet in order to attempt to resolve the dispute. If within 30 (thirty) calendar days of the Dispute Notice the Dispute is not settled by the Quality Representatives the Dispute shall be referred to the Parties' respective Chief Executive Officers who shall meet in order to attempt to resolve the dispute. If within 30 (thirty) calendar days of the Dispute Notice (i) the Dispute is not settled by agreement in writing between the parties or (ii) the parties have failed to discuss the Dispute or use good faith negotiations the provisions of Clauses 17.3, 17.4 and 17.5 below shall apply.

17.3 Any Dispute which cannot be resolved in accordance with Clause 17.2 shall be mediated through non-binding mediation facilitated by the International Chamber of Commerce ("ICC") in accordance with Commercial Arbitration Rules and Mediation Procedures (including Procedures for Large, Complex Commercial Disputes) (the "ADR Rules"), except where that procedure conflicts with these provisions, in which case these provisions control. If the ICC is not in existence at the time of such dispute, the Parties shall agree upon a method for mediation or an alternate party to conduct mediation, as applicable. The mediation shall be conducted in New York, New York and shall be attended by an individual or individuals from each party with authority to resolve the dispute. For purposes of such mediation:

17.3.1.1 The mediator shall be neutral, independent, disinterested and shall be selected from a professional mediation firm mutually agreed upon by the Parties;

17.3.1.2 The Parties shall promptly confer in an effort to select a mediator by agreement. In the absence of such an agreement, within ten (10) days of initiation of the mediation, the mediator shall be selected by ICC;

- 17.3.1.3 The mediator shall confer with the parties to design procedures to conclude the mediation within no more than forty-five (45) days after initiation. Under no circumstances may the commencement of arbitration be delayed by more than forty-five (45) days by the mediation process specified herein absent contrary agreement of the Parties; and
- 17.3.1.4 Each Party agrees not to use the period or pendency of the mediation to disadvantage the other party, procedurally or otherwise save that the foregoing shall not prevent either Party taking any steps to preserve its rights or remedies in connection with the Dispute. No statements made by either side during the mediation may be used by the other or referred to during any subsequent proceedings. Notwithstanding anything to the contrary in this Clause 17.3.1.4, each Party has the right to pursue provisional relief from any court, such as attachment, preliminary injunction or replevin, to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the Dispute, even though mediation has been commenced or completed.

17.4 Any Dispute that has not been resolved following the Parties undertaking the procedures outlined in 17.2 and 17.3 above shall be referred to and finally resolved by arbitration under the Rules of Arbitration of the ICC as in force from time to time, which Rules are deemed to be incorporated by reference into this Clause 17.4. For the purpose of any such arbitration the Parties hereby agree that:

- 17.4.1.1 The number of arbitrators shall be one who shall be selected in accordance with Clause 17.5 below;
- 17.4.1.2 The seat, or legal place, of arbitration shall be New York, NY.
- 17.4.1.3 The language to be used in the arbitral proceedings shall be English;
- 17.4.1.4 The arbitrator shall decide the dispute in accordance with the laws of the State of Delaware;
- 17.4.1.5 The Parties will give conclusive effect to the arbitrator's determination and award and that judgment thereon may be entered in any court having jurisdiction;
- 17.4.1.6 The Parties shall be permitted to pursue injunctive relief in a court of competent jurisdiction within New York, NY; and
- 17.4.1.7 nothing in this Clause 17.4 will prevent a Party from seeking interlocutory relief in the courts of appropriate jurisdiction provided in this Clause 17.4, pending the arbitrator's determination of the merits of the controversy, if applicable to protect the Confidential Information, property or other rights of that Party;

17.4.1.8 notwithstanding any provision of this Clause 17 or the relevant Rules of Arbitration of the ICC, CMC shall not be obliged to disclose to Customer or Customer's attorneys, agents or representatives any details or information relating to its margins under this Agreement or any other agreement and where any information or documents relating to CMC's profit or margins are provided to the Arbitrator. The Arbitrator shall keep all such details and information confidential and shall not disclose the same to Customer but shall use the information to determine whether or not, where such issue is a Dispute, CMC has calculated the correct Additional Charges or whether they should be amended up or down.

17.5 Upon the unsuccessful termination of mediation conducted in accordance with Clause 17.3 above, a Party shall notify the other Party that it wishes to proceed with arbitration of the Dispute. The Parties shall use commercially reasonable endeavours to mutually agree upon an arbitrator within ten (10) Business Days after receipt by the other Party of such notice. Should the Parties not agree upon an arbitrator within the ten (10) Business Day period, then the Parties or any one of them may immediately, by petition to the ICC, or its successor, request the appointment of three (3) persons, each of whom shall be qualified to serve as an arbitrator, and none of whom shall have any interest in or in any way affiliated with or related to any Party as a stockholder, officer, employee or agent of a relative of any such person. From the three (3) persons thus appointed, each Party shall, within fifteen (15) days after both Parties' written receipt of such appointment, strike one (1) name, the Party who initiated the arbitration striking first. The remaining person shall act as an arbitrator. If any Party shall fail or refuse within the time provided to strike from the list of the three (3) persons appointed by the court as set forth above, the other Party shall proceed to strike the other arbitrator from said list. Notwithstanding and in addition to anything else contained in this Agreement, the arbitrator(s) shall be chosen from a class of disinterested experts qualified by education, training and/or experience to resolve the particular issue in dispute in an informed and efficient manner. By way of illustration and not limitation, if the issue in dispute pertains to how a transaction shall be treated under accounting principles, then the arbitrator(s) shall be a certified public accountant(s) with at least five (5) years experience, or, if the issue in dispute pertains to proper manufacturing procedures, then the arbitrator shall have at least five (5) years experience in business similar to that of CMC.

17.6 Any mediation or arbitration proceeding shall be conducted in complete confidence. The parties undertake not to disclose details of the Dispute or of the mediation or arbitration, as applicable, except to their professional advisers, and shall procure that their professional advisers do not disclose such details. The parties shall keep confidential and not use for any collateral or ulterior purpose all documents and materials relating to the Dispute, produced for, or arising in relation to, the mediation or arbitration except:

17.6.1 so far as is necessary to implement and enforce any agreement in writing settling a Dispute;

- 17.6.2 as required by court order; or
- 17.6.3 otherwise as required by law.

18. **COMMERCIAL QUALITY AGREEMENT**

- 18.1 Contemporaneously with the execution of this Agreement, or as soon as practicable after the execution hereof, the Parties will develop and agree upon a Commercial Quality Agreement, the format and content of which is to be agreed upon by the Parties from time to time during the Term, and which will to the extent practicable, reflect each Party's obligations with respect to the quality of a medicinal product, including their respective obligations to Third Parties.
- 18.2 CMC shall provide a complete Certificate of Analysis for each Batch of Product supplied hereunder at the time of Delivery unless such Batch is the subject of Release For Further Processing, whereupon, CMC shall deliver a complete Certificate of Analysis in respect of such Batch following it having undertaken all applicable testing and it meeting the necessary criteria to qualify for a Certificate of Analysis.
- 18.3 CMC shall maintain complete and accurate documentation of all validation data, stability testing data, batch records, quality control and laboratory testing and any other data required under cGMP or other Regulatory Obligations in connection with the supply of Product hereunder.

19. **MISCELLANEOUS**

Amendment

- 19.1 Other than as provided for elsewhere in this Agreement, any modification, extension or variation of this Agreement (or any document entered into pursuant to or in connection with this Agreement) shall only be valid if it is in writing and signed by or on behalf of each Party to this Agreement. No modification or variation of this Agreement shall be valid if made by e-mail.
- 19.2 Unless expressly so agreed, no modification or variation of this Agreement shall constitute or be construed as a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under this Agreement which have already accrued up to the date of such modification or waiver, and the rights and obligations of the Parties under this Agreement shall remain in full force and effect, except and only to the extent that they are so modified or varied.

Assignment

- 19.3 Except as provided in Clauses 19.4, 19.5 and 19.6, no Party shall without the prior written consent of the other Party (such consent not to be unreasonably withheld) assign at law or in equity (including by way of a charge or declaration of trust), sub-license or deal in any other manner with this Agreement or any rights under this Agreement, or sub-contract any or all of its obligations under this Agreement, or purport to do any of the same. Any purported assignment in breach of this Clause 19.3 shall confer no rights on the purported assignee. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of termination of such assignment.
- 19.4 Customer shall be entitled upon giving written notice to CMC to assign its rights under this Agreement to any member of its Group provided that in assigning its rights Customer shall procure that the assignee shall assign those rights to a continuing member of its Group on ceasing to be a member of that Group. Any assignment made pursuant to this Clause 19.4 shall be subject to the following terms:
- 19.4.1 no assignment shall relieve Customer upon assigning its rights of any of its obligations under this Agreement; and
- 19.4.2 any assignment shall be made on terms that the assignee acknowledges that CMC may continue to deal exclusively with Customer in respect of all matters relating to this Agreement at all times unless and until the assignee notifies CMC in writing that it is exercising its rights as assignee.
- 19.5 CMC shall be entitled upon giving written notice to Customer to assign its rights under this Agreement to any acquiror of all or substantially all the assets of CMC (other than the sales and leaseback transaction in respect of buildings 2, 4 and 6 of the CMC Facility) concerning this Agreement or to any successor of CMC provided that no assignment shall relieve CMC upon assigning its rights of any of its obligations under this Agreement. The Parties further acknowledge and agree that, in the event this Agreement is assigned by CMC in accordance with this Clause 19.5, CMC shall provide written notice to Customer within fifteen (15) days of the effective date of such assignment and for a period of 130 days thereafter (the "Assignment Option Period"), Customer will have the irrevocable option, but not the obligation, to, upon written notice to CMC at any time within the Assignment Option Period (i) initiate Technology Transfer in accordance with the provisions of Clause 15 above, and (ii) extend the term of this Agreement beyond the then current term for further one-year periods until such time as Customer is duly licensed in all relevant markets.
- 19.6 Customer shall also be entitled upon giving written notice to CMC to assign its rights under this Agreement upon the occurrence of either (i) the exercise by Customer of its drag along rights or (ii) the exercise by Ipsen Pharma, S.A.S. ("Ipsen") of its Call Right, in each case pursuant to the terms of that certain Second Amended and Restated Stockholders Agreement by and among Customer, Ipsen and the Stockholders identified therein dated as

of January 20, 2010, as the same may be amended, provided that such assignee agrees to be bound by the terms of this Agreement. No assignment under this Clause 19.6 shall relieve Customer of responsibility for the performance of any obligation that accrued prior to the effective date of termination of such assignment.

Entire Agreement

- 19.7 Except for those provisions of Letter of Agreement which are expressed to survive, this Agreement supersedes and replaces the Letter of Agreement. This Agreement, and the documents referred to in it, constitutes the entire Agreement and understanding of the Parties and supersedes any previous agreement between the Parties relating to the particular subject matter of this Agreement. For the avoidance of doubt, the terms of the Clinical License Agreement, Existing Supply Agreement and the Existing License Agreement are not superseded by the terms of this Agreement and shall continue in full force and effect until such agreements expire or are terminated in accordance with their terms. If any term of this Agreement conflicts with any term of the Commercial Quality Agreement, the conflicting term of this Agreement shall prevail unless otherwise stated in the Commercial Quality Agreement.

Waiver and amendment

- 19.8 In no event will any delay, failure or omission (in whole or in part) in enforcing, exercising or pursuing any right, power, privilege, claim or remedy conferred by or arising under this Agreement or by law, be deemed to be or construed as a waiver of that or any other right, power, privilege, claim or remedy in respect of the circumstances in question, or operate so as to bar the enforcement of that, or any other right, power, privilege, claim or remedy, in any other instance at any time or times subsequently.

Severability

- 19.9 If any provision of this Agreement shall be found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, such invalidity or unenforceability shall not affect the other provisions of this Agreement which shall remain in full force and effect. The Parties agree, in the circumstances referred to in this Clause 19.9 to attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision which achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision. The obligations of the Parties under any invalid or unenforceable provision of this Agreement shall be suspended while an attempt at such substitution is made.

Notices

- 19.10 Any notice or other communication given or made under this Agreement shall be in writing and in English and signed by or on behalf of the Party giving it and shall be served by hand, delivering it or sending it by prepaid recorded or special delivery post or prepaid international recorded airmail, to the address and for the attention of the relevant Party set

out in this Clause 19.10 (or as otherwise notified by that Party hereunder). Any such notice shall be deemed to have been received:

- 19.10.1 if hand delivered or sent by prepaid recorded or special delivery post or prepaid international recorded airmail, at the time of delivery;
- 19.10.2 if sent by post (other than by prepaid recorded or special delivery post), 5 (five) calendar days from the date of posting; or
- 19.10.3 if sent by airmail (other than by prepaid international recorded airmail), 5 (five) calendar days from the date of posting;

Provided that if deemed receipt occurs before 9.00 a.m. on a Business Day the notice shall be deemed to have been received at 9.00 a.m. on that day, and if deemed receipt occurs after 5.00 p.m. on a Business Day, or on any day which is not a Business Day, the notice shall be deemed to have been received at 9.00 a.m. on the next Business Day.

The addresses of the Parties for the purposes of this **Clause 19.10** are:

CMC

22021 20th AVENUE SE, BOTHELL, WA, USA 98021

For the attention of: President

Customer

28202 Cabot Road, Suite 300, Laguna Niguel, CA 92677

For the attention of: Chief Financial Officer

Or such other address as may be notified in writing from time to time by the relevant Party to the other Party. Any such change to the place of service shall take effect five Business Days after notice of the change is received or (if later) on the date (if any) specified in the notice as the date on which the change is to take place.

Counterparts

- 19.11 This Agreement may be executed in any number of counterparts and by the Parties to it on separate counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement is not effective until each Party has executed at least one counterpart.

No partnership or agency

- 19.12 Nothing in this Agreement is intended to or shall operate to create a partnership or joint venture of any kind between the Parties or to authorize either Party to act as agent for the

other, and no Party shall have authority to act in the name or on behalf of or otherwise to bind the other in any way (including but not limited to the making of any representation or warranty, the assumption of any obligation or liability and the exercise of any right or power). Each Party is entering into this Agreement as principal not agent, and may not enforce any of its rights under or in connection with this Agreement for the benefit of any other person.

Parent Guarantee

19.13 CMC Luxembourg S.a.r.l (“Parent”) will in all respects:

19.13.1 and subject to the limitation of its liability being equal to the maximum cap on liability of CMC to Customer as set forth in Clauses 12.10 and 12.11 less any liability of CMC to Customer, that Parent during the Term shall not transfer all or substantially all of the assets of CMC to an affiliate of the Parent without assigning the burden of this Agreement to that same affiliate or itself; and:

19.13.2 shall guarantee CMC’s obligation to repay the Fund pursuant to its obligations under **Clause 7.2.2**;

it being acknowledged that this guarantee is (i) unconditional, (ii) binding on Parent’s successors and assigns, and (iii) enforceable by Customer, its successors and assigns and shall survive the termination of this Agreement.

19.14 If, at any time, either Party shall breach or threaten to breach or violate in any manner any of its obligations set forth in Clauses 2.8, 10 or 11, the non-breaching party shall be entitled to seek equitable relief by way of injunction in addition to, but not in substitution for, any and all other relief to which such Party may be entitled at law or in equity.



THIS AGREEMENT has been executed by or on behalf of the Parties on the date at the top of this Agreement.

Signed on behalf of)
CMC ICOS Biologies, Inc.)
 by)
)
)
)
)
 Name: /s/ G. MAHLER)
 Position: PRESIDENT & COO)
)

Signed on behalf of)
INSPIRATION BIOPHARMACEUTICALS, INC.)
 by)
)
)
)
 Name: /s/ Andrew J. Grethleih)
 Position: EVP & COO)
)

CMC Parent hereby agrees to be bound solely by Clause 19.3 Signed on)
 behalf of)
CMC Luxembourg S.a.r.l)
 by)
)
)
)
 Name: /s/ [Illegible])
 Position: Chairman)
)
)

APPENDIX ONE

Cell Line details

The WCB held by CMC referenced as F90W01 (the lot number is 08-0009)

The MCB held by CMC referenced as F90M01 (the lot number is 06-0041)

Drug Substance Specification

Specifications:

<u>Test</u>	<u>Test Method Number</u>	<u>Parameter Monitored</u>	<u>Release Acceptance Criteria</u>
Concentration by UV ¹	TME-0131	Quantity	2.5 mg/mL ±0.3 mg/mL
Size Exclusion HPLC (presence of calcium)	TME-0387	Purity	> 93% Main Peak < 5% Pre Peak
		Purity	Report % Peak A and % Peak B Total % Peak A + % B > 95%
Reversed Phase HPLC	TME-0343	Identity	Retention Time Ratio of Peak B 0.95 – 1.05
Visual Appearance	TME-0007	Appearance	Clear, Colorless May contain a Few Particles
Osmolality	TME-0008	Physicochemical Properties	335 ± 50 mOsm/kg
pH	TME-0004	Physicochemical Properties	6.8±0.3@25°C
Insulin	TME-0435	Purity	< 0.5 ng/mg
Glycan Analysis / % Tetra Sialylated Species	TME-0417	Quality	³ 33 %
Residual Host Cell Protein (CHOP)	TME-0123	Purity	< 100 ng CHOP equivalents/mg protein
Residual Host Cell DNA	Vendor	Purity	< 100 pg/mg
Endotoxin	TME-0003	Safety	< 5.0 EU/mg

<u>Test</u>	<u>Test Method Number</u>	<u>Parameter Monitored</u>	<u>Release Acceptance Criteria</u>
Bioburden	TME-0002	Safety	£ 2 CFU/mL TAMC £ 2 CFU/mL TYMC
NAPTT Clotting Time	Vendor	Safety	> 150 seconds clotting time

1 Extinction coefficient for TME-0131 is 1.34.

Services that may be sub-contracted comprise (i) Raw Materials testing (ii) currently outsourced (as of the Effective Date) QC quality controlled matters/activities

APPENDIX TWO

Milestones & Milestone Payments

<u>Milestone Event</u>	<u>Milestone Payment (US\$)</u>	<u>Payment Terms</u>
January 3, 2011	US\$[**]	Paid
CMC has shut down its facility in order to commence the Line 2 Expansion project	US\$[**]	Paid
Earlier of August 20, 2011 or date of Vial thaw for the first shakedown run performed following recommissioning of the Facility	US\$[**]	Net thirty (30) calendar days of the relevant event

The Parties acknowledge that Customer has paid CMC the aggregate amount of US\$[] in settlement of the First Payment (as defined in the Letter of Agreement), the US\$[**] due under the Letter of Agreement section defined as the Execution of Commercial Supply Agreement by reference to (i) (completion of the conformance lot), the US\$[**] due under the Letter of Agreement section defined as the Execution of Commercial Supply Agreement by reference to (ii) (January 3, 2011) and the US\$[**] due under the Letter of Agreement section defined as the Execution of Commercial Supply Agreement by reference to (iii) (shutdown).**

APPENDIX THREE

Price

The following prices will be administered and adjusted in accordance with Section 7 of this Agreement.
 (Note: all prices are subject to an annual price index increase)

Price per Batch that is subject to the Forecast (but not an Additional Order)

Batch Pricing for the period 2011-2013: pricing terms (not including materials and supplies and resins) based on thaw date and date of Firm Order for the relevant Batch:

Batches thawed before July 1 2012 for 2012 Firm Orders: \$[**] per Lot*

Batches thawed on or after July 2 2012 and delivered to 2012 Firm Orders: \$[**]* per Lot

Batches thawed on or after July 2, 2012 and delivered to 2013 Firm Orders: \$[**]* per Lot

* Reflects Discount

Minimum Amount

Should the total number of Firm Orders being the subject of a Purchase Order placed in any given Year be less than twelve (12), then the price for each Batch ordered in that Year shall, notwithstanding the prices set out above be adjusted upwards as set forth below:

# batches	2012* US\$ (000's)	Total value US\$ (000's)	2013 US\$ (000's)	Total value US\$ (000's)
12	[**]	[**]	[**]	[**]
11	[**]	[**]	[**]	[**]
10	[**]	[**]	[**]	[**]
9	[**]	[**]	[**]	[**]
8	[**]	[**]	[**]	[**]

<8 Price to be calculated according to clause 5.12

* to be prorated with batches produced prior to July 1st, 2012

Unit Pricing for the period 2014-2016: pricing terms (not including materials and supplies and resins):

First five (5) million IU per Lot supplied at \$[**]/IU

Next five (5) million IU per Lot supplied at \$[**]/IU

Next five (5) million IU per Lot supplied at \$[**]/IU

All IU per Lot in excess of fifteen (15) million IU supplied at \$[**]/IU

Price per Additional Batch

Shall be determined according to CMC's then current list price per batch, which as of the Effective Date is US\$[**]

Payment Terms (for all other monies due under this Agreement for which payment terms are not expressly identified in Clause 7)

- 30 days net of invoice date.

APPENDIX FOUR

Initial Competitor List

Baxter International Inc

Novo Nordisk AS

Biogen Idec Inc

Bayer AG

Pfizer Inc

Commercial Supply Agreement – JUNE 2011

AMENDMENT 1

TO COMMERCIAL SUPPLY (MANUFACTURING SERVICES) AGREEMENT

BETWEEN

**CMC ICOS BIOLOGICS, INC. ("CMC ICOS") AND INSPIRATION
BIOPHARMAEUTICALS, INC. ("Inspiration")**

dated June 17, 2011 (the "Effective Date")

Date of Amendment: 29 Sept., 2012

WHEREAS, CMC ICOS and Inspiration entered into a Commercial Supply (Manufacturing Services) Agreement, effective June 17, 2011, as amended (the "Agreement"); and

WHEREAS, by executing this Amendment Inspiration makes a commitment to pay for Manufacturing Capacity and other Services, and CMC ICOS reserves such Manufacturing Capacity for Inspiration; and

WHEREAS, CMC ICOS and Inspiration have executed this Amendment for the purpose of setting forth such terms and conditions.

NOW, THEREFORE, the Parties agree as follows:

Any defined term used herein that is not defined herein has the definition ascribed to such term in the Agreement.

I. Product

"**Product**" means Recombinant Human Blood Coagulation Factor IX

II. Scope of Services

Attached as Appendix A

III. Timing

Attached as Appendix B

IV. Price and Payment Terms

Attached as Appendix C

IN WITNESS WHEREOF, this Amendment No. 1 has been executed by the Parties hereto through their duly authorized officers as of the Effective Date.

INSPIRATION BIOPHARMACEUTICALS, INC.

CMC ICOS BIOLOGICS, INC.

By: /s/ Neil Schauer
Neil Schauer

By: /s/ illegible

Date: 29 Sept. 2012

Date: Oct. 11, 2012

Amendment 1

- 2 -

Confidential

**FACTOR IX
APPENDIX A
SCOPE OF SERVICES**

Objective

The objective of this amendment is to develop, implement and validate a process operation to reduce the levels of HCP present in the Factor IX API. This amendment includes three parts:

- Stage 1: Bench scale development, optimization and characterization of a new process operation
- Stage 2: Method validation/re-validation to support new in-process testing
- Stage 3: Implementation and Validation of new process operation into GMP manufacturing

Assumptions

The activities shown in the attached timeline will be re-set (day-for-day) when work on HCP reduction is re-started upon the signature of this amendment

If in the course of development and implementation the scope of work deviates significantly from the scope outlined below, a new amendment will be prepared or the work will be charged as out-of-scope

Out-of-scope work associated with HCP reduction and not covered as part of this amendment or covered in a superseding amendment will be charged at \$XXX/hr

The goal of the work is to develop a new downstream process that results in:

A process that results in API with HCP of less than approximately 50 ng/mg

No impact to product quality as measured by API release assays

Minimum impact to yield and validated state of process

The immunoblot will not be run at CMC and will not be used for product release

Silver Stain gels will be considered characterization assays; these methods will not be validated

Objective

The objective of this Stage is to develop a modified downstream process that results in:

A process that results in API with HCP of less than approximately 50 ng/mg

No impact to product quality as measured by API release assays

Minimum impact to yield and validated state of process

After development of the modified process, a bench scale model will be qualified and the modified process characterized

Prerequisites and Assumptions

Work that has already been completed is summarized in the Work Scope below

It is assumed that the modified downstream process (called A03) that will be implemented and validated will include the implementation of a new HIC column that will be operated in bind-elute mode with the elution being a step elution

If the modified downstream process requires additional changes beyond the HIC column, development of these additional changes will be considered out-of-scope

If additional Characterization Studies not outlined below are required the studies will be considered out-of-scope

See attached timeline and associated assumptions for outline of timing of execution of this work (Appendix B)

Scope of Work

The Scope outlined below is a high level non-inclusive summary of work that has been completed to-date

Explore options for reducing HCP level through exploratory bench scale development work including:

Harvest Clarification (filtration): Reduction of HMW impurities with a modified clarification filter train. Specifically, replace CUNO filters with Millipore X0HC.

Hydrophobic Interaction Chromatography and Membrane technology: Flow through mode of operation for removal of HMW impurities, with high product yield (>90%) and ease of incorporation into the process

Tangential Flow Filtration: Size-based separation of F90 from HMW impurities using TFF with High product yield (>90%).

Process Optimization for the HIC membrane based on preliminary work.

Evaluate alternate salts and salt concentrations for promoting HIC binding

Determine appropriate membrane/filter capacity

Execute TFF experiments subsequent to HIC filtration to ensure salt solution does not negatively impact product during formulation step

Column Chromatography Alternate Collection/ Pooling

Evaluate alternate elution collection or pooling strategies on the three chromatography columns

Combine alternate collection or pooling strategies with and without the HIC membrane

Evaluate revised wash steps for IEX1 and IEX3

Evaluate additional wash steps for IEX1 and determine impact on HCP levels in IEX1 eluate

Develop new IEX3 wash strategy:

Load column in absence of calcium

Perform salt wash

Elute Factor IX with Calcium

Determine impact to HCP levels in eluate and confirm no product quality impact

Evaluation of Different Separation Technologies

Compare advantages of resins vs. membranes, and flowthrough vs. elution strategies

Screen three alternate HIC ligands (one phenyl and two butyl)

Further evaluate phenyl resin and one butyl resin in bind-elute mode

Evaluate impact of different salt types, and salt concentrations on column performance

Evaluate gradient vs. step elution options

Based on development work completed to-date, the modified process is assumed to consist of the implementation of a HIC column that will be operated in bind-elute mode with the elution being a step elution. Using this base new process, complete one full bench scale run (the "pre demo run") where the modified process is executed from start-to-finish (IEX1 through TFF)

The Scope outlined below represents the remaining bench scale work required to complete development, characterization, implementation and validation of the modified process

Unit Operation optimization and Process Lock-in

Perform series of DOE studies on the new HIC column unit operation

Optimize operation to minimize yield loss and maximize HCP removal

Evaluate loading

Evaluate salt concentration used for step elution

Evaluate peak collection criteria

Confirm no impact to product quality

Bench Scale Demonstration Runs

Execute four bench scale demonstration runs under the optimized process conditions both prior to and during at-scale process validation runs. Latter demonstration runs are included to evaluate other feedstreams and/or to provide linkage between bench scale and at-scale operations

Demonstration runs will start at IEX1 or, if material is available, will start at the HIC step using material from IEX3 collection pool

The bench scale demonstration runs will consist of the new HIC column, followed by UFDF. The runs will be conducted at the setpoints or selected range limits which were determined by process development and which are transferred to manufacturing for scale up.

Bench Scale Model Qualification

Develop and approve Bench Scale Model Qualification Protocol for the HIC step

Three runs will be performed in DPD with the same setpoints as used at-scale

Material for the Qualification will come from at-scale manufacturing (e.g., IEX3 collection pool)

Draft and approve Bench Scale Model Qualification Report

Bench Scale Process Characterization

Develop and approve Characterization Protocol

Using the Qualified Bench Scale Model, perform Process Characterization studies on the bench scale using a DOE strategy for new HIC column unit operation

Characterization parameters are to-be-determined but may include:

- Column loading
- Salt concentration
- pH

Full and fractional factorial designs will be considered

Characterization studies will include analysis of HCP levels as well as product quality analysis via SE-HPLC, RP-HPLC and N-linked glycan analysis

Draft and approve Characterization Summary Report summarizing results of process characterization. The approved Executive Summary of this report is a required prerequisite for at-scale Process Validation

Stability Validation of New High Salt Feedstreams (HIC Load & Eluate)

HIC load and elution samples from representative small-scale or large scale runs will be evaluated for stability against aggregation and/degradation

Data will be used to support intermediate hold times in Manufacturing

Resin Cleaning and Lifetime Validation (15 cycles)

An HIC cycling study, plus blank runs, will be performed to validate resin cleaning and reuse

Data will be used to validate maximum number of cycles for Manufacturing

Viral Clearance Validation

The HIC step will not be validated as a virus reduction step

Viral clearance of the nano-filtration step will be re-validated for the new high salt feedstream

Deliverables

- Bench Scale Model Qualification Protocol (client approval not required)
- Bench Scale Model Qualification Report
- Bench Scale Characterization Protocol (client approval not required)
- Bench Scale Characterization Report

Objective

The objective of this Stage is to validate and/or re-validate all analytical methods required to support the modified downstream process

Prerequisites and Assumptions

- It is assumed that the modified downstream process (called A03) that will be implemented and validated will include the implementation of a new HIC column that will be operated in bind-elute mode with the elution being a step elution
- If additional methods not outlined below need development, qualification and/or validation the work will be considered out-of-scope of this Amendment

Scope of Work

- Re-validate HCP test method TME-0488 (F90 specific HCP ELISA) with additional background matrices to enable testing of HCP levels for HIC eluates
 - Develop a sample preparation procedure for samples in a high salt matrix so that they are suitable for assay in the HCP assay
 - Validate the HCP assay for use at the HIC step
 - Re-validate the assay for the BDS (API) step; this is required to validate new dilutions that are necessary in order to assay for the lower HCP levels that are achieved in the new downstream process
- Re-validate bioburden test method with additional background matrices to enable testing of bioburden levels for HIC eluates
- Re-validate endotoxin test method with additional background matrices to enable testing of endotoxin levels for HIC eluates

Objective

The objective of this Stage is to implement the modified downstream process into at-scale manufacturing, initiate GMP manufacturing and complete Process Validation

Prerequisites and Assumptions

- The initial at-scale implementation of the modified downstream process included the implementation of a HIC flow-through membrane filter (Engineering run 12-20) and the combination of the HIC membrane filter with a reduced pooling of IEX3 fractions (Engineering run 12-30). These runs demonstrated that the HCP levels in the API would not meet the targeted level of 50 ng/mg. Thus, it is assumed the HIC membrane filter will not be part of the modified process
- It is assumed that the modified downstream process (called A03) that will be implemented and validated will include the implementation of a new HIC column that will be operated in bind-elute mode with the elution being a step elution
- Prerequisites for the initiation (thaw) of a GMP batch are outlined in the Scope of Work below
- Prerequisites for the initiation (thaw) of the Process Validation campaign are outlined in the Scope of Work below
- It is assumed that data only from Line A will be used to validate the modified process. The validation of Line B is not within the scope of this amendment
- See attached timeline and associated assumptions for outline of timing of execution of this work (Appendix B)

Scope of Work

- Implement HIC membrane flow-through filter into at-scale Engineering run (note: this work was completed as part of Engineering Run 12-20 and Engineering Run 12-30)
 - Develop draft batch records & operational implementation plan
 - Executed Engineering Run 12-20: Implement HIC filter into downstream process
 - Executed Engineer Run 12-30: Combine reduced fraction pooling from IEX3 with the implementation of the HIC filter
 - Performed parallel scale-down studies on the bench scale
 - Performed analytics for load, flow through and strip (ELISA and SDS-PAGE) and shipped material for immunoblot
- Implement modified downstream process developed on the Bench Scale into at-scale Engineering run
 - The batch price for the Engineering batches are not within the scope of this amendment
 - Develop draft batch records and operational implementation plan for the implementation of a modified wash step for IEX3. Batch records have been developed but the process change will not be implemented

Develop draft batch records and operational implementation plan for the implementation of a new HIC column that will be operated in bind-elute mode with the elution being a step elution

Execute Engineering Batch

Perform the standard set of analytics on the Engineering Batch that is normally performed during GMP manufacturing

Execute additional Engineering Batches until the initiation of GMP manufacturing

If the modified downstream process requires changes prior to initiation of GMP manufacturing, the implementation of the additional changes will be considered out-of-scope

- Implement modified downstream process for GMP manufacturing

The following are prerequisites prior to thaw for a GMP manufacturing batch:

QST revised and approved

A minimum of one bench-scale demonstration run completed where the modified process is executed in entirety on the bench scale and the results are back from the analytical analysis (minimally, testing of the API for HCP, SDS-PAGE, SE-HPLC, RP-HPLC, and N-linked glycans)

Master Batch Records (MBRs) may be approved in a rolling fashion

Materials are on-site and released

Test Methods approved and qualified for API and IPC to support specifications

In absence of a complete set of data back from a bench scale run, and at the sole discretion of the CMC Quality Assurance Department, a thaw to initiate a GMP run may occur under the following scenario:

At least one bench-scale demonstration run has been completed with the analytical results pending

Prior to thaw of the GMP batch, a Change Request (CR) will be initiated for the new downstream process. The CR will include key acceptance criteria that must be achieved by the time of the inoculation of the 750 L bioreactor. If the criteria are not met, the batch will be terminated. The CR content will be at CMC discretion and the acceptance criteria for moving forward will be the sole discretion of the CMC quality department

Approve the MBRs for GMP production

Approve the QST

Execute GMP batch (note: the batch price is not included as part of this amendment)

Perform standard GMP testing on the GMP batch

- Perform at-scale Validation

The following are prerequisites prior to thaw for Process Validation:

All GMP Lot prerequisites listed above

A minimum of one GMP at-scale successful run with analytical results back

Characterization executive summary report approved with key content including:

Summarize process changes for modified process

Captures previous risk assessments for reduction of HCP

Summarizes bench and at-scale development

Process risk assessment completed/approved g assess impact of changes for modified process to the validated state and supporting studies

PVMP approved

CPPs/CQAs redefined g update upstream and downstream PERs (or equivalent summary document)

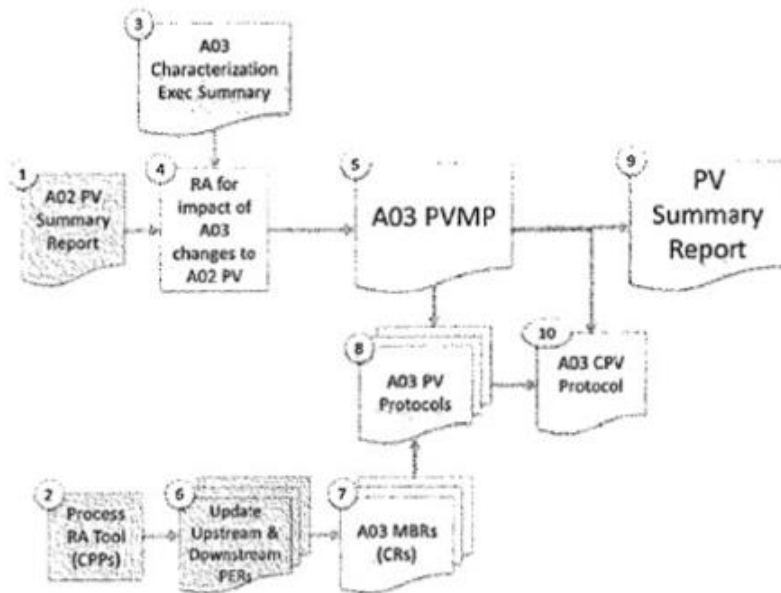
PV protocols approved

All MBRs approved prior to thaw (no rolling approval)

The documentation and Validation strategy is shown in the figure below

Items shown in grey are not part of the scope of this amendment

The numbers list the order of prioritization for the documents



Complete documentation and Validation strategy as outlined in the Figure above

A03 Characterization Executive Summary (#3 above)

High-level summary document that outlines

- Process changes for modified process
- Captures previous risk assessments for reduction of HCP
- Bench and at-scale development

Risk Assessment for Impact of A03 Changes to A02 Process Validation (#4 above)

Draft and approve Risk Assessment on Unit Operation by Unit Operation basis

Risk Assessment will guide PVMP and scope of Validation

A03 Process Validation Master Plan (PVMP, #5 above)

Draft and approve PVMP for the A03 process

PVMP will require a minimum of three at-scale batches to be completed

A03 MBRs (#7 above)

Revise and approve MBRs

A03 Process Validation Protocols (#8 above)

Draft and approve Validation Protocols on a Unit Operation basis required to validate the A03 process

PV Summary Report (#9 above)

Will be completed after successful execution of at-scale validation batches

Draft and approve PV summary report. Completion of this report will document the completion of the at-scale Process Validation of the A03 process

A03 CPV Protocol (#10 above)

Update and approve the new Continued Process Validation Protocol to support the A03 Process

Execute three at-scale validation batches per the strategy outlined in the PVMP

Price of the validation batches is not included in the scope of this amendment

Complete Process Validation protocols for all required Unit Operations

Perform analytical testing as outlined in the PV protocols and MBRs

Deliverables

- Documentation as outlined above

Estimated Timeline

- At-scale validation is anticipated to start in December 2012

**FACTOR IX
APPENDIX B
TIMING**

See attached timeline

Assumptions to Attached Timeline

- Adherence to timeline and deliverables will be managed per the terms outlined in the Commercial Supply Agreement (CSA)
- CMC will provide a weekly timeline update to Inspiration. This will include an update for the tasks for percent completion, actual start dates and actual/target dates for completion
- The timeline for activities supporting at-scale validation, including bench scale model qualification, bench scale characterization, viral clearance, resin lifetime validation, and stability validation will need finalization. This work will need to be prioritized against other deliverables associated with the MAA and BLA filings. CMC and Inspiration will prioritize and finalize the timing for these activities after signature of this amendment. The target date for completing the prioritization is 14 days after signature of the amendment
- The attached timeline assumes that the Validation campaign will occur in Line A and occur in manufacturing slots already reserved by Inspiration. Inspiration has requested evaluation of an option for two Inspiration manufacturing batches scheduled in Line B in the December 2012 to January 2013 timeframe be eliminated so as to execute batches only in Line A. This would provide the ability to compress the timing for the Process Validation/manufacturing batches in Line A and thus enables a more timely completion of the Process Validation batches and subsequent reports. Such a change would have financial considerations as well as implications for the Line B validation and approval plans. These implications and considerations are not subject of this amendment and will need to be resolved per the terms of the relevant amendments and the CSA. The timeline compression options will be evaluated and agreed to by both parties after signature of this amendment. The target date for completing this agreement is 14 days after signature of the amendment
- The attached timeline for Validation is based on the process knowledge known to-date. Delays (due to contract negotiations, delay in the re-start of the HCP reduction work, technical challenges, or change in plans for the process to be implemented) will impact the proposed timeline

**FACTOR IX
APPENDIX C
PRICE AND PAYMENT TERMS**

<u>Stage</u>	<u>Services</u>	<u>Price and Payment Terms for Stage</u>
		[**]
Stage 1	Bench scale development, optimization and characterization of a new process operation	<ul style="list-style-type: none"> • [**]% payable upon initiation of Stage • [**]% payable upon completion of Stage
		[**]
Stage 2	Method validation/re-validation to support new in-process testing	<ul style="list-style-type: none"> • [**]% payable upon initiation of Stage • [**]% payable upon completion of Stage
		[**]
Stage 3	Implementation and Validation of new process operation into GMP manufacturing	<ul style="list-style-type: none"> • [**]% payable upon initiation of Stage • [**]% payable upon completion of Stage

Note

Final payment for each stage (the [**]% due upon completion) is contingent upon IBI approving stage deliverables

Additional Costs

In addition to the costs outlined above:

Materials.

Development General Materials' costs shall be covered by a flat [**] percent ([**]%) fee applied to the price of the applicable stage. For clarity, Development General Materials include all the elementary chemicals and laboratory raw materials that are typically required in the process of biological development and used outside of the cGMP area (including, but not limited to, kits, reagents, tubing, single-use bags, pipettes, salts, etc). Development General Material' costs may be invoiced to Inspiration up to sixty (60) days in advance of the commencement of the applicable Stage.

Development Specific Materials include specific raw materials that are unique to the Inspiration's project and will be necessary for work performed outside of CMC ICOS' cGMP areas. Development Specific Materials shall be invoiced at the vendor's list price plus a handling charge of [**]%. An initial estimated invoice may be sent to Inspiration sixty (60) calendar days prior to start of the relevant Stage. A complete detailed invoice setting out any additional payment required by Inspiration or that a credit i Inspiration shall be sent on completion of the Stage.

A General Manufacturing Consumables Fee of \$[**] will be invoiced in advance of all Manufacturing Stages.

Manufacturing Materials listed on the Bill of Materials shall be invoiced at the vendor's list price plus a handling charge of [**]%. An initial estimated invoice will be sent to Inspiration sixty (60) calendar days prior to start of the relevant Stage. A complete detailed invoice setting out any additional payment required by Inspiration or that a credit is due to Inspiration shall be sent on completion of the Stage.

External testing and other external costs will be invoiced as specified in the Agreement, i.e. at vendor's list price plus a handling charge of [**] percent ([**]%).

CMC ICOS will invoice Inspiration on a monthly basis for any packing, shipping and handling charges (handling charges are \$500/domestic and \$1000/international shipment).

Necessary travel and related costs will be passed through to Inspiration and will be consistent with CMC ICOS' internal travel policy.

Out of scope work under this Amendment No. 1 to the Agreement, if requested by Inspiration and agreed to by Inspiration and CMC ICOS Biologics in writing via a Change Order, will be invoiced at \$[**] per FTE hour.

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

**SETTLEMENT & AMENDMENT CONCERNING A
MANUFACTURING AGREEMENT DATED DECEMBER 2,
2005 AND A COMMERCIAL SUPPLY AGREEMENT
DATED JUNE 20, 2011**

- (1) CMC ICOS BIOLOGICS, INC.,
- (2) INSPIRATION BIOPHARMACEUTICALS, INC.,

BETWEEN:

- (1) **CMC ICOS BIOLOGICS, INC.**, a corporation duly incorporated under the laws of the State of Washington and having its principal place of business at 22021 20th Avenue SE, Bothwell, WA, 98021, United States of America (hereinafter referred to as “**CMC**”); and
 - (2) **INSPIRATION BIOPHARMACEUTICALS, INC.**, a corporation duly incorporated under the laws of the State of Delaware and having its principal place of business at One Kendall Square, Building 1400E, Cambridge, MA 02139, United States of America (hereinafter referred to as “**IBI**”),
- each referred to as a “**Party**” or collectively as “**Parties**”

WHEREAS:

- (A) IBI is engaged in the development of products for the treatment of hemophilia including its proprietary recombinant Factor IX product described in BB-IND 13551 (known as “**IB1001**”) and its proprietary Factor VIIa product (known as “**IB1007**”);
- (B) CMC and IBI are parties to a Manufacturing Agreement dated December 2, 2005 (as amended) under which CMC agreed to provide biological manufacturing and development services on behalf of IBI (the “**MSA**”);
- (C) CMC and IBI are also parties to a Commercial Supply Agreement dated June 20, 2011 (as amended) under which CMC has agreed to reserve certain slots and capacity in its facilities and to provide certain services each relating to the manufacture for commercial supply of IB1001 (the “**CSA**”);
- (D) On October 30, 2012 (the “**Petition Date**”), IBI filed a voluntary petition for relief under chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (the “**Bankruptcy Court**”) commencing Case Number 12-18687-WCH (the “**Bankruptcy Case**”) and IBI remains in possession of its property and continues to manage its business as a debtor in possession pursuant to sections 1107 and 1108 of the Bankruptcy Code; and
- (E) the Parties now wish, subject to Bankruptcy Court approval, to amend the CSA and agree to a settlement in respect of the current outstanding sums due under the MSA and CSA.

IN CONSIDERATION of the mutual promises contained in this Agreement, the Parties hereby **AGREE AS FOLLOWS:**

1. **DEFINITIONS**

- 1.1 Capitalised terms used in this Agreement which are not defined in this Agreement shall have the same meaning defined for such term in the CSA (as amended by this Agreement).

Notwithstanding the foregoing, the following terms defined in this clause 1.1 shall have the respective meanings set forth below:

- “Acquisition Payment”** any and all consideration (whether cash or non-cash), value, monies, rights, benefits or waivers (including any future or conditional payments) payable or received, directly or indirectly, in exchange for the bona fide sale, transfer, issuance, grant or license of any assets, rights, benefits, stock, shares or control of IBI existing from time to time, and where such consideration is other than for cash, such non-cash consideration shall be valued on an arms-length, good faith, market-value basis;
- “Additional Services”** (i) the HCP Development Services and those additional development services with respect to the latest Process (appended to this Agreement at Schedule 1-A), (ii) additional Services agreed upon by the Parties and set forth in a work order appended to this Agreement as Schedule 1-B, and (iii) the manufacture of Conformance Batches of Product;
- “Conformance Batch(es)”** three (3) consecutive manufacturing Batches of IB1001 Product under GMP for the purpose of validating the changes in the modified Process;
- “CSA Breach”** means IBI’s default under the CSA, specifically, the non-payment of any and all outstanding invoices under the CSA for Services provided by CMC prior to October 30, 2012;
- “Factor VIIa Cell Banks”** all cell banks and cell lines (including master cell banks and research cell banks) owned, held or controlled by or on behalf of IBI which have been developed or constructed for the manufacture of Factor VIIa Product, including all intermediates and progeny of the same;
- “Factor VIIa Product”** means IBI’s proprietary, recombinant Factor VIIa product known as IB-1007;
- “Factor VIIa Product Assets”** means (i) Factor VIIa Cell Banks, and (ii) all biological and raw materials, process data and methodology (including manufacturing processes), clinical and pre-clinical data, media formulations, methodologies, IPRs, documents, records, know-how, regulatory submissions and approvals, correspondence and reports (including regulatory authority interactions), and all other materials concerning or relating to the Factor VIIa Product;
- “HCP Development Services”** means those development services stipulated and identified in the Statement of Work appended to this Agreement at Schedule 1-A;

“IPRs”	all intellectual property rights, including (without limitation) patents and patent rights, supplementary protection certificates, petty patents, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know-how, techniques and confidential information and other proprietary knowledge and information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term and together with any renewals or extensions;
“MSA Breach”	means IBI’s default under the MSA, specifically, the non-payment of those outstanding invoices under the MSA for work performed by CMC prior to October 30, 2012;
“Person”	any individual, partnership, firm, corporation, company, association, trust, unincorporated organisation or other entity in each case in any jurisdiction;
“UNC License”	the Amended and Restated License Agreement dated November 28, 2008, including any amendments thereto, entered into between The University of North Carolina and IBI;
“Upfront Acquisition Payment”	Acquisition Payments made, received or payable that are triggered by the completion of a sale, transfer, issuance, grant or license of any assets, rights, benefits, stock, shares or control of IBI.

1.2 In this Agreement (except where the context otherwise requires):

- 1.2.1 any reference to a recital, clause (unless identified as being in another document) or appendix is to the relevant recital, clause or appendix of or to this Agreement and any reference to a sub-clause or paragraph is to the relevant sub-clause or paragraph of the clause or appendix in which it appears;
- 1.2.2 the table of contents and clause headings are included for convenience only and shall not affect the interpretation of this Agreement;
- 1.2.3 use of the singular includes the plural and vice versa and use of any gender includes the other genders;
- 1.2.4 any reference to “persons” includes natural persons, firms, partnerships, companies, corporations, associations, organizations, governments, states, governmental or state agencies, foundations and trusts (in each case whether or not having separate legal personality and irrespective of the jurisdiction in or under the law of which it was incorporated or exists);

- 1.2.5 a reference to a “Party” is a reference to a party to this Agreement and a reference to a “Party” includes a reference to that Party’s successors in title, permitted assignees and transferees (if any) and in the case of an individual, to his or her estate and personal representatives;
 - 1.2.6 a reference to “writing” does not include email;
 - 1.2.7 any phrase introduced by the terms “including”, “include”, “in particular” or a similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.
- 1.3 The Appendices form an integral part of this Agreement and shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the Appendices.
- 1.4 Where there is any inconsistency between the Appendices and the main body of this Agreement, the conflicting terms of the main body of this Agreement shall, unless expressly specified to the contrary, prevail.

2. **SETTLEMENT & RELEASE OF CERTAIN OBLIGATIONS**

- 2.1 In consideration of and subject to IBI’s compliance with all other terms and conditions of this Agreement, including without limitation the provisions of Clauses 3, 4 and 8, CMC hereby waives, releases and discharges IBI from:
- 2.1.1 its obligation to cure the CSA Breach as well as any interest charges on the sums due under the CSA Breach;
 - 2.1.2 its obligation to cure the MSA Breach as well as any interest charges on the sums due under the MSA Breach; and
 - 2.1.3 its obligation to order and pay for those Batches of Product which are the subject of Firm Orders and Semi-Binding Orders included in the most recent Forecast under the CSA provided by IBI to CMC.
- 2.2 In consideration of the waiver granted by CMC hereunder, IBI hereby releases CMC from its obligation to manufacture Batches of Product under the CSA in accordance with those Forecasts existing as of the Effective Date, *provided, however*, that the foregoing shall not affect CMC’s obligation to perform the Additional Services pursuant to the terms of this Agreement.

2.3 **RELEASES**

- 2.3.1 IBI warrants and represents that it has no claim, whether known or unknown, against CMC or its Affiliates in law or equity which IBI or its Affiliates, assigns and/or transferees have as of the Effective Date arising out of or in connection with the MSA or the CSA. Accordingly, IBI hereby waives, releases and discharges CMC from any claim, action, recovery or other liability existing as

of the Effective Date, whether known or unknown, against CMC or its Affiliates in law or equity which IBI or its Affiliates, assigns and/or transferees, have arising out of or in connection with the MSA and the CSA.

2.3.2 CMC warrants and represents that it has no claim, whether known or unknown, against IBI or its Affiliates in law or equity which CMC or its Affiliates, assigns and/or transferees have as of the Effective Date arising out of or in connection with the MSA or, the CSA. Accordingly, CMC hereby waives, releases and discharges IBI from any claim, action, recovery or other liability existing as of the Effective Date, whether known or unknown, against IBI or its Affiliates in law or equity which CMC or its Affiliates, assigns and/or transferees, have arising out of or in connection with the MSA and the CSA.

3. FUND PAYMENTS

3.1 The Parties acknowledge that pursuant to the provisions of clause 7 of the CSA, IBI has paid CMC the Fund comprising US\$[**] US dollars) and that:

3.1.1 US\$[**] US dollars) of the Fund shall be irrevocably paid to CMC for the settlement of the CSA Breach and MSA Breach (“**IBI Payment**”) and shall cease to be part of the Fund or subject to the CSA, and such IBI Payment shall be non-refundable and not repayable under clause 7.2.2 of the CSA or otherwise;

3.1.2 clause 7.2 of the CSA shall be amended such that Fund shall now mean a fund with an amount of US\$[**] US dollars);

3.1.3 IBI shall not be obliged to replenish the Fund beyond a value of US\$[**] US dollars); *provided, however*, that if IBI or any party who acquires all or substantially all of IBI’s rights to IB1001 (**the “Acquiror”**) decides to increase the Maximum Value above sixteen (16) Batches, IBI or the Acquiror must comply with Section 5.2 hereof; and,

3.1.4 IBI hereby waives and forever releases CMC from any rights IBI may have in respect of the IBI Payment.

4. FEES & PAYMENTS

4.1 Appendix 3 of the CSA shall be deleted and replaced in its entirety with Schedule 2 of this Agreement. Schedule 2 contains pricing for all Batches other than Conformance Batches, which shall be included in the payments set forth in Section 4.2 below.

4.2 The Parties acknowledge that IBI has already paid CMC the non-refundable sum of US\$[**] toward the performance of the Additional Services. In addition to that payment, IBI shall pay the following amounts to CMC:

4.2.1 as consideration for CMC performing Additional Services from the Effective Date up to and including 31 January 2013 (the “**Pre-pay Period**”), IBI shall

make an initial payment of US\$[**] US dollars) split into two equal installments as follows (i) the first payment of US\$[**] US dollars) due on 30 November 2012 and (ii) a second payment of US\$[**] US dollars) due on 10 December 2012; and

4.2.2 (i) US \$[**] US dollars) for services provided in February 2013, to be paid prior to February 1, 2013, and (ii) US \$[**] US dollars) to be paid prior to March 1, 2013, for services provided in March and April 2013 in accordance with the timeline set forth in Schedule 1-A and Schedule 1-B; *provided*, that the payments set forth in this Clause 4.2.2 shall only be made by IBI for each month(s) (or part thereof) beyond the Pre-pay Period during which IBI requests, in IBI's sole discretion and in accordance with Clause 6.1.4, that CMC continue to perform the Additional Services.

4.3 In consideration of the waiver under Clause 2 and subject to the approval of the Bankruptcy Court, IBI (or any successor trustee or liquidating agent) shall pay consideration from the sale of the Combined Assets (as such term is defined in the "Motion for Order Approving Bidding Procedures in Connection with Marketing and Proposed Sale of Substantially All of Its Assets, Credit Bid Waiver Threshold, and Release of Certain Claims" dated November 5, 2012 filed in the Bankruptcy Case ("**Bidding Procedures Motion**")) to CMC in accordance with the "Waterfall Distribution" attached as Exhibit C to the Bidding Procedures Motion. Specifically:

4.3.1 [**]%) percent of the aggregate of all Upfront Acquisition Payments in excess of US \$[**], subject to a maximum payment of US \$[**], shall be paid to CMC as set forth in the Waterfall Distribution; and,

4.3.2 [**]%) percent of the aggregate of all Acquisition Payments, subject to a maximum payment (including any payment due under Clause 4.3.1) of US \$[**], shall be paid to CMC as set forth in the Waterfall Distribution (collectively the "**Acquisition Consideration**"). For the removal of doubt, the total Acquisition Consideration shall not exceed US\$[**].

4.4 The Acquisition Consideration as set forth in Section 4.3 above shall be paid to CMC after such sums are paid by the Successful Bidder, who will be approved by the Bankruptcy Court after the Sale Hearing (as such terms are defined in the Bidding Procedures Motion). Specifically, the amount set forth in Section 4.3.1 shall be paid to CMC immediately after payments on Priority One, Two, Three and Four Distributions are made under the Waterfall Distribution and the amount set forth in Section 4.3.2 shall be paid to CMC no later than payment on other Priority Six Distributions are made under the Waterfall Distribution. If the Waterfall Distribution is not approved by an order of the Bankruptcy Court or if no distribution is due to CMC pursuant to the Waterfall Distribution that is ultimately approved by the Bankruptcy Court, CMC shall have an allowed unsecured claim in the amount of US \$10,000,000, with recourse only against the Fund.

5. **VARIATION TO CAPACITY OBLIGATIONS**

5.1 CMC's obligations under the CSA with respect to its capacity for manufacture of Product shall be amended such that CMC shall now be required to maintain a maximum capacity of sixteen (16) Batches per full Year for the production of IB1001 and, prior to 1 January 2014, shall not be in breach of its obligations under the CSA to meet the timeline stipulated in the non-binding Forecast submitted by IBI *provided* that it has used Commercially Reasonable Endeavors to manufacture such Batches. Accordingly, the Parties further agree that:

- 5.1.1 any Forecasts in respect of Batches to commence manufacture prior to 1 January 2014 shall be non-binding and shall not, notwithstanding the provisions of the CSA, comprise Firm Orders or Semi-Binding Orders; *provided, however*, that if any Purchase Order issued by IBI is less than the Forecast or exceeds the Forecast by less than 20%, then the Forecast shall become binding once that Purchase Order is issued by IBI;
- 5.1.2 references to the maximum number of Batches in clause 5.1 of the CSA that may be requested in any Calendar Quarter shall be amended from eight (8) Batches to four (4) Batches, being two (2) per each of Line 1 Suite or Line 2 Expansion;
- 5.1.3 the Maximum Value definition defined in clause 5.5 of the CSA shall be amended from thirty-two (32) Batches per full Year to sixteen (16) Batches per full Year;
- 5.1.4 IBI shall provide a Forecast (i) for Q2 2013 by January 31, 2013, and (ii) for Q3 and Q4 2013 by March 31, 2013; and
- 5.1.5 The provisions of clauses 5.7.1 to 5.7.3 (inclusive) of the CSA shall cease to have effect on Forecasts for the calendar years of 2012 and 2013.

5.2 Upon request, CMC shall enter into good faith negotiations with IBI or the Acquiror to increase the Maximum Value of Batches of IB1001 that may be ordered per full Year *provided* that any increase in the Maximum Value shall require, in IBI or the Acquiror's sole discretion, either (i) an additional payment of US\$[**] US dollars) to the Fund or (ii) the renegotiation of the CSA, which renegotiated terms shall include a provision for an additional cash payment to CMC.

6. **CMC SERVICES & MANUFACTURING OBLIGATIONS**

6.1 CMC shall include the Additional Services as Services under the CSA subject to the following:

- 6.1.1 IBI continuing to comply with the terms of the CSA;
- 6.1.2 IBI continuing to comply with all of the terms of this Agreement;

- 6.1.3 the Conformance Batches shall count towards the Maximum Value;
- 6.1.4 in respect of Additional Services to be performed beyond the Pre-pay Period, IBI shall be required to provide CMC with at least ten (10) Business Days' notice in advance of each additional month in which it wishes CMC to undertake the Additional Services; and
- 6.1.5 If IBI requests that CMC perform Additional Services beyond 30 April 2013, IBI shall pay for such Additional Services pursuant to the terms of the CSA.

6.2 Except for the Conformance Batches, which are to be paid for pursuant to Clause 4.2, prior to 1 January 2014 and notwithstanding the provisions of clause 7 of the CSA or any payment terms contained therein, IBI shall be obliged to pay CMC per Batch (as listed in Schedule 2 to this Agreement) in four (4) equal installments of twenty five percent (25%) of the price per Batch due as follows: (i) on the date on which an order for that Batch is placed; (ii) on the date the applicable vial(s) of Cell Line are proposed to be thawed by CMC to commence manufacture of the Batch, which date shall be notified to IBI by CMC; (iii) on the completion of manufacture of the Batch; and (iv) upon delivery of the Batch by CMC to IBI. After January 1, 2014, payments for Batches shall be in accordance with Clause 7 of the CSA.

7. FORECASTS & STEERING COMMITTEE

7.1 IBI shall continue to provide Forecasts during 2013 in accordance with Clause 5.1.4 above. Accordingly, the Parties hereby agree that:

- 7.1.1 IBI shall at all times provide Forecasts which are good faith estimates of its requirements for the numbers of Batches required in the applicable Calendar Quarter(s); and
- 7.1.2 all Forecasts issued in accordance with the CSA (as amended by this Agreement) that identify Batches for manufacture on or after 1 January 2014 shall be binding on the Parties pursuant to the terms of the CSA provided that any Forecasts for Q1 2014 must be provided to CMC by 30 June 2013.

7.2 The Parties hereby agree that Ipsen Pharma S.A.S. shall be entitled to appoint a Committee Member to the Joint Steering Committee to participate in all meetings of the Joint Steering Committee (the "**Ipsen Committee Member**"). The Ipsen Committee Member shall only have the right to participate as an observer and shall have no voting right or right of veto.

8. FACTOR VIIA ASSETS

8.1 In consideration of the waivers under the CSA and MSA agreed to hereunder by CMC, IBI hereby:

- 8.1.1 licenses to CMC on an exclusive (to the exclusion of IBI, its successors, assigns and licensees), worldwide, royalty free basis, such license being freely assignable: (i) all IPR relating to the Factor VIIa Product licensed to IBI and (ii)

all IPR relating to the Factor VIIa Product owned by IBI including, but not limited to, the patents set out in Schedule 3 to this Agreement, to make, have made, use and sell the Factor VIIa Product; and

8.1.2 assigns to CMC, free of any encumbrances, all rights to (i) the Factor VIIa Cell Banks; and (ii) all other Factor VIIa Product Assets other than IPR.

For the avoidance of doubt, IBI shall retain all rights under any and all IPR licensed to CMC pursuant to Clause 8.1.1 above to the extent such IPR is necessary or useful to make, have made, use or sell IB1001 or IBI's other proprietary products.

8.2 IBI hereby warrants and represents that:

8.2.1 IBI is free and able to grant the licence and assign the assets as set forth in clause 8.1;

8.2.2 IBI has not assigned or licensed any of the Factor VIIa Product Assets to any third party;

8.2.3 IBI shall keep confidential and not use for any purpose any of the Factor VIIa Product Assets other than to comply with its obligations under this Agreement;

8.2.4 IBI has disclosed the full terms of all licenses of IPR under which IBI receives a license in respect of the Factor VIIa Product and will disclose to CMC, within 30 days following the Effective Date and upon CMC's request, any techniques or materials used for the manufacture of the Factor VIIa Product;

8.2.5 To IBI's knowledge, all patent registration fees due or incurred prior to the Effective Date in respect of IPR in the Factor VIIa Product Assets have been paid;

8.2.6 IBI will use reasonable commercial efforts to obtain approval from the University of North Carolina ("UNC"), the owner of certain patents relating to the Factor VIIa Product which are licensed to IBI pursuant to the UNC License, to grant CMC the right to grant further sublicenses to the Factor VIIa Product; and

8.2.7 the UNC License will not terminate as a result of the Bankruptcy Case; *provided, however*, that IBI makes no representation or warranty as to whether an Acquiror would accept or reject the UNC License.

8.3 At the reasonable request of CMC and at CMC's reasonable cost, IBI shall at all times hereafter do all such acts and execute all such documents as may reasonably be necessary or desirable to give effect to the transfer of the Factor VIIa Product Assets to CMC including, without limitation, disclosing all know-how and information required and liaising with any regulatory authorities.

- 8.4 IBI shall, upon CMC's reasonable request and CMC's expense (provided such costs are reasonably incurred):
- 8.4.1 transport and deliver to CMC or its designee the Factor VIIa Cell Banks, and transporting and storing the same in accordance with industry standards to preserve the viability and quality of the same;
 - 8.4.2 deliver to CMC all documents, records, data, files and information in respect of the Factor VIIa Product Assets;
 - 8.4.3 provide all documents containing know-how and information concerning the Factor VIIa Product in the possession or control of IBI (including without limitation all documents relating to any interactions with regulatory authorities);
 - 8.4.4 provide CMC with reasonable access to IBI's Head of Regulatory and procure his co-operation and assistance with CMC as may reasonably be required to help transfer knowledge and regulatory information concerning the Factor VIIa Product and the transfer of the Factor VIIa Product Assets;
 - 8.4.5 notify CMC of all individuals, contractors, service providers and consultants who have worked on the development of the Factor VIIa Product with or on behalf of IBI and provide their professional contact details, to the extent IBI is in possession of such contact details.
- 8.5 CMC shall:
- 8.5.1 use diligent efforts to pursue development of and/or exploit the Factor VIIa Product, *provided, however*, that such diligence obligation shall be subject to CMC first receiving the right (as a sublicensee of IBI) to grant further sublicenses under the IPR associated with the Factor VIIa Product (such right to be procured for CMC by IBI pursuant to Clause 8.2.6 of this Agreement on terms consistent with those under the UNC License). CMC shall be free to develop or exploit any other factor VIIa product;
 - 8.5.2 be responsible for all expenses associated with the IPR not already incurred by IBI at the Effective Date, and shall reimburse IBI for any such expenses associated with the IPR that continue to be incurred by IBI after the Effective Date. In addition, CMC has the option, at its sole discretion, to pay the outstanding expenses incurred by or on behalf of IBI in relation to such IPR prior to the Effective Date, subject to IBI first informing CMC of the value of such expenses;
 - 8.5.3 be entitled to approach UNC to obtain a direct license from UNC in respect of the IPR associated with the Factor VIIa Product currently licensed to IBI by UNC (and sublicensed to CMC pursuant to Clause 8.1.1(i) hereof), which license shall be consistent with the sublicense grant set forth in Clause 8.1.1 hereof; *provided, however*, that CMC shall approach UNC in coordination with

IBI and IBI shall be present for all discussions (except for discussions of the economic terms of a direct license between UNC and CMC if and when UNC, CMC and IBI agree that a direct license between CMC and UNC is in the best interest of all three parties).

- 8.6 CMC acknowledges the disclaimer of warranty and limitation on UNC's liability as set forth in Article 10 of the UNC License.
- 8.7 At any time after the Effective Date, if CMC intends to seek a partner to purchase and/or exclusively license the Factor VIIa Product Assets for the purposes of development and commercialisation of the Factor VIIa Product in Europe and/or the United States, then, subject to Clause 8.9, CMC shall so notify IBI and observe the following terms ("**ROFR**"):
- 8.7.1 CMC shall notify IBI in writing of its intent to sell and/or license the Factor VIIa Product Assets in the United States and/or Europe ("**ROFR Notice**");
- 8.7.2 If IBI wishes to acquire the Factor VIIa Product Assets for the territory identified in the ROFR Notice, IBI shall serve written notice on CMC within fifteen (15) Business Days of receipt the ROFR Notice ("**ROFR Acceptance**"), receipt being deemed two (2) Business Days after sending where sent by pre-paid international courier;
- 8.7.3 If no ROFR Acceptance is served within the fifteen (15) Business Day period, then CMC shall be automatically released from the provisions of this Clause 8.7 and this Clause 8.7 shall cease thereafter to apply in respect of the territory that was the subject of the ROFR Notice unless the ROFR Notice was only with respect to either Europe or the United States;
- 8.7.4 If a ROFR Acceptance is served within the 15 Business Day period, then:
- 8.7.4.1 CMC and IBI shall, in good faith and at arm's length, exclusively negotiate terms for the license or purchase of the Factor VIIa Product Assets for the development and commercialization of the Factor VIIa Product in the territory identified in the ROFR Notice, which terms shall be based on fair market value;
- 8.7.4.2 if a definitive agreement between the Parties cannot be consummated within ninety (90) days of the ROFR Acceptance (or such longer period as may be agreed between the Parties), CMC shall have no further obligation to negotiate with IBI under this Clause 8.7 and this Clause 8.7 shall cease thereafter to apply except as set forth in Clause 8.7.4.3 below; and
- 8.7.4.3 if CMC ultimately does not sell or license the Factor VIIa Product Assets within six (6) months from the end of the ninety (90) days following the ROFR Acceptance, the ROFR shall be reinstated.

- 8.7.5 Nothing in this Agreement shall prevent CMC from entering into development or subcontracting agreements with third parties concerning the Factor VIIa Product Assets nor from holding discussions with prospective partners for commercialisation rights to the Factor VIIa Product Assets for commercialisation of Factor VIIa Product in the United States and/or Europe, *provided, however,* that CMC observes the provisions of Clauses 8.7 and 8.8 hereof and that any such agreements are subject to Clauses 8.7 and 8.8 hereof.
- 8.8 At any time after the Effective Date, if IBI wishes to acquire from CMC the Factor VIIa Product Assets for the purposes of development and commercialisation of the Factor VIIa Product in Europe and the United States, then, subject to Clause 8.9, IBI shall so notify CMC in writing (“**IBI Notice**”) and the Parties shall observe the following terms (“**IBI ROFR**”):
- 8.8.1 CMC shall, in good faith, respond to IBI with a draft term sheet within forty-five (45) days of the date CMC receives the IBI Notice, setting out the terms on which CMC is prepared to assign or license those Factor VIIa Product Assets to IBI for development and commercialisation of the Factor VIIa Product for the United States and Europe;
- 8.8.2 Upon receipt of that term sheet:
- 8.8.2.1 CMC and IBI shall, in good faith and at arms length, exclusively negotiate terms for the license or purchase of the Factor VIIa Product Assets for the development and commercialization of the Factor VIIa Product in Europe and the United States, which terms shall be based on fair market value;
- 8.8.2.2 if a definitive binding agreement between the Parties cannot be consummated within ninety (90) days of the date the term sheet is provided by CMC (or such longer period as may be agreed between the Parties), CMC shall have no further obligation to negotiate with IBI under this Clause 8.8 and this Clause 8.8 shall cease thereafter to apply except as set forth in Clause 8.8.2.3 below; and
- 8.8.2.3 if CMC ultimately does not sell or license the Factor VIIa Product Assets within six (6) months from the end of the ninety (90) days following the date the term sheet is provided by CMC, the IBI ROFR shall be reinstated.
- 8.9 The ROFR and the IBI ROFR set forth in Clauses 8.7 and 8.8 hereof shall not apply (or otherwise restrict CMC) where CMC or any of its Affiliates elects to sell the Factor VIIa Product to third parties (or partner with them) for the purpose of developing a chemically modified version of the Factor VIIa Product, or any other factor VIIa product, which chemical modifications would affect the pharmacokinetic profile of the Factor VIIa Product.

9. **OTHER AMENDMENTS TO THE CSA**

9.1 The address for IBI under clause 19.10 of the CSA shall be amended to One Kendall Square, Building 1400E, Cambridge, MA 02139, United States of America.

10. **AGREEMENT**

10.1 Save for the amendments to the CSA as expressly provided in this Agreement and the specific waivers under the CSA and MSA, no other amendments are made to the CSA or waivers given in respect of the CSA or MSA and all other terms and conditions of the CSA and MSA will remain in full force and effect and are not affected, varied or amended by this Agreement.

10.2 The CSA and MSA shall be subject to the provisions of this Agreement and where there is any conflict between the provisions of this Agreement and the CSA or MSA, the provisions of this Agreement shall prevail.

11. **MISCELLANEOUS**

11.1 Other than as expressly set out herein, no Party has relied upon any statement, representation, warranty, understanding, undertaking, promise or assurance in entering into this Agreement and no warranties, representations, covenants or guarantees express or implied are given, made or renewed by entering into this Agreement.

11.2 This Agreement may be executed in any number of counterparts, each of which will be an original, but all of which together will constitute one and the same instrument. The Agreement is not effective until each Party has executed at least one counterpart and the Bankruptcy Court has issued an order as set forth below in Section 11.8.

11.3 Any specific rights or remedies conferred on the Parties under this Agreement are in addition to and without prejudice to all other rights and remedies which any such Party may have available to it against the other or otherwise.

11.4 Nothing in this Agreement shall create or be deemed to create a partnership, joint venture or principal-agent relationship between the parties and no Party shall have authority to bind the other in any way.

11.5 No provision of this Agreement (or any document entered into in connection with this Agreement) shall be modified or varied without the written consent of the Parties. For the avoidance of doubt, no modification or variation of this Agreement shall be valid if made by email or fax, *provided, however*, that binding, executed amendments to this Agreement may be exchanged in PDF format.

11.6 Any notices to be served pursuant to this Agreement shall be valid only if served in accordance with the notice provisions of the CSA (as amended by this Agreement).

11.7 Section 19.6 of the CSA shall be amended to provide that IBI may, upon providing advance written notice to CMC, assign its rights (subject to the assignee also assuming and

accepting IBI's obligations) under the MSA, the CSA, this Agreement and all amendments to the foregoing documents only to an Acquiror. Notwithstanding the foregoing, (i) no assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment and (ii) this Agreement and its terms shall be binding on its successors and assigns and IBI shall procure that this Agreement and its terms and effect shall be binding upon its successors and assigns.

11.8 This Agreement shall not be effective until approved by a final order of the Bankruptcy Court pursuant to Bankruptcy Code Sections 105, 363, and 365 and Rule 9019 of the Federal Rules of Bankruptcy Procedure, which order shall be satisfactory in form and substance to CMC. IBI shall seek approval of this Agreement by the Bankruptcy Court on an expedited basis.

12. **GOVERNING LAW**

This Agreement shall be interpreted and governed, and all rights and obligations of the Parties shall be determined, in accordance with the laws of the State of Delaware (regardless of choice of law provisions). The Parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.

SCHEDULE 1-A

Amendment 1 to the CSA

AMENDMENT 1

TO COMMERCIAL SUPPLY (MANUFACTURING SERVICES) AGREEMENT

BETWEEN

**CMC ICOS BIOLOGICS, INC. ("CMC ICOS") AND INSPIRATION
BIOPHARMAEUTICALS, INC. ("Inspiration")**

dated June 17, 2011 (the "Effective Date")

Date of Amendment: 29 Sept. 2012

WHEREAS, CMC ICOS and Inspiration entered into a Commercial Supply (Manufacturing Services) Agreement, effective June 17, 2011, as amended (the "Agreement"); and

WHEREAS, by executing this Amendment Inspiration makes a commitment to pay for Manufacturing Capacity and other Services, and CMC ICOS reserves such Manufacturing Capacity for Inspiration; and

WHEREAS, CMC ICOS and Inspiration have executed this Amendment for the purpose of setting forth such terms and conditions.

NOW, THEREFORE, the Parties agree as follows:

Any defined term used herein that is not defined herein has the definition ascribed to such term in the Agreement.

I. Product

"**Product**" means Recombinant Human Blood Coagulation Factor IX

II Scope of Services

Attached as Appendix A

III. Timing

Attached as Appendix B

IV. Price and Payment Terms

Attached as Appendix C

IN WITNESS WHEREOF, this Amendment No. 1 has been executed by the Parties hereto through their duly authorized officers as of the Effective Date.

INSPIRATION BIOPHARMACEUTICALS, INC.

CMC ICOS BIOLOGICS, INC.

By: /s/ Neil Schauer
Neil Schauer

By: /s/ [Illegible]

Date: 29 Sept. 2012

Date: Oct. 11, 2012

Amendment 1

- 2 -

Confidential

**FACTOR IX
APPENDIX A
SCOPE OF SERVICES**

Objective

The objective of this amendment is to develop, implement and validate a process operation to reduce the levels of HCP present in the Factor IX API. This amendment includes three parts:

- Stage 1: Bench scale development, optimization and characterization of a new process operation
- Stage 2: Method validation/re-validation to support new in-process testing
- Stage 3: Implementation and Validation of new process operation into GMP manufacturing

Assumptions

- The activities shown in the attached timeline will be re-set (day-for-day) when work on HCP reduction is re-started upon the signature of this amendment
- If in the course of development and implementation the scope of work deviates significantly from the scope outlined below, a new amendment will be prepared or the work will be charged as out-of-scope
- Out-of-scope work associated with HCP reduction and not covered as part of this amendment or covered in a superseding amendment will be charged at \$XXX/hr
- The goal of the work is to develop a new downstream process that results in:
 - A process that results in API with HCP of less than approximately 50 ng/mg
 - No impact to product quality as measured by API release assays
 - Minimum impact to yield and validated state of process
- The immunoblot will not be run at CMC and will not be used for product release
- Silver Stain gels will be considered characterization assays; these methods will not be validated

Objective

The objective of this Stage is to develop a modified downstream process that results in:

- A process that results in API with HCP of less than approximately 50 ng/mg
- No impact to product quality as measured by API release assays
- Minimum impact to yield and validated state of process

After development of the modified process, a bench scale model will be qualified and the modified process characterized

Prerequisites and Assumptions

- Work that has already been completed is summarized in the Work Scope below
- It is assumed that the modified downstream process (called A03) that will be implemented and validated will include the implementation of a new HIC column that will be operated in bind-elute mode with the elution being a step elution
- If the modified downstream process requires additional changes beyond the HIC column, development of these additional changes will be considered out-of-scope
- If additional Characterization Studies not outlined below are required the studies will be considered out-of-scope
- See attached timeline and associated assumptions for outline of timing of execution of this work (Appendix B)

Scope of Work

- The Scope outlined below is a high level non-inclusive summary of work that has been completed to-date
 - Explore options for reducing HCP level through exploratory bench scale development work including:
 - Harvest Clarification (filtration): Reduction of HMW impurities with a modified clarification filter train. Specifically, replace CUNO filters with Millipore X0HC.
 - Hydrophobic Interaction Chromatography and Membrane technology: Flow through mode of operation for removal of HMW impurities, with high product yield (>90%) and ease of incorporation into the process
 - Tangential Flow Filtration: Size-based separation of F90 from HMW impurities using TFF with High product yield (>90%).
 - Process Optimization for the HIC membrane based on preliminary work.
 - Evaluate alternate salts and salt concentrations for promoting HIC binding
 - Determine appropriate membrane/filter capacity
 - Execute TFF experiments subsequent to HIC filtration to ensure salt solution does not negatively impact product during formulation step
 - Column Chromatography Alternate Collection/ Pooling
 - Evaluate alternate elution collection or pooling strategies on the three chromatography columns

- Combine alternate collection or pooling strategies with and without the HIC membrane
- Evaluate revised wash steps for IEX1 and IEX3
 - Evaluate additional wash steps for IEX1 and determine impact on HCP levels in IEX1 eluate
 - Develop new IEX3 wash strategy:
 - Load column in absence of calcium
 - Perform salt wash
 - Elute Factor IX with Calcium
 - Determine impact to HCP levels in eluate and confirm no product quality impact
- Evaluation of Different Separation Technologies
 - Compare advantages of resins vs. membranes, and flowthrough vs. elution strategies
 - Screen three alternate HIC ligands (one phenyl and two butyl)
 - Further evaluate phenyl resin and one butyl resin in bind-elute mode
 - Evaluate impact of different salt types, and salt concentrations on column performance
 - Evaluate gradient vs. step elution options
- Based on development work completed to-date, the modified process is assumed to consist of the implementation of a HIC column that will be operated in bind-elute mode with the elution being a step elution. Using this base new process, complete one full bench scale run (the “pre demo run”) where the modified process is executed from start-to-finish (IEX1 through TFF)
- The Scope outlined below represents the remaining bench scale work required to complete development, characterization, implementation and validation of the modified process
 - Unit Operation optimization and Process Lock-in
 - Perform series of DOE studies on the new HIC column unit operation
 - Optimize operation to minimize yield loss and maximize HCP removal
 - Evaluate loading
 - Evaluate salt concentration used for step elution
 - Evaluate peak collection criteria
 - Confirm no impact to product quality
 - Bench Scale Demonstration Runs
 - Execute four bench scale demonstration runs under the optimized process conditions both prior to and during at-scale process validation runs. Latter demonstration runs are included to evaluate other feedstreams and/or to provide linkage between bench scale and at-scale operations
 - Demonstration runs will start at IEX1 or, if material is available, will start at the HIC step using material from IEX3 collection pool
 - The bench scale demonstration runs will consist of the new HIC column, followed by UFDF. The runs will be conducted at the setpoints or selected range limits which were determined by process development and which are transferred to manufacturing for scale up.

- Bench Scale Model Qualification
 - Develop and approve Bench Scale Model Qualification Protocol for the HIC step
 - Three runs will be performed in DPD with the same setpoints as used at-scale
 - Material for the Qualification will come from at-scale manufacturing (e.g., IEX3 collection pool)
 - Draft and approve Bench Scale Model Qualification Report
- Bench Scale Process Characterization
 - Develop and approve Characterization Protocol
 - Using the Qualified Bench Scale Model, perform Process Characterization studies on the bench scale using a DOE strategy for new HIC column unit operation
 - Characterization parameters are to-be-determined but may include:
 - Column loading
 - Salt concentration
 - pH
 - Full and fractional factorial designs will be considered
 - Characterization studies will include analysis of HCP levels as well as product quality analysis via SE-HPLC, RP-HPLC and N-linked glycan analysis
 - Draft and approve Characterization Summary Report summarizing results of process characterization. The approved Executive Summary of this report is a required prerequisite for at-scale Process Validation
- Stability Validation of New High Salt Feedstreams (HIC Load & Eluate)
 - HIC load and elution samples from representative small-scale or large scale runs will be evaluated for stability against aggregation and/degradation
 - Data will be used to support intermediate hold times in Manufacturing
- Resin Cleaning and Lifetime Validation (15 cycles)
 - An HIC cycling study, plus blank runs, will be performed to validate resin cleaning and reuse
 - Data will be used to validate maximum number of cycles for Manufacturing
- Viral Clearance Validation
 - The HIC step will not be validated as a virus reduction step
 - Viral clearance of the nano-filtration step will be re-validated for the new high salt feedstream

Deliverables

- Bench Scale Model Qualification Protocol (client approval not required)
- Bench Scale Model Qualification Report
- Bench Scale Characterization Protocol (client approval not required)
- Bench Scale Characterization Report

Objective

The objective of this Stage is to validate and/or re-validate all analytical methods required to support the modified downstream process

Prerequisites and Assumptions

- It is assumed that the modified downstream process (called A03) that will be implemented and validated will include the implementation of a new HIC column that will be operated in bind-elute mode with the elution being a step elution
- If additional methods not outlined below need development, qualification and/or validation the work will be considered out-of-scope of this Amendment

Scope of Work

- Re-validate HCP test method TME-0488 (F90 specific HCP ELISA) with additional background matrices to enable testing of HCP levels for HIC eluates
 - Develop a sample preparation procedure for samples in a high salt matrix so that they are suitable for assay in the HCP assay
 - Validate the HCP assay for use at the HIC step
 - Re-validate the assay for the BDS (API) step; this is required to validate new dilutions that are necessary in order to assay for the lower HCP levels that are achieved in the new downstream process
- Re-validate bioburden test method with additional background matrices to enable testing of bioburden levels for HIC eluates
- Re-validate endotoxin test method with additional background matrices to enable testing of endotoxin levels for HIC eluates

Objective

The objective of this Stage is to implement the modified downstream process into at-scale manufacturing, initiate GMP manufacturing and complete Process Validation

Prerequisites and Assumptions

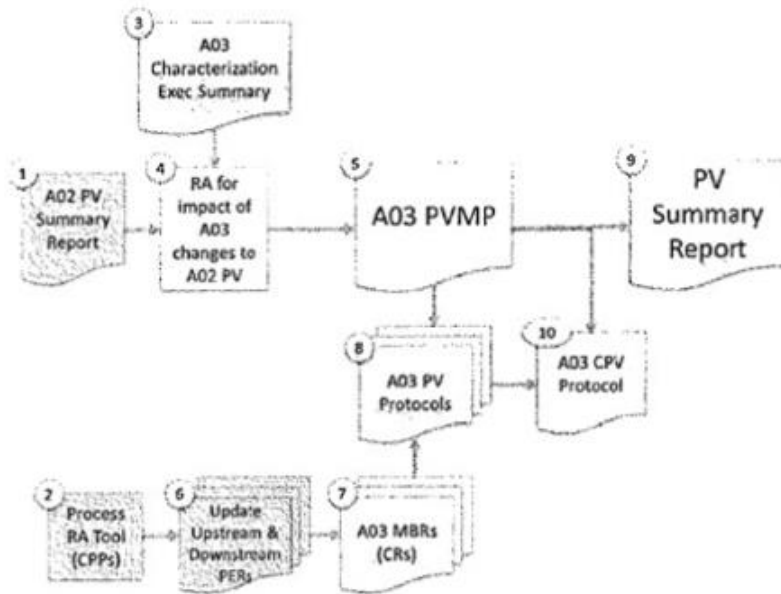
- The initial at-scale implementation of the modified downstream process included the implementation of a HIC flow-through membrane filter (Engineering run 12-20) and the combination of the HIC membrane filter with a reduced pooling of IEX3 fractions (Engineering run 12-30). These runs demonstrated that the HCP levels in the API would not meet the targeted level of 50 ng/mg. Thus, it is assumed the HIC membrane filter will not be part of the modified process
- It is assumed that the modified downstream process (called A03) that will be implemented and validated will include the implementation of a new HIC column that will be operated in bind-elute mode with the elution being a step elution
- Prerequisites for the initiation (thaw) of a GMP batch are outlined in the Scope of Work below
- Prerequisites for the initiation (thaw) of the Process Validation campaign are outlined in the Scope of Work below
- It is assumed that data only from Line A will be used to validate the modified process. The validation of Line B is not within the scope of this amendment
- See attached timeline and associated assumptions for outline of timing of execution of this work (Appendix B)

Scope of Work

- Implement HIC membrane flow-through filter into at-scale Engineering run (note: this work was completed as part of Engineering Run 12-20 and Engineering Run 12-30)
 - Develop draft batch records & operational implementation plan
 - Executed Engineering Run 12-20: Implement HIC filter into downstream process
 - Executed Engineer Run 12-30: Combine reduced fraction pooling from IEX3 with the implementation of the HIC filter
 - Performed parallel scale-down studies on the bench scale
 - Performed analytics for load, flow through and strip (ELISA and SDS-PAGE) and shipped material for immunoblot
- Implement modified downstream process developed on the Bench Scale into at-scale Engineering run
 - The batch price for the Engineering batches are not within the scope of this amendment
 - Develop draft batch records and operational implementation plan for the implementation of a modified wash step for IEX3. Batch records have been developed but the process change will not be implemented

- Develop draft batch records and operational implementation plan for the implementation of a new HIC column that will be operated in bind-elute mode with the elution being a step elution
- Execute Engineering Batch
- Perform the standard set of analytics on the Engineering Batch that is normally performed during GMP manufacturing
- Execute additional Engineering Batches until the initiation of GMP manufacturing
- If the modified downstream process requires changes prior to initiation of GMP manufacturing, the implementation of the additional changes will be considered out-of-scope
- Implement modified downstream process for GMP manufacturing
 - The following are prerequisites prior to thaw for a GMP manufacturing batch:
 - QST revised and approved
 - A minimum of one bench-scale demonstration run completed where the modified process is executed in entirety on the bench scale and the results are back from the analytical analysis (minimally, testing of the API for HCP, SDS-PAGE, SE-HPLC, RP-HPLC, and N-linked glycans)
 - Master Batch Records (MBRs) may be approved in a rolling fashion
 - Materials are on-site and released
 - Test Methods approved and qualified for API and IPC to support specifications
 - In absence of a complete set of data back from a bench scale run, and at the sole discretion of the CMC Quality Assurance Department, a thaw to initiate a GMP run may occur under the following scenario:
 - At least one bench-scale demonstration run has been completed with the analytical results pending
 - Prior to thaw of the GMP batch, a Change Request (CR) will be initiated for the new downstream process. The CR will include key acceptance criteria that must be achieved by the time of the inoculation of the 750 L bioreactor. If the criteria are not met, the batch will be terminated. The CR content will be at CMC discretion and the acceptance criteria for moving forward will be the sole discretion of the CMC quality department
 - Approve the MBRs for GMP production
 - Approve the QST
 - Execute GMP batch (note: the batch price is not included as part of this amendment)
 - Perform standard GMP testing on the GMP batch
- Perform at-scale Validation
 - The following are prerequisites prior to thaw for Process Validation:
 - All GMP Lot prerequisites listed above
 - A minimum of one GMP at-scale successful run with analytical results back
 - Characterization executive summary report approved with key content including:
 - Summarize process changes for modified process

- Captures previous risk assessments for reduction of HCP
 - Summarizes bench and at-scale development
- Process risk assessment completed/approved g assess impact of changes for modified process to the validated state and supporting studies
- PVMP approved
- CPPs/CQAs redefined g update upstream and downstream PERs (or equivalent summary document)
- PV protocols approved
- All MBRs approved prior to thaw (no rolling approval)
- The documentation and Validation strategy is shown in the figure below
 - Items shown in grey are not part of the scope of this amendment
 - The numbers list the order of prioritization for the documents



- Complete documentation and Validation strategy as outlined in the Figure above
 - A03 Characterization Executive Summary (#3 above)
 - High-level summary document that outlines
 - Process changes for modified process
 - Captures previous risk assessments for reduction of HCP
 - Bench and at-scale development
 - Risk Assessment for Impact of A03 Changes to A02 Process Validation (#4 above)
 - Draft and approve Risk Assessment on Unit Operation by Unit Operation basis
 - Risk Assessment will guide PVMP and scope of Validation
 - A03 Process Validation Master Plan (PVMP, #5 above)
 - Draft and approve PVMP for the A03 process

- PVMP will require a minimum of three at-scale batches to be completed
- A03 MBRs (#7 above)
 - Revise and approve MBRs
- A03 Process Validation Protocols (#8 above)
 - Draft and approve Validation Protocols on a Unit Operation basis required to validate the A03 process
- PV Summary Report (#9 above)
 - Will be completed after successful execution of at-scale validation batches
 - Draft and approve PV summary report. Completion of this report will document the completion of the at-scale Process Validation of the A03 process
- A03 CPV Protocol (#10 above)
 - Update and approve the new Continued Process Validation Protocol to support the A03 Process
- Execute three at-scale validation batches per the strategy outlined in the PVMP
 - Price of the validation batches is not included in the scope of this amendment
 - Complete Process Validation protocols for all required Unit Operations
 - Perform analytical testing as outlined in the PV protocols and MBRs

Deliverables

- Documentation as outlined above

Estimated Timeline

- At-scale validation is anticipated to start in December 2012

**FACTOR IX
APPENDIX B
TIMING**

See attached timeline

Assumptions to Attached Timeline

- Adherence to timeline and deliverables will be managed per the terms outlined in the Commercial Supply Agreement (CSA)
- CMC will provide a weekly timeline update to Inspiration. This will include an update for the tasks for percent completion, actual start dates and actual/target dates for completion
- The timeline for activities supporting at-scale validation, including bench scale model qualification, bench scale characterization, viral clearance, resin lifetime validation, and stability validation will need finalization. This work will need to be prioritized against other deliverables associated with the MAA and BLA filings. CMC and Inspiration will prioritize and finalize the timing for these activities after signature of this amendment. The target date for completing the prioritization is 14 days after signature of the amendment
- The attached timeline assumes that the Validation campaign will occur in Line A and occur in manufacturing slots already reserved by Inspiration. Inspiration has requested evaluation of an option for two Inspiration manufacturing batches scheduled in Line B in the December 2012 to January 2013 timeframe be eliminated so as to execute batches only in Line A. This would provide the ability to compress the timing for the Process Validation/manufacturing batches in Line A and thus enables a more timely completion of the Process Validation batches and subsequent reports. Such a change would have financial considerations as well as implications for the Line B validation and approval plans. These implications and considerations are not subject of this amendment and will need to be resolved per the terms of the relevant amendments and the CSA. The timeline compression options will be evaluated and agreed to by both parties after signature of this amendment. The target date for completing this agreement is 14 days after signature of the amendment
- The attached timeline for Validation is based on the process knowledge known to-date. Delays (due to contract negotiations, delay in the re-start of the HCP reduction work, technical challenges, or change in plans for the process to be implemented) will impact the proposed timeline

**FACTOR IX
APPENDIX C
PRICE AND PAYMENT TERMS**

<u>Stage</u>	<u>Services</u>	<u>Price and Payment Terms for Stage</u>
		[**]
Stage 1	Bench scale development, optimization and characterization of a new process operation	<ul style="list-style-type: none"> • [**]% payable upon initiation of Stage • [**]% payable upon completion of Stage
		[**]
Stage 2	Method validation/re-validation to support new in-process testing	<ul style="list-style-type: none"> • [**]% payable upon initiation of Stage • [**]% payable upon completion of Stage
		[**]
Stage 3	Implementation and Validation of new process operation into GMP manufacturing	<ul style="list-style-type: none"> • [**]% payable upon initiation of Stage • [**]% payable upon completion of Stage

Note

- Final payment for each stage (the [**]% due upon completion) is contingent upon IBI approving stage deliverables

Additional Costs

In addition to the costs outlined above:

- **Materials.**
 - Development General Materials' costs shall be covered by a flat [**] percent ([**]%) fee applied to the price of the applicable stage. For clarity, Development General Materials include all the elementary chemicals and laboratory raw materials that are typically required in the process of biological development and used outside of the cGMP area (including, but not limited to, kits, reagents, tubing, single-use bags, pipettes, salts, etc). Development General Material' costs may be invoiced to Inspiration up to sixty (60) days in advance of the commencement of the applicable Stage.
 - Development Specific Materials include specific raw materials that are unique to the Inspiration's project and will be necessary for work performed outside of CMC ICOS' cGMP areas. Development Specific Materials shall be invoiced at the vendor's list price plus a handling charge of [**]%. An initial estimated invoice may be sent to Inspiration sixty (60) calendar days prior to start of the relevant Stage. A complete detailed invoice setting out any additional payment required by Inspiration or that a credit i Inspiration shall be sent on completion of the Stage.

- A General Manufacturing Consumables Fee of \$[**] will be invoiced in advance of all Manufacturing Stages.
- Manufacturing Materials listed on the Bill of Materials shall be invoiced at the vendor's list price plus a handling charge of [**]%. An initial estimated invoice will be sent to Inspiration sixty (60) calendar days prior to start of the relevant Stage. A complete detailed invoice setting out any additional payment required by Inspiration or that a credit is due to Inspiration shall be sent on completion of the Stage.
- External testing and other external costs will be invoiced as specified in the Agreement, i.e. at vendor's list price plus a handling charge of [**] percent ([**]%).
- CMC ICOS will invoice Inspiration on a monthly basis for any packing, shipping and handling charges (handling charges are \$500/domestic and \$1000/international shipment).
- Necessary travel and related costs will be passed through to Inspiration and will be consistent with CMC ICOS' internal travel policy.
- Out of scope work under this Amendment No. 1 to the Agreement, if requested by Inspiration and agreed to by Inspiration and CMC ICOS Biologics in writing via a Change Order, will be invoiced at \$[**] per FTE hour.

SCHEDULE 1-B

Amendment 2 to the CSA

AMENDMENT 2

TO COMMERCIAL SUPPLY (MANUFACTURING SERVICES) AGREEMENT

BETWEEN

CMC ICOS BIOLOGICS, INC. ("CMC ICOS") AND INSPIRATION
BIOPHARMACEUTICALS, INC. ("Inspiration")

dated June 17, 2011 (the "Effective Date")

Date of Amendment: _____, 2012

WHEREAS, CMC ICOS and Inspiration entered into a Commercial Supply (Manufacturing Services) Agreement, effective June 17, 2011, as amended (the "Agreement"); and

WHEREAS, by executing this Amendment Inspiration makes a commitment to pay for Manufacturing Capacity and other Services, and CMC ICOS reserves such Manufacturing Capacity for Inspiration; and

WHEREAS, CMC ICOS and Inspiration have executed this Amendment for the purpose of setting forth such terms and conditions.

NOW, THEREFORE, the Parties agree as follows:

Any defined term used herein that is not defined herein has the definition ascribed to such term in the Agreement.

I. Product

"**Product**" means Recombinant Human Blood Coagulation Factor IX

II. Scope of Services

Attached as Appendix A

III. Timing

Attached as Appendix B

IV. Price and Payment Terms

Attached as Appendix C

IN WITNESS WHEREOF, this Amendment No. 1 has been executed by the Parties hereto through their duly authorized officers as of the Effective Date.

INSPIRATION BIOPHARMACEUTICALS, INC.

By: /s/ [Illegible]

Date: 11/20/12

CMC ICOS BIOLOGICS, INC.

By: _____

Date: _____

**FACTOR IX
APPENDIX A
SCOPE OF SERVICES**

Objective

The objective of this amendment is to define the additional activities that will be executed at CMC in support of the process validation and regulatory filings for Factor IX. This work is outlined below.

Assumptions

- The attached timeline summarizes activities outlined in this work statement. The timeline shows some activities extending into April 2013 and beyond (e.g., lot release, completion and approval of final reports, etc.). However, the timeline is built around the assumption that CMC and IBI will work to deliver all necessary information (e.g., process validation data, data from bench scale work, draft reports, etc.) in time to support a complete response to the EMA due at the end of April 2013. The target date for the completion/generation of this work is the end of March 2013 in order to enable sufficient time to generate the response for the EMA.
- Many of the activities outlined below will require material (e.g., harvest fluid, column eluates, etc) taken from an at-scale manufacturing run. Thus, material taken from the conformance run(s) will be a pre-requisite for these activities
- If in the course of execution of this Amendment the scope of work deviates significantly from the scope outlined below, a new amendment will be prepared
- CMC will support sample shipment to domestic locations only

Scope of Work

Resin Cleaning and Lifetime Validation

- Execute bench scale resin and cleaning and lifetime validation for the new HIC chromatography step
- Develop validation protocol (target approximately 15 cycles)
- Execute HIC cycling study plus blank runs, on the bench scale; data will be used to validate maximum number of cycles for Manufacturing
- Summarize work in Validation Report

Viral Clearance Validation

- The HIC step will not be validated as a virus reduction step
- Viral clearance of the nano-filtration step will be re-validated for the new high salt feedstream
- Develop validation protocol
- Execute virus reduction studies at CMC and third party vendor
- Summarize results in Validation report

Impurities Spiking Studies

- Scope of work and estimates are based on draft version of VAL-30180-01, F90 Process Related Impurity Clearance Validation Plan. Changes to the scope may affect effort and duration estimates.
- The scope of impurity clearance is limited to the seven process-related impurities that were part of the F90 process validation protocols: Triton X-100, tri-n-butyl phosphate (TnBP), phenol red, insulin, vitamin K, Pluronic F-68, and CHO host cell DNA
- Protocols will be written for process-related impurity clearance. Clearance for each impurity will be a combination of results from at-scale GMP runs and small-scale spiking runs. The use of at-scale GMP runs vs. small scale runs is determined by whether spiking studies are necessary to demonstrate impurity clearance.
- At least three runs will be performed or assayed for each impurity. Spiked runs involving a chromatography column will be followed by an unspiked run to check for any column carryover. The exception to the above description is DNA spiking, for which small-scale spiking studies will be performed on all three column chromatography steps to ascertain total process clearance capacity. Selected impurities may be spiked simultaneously if preliminary experiments indicate there is no interference with either elution profiles or with assay results.
- Impurity clearance report(s) will summarize the total clearance capacity (i.e. validated impurity clearance capacity of all tested steps in the F90 purification process) for each process-related impurity.

Day 120 Commitments

- Redefine process control strategy
 - Develop project plan for change to definitions of CPPs, CQAs
 - Perform modified risk assessments for each unit operation and all parameters under current process control strategy
 - Revise PERs (PJR and PRA will not be revised)
 - Revise CPV protocol to set new baseline for parameters
 - Revise CPV summary report template

-
- Additional activities required for each F90 batch
 - Data entry and verification for CPV
 - Additional assays from revised QST

Generation of Material for HCP ELISA Method Development

- Execute bench scale bioreactor/spinner process using mock cell line under approved protocol
- Collect cells from bioreactor/spinner and generate cell lysate per protocol
- Ship cell lysate material to support development of next generation ELISA

**FACTOR IX
APPENDIX B
TIMING**

See attached timeline

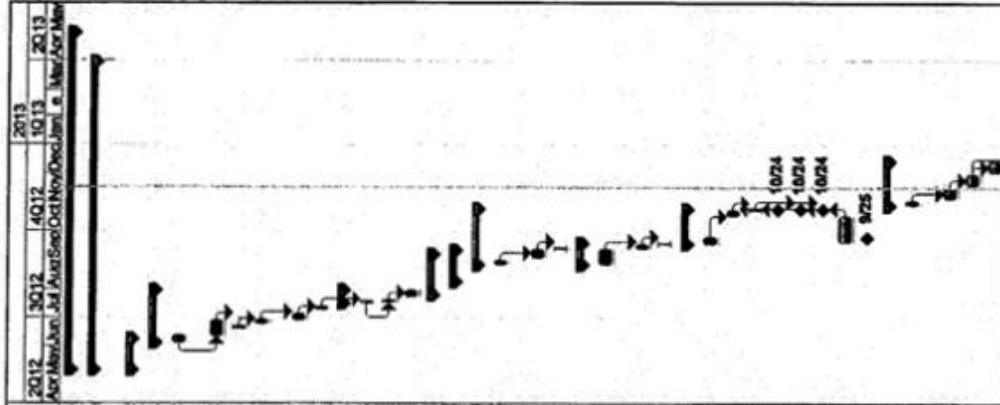
Assumptions to Attached Timeline

- CMC will provide a regular timeline updates. This will include an update for the tasks for percent completion, actual start dates and actual/target dates for completion
- The attached timeline assumes that the Validation campaign will occur in Line A and occur in manufacturing slots already reserved by Inspiration.
- The attached timeline for Validation is based on the process knowledge known to-date.

**FACTOR IX
APPENDIX C
PRICE AND PAYMENT TERMS**

- IBI will pay CMC per the following terms:
 - \$[**] due February 1, 2013
 - \$[**] due March 1, 2013

ID	Task Name	% Complete	Start	Finish
1	CSA Amendment 1: HCP Reduction			
2	Stage 1: Bench Scale Development, Optimization and Characterization of a new process operation	37%	Mon 5/7/12	Mon 4/29/13
3	Bench Scale HCP Reduction exploratory work	42%	Mon 5/7/12	Fri 3/29/13
8	Process Optimization	100%	Mon 5/7/12	Fri 6/8/12
9	Evaluate alternate salts and salt concentrations for promoting HIC binding	100%	Tue 6/5/12	Mon 7/30/12
10	Determine appropriate membrane/filter capacity	100%	Tue 6/12/12	Thu 6/28/12
11	Additional alternate salts and salt concentrations	100%	Wed 6/20/12	Fri 6/22/12
12	Execute TFF experiments to ensure salt job from HIC does not negatively impact product during formulation	100%	Mon 6/25/12	Fri 6/29/12
13	Additional Membranes & Cycling Experiments	100%	Fri 6/29/12	Thu 7/5/12
14	Representative HIC Membrane Set-point Run	100%	Tue 7/10/12	Fri 7/13/12
15	Bench Scale Demo Runs (Load VF from GMP 29-412-0044)	100%	Tue 7/17/12	Mon 7/30/12
16	BSRF1 = 1 x 3mL Membrane & UF/DF	100%	Tue 7/17/12	Thu 7/19/12
17	BSRF2 = Cycle x 3mL Membrane & UF/DF	100%	Wed 7/18/12	Fri 7/20/12
18	Analysis (Silver SDS-PAGE, HCP ELISA, SEC)	100%	Tue 7/24/12	Mon 7/30/12
19	Column Chromatography Alternate Collection/Pooling	100%	Thu 7/26/12	Thu 8/6/12
28	Evaluation of Different Separation Technologies	100%	Thu 8/9/12	Tue 8/11/12
34	Evaluate revised wash steps for IEX1 and IEX3	99%	Mon 8/27/12	Wed 10/24/12
35	Evaluate add wash steps for IEX1 and determine impact on HCP levels in IEX1 eluate	100%	Mon 8/27/12	Fri 8/31/12
36	Testing (SDS-PAGE NP, HCP ELISA for decisions)	100%	Mon 9/3/12	Wed 9/12/12
37	Data Analysis	100%	Thu 9/13/12	Thu 9/13/12
38	Develop new IEX3 wash strategy	100%	Mon 8/27/12	Tue 9/18/12
39	Execution: Load column in absence of calcium, salt wash, elute IEX w/ calcium	100%	Mon 8/27/12	Wed 9/12/12
40	Testing (HCP ELISA for decisions)	100%	Thu 9/13/12	Mon 9/17/12
41	Data Analysis Evaluation for BSR Demonstration	100%	Tue 9/19/12	Tue 9/18/12
42	Bench Scale Pre-Demo Run (start @ IEX3 eluate from GMP9)	99%	Tue 9/18/12	Wed 10/24/12
43	Execution	100%	Tue 9/19/12	Tue 9/25/12
44	Testing (SEC, RP-HPLC, n-Glycan)	100%	Thu 10/18/12	Tue 10/23/12
45	Data Review	100%	Wed 10/24/12	Wed 10/24/12
46	Sample Shipments NOT PERFORMED	0%	Wed 10/24/12	Wed 10/24/12
47	HTI - Shipment NOT PERFORMED	0%	Wed 10/24/12	Wed 10/24/12
48	Kevin VanCott - Shipment NOT PERFORMED	0%	Wed 10/24/12	Wed 10/24/12
49	HCP Reduction Effort - HOLD	0%	Thu 9/20/12	Wed 10/17/12
50	Process Lock Decision	100%	Tue 9/25/12	Tue 9/25/12
51	Bench Scale Model Qualification	25%	Mon 10/29/12	Fri 12/14/12
52	Develop and approve Bench Scale Model Qualification Protocol for HIC step (F80-CP-153)	100%	Mon 10/29/12	Fri 11/2/12
53	Bench Scale Model Qualification Run#1-4 + 2 blank runs	50%	Mon 11/5/12	Fri 11/16/12
54	Analytics	0%	Mon 11/19/12	Fri 11/30/12
55	Bench Scale Model Qualification Draft Report for approval	0%	Mon 12/3/12	Fri 12/14/12



ID	Task Name	% Complete	Start	Finish	2013		
					30/12	10/12	20/13
91	Process Control Strategy - Redefines CPPs/COAs (0120 containment/responses)	14%	Thu 9/20/12	Mon 4/29/13			
92	Develop project plan for change to redefining CPPs/COAs	100%	Thu 9/20/12	Thu 9/20/12			
93	Complete RAMM	100%	Thu 9/20/12	Wed 10/3/12			
94	Risk Assessment Approval	100%	Wed 10/24/12	Mon 10/29/12			
95	Upstream Process Control Strategy	99%	Wed 10/24/12	Fri 11/16/12			
96	Downstream Process Control Strategy	99%	Wed 10/24/12	Fri 11/16/12			
97	Conformance Summary Report	0%	Mon 12/3/12	Mon 4/15/13			
98	PV Summary Report (DRAFT) to IRI	0%	Fri 11/16/12	Fri 3/29/13			
99	PV Summary Report FINAL	0%	Fri 11/16/12	Mon 4/29/13			
100	Client COAs	100%	Mon 9/24/12	Mon 9/24/12			
101	Characterization/Development Executive Summary	90%	Fri 10/19/12	Thu 11/15/12			
102	Include new operations into continued process verification system	0%	Tue 1/29/13	Tue 2/19/13			
103	Implementation for GMP Manufacturing	52%	Wed 9/13/12	Fri 1/11/13			
104	Revise and approve GMP batch records	30%	Wed 9/12/12	Sun 10/21/12			
105	F90A03 Specifications Approved - IRI and CMC Biologics	85%	Tue 9/25/12	Sun 10/21/12			
106	GMP Manufacturing Pre-requirements	0%	Wed 9/26/12	Sun 10/21/12			
107	QST revised and approved	95%	Sun 10/21/12	Sun 10/21/12			
108	Minimum of one A03 run completed w/ and the results are back from the analytical analysis (minimally testing of the API for HCP, MBRs approved in rolling fashion)	0%	Thu 10/18/12	Thu 10/18/12			
109	F90A03 Materials are on-site and released	100%	Sun 10/21/12	Sun 10/21/12			
110	F90A03 Test Methods Approved and Qualified for API and IPC to Support F90A03 Specifications	5%	Wed 9/26/12	Wed 9/26/12			
111	Regulatory impact statement to release lot	100%	Thu 9/27/12	Thu 9/27/12			
112	QC Support scope	0%	Fri 1/11/13	Fri 1/11/13			
113	Qualify a dialysis or buffer exchange method for sample prep of HCP loads	100%	Tue 9/18/12	Tue 10/9/12			
114	Amend VAL60456-02 (F90 specific HCP assay)	100%	Tue 9/18/12	Tue 9/18/12			
115	Commercial Scale Development	55%	Wed 6/20/12	Tue 4/30/13			
116	Line A ENGR12-19/ENGR12-30 Development Run	100%	Wed 6/20/12	Fri 9/28/12			
117	BOS Production Run (Line B) - ENGR12-19 Upstream	100%	Wed 6/20/12	Wed 6/20/12			
118	BOS Production Run (Line B) - ENGR12-30 Downstream	100%	Wed 6/20/12	Wed 6/20/12			
119	HCP Testing ENG run (ELISA) and Evaluation	100%	Wed 6/20/12	Thu 7/26/12			
120	Characterization & CMC Release Assay Evaluation (Potency @ HTI)	100%	Thu 7/26/12	Tue 7/31/12			
121	Line A Run 40/ENGR12-30 Development Run	100%	Tue 7/31/12	Tue 8/7/12			
122	BOS Production Run (Line A) - GMP40 (Lot-12-055) Upstream	100%	Mon 7/23/12	Fri 9/28/12			
123	BOS Production Run (Line A) - ENGR12-30 Downstream	100%	Mon 7/23/12	Tue 8/7/12			
124	HCP Testing ENG run (ELISA) and Evaluation	100%	Mon 8/13/12	Wed 9/12/12			
125	Characterization & CMC Release Assay Evaluation (Potency @ HTI)	100%	Mon 8/13/12	Wed 9/12/12			
126	Commercial Scale Process Demonstration	91%	Mon 8/13/12	Fri 9/28/12			
127			Mon 8/13/12	Fri 9/28/12			
128			Mon 8/13/12	Fri 9/28/12			
129			Wed 8/22/12	Mon 11/6/12			

ID	Task Name	% Complete	Start	Finish	2013	
					10/13	10/13
130	Line B Run 206 Process Demo 1 (ENGR12-33/ENGR12-38) - Locked Process	100%	Wed 8/22/12	Thu 10/18/12	2012	2013
131	BDS Production Run (Line B) - ENGR12-33 Upstream	100%	Wed 8/22/12	Thu 9/27/12	10/12	10/13
132	BDS Production Run (Line B) - ENGR12-35 Downstream	100%	Thu 9/27/12	Tue 10/2/12	10/12	10/13
133	Sample Shipments	100%	Wed 10/3/12	Wed 10/3/12	10/12	10/13
134	HTI - Shipment	100%	Wed 10/3/12	Wed 10/3/12	10/12	10/13
135	HBS - Shipment	100%	Wed 10/3/12	Wed 10/3/12	10/12	10/13
136	Evaluation	100%	Tue 10/2/12	Thu 10/18/12	10/12	10/13
137	HCP Testing GMP run (ELISA) and Evaluation	100%	Tue 10/2/12	Mon 10/8/12	10/12	10/13
138	Characterization & CMC release assay evaluation	100%	Tue 10/2/12	Mon 10/15/12	10/12	10/13
139	HTI release test evaluation	100%	Tue 10/2/12	Thu 10/18/12	10/12	10/13
140	Other outsource release test evaluation	100%	Tue 10/2/12	Thu 10/18/12	10/12	10/13
141	Line A Run 43 Process Demo 2 (ENGR12-36/ENGR12-37) - Locked Process	76%	Mon 9/3/12	Mon 11/5/12	10/12	10/13
142	BDS Production Run - ENGR12-36 Upstream	100%	Mon 9/3/12	Tue 10/9/12	10/12	10/13
143	BDS Production Run - ENGR12-37 Downstream	100%	Tue 10/9/12	Mon 10/15/12	10/12	10/13
144	Sample Shipments	0%	Wed 10/17/12	Mon 11/5/12	10/17	10/18
145	HBS STAT Potency - Shipment	0%	Wed 10/17/12	Wed 10/17/12	10/17	10/18
146	Battelle Labs for Rat PK Studies - Shipment ON HOLD PER BM	0%	Mon 11/5/12	Mon 11/5/12	10/17	10/18
147	HBS - Stability Samples	0%	Wed 10/17/12	Wed 10/17/12	10/17	10/18
148	HTI - Shipment	0%	Wed 10/17/12	Wed 10/17/12	10/17	10/18
149	Evaluation - only sent mycoplasma, in vitro viral & MMSV	0%	Mon 10/15/12	Wed 10/31/12	10/17	10/18
150	HCP Testing GMP run (ELISA) and Evaluation	0%	Mon 10/15/12	Fri 10/19/12	10/17	10/18
151	Characterization & CMC release assay evaluation	0%	Mon 10/15/12	Fri 10/26/12	10/17	10/18
152	HTI release test evaluation	0%	Mon 10/15/12	Wed 10/31/12	10/17	10/18
153	Other outsource release test evaluation	0%	Mon 10/15/12	Wed 10/31/12	10/17	10/18
154	Line B Run 207 Process Demo 3 (ENGR12-38/ENGR12-39) - Locked Process	100%	Wed 8/13/12	Sun 10/14/12	10/17	10/18
155	BDS Production Run Upstream CONTAMINATION - N-Stage Day 8	100%	Wed 9/12/12	Sun 10/14/12	10/17	10/18
156	cGMP Manufacturing	52%	Wed 8/26/12	Fri 11/1/12	10/17	10/18
157	Line A GMP44 A03 - 12-006912-0070	52%	Wed 8/26/12	Fri 11/1/12	10/17	10/18
158	Line A GMP44 Upstream	100%	Mon 10/1/12	Tue 11/6/12	10/17	10/18
159	Line A GMP44 Downstream	100%	Mon 10/1/12	Tue 11/6/12	10/17	10/18
160	Line A GMP44 RFFP	100%	Tue 11/6/12	Fri 11/9/12	10/17	10/18
161	Line A GMP44 Testing and CMC batch disposition	10%	Fri 11/9/12	Fri 11/9/12	10/17	10/18
162	Sample Shipments	0%	Fri 11/9/12	Fri 11/9/12	10/17	10/18
163	HBS STAT Potency - Shipment	0%	Tue 11/13/12	Tue 11/13/12	10/17	10/18
164	HBS - Stability Samples	0%	Tue 11/13/12	Tue 11/13/12	10/17	10/18
165	HTI - Shipment	0%	Tue 11/13/12	Tue 11/13/12	10/17	10/18
166	Pathcon Shipment	0%	Fri 12/7/12	Fri 12/7/12	10/17	10/18
167	Line A GMP45 A03 - Terminated	100%	Mon 10/22/12	Mon 10/22/12	10/17	10/18
168	Line A GMP46 A03 - Terminated	100%	Wed 9/26/12	Wed 9/26/12	10/17	10/18
169	Process Validation	0%	Mon 12/3/12	Tue 4/30/13	10/17	10/18

ID	Task Name	% Complete	Start	Finish	2013		
					30/12	4Q12	2Q13
170	Line A GMP47 A03	0%	Mon 12/24/12	Fri 3/29/13			
171	Line A GMP47 Upstream	0%	Mon 12/24/12	Tue 1/8/13			
172	Line A GMP47 Downstream	0%	Tue 1/8/13	Mon 1/14/13			
173	Line A GMP47 Testing and CMC batch disposition	0%	Mon 1/14/13	Fri 3/29/13			
174	Sample Shipments	0%	Wed 1/16/13	Wed 1/16/13			
175	HBS STAT Potency - Shipment	0%	Wed 1/16/13	Wed 1/16/13			
176	HBS - Stability Samples	0%	Wed 1/16/13	Wed 1/16/13			
177	HTI - Shipment	0%	Wed 1/16/13	Wed 1/16/13			
178	Line A GMP48 A03	0%	Mon 12/24/12	Fri 4/19/13			
179	Line A GMP48 Upstream	0%	Mon 12/24/12	Tue 1/29/13			
180	Line A GMP48 Downstream	0%	Tue 1/29/13	Sun 2/3/13			
181	Line A GMP48 Testing and CMC batch disposition	0%	Mon 2/4/13	Fri 4/19/13			
182	Sample Shipments	0%	Wed 2/6/13	Wed 2/6/13			
183	HTI - Shipment	0%	Wed 2/6/13	Wed 2/6/13			
184	HBS - Shipment	0%	Wed 2/6/13	Wed 2/6/13			
185	Line A GMP49 A03	0%	Mon 1/14/13	Tue 4/30/13			
186	Line A GMP49 Upstream	0%	Mon 1/14/13	Tue 2/19/13			
187	Line A GMP49 Downstream	0%	Tue 2/19/13	Sun 2/24/13			
188	Line A GMP49 Testing and CMC batch disposition	0%	Mon 2/25/13	Fri 4/26/13			
189	Sample Shipments	0%	Wed 2/27/13	Wed 2/27/13			
190	HTI - Shipment	0%	Wed 2/27/13	Wed 2/27/13			
191	HBS - Shipment	0%	Wed 2/27/13	Wed 2/27/13			
192	Pathron Shipment All PV Lots	0%	Tue 4/30/13	Tue 4/30/13			
193	Insulin Spiking Studies (NOT INCLUDED IN Amend 1, 008)	0%	Mon 11/26/12	Fri 4/12/13			
194	Pluronic Clearance Validation Study	0%	Mon 11/26/12	Tue 1/29/13			
195	Practice Spiking Studies	0%	Mon 11/26/12	Thu 12/13/12			
196	Execution (2 runs) - Need Start Date	0%	Mon 11/26/12	Thu 11/29/12			
197	Analytics	0%	Fri 11/30/12	Thu 12/13/12			
198	Validation Protocol	0%	Fri 12/14/12	Thu 12/20/12			
199	Execution (4 runs)	0%	Fri 12/14/12	Thu 12/20/12			
200	Analytics	0%	Fri 12/21/12	Tue 1/1/13			
201	Pluronic Clearance Validation draft report for approval	0%	Wed 1/2/13	Tue 1/15/13			
202	DNA Clearance Validation Studies	0%	Wed 1/16/13	Tue 1/29/13			
203	Practice Spiking Studies	0%	Mon 11/26/12	Thu 12/13/12			
204	Execution (2 runs)	0%	Mon 11/26/12	Thu 12/13/12			
205	Analytics	0%	Fri 11/30/12	Thu 12/13/12			
206	Validation Protocol	0%	Fri 12/14/12	Thu 12/20/12			
207	Execution (4 runs)	0%	Fri 12/14/12	Thu 12/20/12			
208	Analytics	0%	Fri 12/21/12	Tue 1/1/13			
209	DNA Clearance Validation draft report for approval	0%	Wed 1/2/13	Tue 1/15/13			
210	Insulin Clearance Validation Study	0%	Wed 1/16/13	Tue 1/29/13			
211	Practice Spiking Studies	0%	Wed 1/23/13	Mon 1/21/13			

ID	Task Name	% Complete	Start	Finish	2013		
					30/12	30/12	30/12
212	Execution (2 runs)	0%	Wed 1/2/13	Mon 17/1/13	Apr	Mar	Apr
213	Analytics	0%	Tue 1/8/13	Mon 1/21/13	Oct	Nov	Dec
214	Validation Protocol	0%	Tue 1/22/13	Mon 1/28/13	Dec	Jan	Feb
215	Execution (4 runs)	0%	Tue 1/29/13	Thu 27/1/13	Jan	Feb	Mar
216	Analytics	0%	Fri 2/8/13	Thu 2/21/13	Feb	Mar	Apr
217	Insulin Clearance Validation draft report for approval	0%	Fri 2/22/13	Thu 3/7/13	Mar	Apr	May
218	Phenol Red Clearance Validation Study	0%	Wed 1/2/13	Thu 3/7/13	Mar	Apr	May
219	Practice Spiking Studies	0%	Wed 1/2/13	Mon 1/21/13	Mar	Apr	May
220	Execution (2 runs)	0%	Wed 1/2/13	Mon 1/21/13	Mar	Apr	May
221	Analytics	0%	Tue 1/8/13	Mon 1/21/13	Mar	Apr	May
222	Validation Protocol	0%	Tue 1/22/13	Mon 1/28/13	Mar	Apr	May
223	Execution (4 runs)	0%	Tue 1/29/13	Thu 27/1/13	Mar	Apr	May
224	Analytics	0%	Fri 2/8/13	Thu 2/21/13	Mar	Apr	May
225	Phenol Red Clearance Validation draft report for approval	0%	Fri 2/22/13	Thu 3/7/13	Mar	Apr	May
226	Vitamin K Clearance Validation Study	0%	Thu 27/1/13	Fri 4/12/13	Mar	Apr	May
227	Practice Spiking Studies	0%	Thu 27/1/13	Tue 2/28/13	Mar	Apr	May
228	Execution (2 runs)	0%	Thu 27/1/13	Tue 2/28/13	Mar	Apr	May
229	Analytics	0%	Wed 27/1/13	Tue 2/28/13	Mar	Apr	May
230	Validation Protocol	0%	Wed 27/1/13	Tue 2/28/13	Mar	Apr	May
231	Execution (4 runs)	0%	Wed 27/1/13	Tue 2/28/13	Mar	Apr	May
232	Analytics	0%	Mon 3/18/13	Fri 3/15/13	Mar	Apr	May
233	Vitamin K Clearance Validation draft report for approval	0%	Mon 3/18/13	Fri 3/29/13	Mar	Apr	May
234	Triton X-100/TrisBP Clearance Validation Study	0%	Mon 4/1/13	Fri 4/12/13	Mar	Apr	May
235	Practice Spiking Studies	0%	Thu 27/1/13	Tue 2/28/13	Mar	Apr	May
236	Execution (2 runs)	0%	Thu 27/1/13	Tue 2/28/13	Mar	Apr	May
237	Analytics	0%	Wed 27/1/13	Tue 2/28/13	Mar	Apr	May
238	Validation Protocol	0%	Wed 27/1/13	Tue 2/28/13	Mar	Apr	May
239	Execution (4 runs)	0%	Wed 27/1/13	Tue 2/28/13	Mar	Apr	May
240	Analytics	0%	Wed 3/6/13	Fri 3/15/13	Mar	Apr	May
241	Triton X-100/TrisBP Clearance Validation draft report for approval	0%	Mon 3/18/13	Fri 3/29/13	Mar	Apr	May
242	Provide Impurities Spiking Data to Client	0%	Mon 4/7/13	Fri 4/12/13	Mar	Apr	May
243	Medc Cell Line Cell Lysate	0%	Fri 3/29/13	Fri 3/29/13	Mar	Apr	May
244	Draft Characterization Protocol	0%	Mon 11/19/12	Fri 12/21/12	Mar	Apr	May
245	Cell Expansion (Production Model)	0%	Mon 11/19/12	Tue 12/18/12	Mar	Apr	May
246	Harvest	0%	Wed 11/21/12	Tue 12/18/12	Mar	Apr	May
247	Ship	0%	Wed 12/19/12	Wed 12/19/12	Mar	Apr	May
248	CMC Response to IBI on D180 Questions	0%	Thu 12/20/12	Fri 12/21/12	Mar	Apr	May

SCHEDULE 2

Price per Batch

APPENDIX THREE

Price

Note: all prices are subject to an annual price index increase

Price per Batch up until 31 December 2015

Shall be US \$[**] per Batch delivered up to and including 31 December 2015. This amount is exclusive of the cost of raw materials.

Price per Batch from 1 January 2016 until 31 December 2016

Shall be US \$[**] per Batch. This amount is exclusive of the cost of raw materials.

Should capacity for manufacture of Product be increased beyond sixteen (16) Batches per Year in accordance with this Agreement, CMC and IBI may, in good faith, consider pricing for Batches in 2016 to be calculated according to the following formula rather than US \$[**] but in the absence of agreement the price per Batch shall remain at US \$[**] per Batch.

Potential alternative pricing terms (not including materials and supplies and resins):

First five (5) million IU per Batch supplied at \$[**]/IU

Next five (5) million IU per Batch supplied at \$[**]/IU

Next five (5) million IU per Batch supplied at \$[**]/IU

All IU per Batch in excess of fifteen (15) million IU supplied at \$[**]/IU

Price per Additional Batch

Shall be determined according to CMC's then current list price per batch, which as of the Effective Date is US\$[**]

Payment Terms (for all other monies due under this Agreement for which payment terms are not expressly identified in the Agreement)

- 30 days net of invoice date.

SCHEDULE 3

IPR Associated with Factor VIIa Product

Inspiration Factor VII Patent Portfolio 11-15-2012

<u>EWP Ref No.</u>	<u>Ref No.</u>	<u>Reference source</u>	<u>Application No. / Patent No.</u>	<u>ATTY REF NO.</u>	<u>Country</u>	<u>Filing Date</u>	<u>Note</u>
METHOD OF PRODUCING RECOMBINANT VITAMIN K DEPENDENT PROTEINS (Inspiration-UNC Co-Owned)							
90160P(311835)	INSPL024PR	Inspiration	61/256,802		US PROV	30/10/2009	EXPIRED
90160WO(311835)	INSPI.024WO	Inspiration	PCT/US2010/054581		PCT	28/10/2010	PUBLISHED Nationalized
90160US(311835)	INSPI.024NP	Inspiration	13/459,743		US	30/04/2012	Published
90160EP(311835)	INSPI.024WO	Inspiration	10827499.4		EP	10/28/2010 (PCT date)	Published
90160JP(311835)	TBD	Inspiration	awaiting		JP	10/28/2010 (PCT date)	Pending
RECOMBINANT VITAMIN K DEPENDENT PROTEINS WITH HIGH SIALIC ACID CONTENT AND METHODS OF PREPARING SAME (Inspiration UNC co-Owned)							
90207(311835)	INSPI.008NP	Inspiration	12/597,456		US	23/10/2009	PUBLISHED
90207P(311835)	INSPI.008PR	Inspiration	607914,281		US PROV	26/04/2007	CLOSED
90207WO(311835)	INSPI.008VPC	Inspiration	PCT/US2008/061822		PCT	28/04/2008	EXPIRED
90207AU(311835)	INSPI.008VAU	Inspiration	2008245524		AU	28/04/2008	Pending
90207CA(311835)	INSPI.008VCA	Inspiration	2683423		CA	28/04/2008	Pending
90207EP(311835)	INSPI.008VEP	Inspiration	8747060.5		EP	28/04/2008	Pending
90207JP(311835)	INSPI.008VJP	Inspiration	2010-506563		JP	28/04/2008	PUBLISHED- pending
90207DIVEP (311835)		Inspiration	12170422.5		EP	28/04/2012	Pending- published
CORRELATION OF SNPS IN THE VITAMIN K EPOXIDE REDUCTASE GENE AND WARFARIN DOSAGE (METHODS AND COMPOSITIONS FOR VITAMIN K EPOXIDE REDUCTASE) (UNC)							
0024(311835)	04-0007	UNC	60/505,527	5470-401 PR	US PROV	23/09/2003	EXPIRED

<u>EWP Ref No.</u>	<u>Ref No.</u>	<u>Reference source</u>	<u>Application No. / Patent No.</u>	<u>ATTY REF NO.</u>	<u>Country</u>	<u>Filing Date</u>	<u>Note</u>
0024(311835)	04-0007	UNC	PCT/US04/031481	5470-401WO	PCTY	23/09/2004	EXPIRED
0024(311835)	04-0007	UNC	10/573,131 7,687,233	5470-401	US	18/04/2006	ALLOWED
0024(311835)	04-0007	UNC	11/516,229 7,524,665	5470-401CT	US CON	06/09/2006	EXPIRES 09/23/2024
0024(311835)	04-0007	UNC	11/699,930 7,482,141	5470-401CT2	US CON	30/01/2007	EXPIRES 09/23/2024
0024(311835)	04-0007	UNC	11/787,072 7,645,602	5470-401P	US CIP	13/04/2007	EXPIRES 09/23/2024
0024(311835)	04-0007	UNC	12/612,154	5470-401PCT2	US CON	04/11/2009	PENDING
0024(311835)	04-0007	UNC	2004275828	5470-401AU	AU	23/09/2004	PENDING
0024(311835)	04-0007	UNC	2539434	5470-401CA	CA	23/09/2004	PENDING
0024(311835)	04-0007	UNC	4789039.7	5470-401EP	EP	23/09/2004	PENDING
0024(311835)	04-0007	UNC	7109353.8	5470-401EP2	EP DIV	23/09/2004	PENDING OPPOSITION
0024(311835)	04-0007	UNC	2006528251	5470-401JP	JP	23/09/2004	PENDING
0024(311835)	04-0007	UNC	61140030	5470-401HK	HK	23/09/2004	PENDING
0024(311835)	04-0007	UNC	81036847	5470-401HK2	HK DIV	23/09/2004	PENDING
0024(311835)	04-0007	UNC	11156979.4	5470-401EP4	EP DIV	23/09/2004	
VITAMIN K-DEPENDENT CARBOXYLASE (UNC)							
0026(311835)	90-62	UNC	07/697,427	5470-24	US	08/05/1991	ABANDONED
0026(311835)	90-62	UNC	07/756,250 5,268,275	5470-34	US	09/09/1991	EXPIRED 12/7/2010

<u>EWP Ref No.</u>	<u>Ref No.</u>	<u>Reference source</u>	<u>Application No. / Patent No.</u>	<u>ATTY REF NO.</u>	<u>Country</u>	<u>Filing Date</u>	<u>Note</u>
0026(311835)	90-62	UNC	PCT/US92/003853	5470-34.1WO	PCT	08/05/1992	EXPIRED
0026(311835)	90-62	UNC	2102702	5470.34.4CA	CA	08/05/1992	EXPIRES 05/08/2012
0026(311835)	90-62	UNC	92913019.3 0587742	5470-34.2EP	EP	18/05/1992	EXPIRES 05/08/2012
0026(311835)	90-62	UNC	92913019.3 692325441	5470-34.2DE	DE	08/05/1992	EXPIRES 05/08/2012
0026(311835)	90-62	UNC	92913019.3 587742	5470-34.2DK	DK	08/05/1992	EXPIRES 05/08/2012
0026(311835)	90-62	UNC	92913019.3 587742	5470-34.2FR	FR	08/05/1992	EXPIRES 05/08/2012
0026(311835)	90-62	UNC	92913019.3 587742	5470-34.2GB	GB	08/05/1992	EXPIRES 05/08/2012
0026(311835)	90-62	UNC	92913019.3 587742	5470-34.2ES	SE	08/05/1992	EXPIRES 05/08/2012
0026(311835)	90-62	UNC		5470-34.2AT	AT	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2BE	BE	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2CH	CH	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2ES	ES	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2GR	GR	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2IT	IT	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2LI	LI	08/05/1992	

<u>EWP Ref No.</u>	<u>Ref No.</u>	<u>Reference source</u>	<u>Application No. / Patent No.</u>	<u>ATTY REF NO.</u>	<u>Country</u>	<u>Filing Date</u>	<u>Note</u>
0026(311835)	90-62	UNC		5470-34.2LU	LU	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2MC	MC	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2NL	NL	08/05/1992	
0026(311835)	90-62	UNC		5470-34.2AU	AU	08/05/1992	
CHIMERIC FACTOR VII MOLECULES (UNC)							
0031(311835)	08-0047	UNC	61/220,278	5470-494	US PROV	25/06/2009	EXPIRED
0031(311835)	08-0047	UNC	PCT/US10/039934 WO 10/151736	5470-494WO	PCT	25/06/2010	EXPIRED
0031(311835)	08-0047	UNC		5470-494AU	AU	25/06/2010	N/A
0031(311835)	08-0047	UNC		5470-494BR	BR	25/06/2010	N/A
0031(311835)	08-0047	UNC		5470-494CA	CA	25/06/2010	N/A
0031(311835)	08-0047	UNC		5470-494CN	CN	25/06/2010	N/A
0031(311835)	08-0047	UNC		5470-494EP	EP	25/06/2010	N/A
0031(311835)	08-0047	UNC		5470-494IN	IN	25/06/2010	N/A
0031(311835)	04-0047	UNC		5470-494JP	JP	25/06/2010	N/A
0031(311835)	04-0047	UNC		5470-494RU	RU	25/06/2010	N/A
0031(311835)	04-0047	UNC	12/823,382		US		N/A
0031(311835)	04-0047	UNC	13/097,609 (co-owned with Inspiration)	5470-494IP	US	29/04/2011	N/A

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

SUPPLY AGREEMENT

**Between CNJ Holdings Inc. and
Rovi Contract Manufacturing, S.L.**

This Supply Agreement, effective as of April 29th, 2014 (the “**Effective Date**”), is entered by and between CNJ Holdings Inc., doing business as Emergent BioSolutions, with an address at c/o 155 Innovation Drive, Winnipeg, Manitoba, Canada R3T 5Y3 (“**Cangene**”), and Rovi Contract Manufacturing, S.L., with an address at Julian Camarillo, 35, 28037 Madrid, SPAIN (“**Company**”).

WHEREAS, Cangene is interested in purchasing certain products from Company, and Company desires to supply such products to Cangene under the terms set forth in this Agreement;

NOW, THEREFORE, in consideration of the foregoing, of the mutual covenants and undertakings contained herein and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Cangene and Company, intending to be legally bound, hereby agree as follows:

1) Definitions:

- a) “**Act**” means the U.S. Federal Food, Drug and Cosmetic Act, as amended.
- b) “**Affiliate**” means, with respect to a party, any individual, corporation or other business entity which, either directly or indirectly, controls such party, is controlled by such party, or is under common control with such party. As used herein, “control” means possession of the power to direct, or cause the direction of the management and policies of a corporation or other entity whether through the ownership of voting securities, by contract or otherwise.
- c) “**Agreement**” means this Supply Agreement, and all exhibits attached hereto including the Quality Agreement, and all accepted Purchase Orders that expressly reference this Supply Agreement.
- d) “**Business Day**” means any day other than a day which is a Saturday, Sunday, or federal bank or federal government holiday in the United States and/or Spain.
- e) “**Cangene Official Correspondent**” means Vicki Wolff-Long, Vice-President and General Manager, Cangene bioPharma Inc., or other person designated by Cangene and noticed to Company.
- f) “**Certificate of Analysis**” means a certificate in form and substance satisfactory to Cangene, signed by an authorized employee of the Company’s Quality Department, and authenticating the pharmaceutical analysis of each batch of the Product delivered to Cangene.

- g) “**Coagulation Products**” means Cangene’s recombinant coagulation products for hemophilia.
- h) “**Company Official Correspondent**” means Mr. Michel GUILLORY International Business Director or such other person designated by Company and noticed to Cangene.
- i) “**Current Good Manufacturing Practices**” or “**cGMPs**” means (a) all European Union (EU) applicable standards relating to manufacturing practices for fine chemicals, intermediates, bulk products or finished pharmaceutical products promulgated by any Governmental Authority having jurisdiction over the manufacture of the Products in the form of Laws or guidance documents (including, without limitation, advisory opinions, compliance policy guides and guidelines) which guidance documents are being implemented within the pharmaceutical manufacturing industry for such Products, and (b) the principles set forth in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211 as established by the FDA.
- j) “**Dossier**” means Company’s Module 2 (Quality Overall Summary) and Module 3 dossiers as well as the Drug Master File (DMF) for the Pre-filled Syringe WFI sterile diluents described in Exhibit A, including but not limited to all documents that have been or may in the future be filed or submitted to any regulatory authority anywhere in the world.
- k) “**Cangene Facility**” means any Cangene location or any ordering and/or receiving facility designated by Cangene.
- l) “**Governmental Authority**” means any nation or government, any state, province, or other political subdivision thereof or any entity with legal authority to exercise executive, legislative, judicial, regulatory or administrative functions or pertaining to the government in any of the relevant markets anywhere in the world.
- m) “**Laws**” means, with respect to the specific activity to be performed by each party under this Agreement, any and all applicable local, municipal, provincial, federal and international laws, statutes, ordinances, rules, regulations or operating procedures now or hereafter enacted, adopted or promulgated by any Governmental Authority having jurisdiction over such specific activity, including without limitation the United States Pharmacopeia and European Pharmacopeia
- n) “**Product**” (collectively, “**Products**”) means those materials to be supplied by Company to Cangene, as described in the Purchase Schedule, that meet the definitions and specifications set forth in the Quality Agreement and the Purchase Specifications. Product that does not meet the definitions and specifications set forth in the Quality Agreement, or the Purchase Specifications, as such definitions and specifications may be amended, modified, supplemented or superseded from time to time, whether in accordance with the terms of this Agreement or by changes or additions to cGMP or to applicable Laws, shall be referred to as “**Nonconforming Product.**”

- o) **“Purchase Order”** means any purchase order issued by Cangene in accordance with the terms and conditions of this Agreement.
- p) **“Purchase Schedule”** means the purchase schedule containing the Products, applicable prices, and manufacturing site, the first of which is attached hereto as Exhibit A, and incorporated herein by reference.
- q) **“Purchase Specifications”** means, with respect to Products, any and all then-current specifications for materials, approved suppliers, formulations, manufacturing, analytical and testing procedures, release, and other processes relating to the manufacture of the Products, as set forth in Exhibit B and in applicable Purchase Orders, as such specifications may be amended from time to time in accordance with this Agreement.
- r) **“Quality Agreement”** means that certain Quality Agreement by and between the parties, incorporated herein as Exhibit C.

2) Company’s Obligations; Quantity; and Orders:

a) **General:** Pursuant to the terms and conditions of this Agreement, Company shall manufacture, supply and sell Products to Cangene or its Affiliates as ordered by Cangene or its Affiliates in the manner set forth in this Agreement. Company acknowledges and agrees that its relationship with Cangene is on a non-exclusive basis. Without limiting the generality of the foregoing, Cangene reserves the right to qualify one or more alternate suppliers for the types of products required by Cangene to be supplied under this Agreement. Cangene shall have the right to promote and sell (either itself or through distributors or licensees) the Products, either alone or as part of the Coagulation Products, worldwide. Likewise, Company reserves its right to promote and market the types of products required by Cangene to be supplied under this Agreement (either itself or through distributors or licensees, either alone or as part of other products), worldwide as well as to manufacture such products for other third parties.

b) **Manufacturing:** Company shall manufacture the Products consistent with the Purchase Specifications and in accordance with the terms of the Quality Agreement (including dispute resolution provisions dealing with the conformance or nonconformance of Product), Current Good Manufacturing Practices and applicable EU Laws. In case a change in the Product specifications and/or manufacturing process is required in order for the manufacture of the Products to be consistent with any other applicable Laws of the U.S. relating to the manufacture of such Product or as a result of a change in such applicable Laws, the terms and conditions of the Quality Agreement shall set forth the parties’ respective roles and responsibilities in terms of identification of any such required change and the change control procedure. In any case, Cangene will assume responsibility to identify changes required by applicable Laws of the U.S. (other than cGMPs) and related costs of such changes. Company shall not change the manufacturing site, or the materials, process or plant used in the manufacture of the Products, without first obtaining the written consent of Cangene to such change, unless it is a type of change or deviation permitted by the Quality Agreement.

c) **Delivery:** Company shall deliver the Products purchased by Cangene Ex Works (Incoterms 2010). Title and risk of loss shall pass to Cangene upon delivery to the carrier selected by Cangene. Cangene shall be responsible for selection of the carrier(s) to arrange pick-up and delivery of the Products, which must be arranged in advance with Company's Shipping Department. In the alternative and in exceptional circumstances, Cangene can direct that Company ship the Products to it, at Cangene's sole expense (including cost of shipping, insurance and all other costs), and Cangene shall reimburse Company for shipping expenses within [**] days of receipt of an invoice for same.

d) **Timing of Delivery:** Time is of the essence in relation to the performance of any and all of Company's obligations pursuant to this Agreement. Products shall be deemed delivered on time if delivered in accordance with all applicable terms and conditions (including location, Purchase Specifications, requirements and date) and no sooner than [**] days prior to, and no later than [**] days following the delivery date stated in the Purchase Order and confirmed by Company in accordance with Section 2(e) below. A delivery of non-conforming Products or of non-conforming quantity, or a delivery later than [**] days following the delivery date stated in the Purchase Order, shall be deemed a late delivery ("Late Delivery"). Company agrees to use its best efforts to meet any request by Cangene for delivery of Products prior to or by the delivery date stated in the applicable Purchase Order. Company shall notify Cangene of any Late Delivery and specify the estimated delivery date and the circumstances causing the delay, keeping Cangene continually informed about the status of the Late Delivery. For sake of clarity, Delivery date means when the Product is made available to Cangene at Company facility.

e) **Forecasts; Supply; Changes:** Cangene will provide a [**] months' written schedule of estimated requirements of Product which estimate will be updated [**] by way of [**] rolling forecast which will not be binding ("[**] Rolling Forecast"). Company will advise Cangene in writing, promptly, and in any event within [**] business days of receipt of a forecast, if any requirements for Product indicated on a forecast conflicts with either an official plant shut down or [**]. Cangene shall submit Purchase Orders for Product in writing to Company for the supply of the Product not later than [**] days prior to the required date of delivery and Company shall confirm such order in writing within [**] business days (failing which Company shall be deemed to have accepted Cangene's order for delivery on the date specified in that order). Company shall accept all Purchase Orders for Product submitted in writing to Company for the quantity of Product identified for the first month of the most recent [**] Rolling Forecast and which are submitted not later than [**] days prior to the required date of delivery (except to the extent Company advised Cangene within [**] business days of receiving the relevant forecast that the requested delivery date(s) conflict with an official plant shut down or [**]). Due to the [**]), Company will order PFS from the supplier based on the [**] Rolling Forecast provided by Cangene. [**] PFS will be charged to Cangene at a fixed cost as set forth in Exhibit A attached hereto. All PFS charged to Cangene shall be used by Company only to fulfill its obligations and complete Purchase Orders under this Agreement. Company shall be responsible for any damage to the PFS while the PFS are in Company's custody and control. Prices of PFS will be reviewed in future, based on PFS supplier prices. The cost of PFS, already paid by Cangene, will be deducted from the price of the final Product which will be invoiced to Cangene.

f) Changes to Time or Destination: Upon notice to Company from Cangene (which may include telephone, email or facsimile), Cangene shall have the right to: (i) postpone a Product delivery by up to [**] days, and (ii) indefinitely delay or cancel any Product delivery made unnecessary or impossible due to a force majeure event affecting either party unless the Products have already been produced or are in production process in accordance with a confirmed Purchase Order. Provided that Product is available in inventory at Company, if requested by Cangene, Company shall deliver a reasonable quantity of Product on a “rush” basis, to be delivered within [**] hours after any such request.

g) Supply; Purchase Orders: Each Cangene Facility will issue its own Purchase Orders for the Products. Company shall supply Products to Cangene in accordance with Purchase Orders that Cangene may issue to Company from time to time. Purchase Orders shall specify the quantity of the Product(s) to be purchased by Cangene, the place of delivery, the delivery date, the method of shipment and price. Company shall be responsible for manufacturing the amount of Product requested plus or minus [**] percent ([**]%). Cangene shall be responsible for payment of all Products manufactured and delivered within this range.

h) Timing & Logistics: The Company Official Correspondent shall notify the Cangene Official Correspondent promptly of the expected delivery of the Products ordered therein, or of any occurrence that would inhibit Company’s ability to supply the Product(s) to Cangene as requested in the Purchase Order and confirmed by Company.

3) Price:

a) General: During the Term, Cangene shall pay Company for the Products provided in accordance with the pricing provisions contained in the Purchase Schedule. Pricing terms are fixed until December 31, 2014. No later than [**] of each year commencing in [**] 2014, prices will be mutually reviewed in good faith by the parties to take into consideration possible cost increase or decrease and possible volume increase or decrease. In any case, price increase for the following calendar year cannot be more than the increase of the Spanish Price Index publically available at www.ine.es (official website of the Spanish National Institute of Statistics).

Notwithstanding the above, Company will be entitled to request Cangene increase the price in excess of such Spanish Price Index (IPC), provided Company can demonstrate that the costs in any material used in the manufacturing of Product have increased more than the applicable IPC. At such request, the parties will negotiate in good faith and should the parties be unable to agree to the applicable increase within a reasonable period of time, any party will be entitled to refer such pricing dispute to binding arbitration pursuant to the provisions of Section 20(g). In such interim period, current prices will be applicable to orders for Product.

b) Fees for the Dossier: Any and all fees in conjunction with the development of the Dossier shall be borne by Company. Subject to Section 6, Company will provide free and unrestricted access to the Dossier to Cangene upon Cangene’s request.

c) **Invoice Payment:** Company shall prepare and deliver to Cangene an invoice for each shipment of Product purchased hereunder. Company shall submit invoices to Cangene Accounts Payable at the following billing address, preferably by electronic mail (except as otherwise directed by Cangene):

CNJ Holdings Inc.
d/b/a Emergent BioSolutions
155 Innovation Drive
Winnipeg, Manitoba R3T 5Y3
Attention: Accounts Payable
[**]

All invoices shall be submitted contemporaneously with or subsequent to the delivery of the Products. The invoices shall be in writing, shall specify the price in respect of the Product delivered, the Purchase Order number, the quantity of Product delivered, any shipping costs and the invoice amounts, and shall be stated and paid in Euros. In no event shall any invoice be dated prior to the date of delivery of the related Product.

d) **Payment Terms:** Payment terms for each shipment of Products (except to the extent disputed in good faith) shall be net [**] days from receipt of invoice; provided that no invoice shall be dated prior to the shipment of corresponding Products. Payment shall be due net of any and all credits due to Cangene, including without limitation, credit for returns, recalls, and/or warranty replacements.

e) **Payment Method:** Payment by Cangene for orders of Product shall be in Euros. Payment shall be made by bank transfer in immediately available funds to Company as follows:

Name on account:	Rovi Contract Manufacturing, S.L.
Account Number:	[**]
Bank Name:	[**]

4) **Specifications and Quality.**

a) **Specifications:** Each Product delivered pursuant to this Agreement shall comply with the Purchase Specifications. Certificates of Analysis showing size and description, lot or batch number, date of manufacture, site or plant of manufacture, and the specifics of the analysis of all Product properties requested by Cangene, will be provided by Company with each lot of Product. Whenever reasonably possible, shipments (to all centers) shall consist of a single manufacturing lot in pallet quantities. All Products delivered hereunder shall be delivered within [**] weeks of the date of manufacture, unless otherwise approved by Cangene.

b) Shipping: Care and Handling Restrictions.

(i) General: Company shall label, pack and deliver all Products in accordance with cGMPs, the applicable Laws to the manufacturing process performed by Company and the Purchase Specifications.

(ii) Purpose and Manner: The storage and distribution of Products by Company shall be such as to maintain the integrity of the Products, including maintaining appropriate conditions of temperature, humidity, and light. Company shall store all ingredients, materials and Products in a clean, dry area, free from insects and rodents, in a manner to prevent entry of foreign materials. Company shall not manufacture, store or process any materials or Products in the same building in which Company manufactures, stores or processes [**].

(iii) Changes: Subject to applicable Laws, Purchase Specifications, or any other characteristic of the Products, may only be changed with Cangene's prior written consent, except for changes and deviations permitted by the Quality Agreement. Company shall not unreasonably withhold its agreement to any change in the Purchase Specifications requested by Cangene. Company shall not make any substitutions for Products ordered without the prior written approval of Cangene, and in any event, no changes shall be made by Company without first providing Cangene with at least [**] days' prior written notice.

c) Testing: Company shall ensure that quality assurance tests agreed by the parties from time to time are adopted. Company shall ensure that testing methodology and testing reference standards comply with cGMPs. Company shall notify Cangene of any adverse trends that become apparent during the testing of the Product. Company shall provide Cangene with a Certificate of Analysis (COA) and a Certificate of Conformity (COC) for each Product lot provided to Cangene, and any and all other documentation required pursuant to the Quality Agreement. Cangene shall have the right to test or have tested Products with respect to all characteristics deemed relevant by Cangene, including without limitation, any aspect of the Purchase Specifications.

d) Acceptance: In the event that a shipment of Products fails to conform to Purchase Specifications, Cangene, at its option and at the expense and risk of Company, shall notify Company and store them pending instructions from Company as to their disposal, which disposal costs shall be borne by Company. The payment obligation in relation to any such delivery may be suspended pending resolution of any dispute with respect to defective Products. Neither payment nor passage of title or risk of loss to the Product(s) to Cangene shall be deemed to constitute acceptance of the Product(s). Acceptance of any lot of Products shall not relieve Company of its warranty obligations under this Agreement.

e) Disputes/Credits/Replacement:

(i) Cangene, or its third party representative, shall inspect any shipment which evidences outward damage and shall notify the Company as soon as practicable but, in any event, in not more than [**] Business Days from delivery, so that Cangene and Company can assess whether the carrier is liable for such damage. Acceptance of a shipment does not relieve Company of its warranty obligations as set forth herein;

(ii) If Cangene shall have performed the same tests as Company and the results from its tests are not consistent with the test results obtained by Company, Cangene shall notify Company as soon as practicable, and the parties agree to use test results obtained by a mutually acceptable qualified third party as a basis for acceptance or rejection of the lot. The cost of such third party testing shall be borne by Company if the shipment of the Product is found not to conform, or by Cangene if found to conform;

(iii) Company will give Cangene credit for, refund, or replace, at Cangene's sole election, any lot of the Products which does not meet the Purchase Specifications for the Products, except to the extent that the lot of the Products did not meet Purchase Specifications as a result of Cangene's negligent acts or omissions. Such credit or refund shall be limited to the invoice amount for the lot of the Products rejected. Company shall have no further obligation relating to the disposition of such rejected shipment, except as provided in subparagraphs (iv) and (v) below;

(iv) Cangene shall hold any rejected lot of the Product until authorized by Company to return or destroy it, which authorization shall be granted as soon as practicable. Company will be responsible for all costs relating to return or destruction of any rejected lot of the Product found not to conform to Purchase Specifications; and

(v) If Cangene elects to request replacement goods, such Product shall be replaced by making replacement Product available for delivery within [**] weeks of request (except to the extent a delay is caused because Prefillable syringes are not in stock at Company) or within such other timeframe agreed upon by the parties. If such replacement Product is not delivered within such time period, Cangene shall have the right to terminate this Agreement, effective immediately upon notice to Company.

f) Samples: Company shall retain samples of each batch of Products for a period not less than [**] following the expiration date of such batch of Products or as otherwise set forth in the Quality Agreement.

g) Facilities, Equipment and Raw Materials. Company shall be responsible for dedicating appropriate Company facilities, and for obtaining, installing and maintaining in such Company facilities all capital equipment, as needed to manufacture the amounts of Products as ordered by Cangene. Company shall allocate sufficient time, effort, equipment and facilities to the program for manufacturing Products, and shall dedicate and use personnel with sufficient skills and experience as are required to accomplish the manufacturing tasks, so as to manufacture and deliver Products on a timely basis and in accordance with the terms of this Agreement. Company shall conduct its manufacturing efforts under this Agreement in compliance with applicable Laws to the manufacturing activity to be performed by Company under this Agreement and cGMPs. Company shall be responsible for procuring all raw materials needed for manufacturing Products. At Cangene's request, Company shall provide Cangene with specifications, sources and other information regarding such raw materials.

h) **Records:** Upon Cangene's request, Cangene shall have the right to review all Company production and control records in relation to the Product to determine compliance with cGMPs, and all approved written procedures and Purchase Specifications prior to the delivery of the Products. Any unexplained discrepancy shall be promptly and thoroughly investigated by Company. A written record of the investigation shall be made and shall include the conclusions and follow-up. A copy of the investigation and follow-up shall be provided to Cangene.

i) **Regulatory and Environmental Compliance:**

(i) As provided in the Quality Agreement, Company shall promptly report to Cangene any and all information reported to Company relating to any adverse experience, whether expected or unexpected, relating to the use of the Product.

(ii) **Inspections:** If Company is notified that the Products or the manufacturing facility at which the Products are manufactured and identified in Exhibit A will be subject to an inspection in relation to, or that could impact, the Product by any Governmental Authority, Company shall: (i) within [**] Business Days advise Cangene regarding such inspection; (ii) fully cooperate with and allow any such inspection to the extent required by Laws; (iii) promptly provide inspection summaries to Cangene; and (iv) promptly send to Cangene a copy of any inspection report observations issued by a Governmental Authority related to the manufacture, generation, processing, storage, treatment, disposal or other management of the Products, as well as responses to any inspection reports prepared in accordance with this Section. Nothing shall oblige Company to disclose information to Cangene relating to any other customer of Company or such products to which the inspection relates, unless such information relates specifically to the Products or is of a general nature relating to the manufacturing facility at which Company manufactures Products, in which case the information shall promptly be disclosed to Cangene.

(iii) **Notice of Inspections:** If any Governmental Authority shall take any action which shall require a response or action by Company with respect to Products, Purchase Specifications, or the manufacturing facility at which Products are manufactured, or any operating procedure affecting the Products, Company shall immediately notify Cangene of the required response or action and allow Cangene to provide Company with input regarding the response or action.

(iv) **Amendments to cGMPs:** The Parties will promptly notify each other of any material revisions or amendment of or additions to cGMPs and will confer with each other with respect to the best means to comply with such requirements.

(v) **Personnel and Safety:** Company is solely responsible for the safety and health of its employees, consultants and visitors and compliance with all applicable Laws related to health, safety and the environment, including, without limitation, providing its employees, consultants and visitors with all appropriate information and training concerning any potential hazards involved in the manufacture, packaging, storage and supply of the Products and/or materials and taking any precautionary measures to protect its employees from any such hazards. Company shall ensure that all waste generated in the manufacturing or processing of the Products is managed and disposed of in accordance with all applicable Laws related to such activity.

(vi) Audit: Cangene shall have the right during the Term to audit and inspect those portions of Company's manufacturing facility used in the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of the Products. Cangene shall have the right to audit and inspect all inventory of the Products contained at such facility. Except as otherwise set forth in this Agreement, such audits or inspections shall occur not more than [**] per year and shall be scheduled during regular business hours by Cangene at least [**] days in advance; provided, however, that in the event of an Adverse Event or any proposed or actual inspection by a Governmental Authority or other emergency involving the Products or such facility, Cangene shall have the right at any time upon [**] Business Days' oral or written notice to Company to conduct an audit or inspection of such facility, which audit or inspection shall not count against the annual cap of [**]. Purposes for such inspections may include cGMP compliance, system audits, compiling information for reporting obligations, compliance with Purchase Specifications, and/or investigations of complaints and/or compliance with any applicable Laws or the terms of this Agreement or the Quality Agreement. Cangene's audit and inspection rights under this Section shall not extend to any portions of such facility, documents, records or other information: (i) which do not relate to the Products, or (ii) to the extent they relate or pertain only to third parties or their products or materials.

(vii) Other Regulatory Support: Subject to Section 6, Company will provide data relating to any of the Products as needed by Cangene for Cangene's regulatory filings of products containing the Products throughout the world, per the charges set forth in Exhibit A.

(viii) Stability: Additional stability studies and associated costs shall be mutually agreed between the parties.

j) Recalls:

(i) General. For the avoidance of doubt, references to "recall" within this Agreement shall be deemed to include any product withdrawal, recovery, or other field correction. Cangene shall direct and control responses to all recalls of any Coagulation Products containing the Products, and Company shall provide reasonable cooperation to Cangene in connection with any such responses as further set forth in the Quality Agreement. In the event: (i) any Governmental Authority or other national government authority issues a request, directive or order that any Product be recalled; (ii) a court of competent jurisdiction orders a recall of any Product; or (iii) Cangene reasonably determines that any Product should be recalled, the parties shall take all appropriate corrective actions, and shall cooperate in any governmental investigations surrounding the recall.

(ii) Expenses. In the event that any recall results from, or relates to a Product, Company shall be responsible for promptly replacing the quantity of Products that were recalled, at no cost to Cangene, or reimbursing Cangene for the cost of the recalled Products. In addition, Company shall be responsible for the administrative expenses of any recall which shall include, but not be limited to, the expenses of notification and destruction or return of the recalled product, and any costs associated with the distribution of the replacement product, but shall not include lost profits of either Party. Notwithstanding the foregoing, in the event that the recall results from Cangene's breach of this Agreement or Cangene's negligence or willful misconduct, Cangene shall be responsible for all of the expenses of the recall.

(iii) Communications. With respect to any recall, Cangene shall make all statements to the media and the public including, but not limited to, press releases and interviews. Company will not issue any press release or otherwise make any public statement, advertisement or disclosure with respect to this Agreement, any of the Products, or any recall relating to any product manufactured by Cangene containing Products without the prior written consent of Cangene; provided, however, that either party shall be entitled to make a public announcement relating to such events if, in the opinion of the announcing party's legal counsel, such announcement is required to comply with Laws and provided to the extent practicable that the other party has received not less than [**] Business Days notice.

k) Labeling: The specific obligations of the Parties with respect to labeling and related requirements for the Product shall be agreed to by the Parties in the Purchase Specifications as set forth in Exhibit B and in applicable Purchase Orders.

- 5) Supply Guarantee: Company guarantees that it shall use its best efforts to supply the quantity of Products ordered by Cangene and confirmed by Company during the Term of this Agreement. In the event Company is unable to supply the quantity of Products requested by Cangene, Company shall provide immediate written notice to Cangene. In the event this Agreement terminates for any reason other than Cangene's failure to pay undisputed amounts, Cangene shall be entitled to purchase Product from Company, pursuant to the terms and conditions of this Agreement, for a period of [**] months following the date of any notice of termination. For sake of clarity, quantities of Product ordered during such [**] month period following the date of any notice of termination, should be in line with quantities previously ordered by Cangene.

- 6) Rights to the Dossier:

a) Grant of Rights. Subject to the limitation set forth in the following paragraph, Company hereby grants to Cangene, and Cangene hereby accepts, the right to utilize the Dossier and its contents for obtaining and/or maintaining marketing authorizations anywhere in the world for the Coagulation Products. For the purpose of obtaining and/or maintaining regulatory approval of its Coagulation Products (which include the Product), Company will provide Cangene a letter of access to its Dossier for relevant Governmental Authorities.

As a limitation in the use of the Dossier, as of the Effective Date, Cangene accepts and commits not to incorporate the stability data included in the Dossier as of the Effective Date, into any Drug Master File (DMF) for their own products or for any third party products. For clarity, nothing herein shall restrict Cangene from incorporating by reference the stability data included in the Dossier (including without limitation the data in the DMF for the Products) in its regulatory submissions (other than a DMF) for the purposes of obtaining or maintaining regulatory approvals for Cangene's Coagulation products (which includes the Product).

b) Changes to Dossier. Company agrees to promptly inform Cangene in writing on a regular and continual basis of any changes or updates to the Dossier that could potentially impact Cangene's marketing authorizations for the Coagulation Products anywhere in the world.

7) Ownership of the Dossier. Company will at all times remain owner of the Dossier. Cangene shall own all the marketing authorizations for the Coagulation Products obtained by Cangene anywhere in the world.

8) Use of the Dossier. Except as otherwise set forth in this Section 8 or otherwise prohibited hereunder, each party shall have the right to sublicense its rights described in Section 6(a) above to third parties, provided that the names of each sublicensee shall have been disclosed to the other party and that the sublicensing party warrants that each sublicensee will satisfy any obligations applicable to such sublicensee.

9) Representations and Warranties:

a) Conflicts: Each party represents and warrants to the other party that the execution and delivery of this Agreement and the performance of its obligations hereunder (i) do not conflict with or violate any requirement of applicable Laws or regulations, and (ii) do not conflict with, or constitute a default under, any contractual obligation of such party.

b) Authority: Company warrants title to Products sold hereunder to be free and clear of all liens, encumbrances and/or colorable claims at the time of delivery.

c) Quality: Company warrants that all Products shall be free from any latent or patent defects, and shall conform to applicable Purchase Specifications. Company further represents and warrants that all Products shall have been manufactured, stored, prepared for shipment and shipped in accordance with cGMPs, standard operating procedures, Purchase Specifications, and Purchase Orders. For any ancillary services rendered in connection with this Agreement, Company represents and warrants that all such services shall be performed in conformity with the highest standards practiced by companies that perform services of a similar nature, at the time and place the services herein are performed, and that Company shall use its best efforts in the performance of all services.

d) Compliance: Company further warrants that in the performance of this Agreement, Company has complied and will comply with cGMPs and all applicable Laws.

e) Ownership of the Dossier. Company represents and warrants that it owns and has good and marketable title to the Dossier and its contents (including stability data with respect to the Product), and, save that the stability data included in the Dossier can not be assigned to any party for the purposes of incorporating such stability data into any DMF, the ownership of the Dossier is free and clear of any liens or encumbrances of any kind.

f) Ownership of Intellectual Property. Company owns, or has a valid license to use, any and all proprietary processes, methods, or models used by Company to manufacture the Product.

g) No Infringement. Company represents and warrants that, to its knowledge, neither (i) the Dossier, (ii) the design, the manufacture, nor the function of the Products (including packaging), nor (iii) the provision, use, or sale of Products shall in anyway infringe upon or violate any intellectual property rights or other rights of any third party.

h) Regulatory Compliance. Company represents and warrants that any Product which constitutes material which is, will become, or is intended to become a part of the Coagulation Products, shall, at the time of delivery, not be adulterated or misbranded within the meaning of any applicable Law.

i) No Litigation. Each party represents and warrants to the other party that no lawsuit, governmental investigation or legal, administrative or arbitration action or proceeding is pending or, to the knowledge of such party, threatened against such party, or any director, officer or employee of such party in his or her capacity as such, which questions the validity of this Agreement or seeks to prohibit, enjoin or otherwise challenge the consummation of the transactions contemplated hereby.

10) Indemnity:

a) By Company: Except to the extent caused by Cangene's intentional misconduct, gross negligence, or material breach of this Agreement, Company shall indemnify, defend and hold harmless Cangene and its Affiliates and the directors, officers, employees, partners, members, agents and counsel of the foregoing, and the successors and assigns of any of the foregoing (the "**Indemnitees**"), from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' and professional fees and other expenses) (collectively, "**Costs**") arising out of, in connection with or as a result of (i) Company's breach of this Agreement, including without limitation the failure to deliver Product in the quantity, at the times and in the manner specified herein, the supply of Nonconforming Product, or breach of any of Company's representations or warranties or other obligations under this Agreement, including without limitation, in respect of recalls pursuant to Section 4(j), (ii) Company's negligence or willful misconduct or (iii) any claim of infringement relating to the Products (each, a "**Claim**").

b) By Cangene: Except to the extent caused by Company's intentional misconduct, gross negligence, or material breach of this Agreement, Cangene shall indemnify, defend and hold harmless Company and its Affiliates and the directors, officers, employees,

partners, members, agents and counsel of the foregoing, and the successors and assigns of any of the foregoing (the “**Indemnitees**”), from and against any and all Costs arising out of, in connection with or as a result of (i) Cangene’s breach of this Agreement, including any of Cangene’s representations or warranties or other obligations under this Agreement, (ii) Cangene’s negligence or willful misconduct or (iii) any claim of infringement relating to the Coagulation Products (but excluding the Products specifically) (each, also a “**Claim**”).

c) **Procedure:** The Indemnitee seeking to be indemnified shall notify in writing the other party (the “**Indemnitor**”) stating the nature of the Claim. In the event of a Claim instituted by a third party, the Indemnitee shall (i) give the Indemnitor, at the Indemnitor’s option, the full opportunity to control the response thereto and the defense thereof, including any agreement relating to the settlement thereof, provided that the Indemnitor shall not settle any such Claim or action without the prior written consent of the Indemnitee (which consent shall not be unreasonably withheld or delayed) or such settlement include as an unconditional term thereof the giving by the claimant of an unconditional release from all liability in favor of the Indemnitee; and (ii) cooperate with the Indemnitor, at the Indemnitor’s cost and expense, in the defense or settlement thereof. Notwithstanding the foregoing, the indemnification obligations hereunder shall not be relieved hereunder for failure to do the foregoing, or delay with so doing, unless the Indemnitor is materially prejudiced thereby. In addition, the Indemnitee may, at its own expense, participate in its defense of any Claim. An Indemnitee shall use its commercially reasonable efforts to mitigate any Claim.

11) **Damages and Liability:**

a) **Damages:** NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS, SAVINGS OR REVENUES OF ANY KIND OR FOR ANY TYPE OF DIRECT OR INDIRECT DAMAGES RELATED TO THE IMAGE OR REPUTATION OF ANY OF THE PARTIES, EXCEPT TO THE EXTENT THAT SUCH DAMAGES ARE CAUSED BY THE WILLFUL MISCONDUCT BY A PARTY, ITS EMPLOYEES, AGENTS, REPRESENTATIVES, OR SUBCONTRACTORS.

b) **Limitation of Liability:** With no prejudice to the foregoing, in no event shall either party incur monetary liability to the other, annually in the aggregate, for breach or violation of this Agreement, or for any other acts or omissions in connection with the performance under this Agreement in excess of three (3) times the amounts invoiced by Company under this Agreement for Product during the 12 months period preceding the incident, with a maximum limit of six (6) million Euros. As an exception to the foregoing and only in case of third party Claims or Costs resulting or arising from defective or infringing product (Company’s or Cangene’s, as the case may be), such limitation of liability to the other Party, annually in the aggregate, shall amount to six (6) million Euros (and for clarity, shall not be limited to the above mentioned multiple of the amounts invoiced). The parties agree that the monetary remedies to which any Party may be entitled hereunder are in addition to any equitable remedies such Party may have.

c) **Specific Performance:** Company acknowledges and agrees that if Company does not timely perform its obligations hereunder to deliver Product, replace Nonconforming Product or provide all required documentation in accordance with the terms of this Agreement, irreparable damage would occur to Cangene. Accordingly, Company agrees that Cangene shall be entitled to seek injunction or injunctions to prevent Company's breach of this Agreement and to enforce specifically such terms and provisions of this Agreement. Company does not waive any other remedies or defenses it may possess at law or equity with regard to any such action(s).

12) **Insurance:**

a) **General:** Each party, at its own expense, shall obtain insurance with carriers approved by the other party in at least the amounts shown below. All required policies shall be issued by an insurer that is licensed to do business in the state where the project is located. All policies shall be issued by an insurer that has an A.M. Best rating of not less than "A" and Standard & Poor's rating of not less than "AA". Each party shall submit to the other party, prior to commencement of Product deliveries under this Agreement, certificates of insurance evidencing that such insurance was obtained. The parties undertake that [**] days advance notice will be given by registered mail to the other party of cancellation, expiration, reduction, or modification in amounts of coverage. Each party shall maintain insurance in force or other insurance with another carrier in at least the same conditions as set out in this clause by the parties during the Term of this Agreement and for [**] years thereafter. Each party shall be financially responsible for all deductibles or self-insured retentions. It is expressly understood that neither party, in any way, represents that the minimum limits of insurance specified herein are sufficient or adequate to protect interests or liability of the party.

b) **Specific Coverage:**

Commercial General Liability

Company shall maintain Commercial General Liability insurance on an occurrence basis with a minimum € [**] per occurrence limit for bodily injury, property damage, personal and advertising injury, € [**] aggregate limit for products/completed operations and a € [**] general aggregate limit. This Commercial General Liability insurance to include coverage for the hazards of the tort liability of another assumed in a business contract, Independent Contractors

Cangene shall maintain Commercial General Liability Insurance, with policy limits of not less than [**] Dollars (CDN \$[**]) for each occurrence and in the aggregate per annum for bodily injury, property damage, product and completed operations liability.

Worker's Compensation

Each party, its subcontractors, if any, and all employees providing work, labor, or materials under this contract are subject employers under the Workers' Compensation Law of the jurisdiction where the party is located, which requires them to provide workers' compensation coverage that satisfies the law of the jurisdiction for all their subject workers. For Company, this shall include employer's liability insurance with coverage limits not less than € [**].

Excess Liability

Each party shall maintain its own umbrella or excess insurance, which provides excess limit of liability over and above each parties respective Commercial General Liability Insurance referred to above, subject to the following minimum limits:

- For Company, a minimum of € [**] limit per occurrence and € [**] annual aggregate limit;
- For Cangene, a minimum of CDN \$[**] limit per occurrence and \$[**] annual aggregate limit.

The required umbrella/excess insurance is not required to sit above the required Product Liability Insurance each party is required to maintain.

Company's Equipment

Company shall be responsible for any loss, damage or destruction of its own property, equipment, and materials used in conjunction with this work. Company will purchase at Company's sole cost and expense such policy to cover Company's owned property. Company will be responsible for any deductibles or self-insured retentions associated with such policy. If Company self-insures owned property then Company acknowledges full responsibility for all owned property and indemnifies owner against any loss incurred. The Company shall require all subcontractor's to provide evidence of Company's equipment floater covering their own equipment, and materials used in conjunction with this work.

Product Liability

Company shall maintain Product Liability Insurance in a minimum amount of [**] euros (€[**]) per occurrence for bodily injury and property damage and [**] euros (€[**]) in the aggregate which will cover each party's activities under this Agreement.

As stated above, Cangene shall maintain Commercial General Liability Insurance, with policy limits of not less than [**] Dollars (CDN \$[**]) for each occurrence and in the aggregate per annum, including products and completed operations liability.

Pollutants and Hazardous Materials

If Company is to work with pollutants (i.e. chemicals, biohazard, etc.) in connection with its obligations hereunder, Company will carry insurance for liability resulting from bodily injury, property damage or clean-up costs arising out of the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of pollutants.

- 13) Subcontracting: Company shall not enter into a subcontract with respect to the subject matter of this Agreement, without the prior written consent of Cangene. No such written consent shall relieve Company from any of its obligations or liabilities hereunder. Nothing herein shall constitute any contractual relationship between Cangene and any subcontractor of Company or any obligation on the part of Cangene to pay, or be responsible for the payment of, any sums to any such subcontractors. Company shall be responsible for all work performed by, and for acts, omissions, or negligence of its subcontractors and for compliance of its subcontractors with the requirements of this Agreement, and all applicable Laws to the same extent that Company would be responsible if Company were doing such work directly.

14) Confidential Matters:

a) General: During the course of the performance of this Agreement, either party (as “**Discloser**”) may disclose certain information relating to this Agreement to the other party (as “**Receiver**”). Receiver shall keep in strictest confidence all information relating to this Agreement which may be acquired in connection with or as a result of this Agreement which has been designated as proprietary to Discloser or which from the surrounding circumstances ought to be treated as proprietary to Discloser (“**Confidential Information**”). During the Term of this Agreement and for [**] years thereafter, without the prior written consent of Discloser, Receiver shall not publish, communicate, divulge, disclose, or use any Confidential Information, except as otherwise provided herein. Upon termination or expiration of this Agreement, Receiver shall deliver all of Discloser’s Confidential Information and all copies thereof to Discloser, to Discloser, and such shall remain the property of Discloser. Purchase Specifications and changes to the Purchase Specifications, the Dossier, and pricing for the Products shall be treated as Confidential Information by both parties.

b) Exceptions: Nothing in this Section shall be construed to impose an obligation of confidentiality on Receiver in connection with any information to the extent such information:

- (i) is at the time of disclosure already known to Receiver, as clearly established by competent evidence;
- (ii) is at the time of disclosure or subsequently becomes part of the public domain through no fault, act or omission by Receiver;
- (iii) is subsequently disclosed to Receiver by a third party whose receipt and disclosure of such information does not constitute a violation of any confidentiality obligation; or
- (iv) is independently developed by the Receiver without use of the Confidential Information.

c) Survival: The obligations of confidentiality imposed on Receiver herein shall survive any termination or expiration of this Agreement.

d) Governmental Requirements: In the event Receiver is asked or subpoenaed by a court of law or governmental agency to provide Confidential Information received hereunder, Receiver shall promptly inform Discloser and shall cooperate with Discloser to obtain any and all protection that may be afforded such Confidential Information, prior to disclosing it, if such disclosure is ultimately required. Further, notwithstanding the above or any other provision herein, Cangene or its authorized agents may provide Confidential Information and documentation to any regulatory authorities to allow Cangene or its authorized agents to pursue regulatory licensure of its products/processes and to become and/or remain in compliance with regulatory requirements and guidelines.

e) Copies: Receiver shall, upon request by Discloser, return or destroy all Confidential Information received hereunder, except, and only upon written request by Receiver, for (i) one (1) photocopy that may be kept in its legal archives solely for the purpose of monitoring Receiver's obligations hereunder, provided such photocopy is reasonably secured to maintain the confidentiality thereof; and (ii) electronic copies of documents created by a party's automatic archiving procedures that are not readily accessible for destruction.

f) Publicity and Disclosures: Each party shall maintain the confidentiality of this Agreement and all provisions of this Agreement and, without the prior consent of the other party, no party shall make any press release or other public announcement of or otherwise disclose this Agreement or any of its provisions to any third party (a) other than to its directors, officers and employees and attorneys, accountants, investment bankers and other professional advisers whose duties reasonably require to maintain the confidentiality of this Agreement and (b) except for such disclosures as may be required by applicable law or by regulation, in which case the disclosing party shall provide the other party with prompt advance notice of such disclosure so that the other party has the opportunity if it so desires to seek a protective order or other appropriate remedy.

15) Records: During the Term of this Agreement and for [**] years thereafter or such longer period as may be required by the Quality Agreement or applicable Laws, Company shall maintain complete and accurate records relating to the supply of Products by Company and Company's compliance with the terms and conditions of this Agreement, including without limitation the Purchase Specifications. All such records shall be made available for inspection and audit by Cangene or its authorized representatives during the Term of this Agreement and for [**] years thereafter.

16) Force Majeure:

a) General: No liability shall result from delay in performance, or non-performance, caused by events including, without limitation, acts of God, fire, flood, war or acts of terrorism or threatened acts thereof, to the extent such events are beyond the reasonable control of the party affected; provided that the party invoking force majeure promptly furnishes the other party with written notice detailing the nature of the force majeure event, and the anticipated duration of its impact on the ability of the affected party to perform its obligations under this Agreement. In order to receive the protection of liability afforded in this Section, the party affected by the force majeure event shall use its best efforts to minimize the impact of the cause or potential cause of its delayed performance or inability to perform. At Cangene's option, quantities of Product so affected may be eliminated from any obligation under a particular Purchase Order or this Agreement without liability, but this Agreement shall remain otherwise unaffected. In the event the force majeure event from which Company claims relief lasts or is reasonably expected to last longer than [**] days, Cangene may, without liability or penalty, terminate this Agreement or any particular Product order issued hereunder.

b) **Allocation:** If due to force majeure or any other shortage not reasonably foreseeable, the quantity of Products available at Company's (or Company's supplier's) facility ordinarily producing Products and deliverable to the Destination Point for sale hereunder should be insufficient to fulfill Company's Product volume commitments, Company has the right and obligation to allocate its available supply of Products equitably among all term contract customers of Company during the period of such shortage. In order to achieve an equitable allocation result, Company shall consider its customers' supply alternatives. If the allocation is expected to cause greater hardship to Cangene due to its dependence on Company as a majority supplier, then Company's allocation arrangements will reflect Cangene's greater need for Company's Products.

17) **Term and Termination:**

a) **Term:** This Agreement shall commence as of the Effective Date and, unless earlier terminated as provided herein, shall expire on the date that is five (5) years from the Effective Date (the "**Term**"). Thereafter, the Agreement shall automatically renew for five-year terms unless Company provides Cangene with written notice of its intent not to renew the Agreement no later than twenty-four (24) months prior to the expiration of the Term or any renewal term.

b) **By Cangene Without Cause:** Cangene shall have right to terminate this Agreement for any reason, with or without cause upon at least twelve (12) months prior written notice.

c) **By Either Party for Breach:** Either party may terminate this Agreement in the event of breach of a material obligation of the other party if such breach remains uncured thirty (30) days after written notice of such breach is delivered to the breaching party.

d) **Effect of Termination:**

(i) **Credits:** Upon termination of this Agreement, Company shall promptly pay to Cangene any credits due to Cangene and Cangene shall pay to Company all undisputed amounts then due and payable.

(ii) **Purchases:** In the event of termination, Cangene shall only be responsible for the purchase of Product that constitutes a firm order as of the effective date of termination; and Cangene shall not otherwise be responsible for any material ordered by Company in anticipation of forecasts or future orders or for costs or profits on Products not supplied. Upon Cangene's request, Company shall promptly ship (at Cangene's expense) any PFS for which Cangene made pre-payment pursuant to Section 2(e) and that has not been used to fulfill its obligations and complete Purchase Orders under this Agreement.

e) **Survival:** The respective rights and obligations of the Parties hereunder shall survive the termination or expiration of this Agreement to the extent necessary for the intended preservation of such rights and obligations including, but not limited to, insurance, indemnification, confidentiality, regulatory compliance, records retention, audit rights, recall responsibilities, and the right to order Product for a [**] month period pursuant to Section 5.

- 18) **Notice:** Any notice required or permitted under this Agreement shall be given to the receiving party in writing by delivery in hand, facsimile transmission (receipt verified), postage prepaid, United States certified mail, return receipt requested, or recognized national overnight courier service to each respective party's Official Correspondent with a copy to:

Cangene:

Vicki Wolff-Long
Vice-President & GM
Emergent BioSolutions
1111 South Paca
Street Baltimore, MD 21230

with a copy to:

Francis St. Hilaire
V.P., Legal Affairs and Associate General Counsel
Emergent BioSolutions
155 Innovation Drive
Winnipeg, Manitoba,
Canada R3T 5Y3
Facsimile: [**]

Company:

Juan LOPEZ- BELMONTE ENCINA
CEO
Rovi Contract Manufacturing, S.L.
Julian Camarillo, 35
28037 Madrid, SPAIN
Facsimile: [**]

In addition, in the event that correspondence with other personnel of Cangene becomes necessary, copies of such correspondence shall be sent to the Official Correspondent of each party so that the Official Correspondent of each party may keep a complete file.

- 19) **Use of Trade Name and Trademarks:** Each party recognizes that the name of the other party represents a valuable asset of such other party and that substantial recognition and goodwill are associated with such trade name and such party's various trademarks. Each party hereby agrees it shall not use the name, insignia, symbol, logo or other identifying information of the other party hereto orally, writing or in electronic format in any advertising, press release, promotional materials or otherwise without the prior written consent of such other party, except as required by Law or stock exchange listing standards. Nothing in this Agreement constitutes a license entitling a party to use the other party's name, logos or trademarks; provided, however, that Cangene may use Company's name in the packaging and/or labeling of the Products as required by applicable Laws or requested by Company.

20) Miscellaneous:

- a) Assignment: This Agreement may not be assigned by either party to any other party without the prior written consent of the other party hereto; provided, however, that Cangene may assign its rights and obligations hereunder, by written notice to Company, to a successor or transferee (whether by merger, consolidation, purchase, stock purchase, or otherwise) of either all, or substantially all, of the affected assets of Cangene. Any purported assignment in violation of this provision shall be void from the beginning.
- b) Independent Contractor: In all matters relating to this Agreement, the parties shall be acting as independent contractors. Neither party shall have any authority to and shall not assume or create any obligation, express or implied, on behalf of the other party and shall have no authority to and shall not represent itself as an agent, employee, or in any other capacity of such other party.
- c) No Third Party Beneficiaries: No provision of this Agreement shall in any way inure to the benefit of any third person so as to constitute to any such person a third-party beneficiary of this Agreement or otherwise give rise to any cause of action in any person not a party hereto.
- d) Severability: If any one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.
- e) Waiver: Waiver of any provision of this Agreement, in whole or in part, in any one instance shall not constitute a waiver of any other provision in the same instance, nor any waiver of the same provision in another instance, but each provision shall continue in full force and effect with respect to any other then-existing or subsequent breach. All waivers by either party must be contained in a written document signed by the party to be charged and, in the case of Cangene, by an executive officer of Cangene or other person duly authorized by Cangene.
- f) Governing Law: This Agreement shall be governed by the laws of England, without regard to conflicts of laws principles.
- g) Dispute Resolution: All disputes, claims or controversies arising out of or relating to this Agreement or subsequent agreements between the parties will be resolved solely and exclusively by binding arbitration to be conducted under the Rules of Arbitration of the International Chamber of Commerce (ICC). The arbitration will be held in the jurisdiction of the head office of the defending party before a panel of three (3) arbitrators (one of which will be selected by Cangene, the next of which will be selected by Company, and the last of which will be selected by the first two arbitrators) and will be conducted in accordance with the rules and regulations promulgated by the ICC. All expenses and fees of the arbitrator and expenses for hearing facilities and other expenses of the arbitration shall be borne equally by the parties involved in the dispute unless the involved parties agree otherwise or unless the arbitrator in the award assesses

such expenses against one of the parties or allocates such expenses other than equally between/among the involved parties. Each of the parties shall bear its own counsel fees and the expenses of its witnesses except (i) to the extent otherwise provided in this Agreement or by applicable law or (ii) to the extent the arbitrator in its discretion determine for any reason to allocate such fees and expenses between/among the parties in a different manner.

h) Remedies: Unless otherwise set forth herein, the rights and remedies set forth in this Agreement are cumulative with and not exclusive of any other remedy. The exercise by either party of any right or remedy conferred by this Agreement does not preclude the exercise of any other rights or remedies that may now or subsequently exist in law or in equity or by statute or otherwise.

i) Injunctive Relief: The parties recognize and agree that remedies at law for breach by the other party of the provisions of this Agreement regarding confidentiality may be inadequate and each party shall, in addition to any other rights which it may have, be entitled to injunctive relief.

j) Amendments: No modification of this Agreement shall be effective unless made in writing and signed by a duly authorized representative of each party.

k) Entire Agreement: This Agreement, with all exhibits hereto (including without limitation, any Purchase Order) constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings between the parties (whether written or oral) relating to the subject matter hereof; provided, however, that (i) in the event the parties have entered or subsequently enter a separate confidentiality agreement related to the subject matter hereof, the provisions with respect to confidentiality obligations shall be cumulative and (ii) any outstanding purchase orders between the parties shall remain in full force and effect in accordance with their terms. In the event of a conflict between the terms and conditions of this Agreement and any exhibit, (including without limitation, any Purchase Order) the terms of this Agreement shall control.

l) Headings: The headings and subheadings contained herein are inserted for convenience of reference only and shall in no way be construed to be interpretations of text.

m) Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument.

IN WITNESS WHEREOF, the Parties have executed this Agreement as set forth below.

CNJ Holdings Inc. doing business as Emergent BioSolutions

By: /s/ Vicki Wolff-Long
Name: Vicki Wolff-Long
Title: V.P and General Manager

Rovi Contract Manufacturing, S.L.

By: /s/ Juan LOPEZ-BELMONTE ENCINA
Name: Juan LOPEZ-BELMONTE ENCINA
Title: CEO

Pricing Effective as of [DATE]

Products:

- 10ml [**] Prefillable syringe [**] with [**] stopper filled with [**]ml WFI [**]. Primary packaging (Syringes) is included in the price below.
- Syringes unlabeled lay down in [**] tubs

<u>NUMBER OF BATCH /YEAR</u>	<u>BATCH SIZE</u>	<u>PRICE per UNIT in € (syringe included)*</u>
[**] batches for initial period	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**] or more	[**]	[**]

Packaging Services. Price/syringe on top of above prices:

<u>ITEM</u>	<u>PRICE per UNIT IN €*</u>
Labelling of syringes**	[**]
Labelling of syringes and Blistering with PR aside**	[**]

** Packaging and labelling Material not included (not already defined by Cangene)

Other Services: Material ordered by Company prior to production and pre-paid by Cangene

<u>ITEM</u>	<u>PRICE per UNIT IN €*</u>
Empty Pre-Fillable Syringes (PFS) – 10ml [**]	[**]
Prefillable syringe [**] with [**] stopper	Euros

* All prices are without taxes

Packaging specs
Product specs

- **Packaging Specifications:** Not currently available. Will be defined in a later stage.
- **Product Specifications:** See next page.

<p>Preparado por: Dpto. de Documentación</p> <p><i>[Signature]</i> 20.06.12 (Firma y fecha)</p>	<p>FOTOCOPIA 25 ABR. 2014 AUTORIZADA</p>	<p>CONFORME Director de Calidad</p> <p><i>[Signature]</i> 20.06.12 (Firma y fecha)</p>
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See next pages.



QUALITY AGREEMENT

Supplier Quality Agreement Between

Cangene bioPharma, Inc.
(doing business as Emergent BioSolutions)
1111 South Paca Street
Baltimore, MD 21230 USA

And

Rovi Contract Manufacturing S.L.
Julian Camarillo, 35
28037 Madrid Spain

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

1. Introduction/ Purpose

1.1 Scope

This Quality Agreement (the “Agreement”) defines the expectations and responsibilities of both parties for quality activities outlined in this Agreement, related to the supply of materials “Product(s)” purchased from Rovi Contract Manufacturing, S.L. (Rovi) by Cangene bioPharma doing business as Emergent BioSolutions (Emergent) and referred to in Exhibit B.

This Agreement shall begin on the date of the final signature of the parties and shall remain in full force and effect as long as Emergent is purchasing Products from Rovi or if later, until the later of: (a) the termination of any sales agreement between the parties; or (b) the last expiry date of any Products purchased by Emergent. Any termination or expiration of this Agreement shall not affect the rights and obligations of either party that by their nature should survive the expiration or termination of this Agreement, including but not limited to those relating to complaints, documentation and those required to continue under applicable CGMPs. This Agreement supersedes and replaces any other prior Quality Agreement between Emergent and Rovi or the Product(s).

These Terms and Conditions will be reviewed and updated as required. Revision history will be outlined in Exhibit E. Unless otherwise defined herein, capitalized terms used herein shall have the meaning defined in Exhibit D Glossary of Terms.

In the event of a quality conflict between the Supply Agreement and these Terms and Conditions, the Supply Agreement shall prevail, unless these Terms and Conditions expressly contemplates the conflict and refers to Supply Agreement, in which case the provisions of these Terms and Conditions shall prevail.

This Supplier Quality Agreement applies to all material identified in Exhibit B.

1.2 Parties to the Agreement

<u>Between</u>	<u>And</u>
Cangene bioPharma (doing business as Emergent BioSolutions) 1111 South Paca Street Baltimore, MD 21230 USA	Rovi Contract Manufacturing, S.L. CL Julian Camarillo, 35 28037 – Madrid Spain

(Referred to as “Emergent”)

(Referred to as “Rovi”)

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

The parties hereto have each caused this Agreement to be executed by their duly-authorized representatives on the date and year hereinafter set forth.

Emergent Approval		Rovi Approval	
Signature:	<u>/s/ Minerva Devera</u>	Signature:	<u>/s/ Ana Sanchez Otero</u>
Name (print):	Minerva Devera, DBA, QSM	Name (print):	Ana Sanchez Otero
Title (print):	Director, Quality Assurance, Regulatory Affairs, and Validation	Title (print):	Quality Director
Date:	May 23, 2014	Date:	June 29, 2014

Neither party shall have the right to assign any or all of its rights or obligations under this agreement without the other party's prior written consent, which shall not unreasonably be withheld.

2. Responsibilities for Quality Activities

This Agreement will outline the responsibilities of Rovi and Emergent with regard to the quality activities described in the quality criteria listed below and in Exhibit C.

3. Definition of the Quality Criteria

Rovi shall conduct all activities concerning the Product(s) in accordance with the quality criteria defined in the current versions of:

- 21CFR11, 210, 211EU Volume 4
- USP and EP Pharmacopeia
- ISO 9001 *Quality Management Systems*

Emergent shall audit Rovi activities concerning the Product(s) to ensure they meet Emergent's requirements for incoming material suppliers in accordance with:

- 21CFR11, 210, 211
- EU Volume 4
- USP and EP Pharmacopeia
- ISO 9001 *Quality Management Systems*

4. Supply Chain: Manufacturing to Distribution Channels—Site(s) Involved

The terms and conditions of this agreement shall apply to all of Rovi's facilities involved in manufacturing, storing, handling, distributing, packaging/re-packaging, labeling/re-labeling, inspection/re-inspection, testing and release activities of the Product(s) provided to Emergent. This includes primary use and alternate use sites.

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

If Rovi uses third parties to perform these activities such use is noted in Exhibit B.

Changes in the use of third parties or change in the sites involved in the supply chain (i.e affiliate sites) as set forth in this Agreement shall not be made without prior written notification to Emergent. Rovi shall, however, retain all obligations under this Agreement whether or not a third party manufactures, stores, handles, distributes, packages/re-packages, labels/re-labels, inspects/re-inspects, tests, or releases Product(s).

5. **Quality Management System**

Rovi shall have an effective, structured quality system in place that implements the following quality activities:

- Compliance
- Processing, Packaging and Labeling
- Documentation and Records
- Storage and Distribution
- Change Control
- Non-Conformance
- Out of Specification
- Deviations
- Complaints
- Recalls
- Auditing
- Training
- Lot Disposition
- Stability Program
- Raw Materials
- Validation and Maintenance
- Inventory Control
- Facility and Equipment Controls

Refer to the Quality Agreement Responsibility Table in Exhibit C for outlined responsibilities in each of the above systems.

6. Issue Resolution

In the event that a quality dispute arises between Rovi and Emergent concerning any Product(s) or services provided, the resolution shall proceed in the following stages:

Stage 1—Emergent's and Rovi's Quality Assurance shall communicate directly to determine the facts of the matter and to produce an investigation report. This report shall contain complete details of the problem together with any discussion and conclusions. This stage may involve engaging in third party testing.

Stage 2—The senior quality personnel from both parties shall discuss the issue and resolution.

Stage 3—If a third party is used to perform confirmatory testing or an evaluation, both parties shall be advised of the reported results.

7. List of Exhibits

Exhibit A—Quality Contacts

Exhibit B—Product/Material and Site List

Exhibit C—Quality Agreement Responsibility Table

Exhibit D—Glossary of Terms

Exhibit E—Revision History

8. References

- 21CFR11, 210, 211,
- EU Volume 4
- USP and EP Pharmacopeia, most current version
- ISO 9001 Quality Management Systems, most current version

Exhibit A: Quality Contacts

The following are the Contact Persons from each party that will be responsible for communications related to this agreement:

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

Rovi Representatives

	Primary Contact	Alternate Contact
Name:	Ana Sanchez Otero	[**]
Title:	Quality Director	Qualified Person
Company:	Rovi contract Manufacturing, S.L.	
Address:	Julian Camarillo 35	
Phone:	[**]	[**]
Fax:	NA	NA
E-mail:	[**]	[**]

Emergent Representatives

	Primary Contact	Alternate Contact
Name:	Minerva Devera, DBA, QSM	[**]
Title:	Director, Quality Assurance, Regulatory Affairs, and Validation	Manager, Technical Quality Systems and Regulatory Affairs
Company:	Cangene bioPharma, Inc. doing business as Emergent BioSolutions	
Address:	1111 South Paca Street 'Baltimore, MD 21230 USA	
Phone:	[**]	[**]
Fax:	[**]	[**]
E-mail:	[**]	[**]

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

Exhibit B: Product/Material and Site List

The following is the complete list of Product(s) and all facilities used by Rovi for manufacturing, storing, handling, distributing, packaging/re-packaging, labeling/re-labeling, inspection/re-inspection, testing and release activities as well as any third party sites that perform any of these activities.

This list is current as of March 1, 2014 and will be updated as necessary to reflect the business agreement between Emergent and Rovi.

<u>Name</u>	<u>Address</u>	<u>City State / Province</u>	<u>Postal/Zip Code. Country</u>	<u>Supply Chain Function</u>
Rovi part number S1250 Injectable Water 5mL EST ROCM				
Rovi Contract Manufacturing S.L.	Julian Camarillo, 35	Madrid, Spain	28037	Manufacturing/Processing, Testing, and Release of Water for Injection
Subcontracted Services				
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]

Note: This exhibit may be updated as required and any change in the supply chain and distribution channel requires prior notification and approval of the Quality Agreement signatories.

Signature (for Cangene bioPharma doing business as Emergent BioSolutions)	Date
/s/ Ana Sanchez Otero	June 29, 2014
Signature (for Rovi Contract Manufacturing S.L.)	Date

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

Exhibit C: Quality Agreement Responsibility Table

<u>RESPONSIBILITIES</u>	<u>Rovi</u>	<u>Emergent</u>	<u>Not Applicable</u>
Compliance			
Conform to the quality criteria defined in Section 3 of this Agreement.	X		
Define specifications for the Product(s) which are the subject of this agreement, in addition to specifications related to the actual Product(s), Emergent's specifications may include packaging materials, pallets, storage conditions, etc.	X		
Changes to the agreed upon specifications will be communicated in writing prior to implementation, except for required compendial changes which can be implemented without prior notification. Compendial changes must be implemented by the compendial implementation date.	X	X	
Ensure that the specifications for compendial Product(s) are in compliance with the current compendia.	X	X	
Rovi Drug Master File [DMF] #25234 shall be made available through the issuance of a DMF Letter of Authorization [LOA] to Emergent. The LOA shall be reissued to Emergent each time updates or changes are made to the Rovi DMF.	X		
Manufacture and Supply Product(s) that conform to the defined specifications.	X		
Upon request, disclose to Emergent recent regulatory agency inspections and findings pertaining to the Product(s).	X		
Notify promptly if, in the course of a regulatory inspection, negative findings are made related to the quality of the Product(s) supplied.	X	X	

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

RESPONSIBILITIES

Shall have a process in place for qualification of third parties used for manufacturing, storing, handling, distributing, packaging/re-packaging, labeling/re-labeling, inspection/re-inspection, testing and release or processing the Product(s) in any manner, which could be reviewed during an audit.

<u>Rovi</u>	<u>Emergent</u>	<u>Not Applicable</u>
X		

Rovi shall employ qualified staff as is necessary for the performance of its obligations under this Agreement.

X		
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Rovi will follow written and approved procedures for their activities.

X		
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Emergent may request to be on site during the processing of its Product(s). Arrangements for this shall be made in advance and shall be mutually acceptable for both parties. This person shall adhere to Rovi standard operating procedures and policies.

X		
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Regulatory and Environmental Compliance

Rovi shall promptly report to Emergent any and all information that is reported to them relating to any adverse experience relating to the use of Product.

X		
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If Rovi is notified that the Product or Product manufacturing facility will be subject to an inspection by any Governmental Authority, Rovi will notify Emergent within [**] business days after receipt of such notice.

X		
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Rovi will promptly send to Emergent a copy of any inspection report observations [redacted], issued by a Governmental Authority, that relate to the manufacture, generation, processing, testing, storage, treatment, or other management of the Product, as well as those observations that are of a general nature relating to the Product manufacturing facility.

X		
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Emergent shall have the opportunity to review and contribute to any response that Rovi prepares, that is directly related to Product, prior to the response being submitted.

X	X	
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A copy of Rovi responses [redacted] to any inspection observations, relating to Product, shall be promptly sent to Emergent once approved.

X		
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RESPONSIBILITIES	<u>Rovi</u>	<u>Emergent</u>	<u>Not Applicable</u>
A copy of the Governmental Authority's acceptance of Rovi responses shall be forwarded to Emergent upon receipt of same.	X		
Establish and maintain an effective Pest Control Plan	X		
Refrain to manufacture, process or store any Critical Compounds in the same building where Products are Manufactured or stored	X		
Processing, Packaging and Labeling			
MANUFACTURER shall Manufacture the Product(s) in full compliance with the requirements of the DMF, including without limitation the Manufacturing processes and testing monographs (including the Specifications and testing methods	X		
MANUFACTURER shall submit the master batch record to Emergent for review and approval prior to Manufacture of the first batch of Product(s).	X	X	
Document that manufacturing and packaging process are fit for purpose.			
Demonstrate the commissioning of critical systems and equipment used in the manufacture and control of the Product(s).			
Demonstrate that cleaning procedures are appropriate and their effectiveness has been demonstrated.			
Rovi shall retain samples of the Product(s) for a period of [**] years from the date of Manufacture.	X		
Adequate retained sample program shall be established. Finished Product(s) samples will be retained for each batch/ lot of Product(s) manufactured.	X		
Rovi shall provide prior notification to Emergent of any lot(s)/ batch(es) that have been reworked in a manner that is not consistent with Rovi's validated manufacturing process that are designated for shipment to Emergent.	X		
Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY			

RESPONSIBILITIES

Emergent reserves the right to accept or refuse Product(s) that have not been produced in conformance with Rovi's validated manufacturing process prior to delivery.

<u>Rovi</u>	<u>Emergent</u>	<u>Not Applicable</u>
	X	

Rovi shall provide lot traceability information to Emergent upon request. This information is available for onsite review.

X

Rovi shall have adequate procedures in place to avoid mix-up of Product(s).

X

Rejected Product shall be disposed of in controlled manner to prevent re-use.

X

Rovi shall maintain traceability of a Product(s) during manufacturing operations.

X

Lot number of the Product(s) shall reflect one continuous production run.

X

Rovi shall have validated maximum hold times for critical control points indentified throughout the processing flow.

X

Rovi shall use adequate inspection of the Product(s).

X

Rovi shall implement adequate sampling plans, to control in-process materials.

X

Documentation and Records

Rovi shall follow Good Documentation Practices.

X

Certificate of Analysis shall be supplied with each batch.

X

Certificate of Analysis shall be prepared with the Approval of Quality Unit Designate and shall contain:

X

- Material code/part number and name
- Lot number
- Actual numerical specification or specification range, where applicable
- Reference to internal product specification or specification file number and/or name
- Specification revision number and/or date
- Statement of Compliance to USP and EP requirements Site address of manufacture
- Date of manufacture

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

RESPONSIBILITIES

Where applicable, electronic signatures used on the Certificates of Analysis must conform to the requirements of 21CFR11.

<u>Rovi</u>	<u>Emergent</u>	<u>Not Applicable</u>
X		

Records required by the agreed upon quality system shall be maintained for a period of [**] years from date of manufacture of the Product(s).

X		
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Storage and Distribution

Maintain and supply upon request validation and/or stability documentation that supports the actual recommended storage and transportation conditions plus recommended retest interval and/or expiration date.

X		
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Ensure that Product(s) are stored and shipped in accordance with required and documented conditions and Emergent's requirements.

X	X	
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Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

RESPONSIBILITIES

Rovi Emergent Not Applicable

Change Control

Changes, impacting DMF registered information, will be initiated and evaluated by Rovi and communicated to Emergent based upon agreed criteria and a timeline of not less than [**] day prior to proposed implementation. This Agreement does not specifically permit any Product or Process changes or deviations without Emergent’s documented consent. A copy of the Rovi Change Control and Client Change Notification SOPs shall be appended to this agreement. X

Some Examples of Notifiable Change include, but are not limited to:

- Site of Manufacture
- Scale of Manufacture
- Equipment
- EU Regulatory requirements applicable to any aspect of Product fulfillment
- Process
- Internal Specifications impacting Product or starting materials.
- Chemical Properties
- Physical Properties
- Functionality
- Bioburden
- Packaging and Labeling (including changes to primary packaging)
- Product specifications including starting materials
- Composition of any starting material [material of construction]
- Source of any starting material
- *Force majeure* impacting ability to manufacture

Any Notification of Change, at minimum, must be e-mailed to: X

[**]

Emergent is responsible for initiating any changes in conjunction with any applicable US Laws and will work closely with Rovi, as necessary, to ensure timely compliance prior to the effective date. X

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

RESPONSIBILITIES

Changes to the Purchasing Specification are the responsibility of Emergent.

<u>Rovi</u>	<u>Emergent</u>	<u>Not Applicable</u>
	X	

Non-Conformance

All non-conformances shall be investigated. Where applicable, this includes the identification of the root cause, a risk analysis (including the risk to other lots and the impact to other test results) of the actions taken for correction of the problem, prevention of future occurrence and the formal conclusion by Rovi's Quality Assurance. If an investigation reveals that there is an impact to Product(s) received by Emergent, Rovi shall inform Emergent promptly so as to provide as much advance notice as possible.

X

Out-of-Specification (OOS)

Out-of-Specification (OOS) tests results shall be investigated and documented according to a documented procedure.

X

Deviations and CAPA

If significant deviations from an established process are recorded, there must be evidence of suitable investigations and a review of the quality of the Product(s).

X

Inform Emergent of any critical deviation during the manufacturing of a particular batch of Product(s).

X

Define effective corrective and preventive actions to ensure root cause are fully solved.

X

Complaints

Rovi shall have a written procedure to investigate and document quality related complaints. A root cause analysis, actions taken for correction of problem, prevention of future occurrence and the formal conclusion will be provided to Emergent within [**] working calendar days from a receipt of notification about nonconforming Product(s) from Emergent.

X

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

RESPONSIBILITIES

Complaints made by Emergent shall at least indicate Rovi's batch number of the Product(s) and complaint subject. The complaint shall be communicated to Rovi within [**] calendar days of detection. Samples will be provided where appropriate and available.

<u>Rovi</u>	<u>Emergent</u>	<u>Not Applicable</u>
	X	

The parties shall cooperate in the exchange of information required to effectively conduct an investigation.

X	X	
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Recalls

In the case of a recall of the Product, Emergent and Rovi CM shall inform each other promptly so as to provide as much advance notice as possible.

X	X	
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Have a written recall procedure.

X	X	
---	---	--

The parties shall cooperate in the exchange of information required to effectively conduct a recall or recall investigation.

X	X	
---	---	--

Auditing

Emergent has the right to audit Rovi's facilities, systems and documentation, as they relate to the manufacturing, storing, distributing, packaging, labeling, testing, releasing and handling of Product(s), at mutually agreed upon times, not more than one compliance audit every [**] years. An audit deemed "For cause" by -Emergent, will be allowed at any time as mutually agreed upon and will not count against the biennial audit. All "For Cause" audits must be linked to the triggering event. The scope of the "For Cause" audit shall be focused on the events associated with the Deviation or Complaint.

	X	
--	---	--

Allow Emergent to audit facilities, systems and documentation, as they relate to the manufacture of Product(s), at mutually agreed upon times.

X		
---	--	--

If required, a confidentiality agreement will be executed within a reasonable period of time prior to the audit or other exchange of information.

X	X	
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Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

RESPONSIBILITIES

	<u>Rovi</u>	<u>Emergent</u>	<u>Not Applicable</u>
Emergent shall issue a confidential written audit report to Rovi, which will include audit observations, within [**] calendar days from the audit date.		X	
Rovi shall issue responses within [**] calendar days to all observations in writing to Emergent Quality Assurance designee. Where Rovi commits to a corrective action, a description and timeframe for completion will be included in the written response.	X		
Where applicable, agree upon requirements for auditing third parties used in association with Product(s) production, processing, warehousing, or testing.	X	X	

Training

Rovi shall have a written training program to ensure that each person engaged in the manufacture, processing, storing, packaging, labeling, distributing, testing, releasing or holding of a product used for injection shall have education, training and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice as they relate to the employee's functions. Training shall be conducted by qualified individuals on a regular basis and with sufficient frequency to assure that employees remain familiar with internal processes and CGMP requirements.	X		
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Lot Disposition

Prior to release of any batch of product/material, Rovi shall ensure all required testing is complete and results are within specifications and that any associated non-conformances have been closed.	X		
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Stability Program

Rovi shall perform On-going stability testing to establish to comply with GMP ([**] per year and additional if any critical manufacturing problem arise)	X		
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Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

RESPONSIBILITIES	Rovi	Emergent	Not Applicable
Raw Materials and Packaging Materials			
Prepare specifications	X		
Approve specifications	X		
Vendor selection, qualification, and approval	X		
Provide prior notification to Emergent of changes to source material vendors	X		
Procurement of starting materials from qualified and approved vendors.	X		
Subcontracting			
MANUFACTURER agrees not to subcontract or delegate any portions of its obligations under this Quality Agreement or the Manufacturing and Supply Agreement, except to an Approved Subcontractor as listed in Exhibit B	X		
Validation, Calibration and Maintenance			
Facilities	X		
Calibration	X		
Equipment	X		
Analytical Method Validation	X		
Cleaning	X		
Process	X		
Computer	X		
Rovi shall maintain records of routine and non-routine maintenance including calibration.	X		
Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY			

RESPONSIBILITIES

**Rovi Emergent Not
Applicable**

Inventory Control

Rovi shall have an inventory control system in place (electronic or physical) that can effectively manage material movement from quarantine to release or rejected status to ensure that materials are handled appropriately.

X

Facility and Equipment Controls

Rovi shall ensure Product(s) are manufactured and handled in an environment that is suitable for the level of cleanliness required for manufacturing and handling the Product.

X

Shall ensure that adequate facility security controls are in place that only authorized personnel have access to Rovi facilities.

X

APR

Provide at Emergent cost an annual Product Quality Review (PQR)/Annual Product Review (APR) for Product(s) that 1 summarizes the regulatory filings, manufacturing history, information on quality, deviations, complaints, change control, stability, validation, trending, process capability, conclusions and other items related to the manufacture of Product(s).

X

Rovi Contract Manufacturing S.L. – SUPPLIER QUALITY AGREEMENT CONFIDENTIAL & PROPRIETARY

Exhibit D: Glossary of Terms

Note: Not all glossary terms may be used in a specific Quality Agreement depending on the material or service provided.

Audit – A systematic and independent examination of manufacturing related activities and documents to determine whether these activities comply with all internal policies and procedures as well as with all applicable governmental requirements.

Audit Report – Written documentation of audit findings and observations. Additionally, the audit report may summarize the recommendations and any corrective or preventative follow-up activities.

Bioburden – The nature and quantity of microorganisms present in the product.

Certificate of Analysis – A document listing the test methods, specification and results of testing a representative sample from the batch to be delivered

Change Control Procedure – A written procedure that describes the action to be taken if a change is proposed to facilities, materials, equipment, and/or processes used in the fabrication, packaging and testing of drugs or that may affect the operation of the quality or support system.

Chemical Property – A quality parameter that is measured by chemical or physiochemical test methods.

Complaints – Any written, electronic, or oral communication that alleges deficiencies related to the identity, durability, quality, safety or effectiveness of the material/product.

Corrective Action – A change implemented to address a weakness identified in a management system.

Critical – A process step, process condition, test requirement or other relevant parameter or item that must be controlled within predetermined criteria to ensure that the product meets its specification.

Customer – The organization receiving the product(s) once it has left the control of the Product(s) manufacturer; including brokers, agents and users.

Date of Manufacture – A date indicating the completion of the final manufacturing process (as defined by the manufacturer for the particular product and process).

Date of Retest – The date when retesting is performed by a supplier to extend the length of the time the material may be used.

Deviation – Departure from an approved instruction or established standard.

Distributor – All parties in the distribution/supply chain starting from the point at which a product is transferred outside the control of the original manufacturer's material management system including parties involved in trade and distribution, (re)processors, (re)packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer.

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Electronic Signature – Means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature. (CFR Part 11)

Excipient – Any substance other than the active pharmaceutical ingredient or drug product which has been appropriately evaluated for safety and is included in a drug delivery system to either aid the processing of the drug delivery system during manufacture, protect, support or enhance stability, bioavailability, or patient acceptability, assist in product identification, or enhance any other attribute of the overall safety and effectiveness of the drug delivery system during storage or use.

Functionality – The set of performance criteria the product is intended to meet.

GDP–Good Distribution Practice—GDP deals with the distribution of Product(s), including requirements for purchase, receiving, storage and export. GDP regulates the movement of Product(s) from the premises of the manufacturer to the end user, or to an intermediate point by means of various transport methods.

GMP–Good Manufacturing Practice—Requirements for the quality system under which certain Product(s) and their ingredients are manufactured. To ensure that Product(s) are consistently produced and controlled to the quality standards appropriate to their use. Current Good Manufacturing Practice (CGMP) is the applicable term in the United States. For the purposes of this agreement, the terms GMP and CGMP are equivalent,

Impurity – Any component of a product that is not the intended entity but is present as a consequence of either the starting materials used or the manufacturing process.

IPEC – International Pharmaceutical Excipients Council

ISO – International Organization for Standardization.

Manufacturer – A party who performs the final processing step.

Manufacturing Process – All operations of receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release and storage of Product(s) and related controls.

Non conforming Material – Material that does not meet the manufacturer’s specifications or has not been manufactured according to applicable GMP’s.

Physical Property – A quality parameter that can be measured solely with mechanical equipment.

Procedure – Written, authorized instruction for performing specified operations.

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Quality Agreements – Legally binding agreements that are mutually negotiated between users and suppliers. They are intended to be an agreement between quality departments. A quality agreement is intended to be a formalized, joint agreement on quality responsibilities and activities defining both the users and suppliers respective obligations as they relate to quality. They are intended to address quality commitments between the parties and are based on the quality procedures in place.

Quality Assurance – The sum total of the organized arrangements made with the object of ensuring all Product(s) are of the quality required for their intended use and that quality systems are maintained.

Quality Representative – Authorized individual(s) identified by the company as the official(s) directly responsible for quality assurance and compliance through which the release of each product/material is performed. Individuals must have the appropriate qualifications, education, training and experience to perform their duties.

Recalls – A process for withdrawing or removing a product from the distribution chain because of defects in the materials or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.

Record – Document stating results achieved and/or providing evidence of activities performed. The medium may be paper, magnetic, electronic or optical, photography etc. or a combination thereof.

Relabelling – The process of putting a new label on the material.

Repackaging – The action of changing the packaging of the material.

Re-packaging – Transfer of an excipient from one container to another.

Reprocessing – Introducing an intermediate or API, including one that does not conform to standards or specifications, back into the process and repeating a crystallization step or other appropriate chemical or physical manipulation steps (e.g., distillation, filtration, chromatography, milling) that are part of the established manufacturing process. Continuation of a process step after an in-process control test has shown that the step is incomplete is considered to be part of the normal process, and not reprocessing.

Retained Sample – Representative sample of a batch/delivery that is sufficient quantity to perform at least 2 full quality control analyses and will be kept for a defined period of time.

Reworking – Subjecting an intermediate or API that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain acceptable quality intermediate or API (e.g., recrystallizing with a different solvent).

Scale – An increase or decrease in the batch size in batch processing or the throughput capability for continuous processing whether or not different equipment is used.

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Site – A location where the product is manufactured. This may be within the facility but in a different operational area or at a remote facility including a contract manufacturer.

Significant Change – A change that alters a Product(s) physical or chemical property outside the limits of normal variability or that is likely to alter the product performance in the dosage form.

Specification – The quality parameters to which the product, component or intermediate must conform and that serve as a basis for quality evaluation.

Standard Operating Procedure (SOP) – A written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g., equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product specific master and batch production documents.

Storage and Transportation Conditions – Pre-determined specification ranges for maintaining product/material quality.

Supply Chain – For the purpose of this agreement, supply chain includes all aspects of the product, from the acquisition of starting materials to use of the finished product by the end user.

Supplier – Person or company providing pharmaceutical starting materials on request. Suppliers may be distributors, manufacturers, traders, etc. A manufacturer or distributor who directly provides the product to the user.

User – A party who utilizes a product in the manufacture of a drug product or another excipient.

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Exhibit E: Revision History

<u>Revision No.</u>	<u>Date Approved by Emergent</u>	<u>Reason for Change</u>
Original		

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10 INFORME DE NO-CONFORMIDAD / DESVIACIÓN

Número de No
Conformidad/Desviación:
N° Test / Fase (AIQ-AOQ):

Descripción de la No Conformidad / Desviación:

Análisis y Acción correctora:

Realizado por: _____
Firma _____ Fecha _____

Aprobado por: _____
Firma _____ Fecha _____

Conclusión y Cierre:

Realizado por: _____
Firma _____ Fecha _____

Aprobado por: _____
Firma _____ Fecha _____

Realizado por: _____ Fecha: _____

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT (the “**Agreement**”) is made as of May 27, 2015 (the “**Effective Date**”) between **PATHEON UK LIMITED**, a corporation existing under the laws of England (“**Patheon**”)

and

CNJ HOLDINGS INC., doing business as Emergent BioSolutions, a corporation existing under the laws of Manitoba, Canada (“**Client**”).

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

Capitalized terms used in this Agreement shall have the meanings ascribed to them in **Schedule A (Definitions)** or as set out below.

1. Services:

- (a) Services. Patheon agrees to perform, at the Manufacturing Site, the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, as set forth in this Agreement, required to manufacture Product using the Active Materials and Components as better described in Patheon’s Proposal Ref. N^o. C-FEP-83755-R0, attached hereto as **Schedule B (“Services”)**, in the Quality Agreement (attached hereto as **Schedule E**) and in the following terms and conditions of this Agreement.

Patheon will perform Services for the Territory for the fees specified in **Schedule C** to manufacture Product for Client and in such quantities as required by Client from time to time in accordance with **Schedule D** of this Agreement.

- (b) Product Rejection for Finished Product Specification Failure. Internal process specifications will be defined and agreed upon. If Patheon manufactures Product in accordance with the agreed upon internal process specifications, the Specifications, the batch production record, cGMP, the Quality Agreement, and Patheon’s standard operating procedures for manufacturing, and a batch or portion of batch of Product does not meet a finished product Specifications, Client will, (provided such non-conformance is not caused by Patheon’s breach of this Agreement), pay Patheon the applicable price per unit for the non-conforming Product.

2. **Payments**

Invoices will be sent by fax or email to the fax number or email address given by Client to Patheon in writing. Invoices will be sent when the Product is manufactured and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 1(d) of Schedule D hereto. Each invoice will, to the extent applicable, identify Client's purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within [**] days of the date thereof. If any portion of an invoice is disputed, the Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Interest on undisputed past due accounts will accrue at [**]% per month which is equal to an annual rate of [**]%.

3. **Supply of API and Components/Equipment:**

- (a) **Active Materials and Client-Supplied Components.** Client will deliver, at least [**] days before the scheduled production date (or such shorter period as may be agreed upon by the parties in writing), the Active Materials (and Client-Supplied Components, if any) to the Manufacturing Site DDP (Incoterms 2010), at no cost or risk to Patheon, with VAT paid by Client, if any, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the agreed delivery date (the "**Delivery Date**"). If the Active Materials and/or Client-Supplied Components, if any, are not received at least [**] days before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. If Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as agreed to by the parties, and provided that Patheon will use its good faith efforts to schedule the Services as soon as reasonably practical taking into account Client's requested delivery date. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications.
- (b) **Damage/Discrepancies.** Within [**] Business Days following Patheon's receipt of the Active Materials and Client-Supplied Components, Patheon shall inform Client of any damage to the materials received that is visually obvious (e.g., damaged or punctured containers, integrity of pallets and cartons). Patheon will perform analytical testing on the Active Materials (and Client-Supplied Components, if any) in accordance with the Specifications and the Quality Agreement, and will inform Client within [**] Business Days from discovery thereof of (i) any failure of Active Materials and Client-Supplied Components to

conform to the Specifications, which is detectable by Patheon by performing the analytical testing according to the Quality Agreement; or (ii) any discrepancy in identity or quantity actually received versus the packing list and/or the delivery note. In the event such deficiency/discrepancy in the Active Materials and Client-Supplied Components causes Patheon to fail to meet its obligations under this Agreement, Patheon shall be excused from performance to the extent Patheon did not cause such deficiency and such deficiency adversely affects Patheon's performance under this Agreement.

- (c) Patheon and the Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. Client's obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client's designated broker will be the "Importer of Record" for Active Materials imported to the Manufacturing Site. Title to the Active Materials will at all times remain the property of Client. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement, the Specifications provided by Client, the Quality Agreement, and with Applicable Laws, including without limitation cGMPs. Patheon shall be responsible and liable for the proper care, handling, and storage of Active Materials in accordance with Specifications provided by Client, the Quality Agreement, and with Applicable Laws, including without limitation cGMPs, such responsibility to commence upon receipt at the Manufacturing Site and end upon delivery of Product by Patheon as specified in this Agreement. Without limiting the generality of the foregoing, Patheon will handle and store all Active Materials in a manner so as not to intermingle Active Materials with any other substances or risk contamination. If any Active Material is lost, damaged or contaminated following delivery to the Manufacturing Site, including due to Patheon's failure to perform the Services in accordance with this Agreement, Patheon shall, subject to the limitations on liability set forth in Section 6.C.(d) below, reimburse Client within [**] days after the applicable calendar quarter for the replacement cost of such materials, or at Client's option, shall credit Client such replacement cost against future invoices for the Product owing hereunder. Any Active Materials received by Patheon will only be used by Patheon to perform the Services.
- (d) If Client asks Patheon to qualify an additional source for the Active Material or any Component, Patheon will, at Client's cost, utilize appropriate change control procedures as identified in the Quality Agreement to evaluate the Active Material or Component to be supplied by the additional source to determine if it is suitable for use in the Product. The parties will mutually agree upon the scope of work to be performed by Patheon at Client's cost. Section 1(b) of the Agreement will apply to all Product manufactured using the newly approved Active Material or Component because of the limited material characterization that is performed on additional sources of supply.

- (e) **Components.** Patheon will purchase and test all Components (with the exception of Client-Supplied Components) at Patheon's expense and as required by the Specifications.
- (f) If any capital equipment expenditures are required to perform the Services, and such equipment is to be exclusively dedicated to the Product, the rights and obligations of the parties and the ownership and use of the equipment will be addressed in a separate agreement between the parties.

4. Term, Termination:

4.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue for three (3) years (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of two Years each, unless either party gives written notice to the other party of its intention to terminate this Agreement at least 18 months prior to the end of the then current term.

4.2 Termination for Cause.

- (a) Either party at its sole option may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within 90 days following receipt of a written notice (the "**Remediation Period**") of the breach that expressly states that it is a notice under this Section 4.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement under this Section 4.2(a) may only be exercised for a period of 60 days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice.
- (b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement is assigned by the other party for the benefit of creditors.
- (c) Client may terminate this Agreement upon 30 days' prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product. But if this occurs, Client must still fulfill all of its obligations under Section 4.4 below.

- (d) Patheon may terminate this Agreement upon six months' prior written notice if Client assigns under Section 10A any of its rights under this Agreement to an assignee that, in the opinion of Patheon acting reasonably, is: (i) not a credit worthy substitute for Client; or (ii) a Patheon Competitor; or (iii) an entity with whom Patheon has had prior unsatisfactory business relations, as jointly discussed in good faith with the Client.

4.3 Product Discontinuation

Client may terminate this Agreement on at least twelve (12) months' notice if it intends to no longer order Services for a Product due to this Product's discontinuance in the market.

4.4 Obligations on Termination.

If this Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

- (a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order, at the price in effect at the time the Firm Order was placed;
- (b) Client will purchase, at Patheon's cost (including all reasonable costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Schedule D, Section 1(d), unless such Inventory can be, with Client's written approval, used by Patheon in the manufacture of product for Patheon's other customers;
- (c) Client will satisfy the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Schedule D, Section 1(d), and provided such orders are non-cancellable (if the orders may not be cancelled without penalty, the same will be assigned to and satisfied by Client);
- (d) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site;

- (e) Except for termination by Patheon under Section 4.2(a), (b) and (d), at Client's request, Patheon shall evaluate, in its reasonable discretion, if it can continue to manufacture Products for Client and its Affiliates until such time as Client has successfully transitioned manufacture of the Products to an alternate supplier; For sake of clarity, if Patheon, acting reasonably, does not intend to continue the supply of Product, as per the above provisions, Patheon shall not be obliged to do so;
- (f) If requested by Client and if agreed between the Parties, Patheon shall provide reasonable assistance to Client, at Client's sole reasonable cost on a time and materials basis, to (i) assist Client in the transfer of relevant manufacturing technology and information to an alternate supplier's manufacturing facility, (ii) participate in teleconferences with Client in connection with the transfer, and/or (iii) provide requested documentation to Client, at Client's sole cost, in order to effectuate such transition.
- (g) Subject to Section 4.4(e) above, Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s) within [**] Business Days following the completion, termination, or expiration of the Agreement) all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("Client Property"). If Client fails to remove the Client Property within the required period specified above, Client will pay Patheon storage fees as set forth in Schedule C, Section 4, for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 2 of this Agreement.

5. **Inventions; Intellectual Property:**

- (a) For the term of this Agreement, Client hereby grants to Patheon and its Subcontractor a limited, non-exclusive, paid-up, royalty-free non-transferable, non-sub-licensable save to Patheon's permitted sub-contractors license of Client's Intellectual Property which Patheon must use in order and solely for Patheon to perform the Manufacturing Services. The foregoing license shall terminate immediately upon termination or expiry of this Agreement.
- (b) All Intellectual Property generated or derived by Patheon while performing the Services, to the extent it is specific to, or dependent upon, the development, manufacture, use, and sale of Client's Product that is the subject of the Services, will be the exclusive property of Client. Patheon hereby assigns to Client, all right, title and interest in and to any and all Intellectual Property generated or developed by Patheon while performing any Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, or dependent upon, Client's Active Material or Product to the extent effective in advance, and where not effective shall promptly do and ensure that its representatives do all acts and sign all documents necessary to perfect Client's right, title and interest in and to such Intellectual Property as shall be reasonably requested by Client, at Client's expense.

- (c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable, license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services in connection with the Product(s).
- (d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.
- (e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by the party.
- (f) Subject to Subsections above of this Section 5, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

6. Indemnity:

A. Indemnification by Client

Client agrees to defend and indemnify Patheon, its Affiliates and their officers, employees, and agents against all losses, damages, costs, expenses (including reasonable attorneys' fees), claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim of infringement or alleged infringement of any third party rights, including any claim of infringement or alleged infringement of any intellectual property rights of third parties, in the Products, in the performance of Services, on the Specifications, or any portion thereof (except to the extent such claim is subject to Patheon's indemnity obligations pursuant to Section 6B), or any claim of personal or bodily injury or property damage to the extent that the injury or damage is the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees, or agents and provided however that for the purposes of this Section 6.A, any Client's warranty contained herein shall be read without giving effect to any knowledge qualifier.

If a claim occurs, Patheon will:

- (a) promptly notify Client of the claim;
- (b) use commercially reasonable efforts to mitigate the effects of the claim;
- (c) reasonably cooperate with Client in the defense of the claim; and
- (d) permit Client to control the defense and settlement of the claim, all at Client's cost and expense, provided, however, that
 - (i) Patheon may join in the defense and settlement of such claim or proceeding and employ counsel at its own expense; and
 - (ii) Client may not settle any claim or proceeding without Patheon's written consent, unless such settlement includes a release of all covered claims or proceedings pending against Patheon, contains no admission of liability or wrongdoing by Patheon, and imposes no material adverse obligations upon Patheon.

B. Indemnification by Patheon

Patheon agrees to defend and indemnify Client, its Affiliates to whom rights under this contract have been assigned in accordance with Section 10A, and their respective officers, employees, and agents against all losses, damages, costs, expenses (including reasonable attorneys' fees), claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to (i) any claim of personal or bodily injury or property damage to the extent that the injury or damage is the result of a failure by Patheon to perform the Services in accordance with the Specifications, cGMPs, the Quality Agreement and/or Applicable Laws except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Client, its officers, employees, agents, or Affiliates; (ii) a breach of Patheon's confidentiality obligations under the Confidentiality Agreement provided under Section 10F; and/or (iii) any infringement or alleged infringement of a third party's Intellectual Property rights due to Patheon's breach of its warranties under Section 7.B(d), provided however that for the purposes of this Section 6.B.(iv), the warranty referenced shall be read without giving effect to any knowledge qualifier.

C. Limitation of Liability

- (a) Defective Product. Client has the right to reject the whole or any portion of any lot of Products that deviates from the Specifications, cGMPs, the Quality Agreement, or Applicable Laws without invalidating any remainder of the lot. Client will inspect the Products manufactured by Patheon upon receipt and will give Patheon written notice (a "Deficiency

Notice”) of all claims for Products that deviate from the Specifications, cGMPs, the Quality Agreement, or Applicable Laws within [**] days after Client’s receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [**] days after discovery by Client, but not after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable [**] day period, then the delivery will be deemed to have been accepted by Client on the [**] day after delivery or discovery, as applicable. Patheon will have no liability for any deviations for which it has not received notice within the applicable [**] day period.

(b) If Client rejects Products in accordance with the provisions above of Section 6C(a) and the deviation is determined to have arisen from Patheon’s failure to provide the Services in accordance with the Specifications, cGMPs, the Quality Agreement, or Applicable Laws, then Client’s sole remedy will be to request Patheon to:

- repeat that part of the Service at Patheon’s costs, if Client supplies the Active Material and Client-Supplied Components;
- offset the amount paid against other amounts due to Patheon hereunder; or
- reimburse Client for the price for that part of the Service.

If Patheon is unable to replace the returned Products, then Patheon will reimburse Client for the price that Client paid to Patheon for Services for the affected Products and for the replacement cost of the Active Materials and Client-Supplied Components incorporated into the defective Products, subject to the limitation of liability specified in Section 6C(d). In all other circumstances, returns or other corrective actions will be made at Client’s cost and expense.

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon’s prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under this Section 6C(a-b-c). In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Services, for any damaged, defective, returned, or Recalled Products.

(c) Recalled/Returned Product. If a Recall or return results from, or arises out of, a failure by Patheon to perform the Services in accordance with the Specifications, cGMPs, the Quality Agreement, or Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will, at Patheon’s expense and at Client’s option,

either replace the Recalled or returned Products with new Products, contingent upon and within [**] calendar days of the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products, or reimburse Client for the price that Client paid to Patheon for Services for the affected Products. For greater certainty, Patheon's responsibility for any loss of Active Materials in Recalled Product will be subject to the limitation of liability specified in Section 6.C.(d). In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

To the extent replacement Product is provided by Patheon pursuant to Section 6.C.(b) or (c) above, such replacement batches shall [**].

- (d) Active Material liability. Under no circumstances whatsoever will Patheon reimburse Client for the cost of the Active Material except if the loss of Active Material occurs because of Patheon's negligence or willful misconduct. In any event, and subject to Section 6C(a) above, Patheon's maximum responsibility for loss or damage to the Active Materials will not exceed in the aggregate in any Year 10% of revenues in said Year to Patheon pursuant to this Agreement.
- (e) Maximum Liability. Except in respect of liability arising under Section 6B in respect of indemnity for third party claims or under the Confidentiality Agreement dated 19th March 2013 for breach of the confidentiality obligations therein provided, Patheon's maximum liability to Client under this Agreement for any reason whatsoever, including, without limitation, any liability arising or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement will not exceed in the aggregate for all claims in any Year 10% of revenues in said Year to Patheon pursuant to this Agreement.
- (f) For the sake of clarity, Patheon's maximum aggregate liability to Client for any obligation to (i) refund, offset or replace any defective Product under Section 6.C(b) or replace any recalled Products under Section 6.C(c), will not exceed 100% of the Price for the defective or recalled Product as applicable. This Section 6.C(f) shall not be subject to Section 6.C(e).
- (g) Under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business or goodwill or (ii) any other liability, damage, cost or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of the damages. This Subparagraph 6C(e) shall not apply to damages due to a party's breach of its confidentiality obligations under Subparagraph 10F (Confidentiality).

- (h) Death, Personal or Bodily Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement shall act to exclude or limit either party's liability for personal or bodily injury, death, or fraudulent misrepresentation caused by the negligence of either party.

D. Sole Remedy

Except for the indemnity set forth in Section 6B (Indemnification by Patheon) and subject to the limitations set forth in Section 6C (Limitation of Liability), the remedies described in Section 6C and in Section 4.2 (Termination for Cause) will be Client's sole remedies for any failure by Patheon to provide the Services in accordance with the Specifications, cGMPs, and Applicable Laws. For the avoidance of doubt, the remedies described in Section 6C and Section 4.2 (Termination for Cause) are to be cumulative and not in lieu of other remedies provided by those Articles.

7. Warranties

A. Client Warranties.

Client covenants, represents, and warrants that:

- (a) Non-Infringement.
- (i) the Specifications for each of the Products are its or its Affiliate's property and that Client may lawfully disclose the Specifications to Patheon;
 - (ii) to the best of Client's knowledge and belief, any Client Intellectual Property, used by Patheon in performing the Services according to the Specifications (A) is Client's or its Affiliate's unencumbered property or is exclusively licensed to Client, and (B) may be lawfully used as directed by Client;
 - (iii) the performance of the Services by Patheon for any Product under this Agreement, except for any Patheon Intellectual Property rights used therefor, and/or to the best of Client's knowledge and belief, the use or other disposition of any Active Materials or Product by Patheon as may be required to perform its obligations under this Agreement, does not infringe any valid and enforceable third party Intellectual Property rights;.

- (iv) as of the Effective Date, to the best of Client's knowledge and belief, there are no actions or other legal proceedings, concerning the infringement of third party Intellectual Property rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;
- (b) Quality and Compliance.
 - (i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;
 - (ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully used, sold and distributed in every jurisdiction in which Client markets the Products; in accordance with the relevant Marketing Authorization, and (ii) will be sold by Client in a safe and responsible manner.
 - (iii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

B. Patheon Warranties.

Patheon covenants, represents, and warrants that:

- (a) it will perform the Services in accordance with the Specifications, cGMPs, the Quality Agreement, and Applicable Laws;
- (b) all Product, upon delivery EXW at the Facility to Client or to a party of Client's designation, shall (i) fully conform to the applicable Specifications and release information; (ii) have been manufactured in compliance with the applicable regulatory requirements, cGMPs, the Specifications, the Quality Agreement, and all Applicable Laws; and (iii) not be adulterated or misbranded within the meaning of any Applicable Law;
- (c) Patheon has, and shall use commercially reasonable efforts to maintain the resources and personnel necessary to fully perform its obligations under this Agreement in a timely manner; and without limiting Patheon's personnel training and qualification obligations under the Quality Agreement (as applicable), any individual used by Patheon to perform the Services are, and will continue to be, qualified and have, and will continue to have, sufficient technical expertise to perform Patheon's obligations under this Agreement;

(d) to the best of Patheon's knowledge and belief, any Patheon Intellectual Property used by Patheon or its Affiliates to perform the Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon and its Affiliates, and (iii) does not infringe and will not infringe any third party rights in the Territory.

C. **No warranty.** NEITHER PARTY MAKES ANY WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. NEITHER PARTY MAKES ANY WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCTS.

8. **Cooperation**

- (a) **Quarterly Review.** Each party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen.
- (b) **Governmental Agencies.** Subject to Section 8(h), each party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding the Products if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.
- (c) **Records and Accounting by Patheon.** Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations, in accordance with the Quality Agreement. Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client, in accordance with the Quality Agreement.
- (d) **Inspection.** Client, and/or Client officially authorised representatives under express duty of confidentiality to Patheon and upon prior written consent of Patheon, such consent not to be unreasonably withheld, conditioned, or delayed, may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, and on dates mutually acceptable to the parties, but a Patheon representative must be present during the inspection.

- (e) Access. Patheon will give Client, and/or officially authorised Client representatives under express duty of confidentiality to Patheon and upon prior written consent of Patheon, such consent not to be unreasonably withheld, conditioned, or delayed, reasonable access at agreed times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, the Quality Agreement, and Applicable Laws. But, with the exception of “for-cause” audits, or as otherwise provided for in the Quality Agreement, Client will be limited each Year to [**], lasting no more than [**] days, and involving no more than [**] auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee as set out in Schedule C, Paragraph 5. The right of access set forth in this Section 8(e) will not include a right to access or inspect Patheon’s financial records.
- (f) Notification of Regulatory Inspections. Patheon will permit Regulatory Authorities to inspect its facilities and otherwise cooperate fully with Regulatory Authorities in connection with the approval process and continuing registration and/or licenses for Products. Patheon will notify Client of any inspections scheduled by any governmental agency in accordance with the terms and conditions of the Quality Agreement. Patheon will also notify Client within [**] (or as otherwise indicated in the Quality Agreement), of receipt of any form 483’s or warning letters or any other significant regulatory action which Patheon’s quality assurance group determines could impact the regulatory status of the Products. For clarity, the fees set forth in Section 8(e) relating to additional audits shall not apply to audits by Regulatory Authorities pursuant to this Section 8(f).
- (g) Reports. Patheon will supply on an annual basis all Product data in its control, including without limitation release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), processing related technical records, and any other data generated or obtained by Patheon in connection with this Agreement, that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including without limitation any annual report that Client is required to file with the FDA or reports that Client is required to file with other Regulatory Authorities. At Patheon’s request, Client will provide a copy of the relevant sections of the Annual Product Review Report to Patheon at no cost. Any data requested by Client pursuant hereto may be subject to an additional fee to be agreed upon between Patheon and the Client; provided however, that such fee shall not exceed Patheon’s standard fee then in effect for such services. For the avoidance of doubt, the obligations of confidentiality set forth in Section 10.F. below shall not prevent Client from disclosing information provided hereunder to Regulatory Authorities as may be required to obtain or maintain product approvals.

- (h) Regulatory Filings: Starting from the date of execution of this Agreement, in respect of all future documentation, prior to filing with the Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls ("CMC") portion of the New Drug Application or of the Abbreviated New Drug Application, Client will give Patheon a copy of the CMC portion relevant to Patheon's Services, as well as all supporting documents which have been relied upon to prepare such CMC portion. This disclosure will permit Patheon to verify that the CMC portion accurately describes the Services that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Patheon requires [**] days to perform this review but the parties shall agree to a shorter time for the review to the extent required to meet regulatory deadlines. If Client does not give Patheon the documents requested above within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its reasonable discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.
- (i) Recall/Return of Product. Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. Client will have the responsibility for handling customer returns of Product. Patheon will co-operate as reasonably required by Client, having regard to all applicable laws and regulations.
- (j) Manufacturing Site, Operations. With respect to its overall operations or the Manufacturing Site, (i) to the best of its knowledge and belief, Patheon shall, during the Term, be in material compliance with Applicable Laws; (ii) Patheon has not received any warning letters or other similar communication related to the Manufacturing Site or its operations from or on behalf of a governmental agency, relating directly or indirectly to the manufacture of the Product; and (iii) any deficiencies noted or otherwise referenced in any Form FDA-483 issued to Patheon have been corrected, or communicated in writing to Client, prior to the Effective Date.

9. **Shipping:**

Shipments of Products will be made EXW (Incoterms 2010) Patheon's shipping point. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client's instructions and as agent for Client, at Client's risk, arrange for shipping to be paid by Client. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

10. **Miscellaneous:**

A. **Assignment and Subcontracting**

Patheon may not assign this Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld. The parties acknowledge that Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of Client. Further it is specifically agreed that Patheon may subcontract the Services under this Agreement to its Affiliate, Patheon [**], ("**Subcontractor**"), provided however, that all Services shall be performed at the Manufacturing Site. Client will have a right of access to the Subcontractor's Manufacturing Site for auditing purposes, in accordance with the terms and conditions set out in Section 8. The subcontracting of any Services hereunder to the Subcontractor by Patheon shall not relieve Patheon of, and Patheon shall remain solely liable for, its obligations under this Agreement. Subject to Section 4.2(d), Client may assign this Agreement or any of its associated rights or obligations without approval from Patheon. Client will give Patheon prior written notice of any assignment and any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement. Any partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or any assigned part thereof, on 12 months' prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Service fees within a reasonable time. Despite the foregoing provisions of this Section 10A, either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder. If the assignee Affiliate is not deemed credit worthy by Patheon, acting reasonably, then Patheon may require Client to enter into a parent company guarantee of assignee's obligations hereunder as a pre-condition to such assignment. For purposes of this Agreement, "**Affiliate**" means an entity controlling, controlled by or under common control with another entity, where control is defined as ownership, directly or indirectly, of more than 50% of the voting rights in the entity.

B. Force Majeure

Except for payment obligations, neither party will be responsible for delay or failure in performance resulting from acts beyond the reasonable control and without the fault or negligence of the party, including, but not limited to, strikes or other labour disturbances, lockouts, quarantines, communicable disease outbreaks, riots, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment not caused by lack of recommended maintenance, lack of or inability to obtain fuel, power or components or compliance with any order or regulation of any government entity.

C. Survival

Any termination or expiration of this Agreement will not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement. The Confidentiality Agreement and Sections 2 (Payments) (to the extent such payments became due and payable prior to the termination or expiration), 4.4 (Obligations on Termination), 5 (Inventions, Intellectual Property), 6 (Indemnity and Limitations), 7 (Warranties), 8 (Cooperation) (i.e. to the extent such provisions by their nature survive expiration or termination), 9 (Shipping), 10C (Survival), 10O (Choice of Law) and 10F (Confidentiality), Schedule A (as relevant), Schedule C (Section 1, Section 2.1(b), Section 2.3, Section 4, Section 7), Schedule D (Payments due under Section 3 to the extent such payments became due and payable prior to the termination or expiration) of the Agreement will survive the expiration or termination of this Agreement.

D. Independent Contractors

The parties are independent contractors and this Agreement will not be construed to create between Patheon and the Client any other relationship such as, by way of example only, that of employer-employee, principal, agent, joint-venturer, co-partners or any similar relationship.

E. Permits

Without prejudice to Patheon's obligations under the following provisions of this Section 10E, Client will be solely responsible for obtaining or maintaining, prior to any distribution or marketing of the Products or at all relevant times, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals. Patheon will maintain, at its own expense (save as set out in this Agreement), at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Services.

F. Confidentiality

The Confidentiality Agreement entered into between Cangene Corporation (an Affiliate of CNJ Holdings Inc.) and Patheon on 19th March 2013 will apply to all confidential information about the parties (and their Affiliates) and the Services to be conducted under this Agreement and the Confidentiality Agreement is deemed to be incorporated herein by reference. If the Confidentiality Agreement expires or terminates prior to the expiration or termination of this Agreement, then the terms of the Confidentiality Agreement will nonetheless continue to govern the parties' obligations of confidentiality for the term of this Agreement and for five years thereafter.

G. Authority

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

H. Other Terms

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties or obligations of the parties, or otherwise modify, this Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both parties.

I. Insurance

Each party will maintain during the term of this Agreement general liability and product liability insurance. Either party may request evidence of this insurance.

J. No Third Party Benefit or Right

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

K. Notices.

Any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client :

•

Attention: General Counsel
CNJ Holdings Inc.
c/o Emergent BioSolutions Inc.
400 Professional Drive, Suite 400
Gaithersburg, MD 20879

With a copy to:

Attention: Legal Affairs
CNJ Holdings Inc. c/o Emergent BioSolutions
155 Innovation Drive, Winnipeg, MB, Canada R3T 5Y3 •
Telecopier No.: [**]

If to Patheon:

Patheon UK Limited
Kingfisher Drive
Covingham
Swindon Wiltshire SN3 5BZ
England
Attention: Legal Director
Facsimile No: [**]

L. Entire Agreement.

This Agreement is the complete agreement between the parties for this subject matter and supersedes all other prior agreements and understandings, whether written or oral. Any modifications, amendment or supplement to this Agreement must be in writing, expressly intending to vary the terms of this Agreement, and signed by authorized representatives of both parties. The terms and conditions of this Agreement may not be varied by the terms of Client's purchase order.

M. Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

N. Facsimile.

This Agreement may be signed in counterparts and by facsimile or by "pdf."

O. Choice of Law.

This Agreement is governed by the laws of the State of New York, without regard to any conflicts-of-law principle that directs the application to another jurisdiction's laws. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement. The parties hereby irrevocably submit to the exclusive jurisdiction of the courts within the State of New York for all matters related to this Agreement.

11. Schedules

The following Schedules are attached to, incorporated in and form part of this Agreement:

Schedule A—Definitions

Schedule B—Patheon Proposal Ref. n. C-FEP-83755-R0

Schedule C—Fees and Adjustments to Fees

Schedule D—Orders and Forecast, Minimum Order Quantity, Annual Yearly Value

Schedule E—Quality Agreement

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IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.

PATHEON UK LIMITED

By: /s/ Mark Newton
Name: Mark Newton 28 May 2015
Title: Dir EU BDS

CNJ HOLDINGS INC. d/b/a Emergent BioSolutions

By: /s/ Sean M. Kirk
Name: Sean M. Kirk 27 May 2015
Title: SVP, Operations

Finance Approved
/s/ illegible
May 26, 2015

Schedule A

Definitions

“**Active Material**” “**Active Pharmaceutical Ingredients**” or “**API**” means coagulation factor IX (recombinant) drug substance;

“**Active Material Value**” means value of the Active Materials for certain purposes of this Agreement, as set forth in a separate letter to be provided by Client to Patheon prior to the execution of this Agreement;

“**Actual Yearly Value**” or “**AYV**” means the value of Services ordered and purchased by Client in any Year of this Agreement as set forth in Schedule D;

“**Applicable Laws**” means (i) for Patheon, the Laws of the jurisdiction where the Manufacturing Site is located; and (ii) for Client and the Products, the Laws of all jurisdictions where the Products are manufactured, distributed, and marketed as these are agreed and understood by the parties in this Agreement;

“**Authority**” means any (a) federal, state, provincial, local, municipal, foreign or other government; (b) governmental or quasi-governmental authority of any nature (including any governmental agency, branch, department, official or entity and any duly authorized court or other tribunal, including an arbitral tribunal); (c) multi-national organization or body; or (d) body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory, or taxing power of any nature.

“**Business Day**” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the UK, [**], or Manitoba, Canada;

“**Binding Yearly Value**” or “**BYV**” means the minimum contractual value of Services to be ordered and purchased by the Client in any Year of this Agreement as set forth in Schedule D;

“**Breach Notice**” has the meaning set forth in Section 4.2(a);

“**cGMPs**” means, as applicable, current good manufacturing practices as described in:

- (a) Division 2 of Part C of the Food and Drug Regulations (Canada);
- (b) Parts 210 and 211 of Title 21 of the United States’ Code of Federal Regulations (“C.F.R.”) and the supplementary requirements for biologics set forth in Parts 600 to 680 of Title 21 of the C.F.R. (as applicable); and
- (c) EC Directive 2003/94/EC,

together with the latest Health Canada, FDA, EMA, and International Conference on Harmonization (ICH) guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

“**Client Intellectual Property**” means Intellectual Property generated or derived by Client before or after entering into this Agreement (including without limitation all information, documents, or materials containing Intellectual Property that Client provides to Patheon in connection with the performance of this Agreement), or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, or dependent upon, Client’s Active Material or Product;

“**Client Property**” will have the meaning specified in Section 4.4(g);

“**Client-Supplied Components**” means those Components to be supplied by Client or that have been supplied by Client;

“**Components**” means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials; “**Deficiency Notice**” has the meaning set forth in Section 6C(a);

“**Delivery Date**” has the meaning set forth in Section 3(a);

“**Effective Date**” has the meaning set forth of the first page of the Agreement;

“**Firm Order**” has the meaning set forth in Schedule D, Section 1(b);

“**Initial Term**” has the meaning set forth in Section 4.1;

“**Intellectual Property**” includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, know how, and any other intellectual property or proprietary rights recognized in any country or jurisdiction worldwide now or in the future;

“**Inventory**” means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

“**Invention**” means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

“**Manufacturing Site**” means the facility owned and operated by Patheon’s Affiliate, Patheon [**];

“**Patheon Competitor**” means a business that derives greater than 50% of its revenues from performing contract pharmaceutical development or commercial manufacturing services; provided however, that Affiliates of Client shall be excluded from this definition;

“Patheon Intellectual Property” means Intellectual Property (i) generated or derived by Patheon before performing any manufacturing Services, or (ii) developed by Patheon while performing the manufacturing Services or otherwise generated or derived by Patheon in its business provided that (a) such Intellectual Property does not arise from, is not based on or does not relate to Patheon’s use of Client Confidential Information or the Active Material or Product(s); (b) reasonably could be used by Patheon without revealing or disclosing any Client Confidential Information; and (c) can be used for purposes not exclusively related to the Client Confidential Information, Active Material or Product(s), including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

“Product” means IXINITY™;

“Quality Agreement” means the agreement between the Parties that sets out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client (Schedule E);

“Recall” means any action (i) by Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall will also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped;

“Regulatory Authority” means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products, including the Products;

“Remediation Period” has the meaning set forth in Section 4.2(a);

“Services” has the meaning set forth in Section 1(b);

“Specifications” means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in Schedule A and which contains documents relating to each Product, including, without limitation:

- (a) specifications for Active Materials and Components;
- (b) manufacturing specifications, directions, and processes;
- (c) storage requirements;
- (d) all environmental, health and safety information for each Product including material safety data sheets;

- (e) the finished Product specifications, packaging specifications and shipping requirements for each Product; and
- (f) quality control and quality assurance testing.

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

“**Subcontractor**” has the meaning set forth in Sections 10A;

“**Territory**” means the geographic area of the United States of America and the twenty-eight Member States of the European Union or as otherwise agreed by the Parties during the term of this Agreement.

“**Year**” means the 365-calendar day period from the Effective Date.

Schedule B

Patheon Proposal Ref. N. C-FEP-83755-R0

Manufacturing Assumptions:

[**]

Packaging Assumptions:

[**]

Testing Assumptions:

[**]

The following cost items are included in the Price for the Products:

[**]

Fees, Adjustments

1. First Year Pricing.

- Euro [**] per batch (without Components)
- Euro [**] per batch (including Components)

“**Price**” means the price per batch of Product, measured in EURO to be charged by Patheon for performing the Services, and, where stated, includes the cost of Components (other than Client-Supplied Components) and certain cost items as set forth in Schedule B, but excludes, for the sake of clarity, the annual stability testing costs .

The tiered Price and annual stability Price for the Products for the first Year as set out in the table above shall remain fixed throughout the term of this Agreement, subject to the adjustments expressly set forth in Section 2 below.

Unless otherwise specifically stated in this Agreement, all monetary amounts to be paid by either party pursuant hereto are to be paid in EURO.

2. Price Adjustments

2.1 Price Adjustments – Subsequent Years’ Pricing.

(a) After the first Year, Patheon may adjust the Price effective January 1st of each Year as follows:

- (i) Manufacturing and Stability Testing Costs. Patheon may adjust the Price for inflation, based upon any increase in the **Consumer Price Index**, published by ISTAT in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the parties otherwise agree in writing. This index is set forth at the following web address: http://www.istat.it/salastampa/comunicati/in_calendario/precon/20110114_00/ the inflation. By no later than [**] of each Year, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year.
- (ii) Component Costs. If Patheon incurs an increase in Component costs during any given Year; Patheon may increase the Price for the next Year to pass through the additional Component costs. By no later than [**] of each Year, Patheon will give Client information and supporting documentation about the increase in Component costs which will be applied to the calculation of the Price for the next Year and that reasonably demonstrates that the Price increase is justified. As Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers, Patheon has the right to provide Client with redacted documentation as necessary to comply with its confidentiality obligations vis-à-vis third parties.

- (iii) **Pricing Basis.** Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity specified in Schedule D, Paragraph 2. If a change to the Minimum Order Quantity is requested by Client, then Patheon will be entitled to an adjustment to the Price to compensate it for the increased costs, if any. For greater certainty, if Patheon and Client agree that the Minimum Order Quantity will be reduced and, as a result of the reduction, Patheon demonstrates to Client that its costs to perform the Services or to acquire the Components for the Product will increase on a per unit basis (including the amount of the increase), then Patheon may increase the Price by an amount sufficient to absorb the documented increased costs. By no later than [**] of each Year, Patheon will give Client a statement and supporting documentation setting forth the information to be applied in calculating those cost increases for the next Year. As Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers, Patheon has the right to provide Client with redacted documentation as necessary to comply with its confidentiality obligations vis-à-vis third parties.
- (b) **Termination Right for Pricing Adjustments.** For all Price adjustments under this Section 2.1, Patheon will deliver to Client on or about [**] (and in any event, no later than [**]) of each Year a revised Table for Schedule C to be effective for Product delivered on or after the first day of the next Year. If the pricing adjustments, in the aggregate, permitted to be made under this Agreement (including without limitation this Article 2) with respect to the Price for the Product in any Year exceed the then-current Price by more than [**] percent (+[**]%), then the Parties shall negotiate in good faith the price adjustments. If the Parties, acting reasonably and in good faith, do not reach an agreement on the price adjustments within [**] months from the date on which Client receives written request of a Price adjustment from Patheon, then either Party will have the right to terminate the Agreement by providing the other Party with a written notice of termination. Such written notice of termination, if any, must be delivered within thirty (30) days following the expiry of the said [**]-month period of the date on which Client receives notice of a Price adjustment that would result in the foregoing [**] percent ([**]%) threshold being exceeded, and termination of the Agreement will be effective [**] months after the delivery of such written termination notice. If the Agreement is so terminated, then during the period prior to termination, the Price for the Product in effect prior to such adjustment will prevail.

2.2 Price Adjustments - Current Year Pricing.

During any Year, the Prices set out in this Schedule C will be adjusted as follows:

Extraordinary Increases in Component Costs. If, at any time, market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: (i) the cost of a Component increases by [**]% of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by [**]% of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 2.2, Patheon will deliver to Client a revised Table for this Schedule C and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. As Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers, Patheon has the right to provide Client with redacted documentation as necessary to comply with its confidentiality obligations vis-à-vis third parties. The revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule C.

2.3 Adjustments Due to Technical Changes.

Amendments to the Specifications, to any manufacturing/packaging requirements (including the analytical methods) and/or to the Quality Agreement requested by Client will only be implemented following a technical and cost review, and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. The parties shall use good faith efforts to agree upon any such increase or decrease in the Price and the date for implementation of any such amendment. Amendments to the Specifications, to any manufacturing/packaging requirements, the Quality Agreement, and/or to the Manufacturing Site requested by Patheon, shall only be implemented: (i) following the written approval of Client, the approval not to be unreasonably withheld; and (ii) utilizing appropriate change control procedures as identified in the Quality Agreement. If Client accepts a proposed Price change (i.e. in respect of an amendment implemented pursuant to this Section 2.3, requested by Client), the proposed change in the Specifications will be implemented at Client's cost, and the Price change will become effective, only for those orders of Products that are manufactured/packaged under the revised Specifications. In addition, in respect of Inventory or Components subject to an amendment requested by Client, (a) Client agrees to purchase, at Patheon's cost (including all reasonable costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory used under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 1(d) of Schedule D, provided that the Inventory can no longer be used under the revised Specifications, or

used by Patheon in the manufacture of product for Patheon's other customers; and (b) open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 1(d) of Schedule D will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client.

2.4 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside of the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components) and the changeover fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

3. Intentionally Omitted.

4. Storage Fees.

Storage Fees: € [**] per pallet, per month for storing the Components or finished Product

Storage Fees: for Components or Product which contain controlled substances or require refrigeration will be charged at €[**] per pallet per month. Storage fees are subject to a [**] minimum charge per month.

5. Audit.

Fees for additional audits as per Section 8(e): €[**] for each additional audit day and €[**] per audit day for each additional auditor.

6. Annual Stability Testing

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. The said agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing.

7. Taxes.

(a) The Client will bear all taxes, duties, levies and similar charges (and any related interest and penalties) ("Tax" or "Taxes"), however designated, imposed as a result of the provision by the Patheon of Services under this Agreement, except:

(i) any Tax based on net income or gross income that is imposed on Patheon by its jurisdiction of formation or incorporation ("Resident Jurisdiction");

- (ii) any Tax based on net income or gross income that is imposed on Patheon by jurisdictions other than its Resident Jurisdiction if such tax is based on a permanent establishment of Patheon; and
 - (iii) any Tax that is recoverable by Patheon in the ordinary course of business for purchases made by Patheon in the course of providing its Services, such as Value Added Tax ("VAT", as more fully defined in subparagraph (d) below), Goods & Services Tax ("GST") and similar taxes.
- (b) If the Client is required to bear a tax, duty, levy or similar charge pursuant to this Agreement by any state, federal, provincial or foreign government, including, but not limited to, Value Added Tax, the Client will pay such tax, duty, levy or similar charge and any additional amounts to the appropriate taxing authority as are necessary to ensure that the net amounts received by Patheon hereunder after all such payments or withholdings equal the amounts to which Patheon is otherwise entitled under this Agreement as if such tax, duty, levy or similar charge did not exist.
- (c) Patheon will not collect an otherwise applicable tax if the Client's purchase is exempt from Patheon's collection of such tax and a valid tax exemption certificate is furnished by the Client to Patheon.
- (d) If subparagraph 7 (a)(iii) above does not apply, any payment due under this Agreement for the provision of Services to the Client by Patheon is exclusive of value added taxes, turnover taxes, sales taxes or similar taxes, including any related interest and penalties (hereinafter all referred to as "VAT"). In the event that any VAT is payable on a Service supplied by Patheon to the Client under this Agreement, this VAT will be added to the invoice amount and will be for the account of (and reimbursable to Patheon by) the Client. If VAT on the supplies of Patheon is payable by the Client under a reverse charge procedure (i.e., shifting of liability, accounting or payment requirement to recipient of supplies), the Client will ensure that Patheon will not effectively be held liable for this VAT by the relevant taxing authorities or other parties. Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to the Client are issued in such a way that these invoices meet the requirements for deduction of input VAT by the Client, if the Client is permitted by law to do so.
- (e) Any Tax that Client pays, or is required to pay, but which Client believes should properly be paid by Patheon pursuant hereto may not be offset against sums due by Client to Patheon whether due pursuant to this Agreement or otherwise.

Orders and Forecasts, Minimum Order Quantities, Annual Yearly Volumes

1. Orders and Forecasts.

- (a) **Rolling [**] Month Forecast.** When this Agreement is executed, subject to Section 1(b) and Section 3 below, Client will give Patheon an initial non-binding [**] month forecast of the volume of Product that Client expects to order in the first [**] months of commercial manufacture of the Product by Patheon. Each monthly forecast shall be sent to Patheon by email. This monthly forecast will then be updated by Client on or before the [**] day of each month on a rolling forward basis. Client will update the monthly forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than +/-[**]. Within [**] Business Days of receipt of each forecast, Patheon shall provide Client with a non-binding feasibility opinion of Patheon's ability to meet such forecast. If for any reason Patheon is, or reasonably believes that it may be, unable to deliver the quantity of Product identified in a forecast, Patheon shall promptly notify Client. The most recent [**] month forecast will prevail. Each Forecast shall be made in number of batches.
- (b) **Firm Orders.** On a rolling basis during the term of this Agreement, Client will issue, consistent with Subparagraph (a) above, an updated [**] month forecast on or before the [**] day of each month. This forecast will start on the first day of the next month. The first [**] months of this updated forecast will be considered binding firm orders. Concurrent with the [**] month forecast, Client will issue a new firm written order in the form of a purchase order or otherwise ("**Firm Order**") by Client to purchase and when accepted by Patheon pursuant to Section 1(c) below (such acceptance not to be unreasonably withheld), for Patheon to manufacture and deliver the agreed quantity of the Products identified for the first [**] months of the most recent forecast. The delivery date will not be less than [**] days following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's purchase order number, quantities of batches by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. Subject to the exceptions expressly provided for in this Agreement, the quantities of Products ordered in those written orders will be firm and binding on Client and may not be changed by Client.
- (c) **[**] Month Forecast.** On or before the [**] of each Year, Client will give Patheon a written non-binding [**]-month forecast, broken down by quarters, of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the [**]-month period.

(d) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within [**] Business Days of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. However, if Patheon, acting reasonably, needs to change the proposed delivery date by more than [**] weeks or to vary the volumes therein provided, then Patheon shall promptly notify the Client thereof and the parties shall negotiate in good faith a delivery date and a volume which are reasonable for both parties. The Delivery Date, as agreed between the parties in accordance with this Section 1(c), may be amended by agreement of the parties or as set forth in Section 3 (a) of the Agreement.

(e) Reliance by Patheon.

Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Subparagraphs 1(a) and 1(b) above in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Subparagraph 1(a) above or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Services requirements for Products for the first [**] months contemplated in the most recent forecast given by Client under Subparagraph 1(a) above. Patheon may make other purchases of Components to meet Services requirements for longer periods if agreed to in writing by the parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. Unless caused by improper action or inaction of Patheon, if Components ordered by Patheon under Firm Orders or this Subparagraph (d) are not included in finished Products manufactured for Client within [**] months after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired during the period or have an insufficient remaining shelf life to use in the Product, then Client will pay to Patheon its actual costs therefor (including all reasonable costs incurred by Patheon for the purchase and handling of the Components). But if these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

If Client fails to take possession or arrange for the destruction of Components within [**] months of purchase or, in the case of finished Product, within [**] months of manufacture (or [**] days from Parties' release provided that Client's batch review and release of Product shall have to be completed within [**] weeks of manufacture), Client will pay Patheon storage fees for storing the Components or finished Product as set forth in Schedule C, Section 4. Patheon may ship finished Product held by it longer than [**] months to the Client at Client's expense on [**] days written notice to the Client.

2. Minimum Order Quantity.

Client may only order Services for the Minimum Order Quantities as indicated below.

Minimum Order Quantity: [**] or multiples thereof ([**] = [**] units)

For the sake of clarity, Minimum Order Quantities means the minimum number of batches to be produced by Patheon during the same cycle of manufacturing.

3. Annual Yearly Value.

- (a) Client agrees to purchase from Patheon, each Year during the Term of this Agreement, Services costing, in total, the lesser of (i) [**] Euros, per Year; or (ii) the price to be paid for [**] batches during such Year if less than [**] Euros (the “Binding Yearly Value” or “BYV”). Client’s purchases from Patheon during 2015 prior to execution of this Agreement (and/or prior to the Effective Date of the Agreement) shall not count towards the Binding Yearly Value purchase commitment for the first Year during the Term with the exception of the cGMP batches scheduled for manufacture during May / June 2015 (which shall count towards the Binding Yearly Value purchase commitment for the first Year during the Term). Purchases for additional services from Patheon to Client or an Affiliate of Client, pursuant to a change of scope agreement, shall also count towards the Binding Yearly Value provided that any such purchases occur subsequent to execution of this Agreement.
- (b) Patheon agrees to accept purchase orders from Client up to the maximum of [**] batches of Product per Year. Patheon agrees to make commercially reasonable efforts to accept purchase orders received from Client for volumes of Product in excess of [**] batches of Product per Year, provided however, that the parties acknowledge that manufacturing dates in respect of such purchase orders must be mutually agreed upon by the parties and subject to the provisions below of this Section 3(b).
- “**Commercially Reasonable Efforts**” shall mean, with respect to Patheon’s efforts to supply volumes of Product in excess of [**] batches per Year, that Patheon shall, at the request of Client, supply the additional volumes of Product as requested by Client only if, and to the extent that, at the time of Client’ request, Patheon believes, acting reasonably and in good faith, that it has the relevant available capacity at the Manufacturing Site to meet such additional Product requirements without prejudice to its contractual and/or commercial relationship vis-à-vis other clients.
- (c) The parties may change the Binding Yearly Value set forth in Section 3(a) above in a written amendment to this Agreement. [**]

Notwithstanding the foregoing, Client shall not be responsible to make the foregoing payment to the extent the amount invoiced by Patheon under Section 2 of the Agreement is less than the BYV solely as a direct result of Patheon's failure to supply the agreed Services in accordance with the Specifications, cGMPs, the Quality Agreement, or Applicable Laws.

Schedule E

Quality Agreement

*(copy to be attached prior to the commencement of any GMP
manufacturing at the Manufacturing Site under this Agreement)*

**QUALITY AGREEMENT
Commercial Product**

Between

**CNJ Holdings, Inc.
c/o 155 Innovation Drive,
Winnipeg, Manitoba, Canada R3T 5Y3**

(hereinafter referred to as “Contract Giver” or the “Customer”)

-and-

**Cangene Corporation
c/o 155 Innovation Drive,
Winnipeg, Manitoba, Canada R3T 5Y3
(hereinafter referred to as “Cangene”)**

-and-

Patheon []
([**] Operations)
[**]**

(hereinafter referred to as “Patheon” or the “Contract Acceptor”)

Effective Date: The last date signature

Version: QG01-05-T001-01

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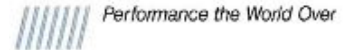


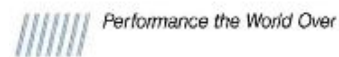


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GLOSSARY/DEFINITIONS

Active Pharmaceutical Ingredient (API) shall mean any substance intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or any function of the body of man or animal.

Batch Record shall mean the documentation needed to trace the complete cycle of manufacture of the Product from the receipt of all materials through all processing and subsequent packaging to dispatch for sale or supply to Cangene Batch record includes, but is not limited to, the following main record types: batch production record, batch packaging record and batch quality control record. Quality control record includes quality control, quality assurance and environmental data specific to the batch.

Facility shall mean either of Patheon manufacturing facility located in [**], or any other facility approved by Cangene for use by Contract Acceptor in the Manufacture and Supply of Product.

Consumables shall mean any material used during production, coming to direct contact with the Product, disposable, by default.

Change shall mean any change that might affect validated status, quality, regulatory compliance or Cangene's Product Quality Standard compliance.

Deviation shall mean any departure from SOPs, methods, specifications, protocols, batch records, instructions, processes, process specifications or normal conditions (e.g. borderline conformances) or other official documentation.

GMP or cGMP shall mean current Good Manufacturing Practices, as such term is defined in the United States Code of Federal Regulations parts 210, 211, 600, 601, 610, and the requirements thereunder imposed by the FDA, all promulgated and published, and in EC Directives 2003/94/EC and 2006/86/EC, Eudralex Vol. IV and all subsequent revisions, laying down the principles and guidelines of good manufacturing practice for medicinal products, in each case as applicable to the circumstances.

GDP shall mean Good Distribution Practice, and deals with the guidelines for the proper distribution of medicinal products for human use. GDP is a quality warranty system, which includes requirements for purchase, import, storage, supply or export of active substances and drugs intended for human use In general, it aims to verify the whole supply chain.

Manufacture, manufacturing or production shall mean any and all operations to process, formulate, sterilize, compound, aseptic fill, lyophilize, label, test, handle, primary or bulk packaging, and warehousing of the Product at the facility, all in accordance with the agreed Manufacturing instructions, Specifications and Standard Operating Procedures (SOPs).

Packaging materials shall mean all materials employed in the packaging of a Product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary packaging materials according to whether or not they are intended to be in direct contact with the medicinal product and as bulk packaging materials.



Periodic Product Review shall mean a regular comprehensive analysis of each Product’s manufacturing process, which includes a review of market performance (including customer complaints), the impact of process changes, quality events (process Deviations and audit findings) and adherence to Specifications and standards. This review is conducted with annual frequency and is in line with EU (Eudralex Vol IV Part 1 Chapter I) and US (US 21CFR Part 211.180) regulations.

Product shall mean product as designated in Annex 1 hereto.

Product Quality Standard shall mean all mandatory aspects of the composition, manufacturing process, control methods and Specifications and Packaging, which are essential to ensure safety, quality and efficacy of the Product.

Qualified Person or “QP” shall mean the person(s) responsible for batch release, as defined in Article 48 of Directive 2003/94/EC.

Quality Agreement shall mean this Agreement, the Annexes, and any amendment.

Raw materials shall mean all materials used in the manufacture of Product, except packaging materials, but including consumables which are not present in the finished product (e.g. water, vial headspace gas).

Reference Samples shall mean samples of APIs, Raw materials, Packaging materials, and the Product that are kept for possible re-examination.

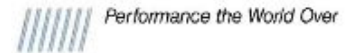
Specifications shall mean the agreed specifications for the Product and related Raw and Packaging materials.

SECTION 1: PREMISES AND AGREEMENT

PREMISES. Under a Manufacturing Services Agreement (the “MSA”) dated May 27, 2015 between Patheon UK Limited and the Customer, Patheon UK Limited agreed to sub-contract the performance of pharmaceutical manufacturing services for certain marketed products in certain countries (as set forth in Appendix A hereto) (“**Products**”) to Patheon (also referred to herein as the “Contract Acceptor”). The parties agreed that Patheon UK Limited will remain solely liable to the Customer for any breach of the duties and responsibilities assumed by Patheon under this Agreement. The Customer is required to give the Contract Acceptor certain Specifications in order for Patheon to perform the manufacturing services. Under the MSA, Patheon UK Limited is required to ensure that Patheon operates within the Specifications and in accordance with cGMP. The Customer and Patheon, as provider of the manufacturing services on behalf of Patheon UK Limited for the benefit of the Customer, desire to allocate the responsibility for procedures and Specifications impacting on the identity, strength, quality and purity of the Products by entering into this Quality Agreement (this “**Agreement**”).

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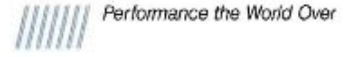




AGREEMENT. NOW THEREFORE in consideration of the Premises and rights conferred and the obligations assumed under the MSA and herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound, the parties agree as follows:

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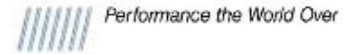
SECTION 2: RESPONSIBILITIES TABLE

Patheon will be responsible for all the operations that are marked with “X” in the column titled “Patheon” and Cangene will be responsible for all the operations that are marked with “X” in the column titled “Cangene”. If marked with “(X)”, cooperation is required from the designated party.

Subject/Terms	Cangene	Patheon
4.1 Quality Management		
4.1.1 GMP, Health and Safety Compliance	(X)	X
4.1.2 Customer Audit Rights	X	(X)
4.1.3 Subcontracting	(X)	X
4.1.4 Self-Inspection		X
4.2 Regulatory Requirements		
4.2.1 Permits (Site licenses & GMP certificates (EU). Site Master File PIC)		X
4.2.2 Product Licenses and Registration files life-cycle management	X	(X)
4.2.3 Product permits: supply of all necessary approved registration information (CTD quality sections) and relevant updates	X	(X)
4.2.4 Regulatory Compliance		X
4.2.5 Components compliance documentation (BSE/TSE, Residual Solvents. API GMP, etc.)	X (materials supplied)	X (materials procured)
4.2.6 Government Agency Inspections, Communications and Requisitions	(X)	X
4.3 Material Control		
4.3.1 Test Methods and Specifications	X	(X for Patheon local requirements)
4.3.2 Material Destruction	(X)	X
4.3.3 Vendor Quality Management	X (materials supplied)	X (materials procured)
4.3.4 Customer Supplied Materials In-coming Material Testing	X	(X)
4.3.5 Patheon Supplied Materials Incoming Material Testing		X
4.3.6 Incoming Material Release	X	X
4.3.7 Storage and Transportation of Materials		X
4.4 Building, Facilities, Utilities and Equipment		
4.4.1 General		X
4.4.2 Equipment, Calibration and Preventative Maintenance	X	
4.4.3 Environmental Monitoring Program		X

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4.5 Product Controls

4.5.1	Test Methods and Specifications	X	(X)
4.5.2	Master Batch Record	(X)	X
4.5.3	Reprocessing and Rework	(X)	X
4.5.4	Personnel and Training		X
4.5.5	Container closure integrity test		X

4.6 Packaging, Labeling and Printed Materials (Not Applicable)

4.6.1	Master Batch Packaging Records (VOID)		
4.6.2	Printed Material and Artwork (VOID)		
4.6.3	Test Methods and Method Validation (VOID)		

4.7 Exception Reports (Deviations / Investigations)

4.7.1	Manufacturing Instruction Deviations	(X)	X
4.7.2	Packaging Instructions Deviations	(X)	X
4.7.3	Notification of Deviations	(X)	X

4.8 Release of Product

4.8.1	Batch Certification for Shipment (QP confirmation)	(X)	X
4.8.2	Product Release to the market	X	
4.8.3	Certificate of Compliance and Certificate of Analysis		X

4.9 Validation

4.9.1	Master Validation Plan	(X)	X
4.9.2	Cleaning Validation Program	(X)	X
4.9.3	Analytical Method Validation	X	X
4.9.4	Manufacturing Process Validation	(X)	X
4.9.5	Shipment Validation	X	
4.9.6	Facilities, Utilities and Equipment Validation		X

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Performance the World Over



4.10 Change Control

4.10.1	General	X	X
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4.11 Documentation

4.11.1	Record Retention		X
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4.11.2	Batch Document Requisition		X
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4.12 Laboratory Controls

4.12.1	Specifications and Test Methods	X (API and DP)	X (others)
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4.12.2	Out of Specifications (OOS) / Out of Trend (OOT)	(X)	X
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4.12.3	Confirmed OOS notification to authorities	X	
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4.13 Stability

4.13.1	Sample Storage		X
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4.13.2	Stability Protocol, and Studies	X	(X)
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4.13.3	Stability Failures	X	(X)
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4.13.4	Stability Support Post Termination of MSA		X
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4.14 Annual Product Review / Product Quality Review

4.14.1	General	X	(X)
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4.15 Storage and Distribution

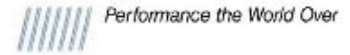
4.15.1	General	(X)	X
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4.15.2	Product Storage and Shipment (Ex Works)	(X)	X
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4.15.3	Product Quarantine	(X)	X
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4.16 Product Complaints

4.16.1	Complaint Investigation	X (medical, non-medical, & quality)	X (quality)
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4.17 Product Recall / Field Alerts (US)

4.17.1	Product Recall Notification and Investigation	X	X (Investigation)
4.17.2	Government Agency Notification	X	
4.17.3	Suspected Falsified Medicine/suspected re-packaging failure within parallel importation Where applicable	X	

4.18 Reference and Retention Samples

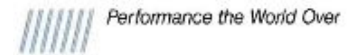
4.18.1	Excipient and Active Ingredient Reference Sample		X
4.18.2	Packaging Retention Sample		X
4.18.3	Finished Product Retention Sample		X

SECTION 3: GENERAL

- 3.1 Any communications about the subject matter of this agreement will be directed, in the first instance, to the person(s) identified in appendix b.
- 3.2 Capitalized terms not otherwise defined herein will have the meaning specified in the MSA. For the purposes of this quality agreement, “business day” means a day other than a Saturday, Sunday, or a day that is a statutory holiday in Winnipeg (Canada), Swinton (UK), [**], and the United States (USA).
- 3.3 If any provision of this agreement should be or found invalid, or unenforceable by law, the rest of the agreement will remain valid and binding and the parties will negotiate a valid provision which meets as close as possible the objective of the invalid provision.
- 3.4 If this agreement requires modification such that either party affected cannot be reasonably expected to continue to perform under this agreement, then the parties will negotiate and revise the agreement accordingly
- 3.5 Any amendment of this agreement will be made in writing and signed by both parties.

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3.6 This agreement will start on the effective date that is set forth on the cover page of this agreement and will remain valid until all quality obligations under all applicable msa's have been fulfilled.

SECTION 4: DESCRIPTION OF RESPONSIBILITIES

4.1 Quality Management

4.1.1 GMP, Health and Safety Compliance

Patheon will conduct operations in compliance with applicable environmental, occupational health and safety laws, and cGMP regulations.

4.1.2 Customer Audit Rights

Patheon will permit audits on reasonable prior written notice, of all relevant premises, procedures and documentation by Cangene; to the extent such audits are related to Customer's Product. Customer audits are limited to [**] per calendar year lasting no more than [**] days, and involving no more than [**] auditors unless for cause. Patheon will provide access to the manufacturing facility, on reasonable prior written notice, to Customer personnel during the manufacturing of Customer product(s).

The rights of access, audit and inspection provided herein do not include any right to access or inspect Patheon's financial records.

Patheon shall respond to Cangene audit report within [**] days of Cangene audit report receipt. Cangene shall provide Patheon with the audit report within [**] days of the audit date.

4.1.3 Subcontracting

Patheon will not subcontract tasks to a third party without Customer's consent. Patheon may subcontract raw material testing to other Patheon facilities and to other qualified third party laboratories (as defined in Appendix E).

4.1.4 Self-Inspection

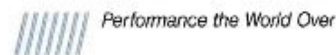
Patheon will perform self-inspections of its premises, facilities, and processes used to manufacture, package, test, and store Cangene's starting, intermediate, and/or finished products in accordance with Patheon's written standard operating procedures ("SOP's") to ensure compliance with cGMP and this Quality Agreement.

4.2 Regulatory Requirements

4.2.1 Permits (Site licences & GMP certificates (EU), Site Master File PIC)

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Patheon will obtain and maintain the appropriate Manufacturing License(s), GMP certificates and Site Master File following the scheme defined by PIC to allow for the Manufacturing services.

4.2.2 Product Licences and Registration files life-cycle management

Cangene will determine whether changes to the Product or related to the Product will impact a regulatory filing and will apply for and receive approval for any required manufacturing amendment, change or addition to their Product marketing authorization.

Upon request, Patheon may provide regulatory support in the preparation and overall regulatory consistency review of pertinent sections of new or supplemental regulatory applications.

For compliance purposes, Cangene will provide Patheon with copy of sections of product registration/regulatory submissions that are relevant to the manufacture of the Product as appropriate.

Prior to any submission based upon Patheon generated data, Cangene will also provide the relevant registration sections to enable Patheon to exercise its right to review the data accuracy as per the legal terms and conditions.

Cangene is responsible for all communications with Regulatory Authorities as well as for the approval, maintenance, and updating of marketing approval in a timely manner.

In particular, in the event of a substantial change to cGMPs or regional governances directly impacting Product Quality compliance, it shall be mutually agreed prior to its implementation.

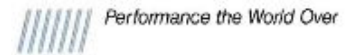
4.2.3 Product Permits: supply of all necessary approved registration information (CTD [Common Technical Document] quality sections) and relevant updates

Cangene will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

It is the responsibility of Cangene to provide Patheon EU sites with the accurate Product registration information as per European legislations (cGMPs guide part I—chapters 1,4,6,7 and annex 16 / directives 2001/83/EC — title IV, articles 46, 48, 51 and 2003/94/EC article 5).

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4.2.4 Regulatory Compliance

Patheon will ensure that Product(s) is manufactured and tested in strict compliance with current US Federal and EC regulatory and statutory requirements relating to Good Manufacturing Practices (GMP) (US 21 CFR parts 210 and 211 and EU Directives 2003/94/EC — 2004/27/EC — 2011/62/EC for the manufacture of finished medicinal product) as applicable, regulatory approvals and local laws and regulations applicable at the site(s) of manufacture and/or testing.

Patheon shall notify Cangene of any quality related inspections of the Manufacturing process of the Products by Regulatory Authorities, particularly CBER. As soon as practicable, and after the inspection by the relevant Regulatory Authorities, Patheon shall provide the results and appropriate reports received from the Regulatory Authorities to Cangene.

4.2.5 Components compliance documentation (BSE/TSE, Residual Solvents, etc)

Patheon will ensure that the procured materials are in compliance with BSE/TSE, Residual Solvents, Viral safety, Residues of Metal Catalyst or Metal Reagents, risk of Melamine contamination guidelines, as per internal procedure if applicable.

Cangene will assure the compliance to the above mentioned guidelines for the supplied materials, as per Appendix M where applicable.

4.2.6 Government Agency Inspections, Communication and Requisitions

Patheon will permit all relevant inspections by regulatory authorities of premises, procedures, and documentation.

Patheon will notify Cangene within [**] Business Days of receipt of any notice of inspection from a regulatory authority and within [**] of any regulatory authority request for Product samples, batch documentation, or other information related to the Product.

Patheon will notify Cangene within [**] of receipt of any Form 483, warning letter, or the like from any regulatory agency that relates to the Product; or if the supply of Product will be affected, or if the facilities used to produce, test or package the Product will be affected. Suitable documentation in a redacted manner, if needed, will be presented.

The responses from Patheon related to the Product will be reviewed and approved by Cangene prior to submission to the regulatory agency. Notwithstanding, Patheon reserves the right to respond to the regulatory agency without approval, if, in the reasonable opinion of Patheon's Legal counsel, it is required to do so.

If relevant inspections by Regulatory Authorities will be performed on Cangene's Product, Cangene reserves the right to be in the Facility during such inspections. Inspections requirements must be communicated in a timely manner to Cangene.



4.3 Material Control

4.3.1 Test Methods and Specifications

Cangene will give Patheon a copy of the Specifications and test methods used if Cangene issues raw material Specifications as well as any relevant updates. Per each raw material delivered to Patheon a MSDS document will be provided by Cangene to detail the handling procedures.

4.3.2 Material Destruction

Patheon has the right to either return to Cangene or dispose of any outdated or rejected material which is of Cangene's property. If the material is disposed of, disposal will be consistent with the nature of the material and sent to a permitted waste disposal facility. Prior to such disposal:

- (i) Patheon will send notice to Cangene about Patheon's intent to dispose of the material. If no direction is received from Cangene, Patheon will dispose of the material no sooner than [**] days after the date of the notice.
- (ii) The materials will be disposed and destroyed in compliance with local environmental regulations and performed in a secure and legal manner that prevents unauthorized use or diversion.

Patheon will maintain destruction records in accordance with Patheon SOP's. A copy of the Certificate of Destruction will be sent to Cangene.

4.3.3 Vendor Quality Management

4.3.3.1 Excipient and API Vendors:

- (i) If Cangene is responsible for supplying an excipient or API, Cangene will audit and approve the manufacturers and ensure cGMP and cGDP compliance in accordance with Section 4.3.4 of this Agreement. Cangene stipulated vendor(s) will be included on Cangene's approved vendor list (attached hereto as Appendix D). Cangene will provide to Patheon all documentation related to API identified in Appendix H.
- (ii) If Patheon is responsible for procuring the excipient, Patheon will audit and approve the manufacturers and ensure cGMP compliance in accordance with Patheon's SOP. The Patheon stipulated vendor(s) will be included on Patheon's approved vendor list (attached hereto as Appendix C).

4.3.3.2 Primary Packaging Component Vendors:

- (i) If Cangene is responsible for the supply of a packaging component vendor, Cangene will audit and approve the manufacturer and ensure cGMP compliance. Cangene stipulated vendor(s) will be included on the approved vendor list (attached hereto as Appendix D).



- (ii) If Patheon is responsible for procuring the packaging component vendor, Patheon will audit and approve the manufacturer and ensure cGMP compliance in accordance with Patheon's SOP. The Patheon stipulated vendor(s) will be included on the approved supplier list (Appendix C).

4.3.4 Customer Supplied Materials Incoming Material Testing

Cangene is responsible for vendor qualification of Customer furnished materials and for providing a certificate of compliance confirming the following where applicable:

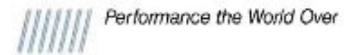
- a. **That the materials are compliant with the provisions outlined in the "Note for Guidance on minimizing the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products" (EMA/410/01, rev.3 since 03.2011 or update) and**
- b. **A residual solvent certificate confirming that there is no potential for specific toxic solvents listed in the EP / USP / ICH residual solvents Class I, Class II or Class III to be present and the material, if tested, will comply with established EP / USP / ICH requirements. If any of the solvents listed in the EP / USP / ICH residual solvents Class I, Class II or Class III are used in the manufacture or are generated in the manufacturing process, solvents of concern will be indicated.**
- c. **Information on genotoxic Impurities, Residues of Metal Catalyst information.**
- d. **An API GMP compliance declaration to the EU directive 2004/27/EC (when sourced from an EU country) or to ICH Q7 (when sourced from a non EU country) and**
- e. **certificate of compliance confirming that such Materials are compliant with the provisions outlined in the US FDA Guideline "Pharmaceutical Components at risk for Melamine contamination"**

Cangene is responsible for providing Patheon with documents on supplied API, as defined in Appendix H.

API lots will be delivered by Customer to Patheon in their fully approved status with all required Certifications i.e. Cangene Certificate of Analysis and API Manufacturer's Certificate of Compliance.

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4.3.5 Patheon Supplied Materials Incoming Material Testing

Patheon is responsible for vendor qualification of Patheon furnished materials and for providing a certificate of compliance confirming the following:

4.3.5.1 That the materials are Animal Component Free

4.3.5.2 That the materials are compliant with the provisions outlined in the “Note for Guidance on minimizing the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products” (EMEA/410/01, rev. 3 since 03.2011 or update)

4.3.6 In-Coming Material Release

Prior to its use in the manufacture of any Product, all material(s) supplied by Cangene, through its designee Cangene, will be inspected, tested, and approved by Patheon against the Specification approved by Cangene.

Cangene will provide to Patheon the API drug substance in [**] packed in a box with [**] for shipping. Patheon shall verify the presence of the temperature monitors, download the data and verify compliance with shipping conditions. Patheon will send evidence of temperature monitoring to Cangene.

The Certificate of Analysis (including among the others ID, bioburden, endotoxin and expiry date), a statement of release (Certificate of Compliance) and a separate shipping sheet will be used to confirm the package contents upon its arrival at Patheon.

Cangene shall provide a sample of the API for identity testing with each shipment and a retain sample for each supplier lot of API. The sample of the API shall be filled at the same time as the API intended for the manufacturing purposes. Representativeness of samples with respect to parent API bulk lot is based on Cangene’s evaluation of manufacturing process and samples collection procedure at the API manufacturing site.

Patheon will perform only an identification test according to the approved Specification.

4.3.7 Storage and Transportation of Material

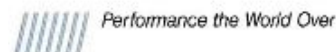
Patheon shall ensure that storage and transport conditions of raw materials used to manufacture the Products are appropriately controlled to ensure that Products meet the agreed Specification throughout the specified storage life and comply with the CGDP (Distribution) requirements.

4.4 Building, Facilities, Utilities and Equipment

4.4.1 General

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All buildings and facilities used in the manufacturing, packaging, testing and storage of any materials and/or Product will be of suitable size, construction and location to facilitate cleaning, and will be maintained in a good state of repair. Maintenance and cleaning records will be kept in accordance with Patheon's SOP's.

4.4.2 Equipment, Calibration and Preventative Maintenance

All equipment used in the manufacturing, packaging, testing and storage of any materials and/or Product will be suitable for its intended use and appropriately located to allow for cleaning and maintenance. Qualification, calibration and maintenance records will be kept according to Patheon SOP's for all critical equipment. Patheon will calibrate instrumentation and qualify computer systems used in the manufacture and testing of the Product in accordance with Patheon's SOP's.

4.4.3 Environmental Monitoring Program

Patheon will perform and maintain an environmental monitoring program. The collected data will be reviewed and interpreted by the responsible person within Patheon's quality unit. Any out of limit results will be managed appropriately in accordance with Patheon SOP's. In any event, Cangene shall be notified if an unresolved adverse EM trend has been identified in advance of its next scheduled fill. Cangene shall have the right to determine whether or not to proceed with the fill.

4.5 Production Controls

4.5.1 Test Methods and Specifications

Cangene will provide to Patheon the finished In Process Control (IPC) and release Product Specifications and will develop and supply validated analytical test methods to Patheon for the finished Product at release (and shelf-life testing if requested). Patheon is responsible to verify the performance of test methods in the actual condition of use.

4.5.2 Master Batch Record

Cangene will provide the Specifications to Patheon and Patheon will manufacture Product in accordance with the Specifications.

Patheon is responsible for preparing the master batch records for the Product, however, Cangene is responsible to review and approve such master batch records prior to the manufacture of the Product.

Patheon will not make changes to master batch records except through the established Patheon change control system, and all master document revisions will be approved by Cangene's quality unit. Any changes made to issued batch records (prior to master revisions) must be reviewed and approved by Cangene's quality unit prior to implementation unless otherwise agreed to in writing.



4.5.3 Reprocessing and Rework

Patheon will not reprocess or rework the Product without the prior written consent from Cangene.

4.5.4 Personnel and Training

Patheon will provide appropriate training for all employees. Each person engaged in the manufacture, packaging, testing, storage, and shipping of the Product. Such employees will have the education, training, and experience necessary, consistent with current GMP and safety training requirements.

4.5.5 Container Closure Integrity Test

Patheon will perform a 100% non-destructive Container Closure Integrity Test, on each batch of final product, as required by (among the others) EU GMP Annex 1.

4.6 Packaging, Labeling and Printed Materials — Section Not Applicable Cangene responsibility

4.6.1 Master Batch Packaging Records

VOID

4.6.2 Printed Material and Artwork

VOID

4.6.3 Test Methods and Method Validation

VOID

4.7 Exception Reports (Deviations / Investigations)

4.7.1 Manufacturing/Packaging Instruction Deviations

Patheon will document, investigate and resolve deviations from approved manufacturing/packaging instructions or Specifications in accordance with Patheon's SOP's. Patheon will report and obtain approval from Cangene's responsible person for deviation report ("DR") type deviations where there is a potential to affect Product quality. Cangene approval will not be unreasonably withheld. Patheon will provide copies of all DR's to Cangene as part of the executed batch record, within [**] calendar days.



4.7.2 Notification of Deviations

Patheon will notify Cangene within [**] of discovery if any significant deviation occurs during manufacture of the Product, where such deviation has the potential to affect the quality, efficacy or availability of the Product.

If the deviation affects, or could affect, batches already released and distributed, Patheon will notify Cangene within [**] after detecting the deviation.

Cangene will provide feedback to Patheon on the investigation report within [**] Calendar days.

4.8 Release of Product

4.8.1 Batch Certification for Shipment (QP Confirmation)

Batch review, release and certification for shipment to Cangene will be the responsibility of Patheon's Quality Assurance department and Qualified Person, who will act in accordance with Patheon's SOP.

4.8.2 Product Release to the Market

The final responsibility of product release to market after secondary packaging is assigned to Cangene, based on preliminary batch certification on bulk batch done by Patheon.

4.8.3 Certificate of Compliance and Certificate of Analysis

For each batch certified by Patheon, prior to release for shipment to Cangene, Patheon will deliver to Cangene a Certificate of Analysis, CoA (signed by QC Manager) which contains a statement of compliance of batch to Specifications and Certificate of Compliance, CoC (signed by Qualified Person) which will include a statement that the batch has been manufactured in accordance with cGMPs and complies with the Specifications. Both documents will be provided under official Patheon letterhead (containing address) and their format will comply with the templates reported in Appendix F and Appendix G in accordance with approved specifications.

Clinical Trial Material (CTM) batches already manufactured in Patheon [**] facility and following Clinical Trials Manufacturing Agreement may be requested by Cangene to be re-designated to commercial destination. In such instances, the batches will be re-examined in the light of requirements of this Quality Agreement, Product Registration and Specification; if such compliance is demonstrated the batches will be re-certified and new CoAs and CoCs will be issued by Patheon. This circumstance shall apply to either batches already released according to CTM requirements and batches still pending release, irrespective if still present in Patheon warehouse or already delivered to Client. Additional reference samples may be collected if necessary.



4.9 Validation

4.9.1 Master Validation Plan

Patheon will establish applicable master validation plans and maintain a validation program for the Product. Cangene will review and approve the master validation plan, performance qualification and process validation protocols and reports for the Product.

4.9.2 Cleaning Validation Program

Cangene will provide to Patheon, toxicological information to be used in the development of a cleaning program. Patheon will maintain an appropriate cleaning and cleaning validation program, and shall provide information to Cangene as necessary to support regulatory filings.

4.9.3 Analytical Method Validation

Cangene must ensure that its analytical methods (including packaging procedures) are validated. If the methods are not validated by Cangene, then Patheon may assist in validation development with the costs being borne by Cangene.

4.9.4 Manufacturing Process Validation

Patheon will establish, together with Cangene, a process validation strategy for the Product. Cangene will review and approve the process validation protocol and process validation report for the Product.

4.9.5 Shipment Validation

Cangene shall establish a qualified shipping method, including controls for temperature and humidity, if necessary. Placement locations for temperature monitors will be provided by Cangene to Patheon.

4.9.6 Facilities, Utilities and Equipment Validation

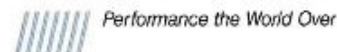
Patheon is responsible for the qualification and/or validation of its facility, equipment, and utilities.

4.10 CHANGE CONTROL

4.10.1 General

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Patheon will notify and obtain approval from Cangene before implementing any proposed changes to the process, materials, testing, equipment or premises, where such changes may affect the Product.

Cangene's approval will not be unreasonably withheld. Cangene approval is expected to be completed in [**] Business days from the receipt of the Patheon notification.

Patheon shall refrain from any activity which could adversely affect the quality of the products. Patheon shall inform Cangene prior to the implementation of any product categories according to the categories listed below which are introduced to the same compounding or clean rooms where the Product is manufactured:

[**]

Such product introduction would need to be assessed using change control at Patheon, and requires Cangene approval prior to implementation.

Cangene will be responsible for determining whether or not to initiate registration variation (EU)/post-approval change (US) procedures and for maintaining adequate control over the quality commitments of the marketing authorization made to the regulatory authorities by Cangene for the Product.

Patheon will evaluate any change proposal initiated by Cangene with opening an internal change control and delivering it to Cangene for notification purposes. Documents whose revision is impacted by change will be presented to Cangene for approval

Following validation of a process change, Patheon will deliver a copy of the related validation report to Cangene and the associated stability data, if applicable, as it becomes available.

In the event of a substantial change to cGMPs or regional governances directly impacting Product Quality compliance, it shall be shared between both parties prior to its implementation.

4.11 Documentation

4.11.1 Record Retention

Patheon will maintain all batch records for a minimum of [**] past Product expiry date of the batches to which it related or at least [**] years after the certification whichever is longer period (EU specificity) and supply all these records to Cangene upon request.

Patheon will maintain records and evidence on the testing of raw materials and packaging/labeling materials for [**] years after the materials were last used in the manufacture or packaging/labeling of the Product.



At the end of the above noted retention period, Cangene will be contacted concerning the future storage or destruction of the documents.

4.11.2 Batch Document Requisition

At the request of Cangene, Patheon will provide a copy of any of the executed batch documents relating to Cangene Product within [**] Business Days of such request.

Patheon will share with Customer a defined Batch numbering rule which will be adopted to identify each product batch.

4.12 Laboratory Controls

4.12.1 Specifications and Test Methods

Patheon will test and approve starting material, intermediate, and the finished Product in accordance with the approved Specifications, analytical methods, and Patheon's SOP's.

Upon receipt, the materials are generally fully tested. Nevertheless, these may be reduced only after approval from Cangene.

Cangene will provide to Patheon the Active Material Specifications.

Cangene will provide to Patheon test methods for Active Material and excipient's (if non-compendial). Cangene is responsible for validating non-compendial testing methods. If these methods are not validated by Cangene, then Patheon may assist in validation development with the costs being borne by Cangene.

4.12.2 Out of Specifications (OOS) / Out of Trend (OOT)

Patheon will notify Cangene's quality unit of confirmed Out-of-Specification ("OOS") or Out-of-Trend ("OOT"), (if latter condition is applicable), results within [**]. Confirmed OOS is treated as a Deviation at Patheon after Phase 1 investigation is complete. Patheon will generate a DR as per Patheon's SOP and obtain approval of the DR from Cangene's responsible person within their quality unit. Cangene's approval will not be unreasonably withheld.

4.12.3 Confirmed OOS Notifications to Authorities

Cangene will notify authorities of confirmed out-of-specification ("OOS") and communicate to Patheon any communication to Regulatory authorities within [**] Business days.

4.13 Stability

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4.13.1 Sample Storage

Patheon will store stability samples as required.

4.13.2 Stability Protocol and Studies

Cangene will develop and validate stability indicating assay(s) prior to process validation. If required, Patheon may assist with the cost being borne by Cangene.

If requested, Patheon will conduct stability studies in accordance with the agreed and validated stability testing analytical methods and specifications at the agreed upon testing points in accordance with the approved stability protocol.

If requested, Patheon will perform the stability testing described in a stability protocol agreed to by both Patheon and Cangene. Stability data will be provided by Patheon to Cangene on an ongoing basis as agreed to by both parties.

4.13.3 Stability Failures

Cangene will notify Patheon of any Stability Failure occurred on batches manufactured by Patheon for proper evaluation to determine existing impact deriving from Patheon activities.

Patheon will notify Cangene of any stability failure for Product supplied to Cangene where employed to conduct such testing. If a result indicates that a Product has failed to remain within Stability Specifications, Patheon will notify Cangene within [**].

For OOS discovered during stability refer to 4.12.3 paragraph.

4.13.4 Stability Support Post Termination of MSA

If the MSA is terminated, Patheon will continue to provide Cangene with stability data supporting the acceptability of the Product until all Product distributed by Cangene has reached the end of its shelf-life, for Product manufactured at Patheon, as applicable.

4.14 Annual Product Review / Product Quality Review

4.14.1 General

Patheon will complete the annual / product quality review (PQR) product review (APR) in accordance with regulatory requirements of the Product marketed authorization. Patheon will provide copies of all information and correspondence necessary to support the APR when requested by Cangene. A complete copy of the final document will be sent to Cangene.



If the PQR is prepared, it will be finalised by Patheon and provided to Cangene, for revision and approval, by the end of the third quarter of the calendar year.

Annually, Patheon shall perform and document an APR with respect to consistency of the process. This review shall include, as a minimum, the number and disposition of Batches Manufactured, changes to the Product and processes, customer complaints, recalls and returns, and a summary of relevant Manufacturing Deviations and rejects. The report will be conducted in accordance with relevant cGMP reference US 21CFR Part 211.180 and Eudralex Vol 4 Chapter 1 and according to Patheon's SOP and shall be sent to Cangene. This document will support the "Customer Annual Product Review" and "Product Quality Review". The report will also include a summary of visual examination of QC retain samples of product batches if destined to US as requested by US 21CFR Part 211.170 for evidence of deterioration. The report will be provided to Cangene within [**] calendar days of the reporting period.

4.15 Storage and Distribution

4.15.1 General

Patheon will ship Product Ex-Works in accordance with the provided Specifications and agreed qualified transportation requirements provided by Cangene to Patheon,

Cangene is responsible for the transport according to local governances (such as EU cGDP and directive 2011/62/EC).

4.15.2 Product Storage and Shipment (Ex Works)

Patheon will communicate any proposed changes in storage or shipping to Cangene for review and approval. Cangene approval will not be unreasonably withheld.

4.15.3 Product Quarantine

Patheon will have a system in place for assuring that unreleased Product is not shipped. Quarantine shipment will be considered as an exceptional practice and will require formal mutual agreement between the parties.

4.16 Product Complaints

4.16.1 Complaint Investigation

Cangene will investigate and resolve all medical and non-medical Product complaints.

Patheon will acknowledge receipt of the complaint and will investigate all Product quality complaints related to the Manufacturing Services provided.

Cangene will endeavour to retrieve complaint sample(s) and forward them to Patheon within [**] calendar days whenever possible to facilitate a complete and comprehensive investigation. In the event that the complaint sample cannot be retrieved from the field and forwarded to Patheon within [**] calendar days, Cangene will communicate such to Patheon. If the investigation cannot be completed within [**] calendar days, Patheon will process the complaint investigation per procedure, and provide a copy of the report to Cangene. Should the complaint sample be provided after the initial report has been completed, Patheon will open a second investigation with clear cross reference to the associated investigation (where/if applicable).

Cangene is responsible for responding to the complainant.

4.17 Product Recall/Fields Alerts (US)

4.17.1 Product Recall Notification/Investigation

Cangene will make reasonable efforts to notify Patheon about any Product recall or other regulatory type product notification (e.g. US field alert) as soon as possible and prior to informing the appropriate regulatory authorities. Cangene will be responsible for all related recall activities.

If Patheon discovers, after release and distribution of a batch(es), any finding which impacts, or could impact, on the quality and safety attributes of the batch(es), Patheon will notify Cangene as soon as possible. Patheon will provide its best effort for the recall of the affected batch(es).

Patheon shall proceed with a comprehensive investigation in a timely manner and feedback to Cangene to enable regulatory actions.

4.17.2 Government Agency Notification

Cangene will perform the Product recall and will inform the appropriate regulatory authorities. Where legislated, Patheon reserves the right to notify regulatory authorities of Product quality issues. Patheon will inform Cangene prior to any notification to the regulatory authorities.

4.17.3 Suspected Falsified Medicine/suspected re-packaging failure within parallel importation

If applicable Cangene shall notify immediately Patheon of any suspected falsified Product to enable the investigation in a timely fashion. In the event of the confirmed falsified Product, all appropriate measures to physically and securely segregate it from the legitimate Products supply chain shall be taken and Cangene shall inform the competent authorities.



In the same way, if brought to the attention of Cangene, Cangene shall notify immediately Patheon of any suspected repacking failure which has occurred within a parallel importation procedure.

4.18 Reference and Retention Samples

4.18.1 Excipient and Active Ingredient Reference Sample

Patheon will keep a reference sample of each material supplied to Patheon and used to manufacture the Product (including but not limited to active pharmaceutical ingredients, excipients and packaging materials with the exception of water and compressed gases). The reference sample size will be in agreement with relevant cGMPs, i.e. 21 CFR211.170 and Eudralex Vol.4 Annex 19 or local regulations. The reference sample will consist of at least [**] times the necessary quantity for all Quality Control tests required to determine whether the materials meet required Specifications.

The reference samples will be stored by Patheon under controlled conditions in accordance with GMP storage requirements for [**] beyond the expiration date of the last batch of the product containing the materials. The reference samples will be made available by Patheon to Cangene, if requested.

4.18.2 Packaging Retention Sample

Patheon shall retain the relevant Retain Samples of packaging materials, related to the manufacture, at least [**] after the last batch manufactured with the material has expired.

4.18.3 Finished Product Retention Sample

Retention samples of finished Product will be retained by Patheon for [**] past Product expiry or such longer period as required by law limited to [**] the quantity necessary for Patheon internal testing.

Where applicable, the legal sample(s) of finished Product must be retained by Cangene.

IN WITNESS WHEREOF, the parties have caused their duly authorized officer to execute and deliver this Quality Agreement as of the Effective Date identified on the first page:

Contract Giver:

CNJ Holdings, Inc.

By: /s/ Jeff Broadfoot

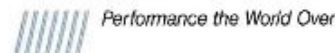
Jeff Broadfoot, Senior Director, Quality Assurance

Date: July 13, 2015

Cangene Corporation, Inc.

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By: /s/ Jeff Broadfoot
Jeff Broadfoot, Senior Director, Quality Assurance

Date: July 13, 2015

CONTRACT ACCEPTOR

Patheon [**]

By: /s/ Alessia D'Ettole
Alessia D'Ettole, Quality Assurance Manager

Date: 25/06/2015

By: /s/ Tiziana Archilletti
Tiziana Archilletti, QA/QC Director

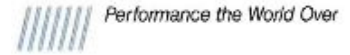
Date: 25/06/15

By: /s/ Alessandro Barbato
Alessandro Barbato, [**] QP

Date: 25-06-2015

Quality
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SECTION 5: APPENDICES

- Appendix A: Product(s) & Markets
- Appendix B: Key Contacts
- Appendix C: Patheon Approved Vendor List
- Appendix D: Customer Approved Vendor List
- Appendix E: Patheon Approved Contract Laboratories List
- Appendix F: Patheon Certificate of Analysis template
- Appendix G: Patheon Certificate of Compliance template
- Appendix H: API Materials EU Requirements

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APPENDIX A: PRODUCT(S)

<u>Products (s)</u>	<u>Galenic Form</u>	<u>Dosage (Strength)</u>	<u>API name</u>
IXINITY TM	[**]	[**] [**]	[**]

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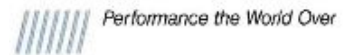
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APPENDIX B: KEY CONTACTS

Responsibility	Patheon		Cangene
	Quality Assurance		General
Name	[**]	[**]	[**]
Title	[**]	[**]	[**]
Phone	[**]	[**]	[**]
Mobile	[**]	[**]	[**]
Fax	[**]	[**]	[**]
E-mail	[**]	[**]	[**]
Address	[**]	[**]	155 Innovation Drive Winnipeg, Manitoba Canada R3T 5Y3
Responsibility	Regulatory Affairs		Regulatory Affairs
	Regulatory Affairs		Regulatory Affairs
Name	[**]	[**]	[**]
Title	[**]	[**]	[**]
Phone	[**]	[**]	[**]
Mobile	[**]	[**]	[**]
Fax	[**]	[**]	[**]
E-mail	[**]	[**]	[**]
Address	[**]	[**]	155 Innovation Drive Winnipeg, Manitoba Canada R3T 5Y3
Responsibility	Product Complaints/Deviations / Documentation		Audits/Product Complaints
	Product Complaints/Deviations / Documentation		Audits/Product Complaints
Name	[**]	[**]	[**]
Title	[**]	[**]	[**]
Phone	[**]	[**]	[**]
Mobile	[**]	[**]	[**]
Fax	[**]	[**]	[**]
E-mail	[**]	[**]	[**]
Address	[**]	[**]	155 Innovation Drive Winnipeg, Manitoba Canada R3T 5Y3

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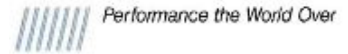


<u>Responsibility</u>	<u>Product Release</u>	<u>Product Release, Deviations, OOS/OOT, Documentation, Inspection Notification</u>
Name	[**]	[**]
Title	[**]	[**]
Phone	[**]	[**]
Mobile	[**]	[**]
Fax	[**]	[**]
E-mail	[**]	[**]
Address	[**] [**] [**] [**]	155 Innovation Drive Winnipeg, Manitoba Canada R3T 5Y3

<u>Responsibility</u>	<u>Business/Account Manager</u>	<u>Project Manager</u>
Name	[**]	[**]
Title	[**]	[**]
Phone	[**]	[**]
Mobile	[**]	[**]
Fax	[**]	[**]
E-mail	[**]	[**]
Address	[**] [**] [**] [**]	155 Innovation Drive Winnipeg, Manitoba Canada R3T 5Y3

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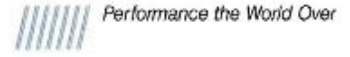


APPENDIX C: PATHEON APPROVED VENDOR LIST

ITEM	SUPPLIER
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

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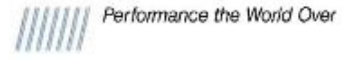


APPENDIX D: CUSTOMER APPROVED VENDOR LIST

ITEM	SUPPLIER
[**]	[**]
[**]	[**]

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APPENDIX E: PATHEON APPROVED CONTRACT LABORATORIES LIST

[**]

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APPENDIX F: PATHEON CERTIFICATE OF ANALYSIS TEMPLATE

CERTIFICATE OF ANALYSIS

Name: IXINITY XXX IU
Specification #: SP- 35XXXX/36XXXX
Version: NN
Category: [**]

Code: 36XXXX
Lot #: xxxxxxxx
Quantity: xxxx vials
Date of Manufacture: dd/mm/yyyy
Recommended storage conditions: 2-8°C

Results

<u>Test Description</u>	<u>Method #</u>	<u>Acceptance Criteria</u>	<u>Results</u>
<description of the test>	<method number>	<acceptance criteria>	<actual results>

Note:

Status

The material identified above has been analyzed and found to be compliant with all approved release requirements.

Approver: Name, Surname

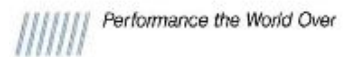
Signature:

Quality
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Quality Control Manager

Date:



APPENDIX G: PATHEON CERTIFICATE OF COMPLIANCE TEMPLATE

INTERIM BATCH CERTIFICATE

IXINITY™ xxxxlU

Batch N.:xxxxxxx

Code: 360xxx

Manufacturing date: dd/mm/yyyy

Quantity: xxxxx

I hereby certify that the above mentioned Batch has been manufactured in the Sterile [] Department of the Pharmaceutical plant of Patheon [**] site, in full compliance with the cGMP requirements (Eudralex Volume 4 and applicable Annexes including but not limited to Ann.1 and Ann.16; US21CFR Parts 210, 211) and applicable Directives (2001/83/EC; 2003/94/EC) of Regulatory Authority as specified in the Quality Agreement. The plant has been approved by the [**].**

The batch also complies with Guideline EMEA/410/01 “Note for guidance on minimising the risk of transmitting animal spongiform encephalopathies”

The documentation of batch manufacturing and process control has been reviewed and found to be in compliance with the above mentioned cGMPs, Product Specifications and Marketing Authorization File issued by the Relavant Regulatory Authorities.

The DS lot number(s) associated to batch manufacture is/are:

Patheon lot number: xxxxx

CMC Biologics lot number: xxxxx

The Bowie Dick test has been carried out one time per day prior to use the autoclave porous load sterilization.

[There have been no deviations impacting product release.]

[Details of deviations (Reference No.....) have been provided and all deviations have been closed.]

Date:

Dr. Alessandro Barbato

[**] Qualified Person

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APPENDIX H: API STARTING MATERIALS EU REQUIREMENTS (2 PAGES)

Cangene is responsible for providing **Patheon** with the following on **any supplied API**:

Registration information

- all registered DS manufacturing sites including addresses & functions;
- approved registered file (CTD module 3.2.S) and any relevant update;
- latest Certificate of suitability to the European Pharmacopoeia (CEP), Active Substance Master File (ASMF) or scientific data in force (as applicable).

Regulatory compliance information

- for DS sourced from US
 - EU Member State or foreign authority GMP certificate or GMP manufacturer declaration ;
- TSE/ BSE (or viral safety where applicable), Residual Solvents, Genotoxic Impurities, Residues of Metal Catalyst and Reagent information as applicable.

Quality compliance information

- Proof of the DS manufacturer GMP/GDP compliance via **audit reports or summary**;
- Well identified and documented DS supply chain (including API manufacturers, brokers, traders, re-packers, re-labellers, micronisers and importers).

Current EU regulation references

- Compilation of the Community Procedures on Inspections and Exchanges of Information (*version in force*):
 - Union format for registration of Manufacturer, Importer or Distributor of Active Substance;
 - Union format for a GMP certificate [including active substances];
 - Union format for a GDP certificate for active substances to be used as starting materials.
- GMP Guide Part I: Basic Requirements for Medicinal Products (**version in force**):
 - Chapter 5: Production ;
 - Chapter 7: Outsourced activities,
- GMP Guide Part II: Basic Requirements for Active Substances used as Starting Material (**version in force**).
- GMP Guide Q&As - Part II: questions 8,9,10 (**version in force**).
- GDP for active substances: [SANCO/D/6/SF/mg/ddg1.d.6(2013)179367] draft (**FEB/2013**).

- Directive 2011/62/EU (**JUL/2011**) articles 46, 46 b (2), 47, 111b and derivative texts:
 - Implementing decision on the assessment of a third country’s regulatory framework applicable to active substances of medicinal products for human use [2013/51/EU] (*JAN/2013*),
 - Template for **written confirmation** [SANCO/SFS/SF/mg/ddg1 .d 6(2013)118630] (*version in force*) & Q&As [SANCO/D/6/] (*version in force*)]
 - Implementing regulation on principles and guideline for GMP for AS [(EU) n°1252/2014] (*MAY/2014*)
- EM A/334808/2014: Qualified Person’s declaration concerning GMP compliance of the active substance manufacture—“The QP declaration template” and guidance for the “QP declaration template EMA/196292/2014 (*version in force*)”.
- EMA/410/01: Note for guidance on guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal product (*version in force*).
- Ph. Eur. 5.2.8: Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.
- EU EMA/CHMP/ICH/82260/2006: (ICH topic Q3C R5) Impurities - guideline for residual solvents (*version in force*) + annexes I & II CPMP/QWP/450/03 (*version in force*)
- Ph. Eur. Chapter 5.4: Residual Solvents,
- EMEA/CHMP/SWP/4446/2000: Guideline on the specification limits for residues of metal catalysts or metal reagents (*version in force*).
- Ph Eur Chapter 5.20: Metal catalyst and metal reagents residues.
- ICHQ3D Draft guideline for elemental impurities (step 4) (*DEC/2014*).
- CPMP/SWP/5199/02 - EMEA/CHMP/QWP/251344/2006: Guideline on the limits of genotoxic impurities (*version in force*) + Q&As EMA/CHMP/SWP/431994/2007 (*version in force*).



●, 2016

Dear Emergent BioSolutions Inc. Stockholder:

In August 2015, we announced our plan to spin off our biosciences business and therefore separate into two publicly-traded companies with distinct strategic plans, growth strategies, and operational and development priorities. We are pleased to report that we are on track to meet our goal of completing this spin-off transaction in mid-2016.

The separation is expected to create two strong, “pure play” companies with focused strategies, and to better align resources to achieve strategic priorities and unlock significant value for both companies.

The new biosciences company, Aptevo Therapeutics Inc., will focus on providing novel oncology and hematology therapeutics to meaningfully improve patients’ lives. The core technology of the biosciences company will be its ADAPTIR platform applied to immuno-oncology. Emergent BioSolutions will continue to operate as a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats.

The spin-off will enable each company to:

- tailor its business strategies to best address opportunities within its target market;
- enhance its business focus and better align resources to achieve strategic priorities;
- pursue distinct capital structures and capital allocation strategies; and
- target investors attracted to its business profile.

The separation will provide current Emergent stockholders with ownership interests in both Emergent and Aptevo. The separation is intended to be tax-free to Emergent stockholders for U.S. federal income tax purposes.

The separation will be in the form of a pro rata distribution of all of the outstanding shares of Aptevo common stock to Emergent stockholders. Each Emergent stockholder will receive ● shares of Aptevo common stock for each share of Emergent common stock held on ●, 2016, the record date for the distribution. You do not need to take any action to receive the common stock of Aptevo to which you are entitled as an Emergent stockholder.

We encourage you to read the attached information statement, which is being provided to all holders of shares of Emergent common stock as of ●, 2016. The information statement describes the separation in detail and contains important business and financial information about Aptevo.

We believe the separation provides tremendous opportunities for our businesses and our stockholders, as we work to continue to build long-term stockholder value. We appreciate your continuing support of Emergent and look forward to your future support of both companies.

Sincerely,

Daniel J. Abdun-Nabi
President and Chief Executive Officer
Emergent BioSolutions Inc.



•, 2016

Dear Future Aptevo Therapeutics Inc. Stockholder:

We are pleased to welcome you as a future stockholder of our new company, Aptevo Therapeutics Inc., a biotechnology company focused on developing novel oncology and hematology therapeutics to meaningfully improve patients' lives.

Our management team is excited for Aptevo to establish itself as a high-growth, "pure play" biotechnology company in the highly attractive immuno-oncology field. Aptevo is well-positioned for the development of bispecific therapeutics, which are antibody-based molecules that are able to bind multiple targets of therapeutic interest, utilizing its innovative ADAPTIR™ (modular protein technology) platform. This allows Aptevo to take a novel approach to cancer immunotherapy.

Aptevo will soon operate independently as a research-based biotechnology company with a sustainable portfolio of commercial products, consisting of WinRho®, HepaGam B®, VARIZIG® and IXINITY®. For our longer-term future, we will seek to continue to build a robust product pipeline, including progressing multiple bispecific therapeutics into pre-clinical and clinical development.

Aptevo's business model is fundamentally different from that of Emergent. The key driver of our success will be the development, commercialization and market penetration of new proprietary therapeutics—discovered or developed in our own laboratories or in collaboration with others. As a result of the separation, our stockholders will be able to evaluate the distinct merits, performance and future prospects of Aptevo.

We have applied to have Aptevo common stock authorized for listing on The NASDAQ Global Market under the symbol "APVO."

We invite you to learn more about Aptevo and our strategic initiatives by reading the attached information statement, which contains important business and financial information about Aptevo. We look forward to our future as a new publicly-traded company and thank you for your trust and support.

Sincerely,

Marvin L. White
Chief Executive Officer

Aptevo Therapeutics Inc.

Information contained herein is subject to completion or amendment. A Registration Statement on Form 10 relating to these securities has been filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

PRELIMINARY AND SUBJECT TO COMPLETION, DATED MAY 31, 2016

INFORMATION STATEMENT

Aptevo Therapeutics Inc.

This information statement is being furnished in connection with the distribution by Emergent BioSolutions Inc. to its stockholders of all of the outstanding shares of common stock of Aptevo Therapeutics Inc., which is currently a wholly-owned subsidiary of Emergent that will hold directly or indirectly certain of the assets and liabilities associated with Emergent's biosciences business. Upon completion of the distribution, Aptevo will become a separate and independent publicly-traded company. To implement the distribution, Emergent will distribute all of the shares of Aptevo common stock on a pro rata basis to Emergent stockholders in a manner that generally is intended to be tax-free for U.S. federal income tax purposes.

For each share of Emergent common stock held of record by you as of the close of business on ●, 2016, the record date for the distribution, you will receive ● shares of Aptevo common stock. You will receive cash in lieu of any fractional shares of Aptevo common stock that you would have received after application of the above ratio. As discussed under "The Separation and Distribution—Trading Between the Record Date and Distribution Date," if you sell your shares of Emergent common stock in the "regular-way" market after the record date and before the distribution date, you also will be selling your right to receive shares of Aptevo common stock in connection with the separation and distribution. Shares of Aptevo common stock are expected to be distributed by Emergent to you on ●, 2016. The date of distribution of the Aptevo common stock is referred to in this information statement as the "distribution date."

No vote of Emergent stockholders is required for the distribution. Therefore, you are not being asked for a proxy, and you are requested not to send Emergent a proxy, in connection with the distribution. You do not need to pay any consideration, exchange or surrender your existing shares of Emergent common stock or take any other action to receive your shares of Aptevo common stock.

There is no current trading market for Aptevo common stock, although Aptevo expects that a limited market, commonly known as a "when-issued" trading market, will develop on or shortly before the record date for the distribution, and that "regular-way" trading of Aptevo common stock will begin on the first trading day following the completion of the distribution. Aptevo has applied to have its common stock authorized for listing on The NASDAQ Global Market under the symbol "APVO." Following the distribution, Emergent common stock will continue to trade on the New York Stock Exchange under the symbol "EBS."

In reviewing this information statement, you should carefully consider the matters described under the caption "Risk Factors" beginning on page 21.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this information statement is truthful or complete. Any representation to the contrary is a criminal offense.

This information statement does not constitute an offer to sell or the solicitation of an offer to buy any securities.

The date of this information statement is ●, 2016.

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Presentation of Information

Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement about Aptevo assumes the completion of all of the transactions referred to in this information statement in connection with the separation and distribution. Unless the context otherwise requires, references in this information statement to “Aptevo,” “we,” “us,” “our,” “our company” and “the company” refer to Aptevo Therapeutics Inc., a Delaware corporation, and its combined subsidiaries as they will exist assuming the completion of all of the transactions referred to in this information statement in connection with the separation and distribution. References to Aptevo’s historical assets, liabilities, products, businesses or activities refer to certain assets, liabilities, products, businesses or activities of Emergent’s biosciences business as the business was conducted as part of Emergent upon completion of the internal reorganization in anticipation of the separation and prior to the completion of the separation. References in this information statement to “Emergent” and “Emergent BioSolutions” refer to Emergent BioSolutions Inc., a Delaware corporation, and its consolidated subsidiaries, unless the context otherwise requires.

“Distribution” or “distribution” refers to the distribution of all of Aptevo’s issued and outstanding shares of common stock to Emergent stockholders as of the close of business on the record date for the distribution.

“Separation” or “separation” refers to the separation of the biosciences business from Emergent and the creation of an independent, publicly-traded company, Aptevo, holding the biosciences business through a distribution of shares of Aptevo common stock to Emergent stockholders as of the close of business on the record date.

Trademarks, Trade Names and Service Marks

Aptevo owns or is pursuing the rights to use the trademarks, service marks and trade names that it uses in conjunction with the operation of its business. Some of the trademarks that Aptevo owns or has rights to use that appear in this information statement include: APTEVO THERAPEUTICS™, APTEVO™, APTEVO BIOTHERAPEUTICS™, APTEVO RESEARCH AND DEVELOPMENT™, ADAPTIR™ (modular protein technology), HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)], VARIZIG® [Varicella Zoster Immune Globulin (Human)], WinRho® SDF [Rho (D) Immune Globulin Intravenous (Human)] and IXINITY® [coagulation factor IX (recombinant)], which may be registered or trademarked in the United States and other jurisdictions. The preceding marks and any and all Aptevo Therapeutics Inc. brand, product, service and feature names, logos and slogans are trademarks or registered trademarks of Aptevo Therapeutics Inc. or its subsidiaries in the United States or other countries. Aptevo’s rights to some of these trademarks may be limited to select markets. Solely for convenience, we only use the ™ or ® symbols the first time any trademark or trade name is mentioned. Each trademark, trade name or service mark of any other company appearing in this information statement is, to Aptevo’s knowledge, owned by such other company.

QUESTIONS AND ANSWERS ABOUT THE SEPARATION AND DISTRIBUTION

What is Aptevo and why is Emergent separating Aptevo’s business and distributing Aptevo’s common stock?

Aptevo, which is currently a wholly-owned subsidiary of Emergent, was formed to hold certain assets of Emergent’s biosciences business. The separation of Aptevo from Emergent and the distribution of Aptevo common stock are intended to provide you with equity investments in two separate and independent publicly-traded companies that will be able to focus on each of their respective businesses. Emergent and Aptevo expect that the separation will result in enhanced long-term performance of each business for the reasons discussed in the section entitled “The Separation and Distribution—Reasons for the Separation.”

[Table of Contents](#)

Why am I receiving this document?

Emergent is delivering this document to you because you are a holder of record of shares of Emergent common stock. If you are a holder of record of shares of Emergent common stock as of the close of business on ●, 2016, you are entitled to receive ● shares of Aptevo common stock for each share of Emergent common stock that you held at the close of business on such date. This document will help you understand how the separation and distribution will affect your investment in Emergent and your investment in Aptevo after the separation.

How will the separation of Aptevo from Emergent work?

As part of the separation, and prior to the distribution, Emergent and its subsidiaries expect to complete an internal reorganization in order to transfer to Aptevo certain assets of the biosciences business that Aptevo will own following the separation. To accomplish the separation, Emergent will distribute all of the outstanding shares of Aptevo common stock to Emergent stockholders on a pro rata basis as a distribution.

Why is the separation of Aptevo structured as a distribution?

Emergent believes that a distribution of shares of Aptevo common stock to the Emergent stockholders in a manner that is generally intended to be tax-free for U.S. federal income tax purposes is an efficient way to separate its biosciences business in a manner that will create long-term value for Emergent, Aptevo and their respective stockholders.

What is the record date for the distribution?

The record date for the distribution will be ●, 2016.

When will the distribution occur?

It is expected that all of the shares of Aptevo common stock will be distributed by Emergent at ● on ●, 2016 to holders of record of shares of Emergent common stock at the close of business on ●, 2016, the record date for the distribution.

What do stockholders need to do to participate in the distribution?

Stockholders of Emergent as of the record date will not be required to take any action to receive Aptevo common stock in the distribution, but you are urged to read this entire information statement carefully. No stockholder approval of the distribution is required. **You are not being asked for a proxy.** You do not need to pay any consideration, exchange or surrender your existing shares of Emergent common stock or take any other action to receive your shares of Aptevo common stock. **Please do not send in your Emergent stock certificates.** The distribution will not affect the number of outstanding shares of Emergent common stock or any rights of Emergent stockholders, although it is expected to affect the market value of each outstanding share of Emergent common stock.

How will shares of Aptevo common stock be issued?

You will receive shares of Aptevo common stock through the same channels that you currently use to hold or trade shares of Emergent common stock, whether through a brokerage account, 401(k) plan or other channel. Receipt of shares of Aptevo common stock will be documented for you in the same manner that you typically receive stockholder updates, such as monthly broker statements and 401(k) statements.

If you own shares of Emergent common stock as of the close of business on the record date, including shares owned in certificated form, Emergent, with the assistance of Broadridge Financial Solutions, Inc., the distribution agent for the distribution, which we refer to as the “distribution agent,” will electronically distribute shares of Aptevo common stock to you or to your brokerage firm on your behalf by way of direct registration in book-entry form. The distribution agent will mail you a book-entry account statement that reflects your shares of Aptevo common stock or your bank or brokerage firm will credit your account for the shares.

How many shares of Aptevo common stock will I receive in the distribution?

Emergent will distribute to you ● shares of Aptevo common stock for each share of Emergent common stock held by you of record as of the close of business on ●, 2016, the record date for the distribution. Based on approximately ● shares of Emergent common stock outstanding as of ●, 2016, a total of approximately ● shares of Aptevo common stock will be distributed. For additional information on the distribution, see “The Separation and Distribution.”

Will Emergent distribute fractional shares of Aptevo common stock in the distribution?

No. Emergent will not distribute fractional shares of Aptevo common stock in the distribution. Fractional shares that Emergent stockholders would otherwise have been entitled to receive will be aggregated and sold in the public market by the distribution agent. The aggregate net cash proceeds of these sales will be distributed pro rata (based on the fractional share such holder would otherwise be entitled to receive) to those stockholders who would otherwise have been entitled to receive fractional shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares.

The receipt of cash in lieu of fractional shares will be taxable for U.S. federal income tax purposes to the recipient. For additional information, see the section entitled “Material U.S. Federal Income Tax Consequences.”

What are the conditions to the distribution?

The distribution is subject to the satisfaction (or waiver by Emergent in its sole and absolute discretion) of a number of conditions, including, among others:

- the continued validity of a private letter ruling received by Emergent from the IRS regarding certain U.S. federal income tax matters relating to the distribution and certain related transactions;
- the receipt of a tax opinion from counsel to Emergent substantially to the effect that, for U.S. federal income tax purposes, the distribution and certain related transactions, taken together, will qualify as a transaction described under Sections 355(a) and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended, or the Code;
- the internal reorganization having been completed and the transfer of certain assets and liabilities of the biosciences business from Emergent to Aptevo having been completed in accordance with the separation agreement;

- no order, injunction, or decree issued by any government authority of competent jurisdiction or other legal restraint or prohibition preventing the consummation of the separation, distribution or any of the related transactions being in effect;
- the actions and filings necessary or appropriate under applicable U.S. federal, U.S. state or other securities laws or blue sky laws and the rules and regulations thereunder having been taken or made, and, where applicable, having become effective or been accepted;
- all governmental approvals necessary to consummate the separation, the distribution and the transactions related thereto and to permit the operation of Aptevo's business after the distribution date having been obtained and being in full force and effect;
- the separation and the distribution not violating or resulting in a breach of applicable law or any material contract of Emergent or Aptevo or any of their respective subsidiaries;
- the approval for listing on The NASDAQ Global Market of the shares of Aptevo common stock to be delivered to the record holders in the distribution having been obtained, subject to official notice of issuance;
- the U.S. Securities and Exchange Commission declaring effective the registration statement on Form 10 of which this information statement is a part, which we refer to as the Form 10, with no order suspending the effectiveness of the Form 10 in effect and no proceedings for such purposes pending before or threatened by the SEC;
- this information statement and such other information concerning Aptevo, its business, operations and management, the distribution and such other matters as Emergent shall determine in its sole and absolute discretion and as may otherwise be required by law having been mailed to the holders of record of Emergent common stock on the record date;
- Emergent's board of directors authorizing and approving the distribution and not having withdrawn such authorization and approval;
- Emergent's board of directors approving the assets and liabilities included in the Aptevo balance sheet; and
- no other events or developments existing or having occurred that, in the judgment of Emergent's board of directors, in its sole and absolute discretion, makes it inadvisable to effect the separation, the distribution or the transactions related thereto.

Emergent and Aptevo cannot assure you that any or all of these conditions will be met, or that the separation and distribution will be consummated even if all of the conditions are met. Emergent can decline at any time to complete the separation. For a complete discussion of all of the conditions to the distribution, see the section entitled "The Separation and Distribution—Conditions to the Distribution."

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<i>What is the expected date of completion of the separation?</i>	The completion and timing of the separation are dependent upon a number of conditions. It is expected that the shares of Aptevo common stock will be distributed by Emergent on ●, 2016 to the holders of record of shares of Emergent common stock at the close of business on the record date. However, no assurance can be provided as to the timing of the separation or that all conditions to the separation will be met.
<i>Can Emergent decide to cancel the distribution of Aptevo common stock even if all the conditions have been met?</i>	Yes. Until the distribution has occurred, Emergent has the right to terminate the distribution, even if all of the conditions are satisfied.
<i>What if I want to sell my Emergent common stock or my Aptevo common stock?</i>	You should consult with your financial advisors, such as your stockbroker, bank or tax advisor.
<i>What is “regular-way” and “ex-distribution” trading of Emergent stock?</i>	Beginning on or shortly before the record date and continuing up to and through the distribution date, it is expected that there will be two markets in shares of Emergent common stock: a “regular-way” market and an “ex-distribution” market. Shares of Emergent common stock that trade in the “regular-way” market will trade with an entitlement to shares of Aptevo common stock distributed pursuant to the distribution. Shares that trade in the “ex-distribution” market will trade without an entitlement to shares of Aptevo common stock distributed pursuant to the distribution. If you decide to sell any shares of Emergent common stock before the distribution date, you should make sure your stockbroker, bank or other nominee understands whether you want to sell your shares of Emergent common stock with or without your entitlement to Aptevo common stock pursuant to the distribution.
<i>Where will I be able to trade shares of Aptevo common stock?</i>	Aptevo has applied for the listing of its common stock on The NASDAQ Global Market under the symbol “APVO.” Aptevo anticipates that trading in shares of its common stock will begin on a “when-issued” basis on or shortly before the record date and will continue up to and through the distribution date and that “regular-way” trading in Aptevo common stock will begin on the first trading day following the completion of the separation. If trading begins on a “when-issued” basis, you may purchase or sell Aptevo common stock up to and through the distribution date, but your transaction will not settle until after the distribution date. Aptevo cannot predict the trading prices for its common stock before, on or after the distribution date.
<i>What will happen to the listing of Emergent common stock?</i>	Shares of Emergent common stock will continue to trade on the NYSE after the distribution.
<i>Will the number of shares of Emergent common stock that I own change as a result of the distribution?</i>	No. The number of shares of Emergent common stock that you own will not change as a result of the distribution.

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Will the distribution affect the market price of my shares of Emergent stock?

Yes. As a result of the distribution, Emergent expects the trading price of shares of Emergent common stock immediately following the distribution to be lower than the “regular-way” trading price of such shares immediately prior to the distribution because the trading price will no longer reflect the value of the biosciences business held by Aptevo. There can be no assurance that the combined aggregate market value of Emergent common stock and Aptevo common stock following the separation will be higher than or equal to the aggregate market value of Emergent common stock if the separation did not occur. This means, for example, that the combined trading prices of one share of Emergent common stock and ● shares of Aptevo common stock after the distribution may be equal to, greater than or less than the trading price of one share of Emergent common stock before the distribution.

What are the material U.S. federal income tax consequences of the distribution?

Assuming that the distribution, together with certain related transactions, qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, no gain or loss should be recognized by, and no amount should be includible in the income of, an Emergent stockholder as a result of the distribution, except to the extent such stockholder receives cash in lieu of fractional shares. An Emergent stockholder will have an aggregate tax basis in the shares of Aptevo common stock received in the distribution and shares of Emergent common stock held immediately after the distribution equal to such stockholder’s aggregate tax basis in the shares of Emergent common stock immediately before the distribution (allocated between the shares of Emergent common stock and Aptevo common stock in proportion to relative fair market values on the distribution date). For more information regarding the material U.S. federal income tax consequences of the distribution, see the section entitled “Material U.S. Federal Income Tax Consequences.”

You should consult your tax advisor about the particular tax consequences of the distribution to you, including the consequences under state, local and non-U.S. tax laws.

What will Aptevo’s relationship be with Emergent following the separation?

Following the separation and distribution, Aptevo and Emergent will operate separately, each as an independent public company. Aptevo will enter into a separation and distribution agreement with Emergent to effect the separation. In connection with the separation, Aptevo will also enter into various other agreements to provide a framework for its relationship with Emergent after the separation, including a non-negotiable promissory note, a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian wholesaler agreement, a trademark license agreement and a product license agreement. These agreements will provide for the allocation between Aptevo and Emergent of Emergent’s assets, employees, liabilities and obligations (including investments, property and employee benefits, and tax-related assets and liabilities) attributable to periods prior to, at and after Aptevo’s separation from Emergent and will govern certain relationships between Aptevo and Emergent after the separation. For additional information regarding the

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separation and distribution agreement and other transaction agreements, see the sections entitled “Risk Factors—Risks Related to the Separation” and “Certain Relationships and Related Party Transactions.”

Following the spin-off, will Aptevo have cash on hand to fund its operating expenses and capital expenditures?

Prior to or upon the completion of the spin-off, Emergent will make a cash capital contribution of \$40 million to Aptevo to fund Aptevo’s operations. In addition, within six to 12 months following the distribution, it is expected that Emergent will transfer to Aptevo an additional \$20 million in cash pursuant to a non-negotiable, unsecured promissory note that Emergent will issue to Aptevo prior to the distribution. This cash capital contribution, together with the cash Aptevo expects to receive under the promissory note, commercial product revenue and partnering revenue, is in an amount that Aptevo estimates will, based on its current plans and expectations, meet its cash needs for at least 12 months after the completion of the spin-off. Prior to or after such time, Aptevo expects that it will be able to access the equity or debt capital markets for additional funding. Aptevo is evaluating entering into a credit facility or other debt financing arrangement with one or more financial institutions that would be entered into in connection with the completion of the spin-off.

Who will manage Aptevo after the separation?

Aptevo will benefit from a management team with a background in the biotechnology industry. Led by Marvin L. White, who will be Aptevo’s Chief Executive Officer after the separation, Aptevo’s management team possesses significant knowledge and experience with our business and in our industry. Aptevo’s executive management team also includes Jeffrey G. Lamothe and Scott C. Stromatt, who have held senior positions of responsibility at Emergent. Dr. Stromatt has served as Chief Medical Officer for the last six years at Emergent and will continue the clinical development programs for the ADAPTIR molecules that he has designed and directed. For more information regarding Aptevo’s management, see “Management.”

Are there risks associated with owning Aptevo common stock?

Yes. Ownership of Aptevo common stock is subject to both general and specific risks relating to Aptevo’s business, the industry in which it operates, its ongoing contractual relationships with Emergent and its status as a separate, publicly-traded company. Ownership of Aptevo common stock is also subject to risks relating to the separation. These risks are described in the “Risk Factors” section of this information statement beginning on page 21. We encourage you to read that section carefully.

Does Aptevo plan to pay dividends?

No. Aptevo currently does not expect that it will pay any dividends. The declaration and payment of any dividends in the future by Aptevo will be subject to the sole discretion of its board of directors and will depend upon many factors. See “Dividend Policy.”

Will Aptevo incur any indebtedness prior to or at the time of the distribution?

No. Aptevo will not incur any indebtedness prior to or at the time of the distribution. However, Aptevo is actively evaluating entering into a credit facility or other debt financing arrangement with one or more financial institutions that would be entered into in connection with the spin-off.

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Who will be the distribution agent, transfer agent and registrar for the Aptevo common stock?

The distribution agent, transfer agent and registrar for the Aptevo common stock will be Broadridge Financial Solutions, Inc. For questions relating to the transfer or mechanics of the distribution, you should contact:

Shareholder Services
Broadridge Corporate Issuer Solutions, Inc.
P.O. Box 1342
Brentwood, NY 11717
Tel: (800) 733-1121
shareholder@broadridge.com

Where can I find more information about Emergent and Aptevo?

If you have any questions relating to Emergent's business performance or, before the distribution, relating to Aptevo's business performance, you should contact:

Emergent BioSolutions Inc.
Investor Relations
400 Professional Drive, Suite 400
Gaithersburg, Maryland 20879
Tel: (240) 631-3280
investorrelations@ebsi.com

After the distribution, if you have any questions relating to Aptevo's business performance, you should contact:

Aptevo Therapeutics Inc.
Investor Relations
2401 4th Ave., Suite 1050
Seattle, Washington 98121
Tel: (206) 838-0500
www.AptevoTherapeutics.com
jlamothe@apvo.com

INFORMATION STATEMENT SUMMARY

The following is a summary of material information discussed in this information statement. This summary may not contain all the details concerning the separation or other information that may be important to you. To better understand the separation and Aptevo's business and financial position, you should carefully review this entire information statement. Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement assumes the completion of all the transactions referred to in this information statement in connection with the separation and distribution. Unless the context otherwise requires, references in this information statement to "Aptevo," "we," "us," "our," "our company" and "the company" refer to Aptevo Therapeutics Inc., a Delaware corporation, and its combined subsidiaries. Unless the context otherwise requires, references in this information statement to "Emergent" refer to Emergent BioSolutions Inc., a Delaware corporation, and its consolidated subsidiaries.

This information statement describes the business to be transferred to Aptevo by Emergent in the separation as if the transferred business were Aptevo's business for all historical periods described. Unless the context otherwise requires, references in this information statement to Aptevo's historical assets, liabilities, products, businesses or activities are generally intended to refer to certain historical assets, liabilities, products, businesses or activities of the biosciences business of Emergent as the business was conducted as part of Emergent prior to completion of the separation.

Our Company

Aptevo Therapeutics Inc. is a biotechnology company focused on novel oncology (cancer) and hematology (blood disease) therapeutics to meaningfully improve patients' lives. Our core technology is the ADAPTIR™ (modular protein technology) platform. We also have four revenue-generating products in the areas of hematology and infectious diseases, as well as various investigational stage product candidates in immuno-oncology. Aptevo, which is currently a wholly-owned subsidiary of Emergent BioSolutions Inc., was formed to own and operate certain assets from the biosciences business of Emergent in connection with the separation and distribution described in this information statement.

We were incorporated in the state of Delaware in February 2016. We have applied for the listing of Aptevo's common stock on the NASDAQ Global Market under the symbol "APVO." Our principal executive offices will be located at 2401 4th Ave., Suite 1050, Seattle, Washington 98121. Our telephone number following the separation will be (206) 838-0500. We will maintain an internet site at www.AptevoTherapeutics.com. Our website and the information contained on the website or connected to the website shall not be deemed to be incorporated into this information statement, and you should not rely on any such information in making an investment decision.

Our Products

Our investigational stage product candidates MOR209/ES414, ES210, ES425 and otlertuzumab are built on our novel ADAPTIR™ (modular protein technology) platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies.¹ The technology can produce monospecific and multispecific

¹ An antibody is a blood protein produced in response to and counteracting a specific antigen, which is a bacteria, virus or other foreign substance that induces an immune response in the body.

immunotherapeutic proteins that specifically bind to one or more targets, for example, bispecific therapeutic molecules, which may have structural advantages over monoclonal antibodies.²

The mechanisms of action for MOR209/ES414, ES210, ES425 and otlertuzumab include redirected T-cell cytotoxicity, or RTCC, by which a therapeutic molecule brings T-cells³ into contact with tumor cells and trigger tumor killing, or targeted delivery of cytokines (or immune modulating protein) to diseased cells. The structural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of new ADAPTIR immunotherapeutics that engage disease targets in a novel manner and produce a unique signaling response. We are skilled at product candidate generation, validation and subsequent pre-clinical and clinical development using the ADAPTIR platform. We have the ability to progress ADAPTIR molecules from concept to marketed product by way of our protein engineering, pre-clinical development and process development capabilities and cGMP manufacturing oversight. We also have the ability to launch, market and commercialize these product candidates upon approval.

Our marketed products are:

- WinRho® SDF [Rh₀(D) Immune Globulin Intravenous (Human)], for treatment of autoimmune platelet disorder, also called immune thrombocytopenic purpura, or ITP,⁴ and, separately, for the treatment of hemolytic disease of the newborn, or HDN;⁵
- HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)], for prevention of hepatitis-B recurrence following liver transplantation in HBsAg-positive liver transplant patients, and for treatment following exposure to hepatitis-B;
- VARIZIG® [Varicella Zoster Immune Globulin (Human)], for treatment following exposure to varicella zoster virus, which causes chickenpox, in high-risk individuals; and
- IXINITY® [coagulation factor IX (recombinant)], indicated in adults and children 12 years of age and older with hemophilia B for control and prevention of bleeding episodes, and management of bleeding during operations.⁶

Our investigational stage product candidates include:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells. It is being developed under our collaboration with MorphoSys AG for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies;

² Monoclonal antibodies are identical antibodies from clones or copies of a unique parent cell that can bind only to one target. A bispecific protein therapeutic can bind to two different targets. Some bispecific protein therapeutics have similar structures to antibodies and are known as “bispecific antibodies.” The function of a bispecific requires two distinct binding domains to perform a unique mechanism that cannot be accomplished by a traditional monospecific antibody.

³ T-cells are a type of white blood cell. T-cells are part of the immune system and develop from stem cells in the bone marrow. They help protect the body from infection and are believed to help fight cancer.

⁴ ITP is a disease in which platelets are destroyed by a patient’s own immune system.

⁵ HDN is a disease in which the mother’s immune system attacks the newborn’s red blood cells.

⁶ Factor IX is a protein produced naturally by the body that assists with blood clotting and wound healing. A deficiency in factor IX protein causes hemophilia B. Some patients with hemophilia B do not naturally produce enough factor IX and can easily be injured. Recombinant factor IX therapeutic provides a benefit to patients by increasing the concentration of factor IX in their blood, which helps the blood form clots to prevent uncontrolled bleeding.

- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease and other autoimmune and inflammatory diseases;
- otlertuzumab, a monospecific ADAPTIR protein therapeutic that is currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL;
- 5E3 mAb, a monoclonal antibody therapeutic that is currently in pre-clinical development for Alzheimer’s disease;
- ES425, a bispecific immunotherapeutic ADAPTIR protein that targets ROR1 (receptor tyrosine kinase-like orphan receptor 1, a protein expressed on solid tumors, leukemias, and lymphomas),⁷ which is currently in pre-clinical development for a variety of hematologic malignancies and solid tumors; and
- Other protein therapeutic product candidates primarily targeting immuno-oncology.

Our Strategies

We seek to grow our business by, among other things:

Advancing our ADAPTIR platform, initially focusing upon immuno-oncology, to develop novel treatments. We intend to focus on product development using ADAPTIR, our modular protein platform technology. We intend to develop the MOR209/ES414 program in collaboration with MorphoSys AG, with the goal of commercializing the product in North America. We plan to select and create bispecific ADAPTIR therapeutics that redirect T-cell cytotoxicity, or RTCC, for early development, potentially with other collaborative partners, to further validate the potential of the ADAPTIR platform and expand the pipeline. As part of the selection process, we intend to strongly favor candidates that we believe have the potential to demonstrate proof of concept early in development. We expect to continue to develop the platform to address unmet medical needs, through directed cytokine delivery via bispecifics in areas including oncology, and multispecific molecules in oncology, autoimmune disease and other therapeutic areas. Our goal is to leverage this technology to seek targeted investment in bispecific ADAPTIR therapeutics.

Continuing to develop new products. We are committed to new product development. We have expertise in molecular biology, antibody engineering and the development of protein therapeutics, including cell line development, protein purification, process development and analytical characterization. We believe that these core areas of expertise enable the development of therapeutics based on the ADAPTIR platform technology from design, pre-clinical testing, and clinical development to preparation of a Biologics License Application, or BLA.

Establishing collaborative partnerships to broaden our pipeline and provide funding for research and development. We intend to continue to develop and grow our product portfolio through internal research and development as well as through collaborations potentially with other biopharmaceutical companies, academia and non-governmental organizations.

Successfully commercializing specialty products to create financial capacity for investment in our pipeline. We intend to continue to expand sales of IXINITY and maximize the financial contribution of our hyperimmune products WinRho, HepaGam B and VARIZIG for the purpose of funding our research and development efforts. We intend to make the investments required to further the launch of IXINITY and to optimize the revenue-generating capacity of our other products.

⁷ ROR1 is an antigen found on several solid tumors and hematologic, or blood-related malignancies.

Risks Related to Our Business, the Separation and our Common Stock

An investment in Aptevo common stock is subject to a number of risks, including risks related to Aptevo's business, risks related to the separation and risks related to Aptevo's common stock. The following list of risk factors is not exhaustive. Please read carefully the information described under "Risk Factors," beginning on page 21 of this information statement, for a more thorough description of these and other risks.

Risks Related to Aptevo's Business

- We have a history of losses and may not be profitable in the future.
- We will require significant additional funding and may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, results of operations and financial condition.
- Our business depends on the continued success of our commercial product portfolio, consisting of WinRho SDF, HepaGam B, VARIZIG and IXINITY.
- Our ability to grow revenues and execute on our long-term strategy depends heavily on our ability to discover, develop, and obtain marketing approval for additional products or product candidates.
- We may not be successful in our efforts to use and further develop our ADAPTIR platform to expand our pipeline of product candidates.
- We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.
- Our Biologic Products may face risks of competition from biosimilar manufacturers.
- The commercial success of our products will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.
- Changes in health care systems and payor reimbursement policies could result in a decline in our potential sales and a reduction in our expected revenue from our products.
- Our revenues also depend on the availability outside the United States of adequate pricing and reimbursement from third-party payors for our current and future drug products, if any.
- If we are not able to convince hospitals and managed care organizations to include our products on their approved formulary lists, our revenues may not meet expectations and our business, results of operations and financial condition may be adversely affected.
- If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations with respect to the purchase of our products, our sales, results of operations and financial condition could be adversely affected.
- We rely on third parties to distribute some of our products and those third parties may not perform.
- Following the separation, the loss of any of our sole source manufacturers, or delays or problems in the manufacture of our products or product candidates, could result in product shortages, leading to lost revenue, and otherwise materially and adversely affect our business, financial condition, results of operations and growth prospects.
- Following the separation, Emergent will continue to own the manufacturing know-how necessary for the manufacture of WinRho SDF, HepaGam B and VARIZIG. If our rights to use this manufacturing know-how are terminated, we will not be able to manufacture these products, which would lead to lost revenue and otherwise materially and adversely affect our business, financial condition, results of operations and growth prospects.

- Manufacturing biologic products, especially in large quantities, is complex and time consuming. Delays or problems in the manufacture of our products or product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects.
- If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, the FDA or their foreign counterparts will not approve their manufacturing facilities, which would result in significant delays in obtaining FDA or foreign marketing approvals for our product candidates.
- If Emergent or other third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations or we are unable to establish or maintain such arrangements, the development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase.
- If we are unable to successfully develop our business infrastructure and operations, our ability to generate future product revenue will be adversely affected.
- We are subject to a number of risks and uncertainties associated with our international activities and operations and may not be successful in our efforts to expand internationally.
- Our long term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize our product candidates and, if we are not successful, our business and operating results may suffer.
- Generally, no product can receive FDA approval, marketing authorization from the European Commission or the competent authorities of the EU Member States, or approval from comparable regulatory agencies in foreign countries unless data generated in human clinical trials demonstrates both safety and efficacy for each target indication in accordance with such authority's standards.
- Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the "off-label" use of any of our products.
- Even after regulatory approval is received, if we, or third parties on whom we rely to manufacture or distribute our products or product candidates, fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market.
- If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.
- If we fail to comply with our obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines.
- The failure to obtain or maintain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business.
- Our international operations increase our risk of exposure to potential claims of bribery and corruption.
- Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.
- The U.S. federal budget sequestration process may have a significant impact on our business.
- Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

- Public concern regarding the safety of drug products could result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.
- Our business depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business would be materially and adversely affected.
- Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products.
- Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.
- We depend on third parties to conduct our clinical and non-clinical trials. If these third parties do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and, as a result, our business may suffer.
- We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.
- If our competitors are able to obtain orphan drug exclusivity for a product that is competitive with one or more of our product candidates and we cannot show that our product candidate is clinically superior, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.
- If we do not obtain orphan drug exclusivity for our drug products, which do not have patent protection, our competitors may then sell the same drug to treat the same condition.
- If we are unable to protect our intellectual proprietary rights, our business could be harmed.
- International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries we may have to expend substantial sums and management resources.
- Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations would be costly, time-consuming, distracting to management and could materially affect our business.
- Our Aptevo trademarks may be opposed which could have a material and adverse effect on our business.
- If a third-party files a trademark infringement claim against us, defending ourselves against such claim could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction and damages, all of which could have a material and adverse effect on our business.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.
- If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

- We may not be successful in establishing and maintaining collaborations that leverage our capabilities in pursuit of developing and commercializing our product candidates.
- We may seek debt financing, which may restrict the operation of our business and limit the cash available for investment in our business operations.
- We may not achieve profitability in future periods or on a consistent basis.
- Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturns.
- Credit and financial market conditions may exacerbate certain risks affecting our business.
- The way that we account for our operational and business activities is based on estimates and assumptions that may differ from actual results.
- We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations.
- We rely significantly on information technology systems and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively or result in data leakage of proprietary and confidential business and employee information.
- Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.
- We are subject to periodic litigation, which could result in losses or unexpected expenditure of time and resources.

Risks Related to the Separation

- Until the separation occurs, Emergent has sole discretion to change the terms of the separation in ways which may be unfavorable to us.
- If the proposed separation is consummated, we may not realize some or all of the anticipated benefits due to a number of factors.
- We have no history operating as an independent company, and our historical and pro forma financial information is not necessarily representative of the results that we would have achieved as a separate, publicly-traded company and may not be a reliable indicator of our future results.
- Emergent may fail to perform under various transaction agreements that will be executed as part of the separation or we may fail to have necessary systems and services in place when certain of the transaction agreements expire.
- As we continue to build our information technology infrastructure and transition our data to our own systems, we could incur substantial additional costs and experience temporary business interruptions.
- Our accounting and other management systems and resources may not be adequately prepared to meet the financial reporting and other requirements to which we will be subject as a standalone publicly-traded company following the distribution.
- In connection with our separation from Emergent, Emergent will indemnify us for certain liabilities and we will indemnify Emergent for certain liabilities. If we are required to pay under these indemnities to Emergent, our financial results could be negatively impacted. The Emergent indemnity may not be sufficient to hold us harmless from the full amount of liabilities for which Emergent will be allocated responsibility, and Emergent may not be able to satisfy its indemnification obligations in the future.

- If the distribution, together with certain related transactions, does not qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, Emergent, Aptevo, and Emergent stockholders could be subject to significant tax liabilities, and, in certain circumstances, we could be required to indemnify Emergent for taxes and related expenses resulting from the failure of the transaction to so qualify.
- We may have received better terms from unaffiliated third parties than the terms we will receive in our agreements with Emergent.
- We expect to incur both one-time and ongoing material costs and expenses as a result of our separation from Emergent, which could adversely affect our results of operations.
- The transfer or assignment to us of certain contracts and other assets requires the consent of a third party. If such consent is not given, we may not be entitled to the benefit of such contracts and other assets in the future.
- If the distribution occurs and you do not want to receive Aptevo common stock in the distribution, your sole recourse will be to divest yourself of your Emergent common stock prior to the record date.
- The combined post-separation value of a share of Emergent common stock and ● shares of Aptevo common stock may not equal or exceed the pre-distribution value of a share of Emergent common stock.
- We may not be able to engage in certain corporate transactions after the separation.
- After the separation, certain of our executive officers and/or directors may have actual or potential conflicts of interest because of their previous positions at Emergent.

Risks Related to Aptevo's Common Stock

- We cannot be certain that an active trading market for our common stock will develop or be sustained after the separation, and following the separation, our stock price may fluctuate significantly.
- The public announcement of data from clinical studies or news of any developments related to our product pipeline may cause significant volatility in our stock price. If the development of any of our key pipeline products is delayed or discontinued, our stock price could decline significantly.
- Your percentage of ownership in Aptevo may be diluted in the future.
- Fuad El-Hibri, the chairman of our Board of Directors, has significant influence over us through his substantial beneficial ownership of our common stock, including an ability to influence the election of the members of our Board of Directors, or delay or prevent a change of control of us.
- Provisions under Delaware law and in our restated certificate of incorporation and amended and restated by-laws may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.
- Our by-laws include an exclusive forum provision that could limit our stockholders' ability to obtain a judicial forum viewed by stockholders as more favorable for disputes with us or our directors, officers or other employees or certain stockholders.
- Because we currently do not expect to pay dividends following the distribution, investors will benefit from an investment in our common stock only if it appreciates in value.
- A significant portion of our shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

The Separation and Distribution

On August 6, 2015, Emergent announced its intention to separate its biosciences business. The separation will occur by means of a pro rata distribution to Emergent stockholders of 100% of the shares of common stock of Aptevo, which was formed to hold certain assets and liabilities of Emergent's biosciences business. In connection with this distribution, we expect that Emergent will complete an internal reorganization, which we refer to as the "internal reorganization". As a result of the internal reorganization, Aptevo will become the parent company of those Emergent operations and will comprise those operations and the entities that will conduct the biosciences business as described in this information statement.

On ●, 2016, the Emergent board of directors approved the distribution of all of the issued and outstanding shares of Aptevo common stock on the basis of ● shares of Aptevo common stock for every share of Emergent common stock held as of the close of business on ●, 2016, the record date for the distribution.

Aptevo's Post-Separation Relationship with Emergent

Following the separation and distribution, Aptevo and Emergent will operate separately, each as an independent public company. Aptevo will enter into a separation and distribution agreement with Emergent to effect the separation. In connection with the separation, Aptevo will also enter into various other agreements to provide a framework for its relationship with Emergent after the separation, including a non-negotiable promissory note, a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian wholesaler agreement, a trademark license agreement and a product license agreement. These agreements will provide for the allocation between Aptevo and Emergent of Emergent's assets, employees, liabilities and obligations (including investments, property and employee benefits, and tax-related assets and liabilities) attributable to periods prior to, at and after Aptevo's separation from Emergent and will govern certain relationships between Aptevo and Emergent after the separation. For additional information regarding the separation agreement and other transaction agreements, see the sections entitled "Risk Factors—Risks Related to the Separation" and "Certain Relationships and Related Party Transactions."

Reasons for the Separation

The Emergent board of directors believes that separating the biosciences business from the biodefense business of Emergent is in the best interests of Emergent and its stockholders for a number of reasons, including the following:

- *Allocation of Capital.* The Emergent board believes that the separation will permit each company to allocate its financial resources in a manner more tailored to its own commercial and strategic priorities and eliminate the competition for capital that has arisen between the two businesses.
- *Targeted Investment Opportunities.* The Emergent board believes that the separation will (1) allow each company to target investors attracted to its business profile, (2) allow investors to separately value each company based on its unique investment identity and (3) attract investors to each company that are not willing to invest in a combined entity but are willing to invest in a distinct "pure play" company.
- *Access to Capital and Acquisition Currency.* The Emergent board believes that the separation will create an independent equity currency for each of Emergent and Aptevo that will afford each company (1) direct, standalone access to the capital markets, (2) the opportunity to capitalize on its unique growth opportunities and (3) facilitate an ability to finance future acquisitions using its capital stock.
- *Management Focus and Operational Efficiency.* The Emergent board believes that the separation will permit the management of each company to tailor business strategies to best pursue targeted

opportunities for long-term growth and profitability and enhance the business focus of each company and better align resources to achieve strategic priorities.

- *Competitive Equity Compensation.* The Emergent board believes that the separation will permit Aptevo to use equity compensation to attract and retain top talent in a manner and degree consistent with its operational priorities and growth prospects and more competitive with its industry peers, and that the separation will better align the value of equity compensation with the performance of the business for which the individual is employed, which is expected to make equity compensation more attractive to potential and existing employees.

The Emergent board of directors also considered a number of potentially negative factors in evaluating the separation, including the following:

- *Increased Administrative Costs.* As a current part of Emergent, Aptevo takes advantage of certain functions performed by Emergent, such as accounting, tax, legal, human resources and other general and administrative functions. After the separation, Emergent will not perform certain of these functions for Aptevo, and, because of Aptevo's smaller scale as a standalone company, Aptevo's cost of performing such functions may be higher than the amounts reflected in Aptevo's historical financial statements, which may adversely affect Aptevo's results of operations.
- *Disruption Related to the Separation.* The actions required to separate Emergent's and Aptevo's respective businesses could disrupt Aptevo's operations.
- *Increased Impact of Certain Costs.* Certain costs and liabilities that were otherwise less significant to Emergent as a whole will be more significant for Aptevo as a standalone company due to Aptevo being smaller than Emergent.
- *Significant Separation Costs.* Emergent and Aptevo will incur costs in connection with the transition to being standalone public companies that may include accounting, tax, legal, and other professional services costs, recruiting and relocation costs associated with hiring key senior management personnel who are new to Aptevo, costs related to establishing a new brand identity in the marketplace, tax costs and costs to separate information systems.
- *Risk of Failure to Achieve Anticipated Benefits of the Separation.* Aptevo may not achieve the anticipated benefits of the separation for a variety of reasons, including, among others: (1) the separation will require significant amounts of management's time and effort, which may divert management's attention from operating and growing its business; and (2) following the separation, Aptevo may be more susceptible to market fluctuations and other adverse events than if Aptevo were still a part of Emergent because its business will be less diversified than Emergent's business prior to the completion of the separation.
- *Limitations on Strategic Transactions.* Under the terms of the tax matters agreement that Aptevo will enter into with Emergent, for a period of two years following the separation, Aptevo will be restricted from taking certain actions that could cause the distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. During this period, these restrictions may limit Aptevo's ability to pursue certain strategic transactions and equity issuances or engage in other transactions that might increase the value of its business.
- *Loss of Scale.* As a current part of Emergent, Aptevo takes advantage of Emergent's size and purchasing power in procuring certain goods and services. After the separation, as a standalone company, Aptevo may be unable to obtain these goods, services, and technologies at prices or on terms as favorable as those Emergent obtained prior to completion of the separation.
- *Loss of Joint Arrangements.* As a current part of Emergent, Aptevo takes advantage of Emergent's overall presence to procure more advantageous distribution arrangements. After the separation, as a

standalone company, Aptevo may be unable to obtain similar arrangements to the same extent as Emergent did, or on terms as favorable as those Emergent obtained, prior to completion of the separation.

- *Uncertainty Regarding Stock Prices.* We cannot predict the effect of the separation on the trading prices of Aptevo or Emergent common stock or whether the combined market value of ● shares of Aptevo common stock and one share of Emergent common stock will be less than, equal to, or greater than the market value of one share of Emergent common stock prior to the distribution.

In determining to pursue the separation, the Emergent board of directors concluded that the potential benefits of the separation outweighed the potential negative factors. See the sections entitled “The Separation and Distribution—Reasons for the Separation” and “Risk Factors” included elsewhere in this information statement.

Corporate Information

Aptevo Therapeutics Inc. was incorporated in Delaware in February 2016 for the purpose of holding certain assets and liabilities of Emergent’s biosciences business in connection with the separation and distribution described in this information statement. Prior to the contribution of this business to Aptevo, which will occur over a period of several months prior to the distribution, Aptevo will have no operations. The address of Aptevo’s principal executive offices will be 2401 4th Ave., Suite 1050, Seattle, Washington 98121. Aptevo’s telephone number following the separation will be (206) 838-0500.

Aptevo will also maintain an internet site at www.AptevoTherapeutics.com. Aptevo’s website and the information contained on the website or connected to the website shall not be deemed to be incorporated into this information statement, and you should not rely on any such information in making an investment decision.

Reason for Furnishing this Information Statement

This information statement is being furnished solely to provide information to stockholders of Emergent who will receive shares of Aptevo common stock in the distribution. It is not and is not to be construed as an inducement or encouragement to buy or sell any of Aptevo’s securities. The information contained in this information statement is believed by Aptevo to be accurate as of the date set forth on its cover. Changes may occur after that date and neither Emergent nor Aptevo will update the information except in the normal course of their respective disclosure obligations and practices.

SUMMARY HISTORICAL AND UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION

The following table sets forth summary historical financial information for the periods indicated below. The summary balance sheet data as of March 31, 2016 and the summary statement of operations data for the three months ended March 31, 2016 and 2015 have been derived from Aptevo's unaudited condensed combined financial statements which are included elsewhere in the information statement. The summary balance sheet data as of December 31, 2015 and 2014 and the summary statement of operations data for the years ended December 31, 2015, 2014 and 2013 have been derived from Aptevo's audited combined financial statements which are included elsewhere in the information statement.

The combined financial statements have been prepared on a "carve-out" basis for the purpose of presenting Aptevo's financial position, results of operations and cash flows. Aptevo did not operate as a standalone entity in the past and accordingly the selected financial data presented herein is not necessarily indicative of Aptevo's future performance and does not reflect what Aptevo's performance would have been had Aptevo operated as an independent publicly-traded company during the periods presented.

The unaudited pro forma combined balance sheet as of March 31, 2016 has been prepared as if the separation had occurred on March 31, 2016. The pro forma adjustments are based on the best information available and assumptions that management believes are reasonable given the information available. The unaudited pro forma financial statement is for illustrative and informational purposes only and is not intended to represent, or be indicative of, what Aptevo's financial position would have been had the separation occurred on the date indicated, nor does it project the financial position at any future date.

The summary financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," the "Unaudited Pro Forma Combined Balance Sheet", and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

(in thousands)	Three Months Ended March 31,		Year Ended December 31,		
	2016	2015	2015	2014	2013
Statements of Operations Data:					
Revenues	\$ 8,067	\$ 11,663	\$ 33,601	\$ 45,631	\$ 170
Loss from operations	(12,982)	(11,102)	(61,100)	(51,492)	(53,355)
Net loss	(12,890)	(11,022)	(59,317)	(51,115)	(53,337)
(in thousands)	As of March 31, Pro Forma		As of December 31,		
	2016	2016	2015	2014	2013
Balance Sheet Data:					
Cash and cash equivalents	\$ 40,000	\$ 3,072	\$ 4,637	\$ 3,593	\$ —
Total assets	136,589	112,605	112,456	119,971	50,528
Total long-term liabilities	4,053	4,053	3,895	5,528	18
Total stockholders' equity	[•]	89,862	88,618	94,608	44,544

RISK FACTORS

You should carefully consider the following risks and other information in this information statement in evaluating Aptevo and Aptevo's common stock. Any of the following risks could materially and adversely affect Aptevo's results of operations, financial condition or financial prospects. The risk factors generally have been separated into three groups: risks related to Aptevo's business, risks related to the separation and risks related to Aptevo's common stock.

RISKS RELATED TO APTEVO'S BUSINESS

Operating Risks

We have a history of losses and may not be profitable in the future.

Our historical combined financial data was carved out from the financial information of Emergent and shows that had we been a standalone company, we would have had a history of losses, and we may be unable to achieve or sustain profitability going forward.

For the quarter ended March 31, 2016, we incurred a net loss of \$12.9 million and had an accumulated deficit of \$244.9 million as of March 31, 2016. For the years ended December 31, 2015, 2014 and 2013, we incurred a net loss of \$59.3 million, \$51.1 million and \$53.3 million, respectively.

For the quarter ended March 31, 2016, net cash used in our operating activities was \$14.1 million. For the years ended December 31, 2015, 2014 and 2013, net cash used in our operating activities was \$48.8 million, \$47.0 million and \$51.4 million, respectively. If we cannot achieve or sustain profitability or generate positive cash from operating activities, our business operations may be adversely impacted and the trading value of our common stock may decline.

We will require significant additional funding and may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, results of operations and financial condition.

In accordance with the separation agreement, Emergent has committed to provide us with a total of approximately \$60 million in cash funding. Emergent will provide us with a cash contribution of \$40 million prior to or upon the completion of the separation to be used to fund our operations. Within six to 12 months following the distribution, it is expected that Emergent will transfer to us an additional \$20 million in cash pursuant to a non-negotiable, unsecured promissory note that Emergent will issue to us prior to the distribution. Emergent's ability to satisfy its obligations under the promissory note will be subject to, among other things, Emergent's capital availability and cash flow following the distribution. As a result, there can be no assurance that we will receive all or any portion of the \$20 million contemplated by the promissory note. For further discussion of this funding arrangement, see "Certain Relationships and Related Party Transactions—Funding Arrangement." In addition to the anticipated cash transfers from Emergent in connection with the separation, in the future we will require significant additional funding to grow our business, including to develop additional products, support commercial marketing activities or otherwise provide additional financial flexibility. Aptevo is evaluating entering into a credit facility or other debt financing arrangement with one or more financial institutions that would be entered into in connection with the completion of the spin-off. There can be no assurance that any such credit facility or other debt financing arrangement will be obtained on favorable terms or at all.

Following the separation, we expect to have approximately \$40 million of cash and cash equivalents. Our future capital requirements will depend on many factors, including, among others:

- the level, timing and cost of product sales;
- the collection of accounts receivable from customers;

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- the extent to which we invest in products or technologies;
- the ability to secure partnerships and/or collaborations;
- capital improvements to new or existing facilities;
- the payment obligations under any future indebtedness;
- the scope, progress, results and costs of our development activities;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs associated with the separation from Emergent and costs associated with performance under agreements to be entered into with Emergent; and
- the costs associated with replicating or outsourcing from other providers certain facilities, systems, operational and administrative infrastructure, including information technology infrastructure, and personnel, to which we will no longer have access after our separation from Emergent.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through bank loans, public or private equity or debt offerings or collaboration and licensing arrangements. Public or bank debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds by issuing equity securities, our stockholders may experience dilution. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Furthermore, to preserve the tax-free treatment to Emergent and its stockholders of the distribution, together with certain related transactions, we will be restricted, under the tax matters agreement that we will enter into with Emergent, from taking any action that prevents such transactions from being tax-free for U.S. federal income tax purposes, including restrictions on equity capital market transactions, as discussed in greater detail in the risk factor below entitled “*We may not be able to engage in certain corporate transactions after the separation*” and the section entitled “Certain Relationships and Related Party Transactions—Tax Matters Agreement.”

Current economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, results of operations, financial condition and financial prospects would be adversely affected and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Our business depends on the continued success of our commercial product portfolio, consisting of WinRho SDF, HepaGam B, VARIZIG and IXINITY.

Our ability to maintain and grow revenues depends significantly on the success of our marketed products, and critical factors in such success include the continued acceptance by the medical community and the future market demand and medical need for our marketed products. If we are unable to continue to maintain and grow revenues from product sales, our future operating results and financial condition could be adversely affected.

Our commercial portfolio consists of four revenue-generating products, consisting of WinRho SDF, HepaGam B, VARIZIG and IXINITY. We expect revenues from our product sales to continue to account for a significant portion of our revenue following the separation. The commercial success of our marketed products depends upon:

- the continued acceptance by regulators, physicians, patients and other key decision-makers of our products as safe, therapeutic and cost-effective options;

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- our ability to further develop our products and obtain marketing approval for their use in additional patient populations and the clinical data we generate to support expansion of the product label;
- the ability of Emergent and our other third-party manufacturing partners to provide us with sufficient saleable quantities of our marketed products;
- the impact of competition from existing competitive products and from competitive products that may be approved in the future;
- the continued safety and efficacy of our marketed products;
- to what extent and in what amount government and third-party payors cover or reimburse for the costs of our marketed products; and
- our success and the success of our third-party distributors in selling and marketing our products, including in countries outside the United States.

The failure to maintain or increase revenue from sales of our products could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We may choose to increase the price of our products, and these price adjustments may negatively affect our sales volumes. In addition, our product sales may fluctuate significantly from quarter to quarter, depending on the number of patients receiving treatment, the availability of supply to meet the demand for the product, the dosing requirements of treated patients and other factors. If sales of our commercial products were to decline, we could be required to make an allowance for excess or obsolete inventory, increase our provision for product returns, or we could incur other costs related to operating our business, each of which could negatively impact our results of operations and our financial condition.

Commercialization Risks

Our ability to grow revenues and execute on our long-term strategy depends heavily on our ability to discover, develop, and obtain marketing approval for additional products or product candidates.

In order for us to achieve our long-term business objectives, we will need to successfully discover and/or develop and commercialize additional products or product candidates. Although we have made, and expect to continue to make, significant investments in research and development, we have had only a limited number of our internally-discovered product candidates reach the clinical development stage. Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure. The failure by us to successfully discover and/or develop, obtain marketing approval for and commercialize additional products and product candidates would likely have a material adverse effect on our ability to grow revenues and improve our financial condition.

We may not be successful in our efforts to use and further develop our ADAPTIR platform to expand our pipeline of product candidates.

A key element of our strategy is to expand our product pipeline of immuno-therapeutics based on our ADAPTIR platform technology. We plan to select and create redirected T-cell cytotoxicity, or RTCC, candidates for early development, potentially with other collaborative partners. We expect to continue to develop the platform to address unmet medical needs through directed cytokine delivery via bispecifics in areas including oncology, and multispecific molecules in oncology, autoimmune disease and other therapeutic areas. Our goal is to leverage this technology to seek targeted investment in bispecific ADAPTIR therapeutics. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based on our ADAPTIR platform technology, our ability to obtain product revenues in future periods may be adversely affected, which likely would result in harm to our financial position and our financial prospects and adversely affect our stock price.

We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

The development and commercialization of new biotechnology products is highly competitive and subject to rapid technological advances. We may face future competition with respect to our products, our current product candidates and any product candidates we may seek to develop or commercialize in the future obtained from other companies and governments, universities and other non-profit research organizations. Our competitors may develop products that are safer, more effective, more convenient or less costly than any products that we may develop or market, or may obtain marketing approval for their products from the U.S. Food and Drug Administration, or the FDA, or equivalent foreign regulatory bodies more rapidly than we may obtain approval for our products. Our competitors may devote greater resources to market or sell their products, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully than we can, or more effectively negotiate third-party licensing and collaborative arrangements. Many of our competitors are substantially larger than we are and have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

We believe that our most significant competitors in the hematology/oncology, inflammation and transplantation markets include: AbbVie Inc., Affirmed N.V., Amgen Inc., Baxter International Inc., Bayer AG, Biogen Idec Inc., Boehringer Ingelheim GmbH, CSL Behring, a subsidiary of CSL Limited, Genentech Inc. (a subsidiary of F. Hoffmann-La Roche Ltd.), Gilead Sciences, Inc., GlaxoSmithKline plc, Grifols USA LLC, Johnson & Johnson, MacroGenics, Inc., Novartis International AG, Pfizer Inc., Takeda Pharmaceuticals U.S.A., Inc., Xencor, Inc. and Zymeworks Biopharmaceuticals, Inc. We compete, in the case of our approved and marketed products, and expect to compete, in the cases of our products in development, on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed. If we are not successful in demonstrating these attributes, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition and results of operations. See “Business—Competition” for a more detailed description of the competition for our other products and products in development.

Any reduction in demand for our products as a result of a competing product could adversely affect our results of operations and lead to loss of market share for our products. These competitive pressures could adversely affect our business and operating results.

In addition, many of our competitors are able to deploy more personnel to market and sell their products than we do. We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other biotechnology companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization internationally, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization. We may not be able to achieve any necessary growth in a timely or cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all. We also have to compete with other biotechnology and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect sales of our products. If our specialty sales force and sales organization are not appropriately-sized to adequately promote any current or potential future products, the commercial potential of our current products and any future products may be diminished. We compete with a significant number of pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in the hematology/oncology markets, and our failure to compete effectively in this area could negatively affect our sales of our commercial products.

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Our products and product candidates may also compete in the future with new products currently under development by others. Any products that we develop are likely to be in a highly competitive market, and many of our competitors may succeed in developing products before we do or in developing products that may render our products obsolete or noncompetitive.

Our Biologic Products may face risks of competition from biosimilar manufacturers.

Competition for WinRho SDF, HepaGam B, VARIZIG and IXINITY, or our Biologic Products, may be affected by follow-on biologics, or biosimilars, in the United States and other jurisdictions. Biologics are medical products made from a variety of natural sources (human, animal or microorganism) intended to prevent, diagnose or treat diseases and medical conditions.

In the U.S., biosimilars are biologics that are highly similar to licensed reference biological products, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety, purity and potency. Regulatory and legislative activity in the United States and other countries may make it easier for our competitors to manufacture and sell biosimilars of our Biologic Products, which might affect our results of operations or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve an application for a biosimilar until the 12-year exclusivity period for the reference product has expired. Thus, if a competitor were to seek regulatory approval for a biosimilar product citing IXINITY as the reference product, such approval could not be granted until April 2027.

Regulators in the European Union review biosimilar products using a similar regulatory process, although the European Medicines Agency, or EMA, has expressly excluded blood or plasma-derived products from the biosimilar process for a period of time. WinRho SDF, HepaGam B, VARIZIG and IXINITY have not received marketing authorization by the EMA. HepaGam B, VARIZIG and IXINITY are not sold in Europe. WinRho SDF is sold in Portugal, with insignificant revenues to date, but the approval is a country-specific approval. Even if WinRho SDF, HepaGam B or VARIZIG receive EMA marketing authorization, it will not be possible for a follow-on product to seek approval using the EMA biosimilar process due to the exclusion of blood or plasma-derived products from the process.

Similarly, if a competitor were to seek regulatory approval for a biosimilar product citing HepaGam B or VARIZIG as the reference product, such approval could not be granted until January 2018 and December 2024, respectively. A biosimilar application citing WinRho SDF as the reference product could be approved at any time. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business and operating results.

The commercial success of our products will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

The success of our products, including our hyperimmune specialty products, will depend upon, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If any of our products do not achieve and maintain an adequate level of acceptance, we may not generate material revenues from sales of these products. The degree of market acceptance of our products will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the ability to offer our products for sale at competitive prices;

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- our ability to continuously supply the market without interruption;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try new products and of physicians to prescribe these products;
- the strength of marketing and distribution support;
- publicity concerning our products or competing products and treatments; and
- the sufficiency of coverage or reimbursement by third parties.

If our products and product candidates do not gain or maintain market acceptance, or do not become widely accepted, by physicians, patients, third-party payors and other members of the medical community, our business, financial condition and operating results could be materially and adversely affected.

Changes in health care systems and payor reimbursement policies could result in a decline in our potential sales and a reduction in our expected revenue from our products.

The revenues and profitability of biotechnology companies like ours may be affected by the continuing efforts of government payors, including Medicare and Medicaid, and other third-party payors to contain or reduce the costs of health care through various means. For example, in certain foreign markets, the pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. Recent U.S. legislation, rules and regulations instituted significant changes to the U.S. healthcare system that could have a material adverse effect on our business, financial condition and results of operations. The trend toward managed health care in the United States, as well as the implementation of the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act), collectively referred to as the Affordable Care Act, and the concurrent growth of organizations such as managed care organizations, accountable care organizations and integrated delivery networks, may result in increased pricing pressures for pharmaceutical products, including any products that may be offered by us in the future. Cost-cutting measures that health care providers are instituting, and the implementation of health care reform, could adversely affect our ability to sell any drug products that are successfully developed by us. We cannot predict what effects, if any, this legislation might have on our company and our products as this legislation continues to be further implemented over the next few years, nor can we predict whether additional legislative or regulatory proposals may be adopted.

In the United States and internationally, sales of our products and our ability to generate revenues on such sales are dependent, in significant part, on the availability and level of reimbursement from third-party payors, including state and federal governments and private insurance plans. Insurers have implemented cost-cutting measures and other initiatives to enforce more stringent reimbursement standards and likely will continue to do so in the future. These measures include the establishment of more restrictive formularies and increases in the out-of-pocket obligations of patients for such products. Third-party payors are also increasingly challenging the prices charged for medical products and services. Third-party payors may limit access to biotechnology products through the use of prior authorizations and step therapy. Any reimbursement granted may not be maintained, or limits on reimbursement available from third parties, may reduce the demand for or negatively affect the price and potential profitability of those products. If these payors do not provide sufficient coverage and reimbursement for our marketed products or any future drug product we may market, these products may be too costly for general use, and physicians may prescribe them less frequently. Our ability to successfully commercialize our products and product candidates and the demand for our products depends, in part, on the extent to which reimbursement and access is available from such third-party payors.

In addition, particularly in the United States and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our

products that are reimbursed by such entities. Various provisions of the Affordable Care Act increased the levels of rebates and discounts that we have to provide in connection with sales of such products that are paid for, or reimbursed by, certain state and federal government agencies and programs. It is possible that future legislation in the United States and other jurisdictions could be enacted, which could potentially impact the reimbursement rates for our products and also could further impact the levels of discounts and rebates we are required to pay to state and federal government entities.

Certain government pricing programs, including Medicare Part B, the Medicaid rebate program, the 340B/PHS drug pricing program and Federal Supply Schedule, affect the revenues that we derive from WinRho SDF, HepaGam B, VARIZIG and IXINITY. Any future legislation or regulatory actions altering these programs or imposing new ones could have an adverse impact on our business. There have been, and we expect there will continue to be, a number of legislative and regulatory actions and proposals to control and reduce health care costs. These measures may, among other things: negatively impact the level of reimbursement for pharmaceutical products; require higher levels of cost-sharing by beneficiaries; change the discounts required to be provided to government payors and/or providers; extend government discounts to additional government programs and/or providers; or reduce the level of reimbursement for health care services and other non-drug items. Any such measures could indirectly affect demand for pharmaceutical products because they can cause payors and providers to apply heightened scrutiny and/or austerity actions to their entire operations, including pharmacy budgets.

Our revenues also depend on the availability outside the United States of adequate pricing and reimbursement from third-party payors for our current and future drug products, if any.

Outside the United States, certain countries, including a number of EU Member States, set prices and reimbursement for pharmaceutical products, or medicinal products as they are commonly referred to in the European Union, with limited participation from the marketing authorization holders. We cannot be sure that these prices and reimbursement will be acceptable to us or our collaborative partners. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement that are not commercially attractive for us or our collaborative partners, our revenues from sales by us or our collaborative partners, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union.

If we are not able to convince hospitals and managed care organizations to include our products on their approved formulary lists, our revenues may not meet expectations and our business, results of operations and financial condition may be adversely affected.

Hospitals and managed care organizations establish formularies, which are lists of drugs approved for use in the hospital or under a managed care plan. If a drug is not included on the formulary, the ability of our engagement partners and engagement managers to promote and sell the drug may be limited or denied. If we fail to secure and maintain formulary inclusion for our products on favorable terms or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our products and our business, results of operations and financial condition could be materially adversely affected.

If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations with respect to the purchase of our products, our sales, results of operations and financial condition could be adversely affected.

Our ability to sell our products, including WinRho SDF, HepaGam B and IXINITY, to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and

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contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors. These negotiated prices are then made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts on the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

We rely on third parties to distribute some of our products and those third parties may not perform.

A portion of our revenues from product sales is derived from sales through exclusive distributors in Canada and international markets. For example, in Canada, only two distributors have rights to our WinRho SDF, HepaGam B and VARIZIG products. As a result, we rely on the sales and marketing strength of these distributors and the distribution channels through which they operate for a portion of our revenues. We may not be able to retain these distribution relationships indefinitely and these distributors may not adequately support the sales, marketing and distribution efforts of our products in these markets. If third parties do not successfully carry out their contractual duties in maximizing the commercial potential of our products, or if there is a delay or interruption in the distribution of our products, it could negatively impact our revenues from product sales.

Following the separation, the loss of any of our sole source manufacturers, or delays or problems in the manufacture of our products or product candidates, could result in product shortages, leading to lost revenue, and otherwise materially and adversely affect our business, financial condition, results of operations and growth prospects.

We will not have manufacturing capabilities following the separation and do not plan to develop such capacity in the foreseeable future. We will depend on a limited number of sole source third-party manufacturers, including Emergent, for each of our products and product candidates. Accordingly, our ability to develop and deliver products in a timely and competitive manner will depend on our third-party manufacturers being able to continue to meet our ongoing commercial and clinical trial needs and perform their contractual obligations. We currently have a limited ability to control the manufacturing process or costs related to the manufacture of our products. Increases in the prices we pay our manufacturers, interruptions in the supply of raw materials or our products themselves or lapses in quality could adversely impact our margins, profitability, cash flows and prospects. We rely on our third-party manufacturers to maintain the facilities at which they manufacture our products or product candidates in compliance with all FDA and other applicable regulatory requirements. If these manufacturers fail to maintain compliance with FDA or other applicable regulatory requirements, they could be ordered to cease manufacturing, which could have a material adverse effect on our revenues and operating results.

If, for any reason, Emergent or our other manufacturers do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our manufacturing arrangements, we may not have adequate remedies for any breach of contract, and their failure to supply us could result in a shortage of our products or product candidates, which could lead to lost revenue and otherwise adversely affect our business, financial condition, results of operations and growth prospects. In addition, if any of our manufacturers fails or refuses to supply us for any reason, we may be forced to consider entering into additional manufacturing arrangements with other third-party manufacturers. In each case, we will incur significant costs and time in obtaining the regulatory approvals for these third-party facilities and in taking the necessary steps to prepare these third parties for the manufacture of our products. Because of contractual restraints and the lead-time necessary to obtain FDA approval of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of these products to our customers, and we may be unable to obtain alternative manufacturing or supply on commercially reasonable terms on a timely basis or at all.

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For example, CMC ICOS Biologics, Inc., or CMC, is the exclusive manufacturer of bulk drug substance for our IXINITY product. During 2015, we ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. We continue to work with CMC to resolve the manufacturing delays, although to date in 2016 no lots of bulk drug substance have been successfully manufactured and released. Additionally, Patheon UK Limited, through an affiliate, is currently the sole source fill-finish service manufacturer for our IXINITY product. The release of drug product by Patheon may be impacted by several factors, including Patheon requiring approval from its affiliate's foreign regulatory authority of recent changes to its facility. If current efforts to proceed with the manufacturing and release of bulk drug substance and filled product are not successful, the resulting lack of supply of bulk drug substance or filled product could lead to a projected supply shortage of IXINITY requiring notification to the FDA. This inability to supply IXINITY would adversely affect its sales, market position and viability.

Following the separation, Emergent will continue to own the manufacturing know-how necessary for the manufacture of WinRho SDF, HepaGam B and VARIZIG. If our rights to use this manufacturing know-how are terminated, we will not be able to manufacture these products, which would lead to lost revenue and otherwise materially and adversely affect our business, financial condition, results of operations and growth prospects.

Emergent will continue to own its human hyperimmune platform manufacturing know-how, which is necessary for the manufacture of WinRho SDF, HepaGam B and VARIZIG. At or prior to the separation, we expect to enter into a manufacturing services agreement with Emergent with respect to the manufacturing of these products. We also expect to enter into a product license agreement with Emergent pursuant to which Emergent will grant to Aptevo an exclusive royalty-free, worldwide license, under certain licensed intellectual property rights, to research, develop, make, have made, use, sell, offer to sell and import WinRho SDF, HepaGam B, and VARIZIG. Under the product license agreement, we will only be permitted to exercise rights with respect to Emergent's human hyperimmune platform manufacturing know-how through a third-party contract manufacturer, and then only if the manufacturer is bound to protect the manufacturing know-how and is either approved by Emergent (in Emergent's sole and absolute discretion) or there has been a manufacturing failure under the manufacturing services agreement.

Emergent will have the right to terminate the product license agreement upon breach by us of any of its terms, including our confidentiality obligations and other obligations, if such breach is not cured within a specified period of time or is incurable. If the product license agreement is terminated, we will no longer be able to research, develop, make, have made, use, sell, offer to sell and import WinRho SDF, HepaGam B and VARIZIG, which would lead to lost revenue and otherwise materially and adversely affect our business, financial condition, results of operations and growth prospects.

Manufacturing biologic products, especially in large quantities, is complex and time consuming. Delays or problems in the manufacture of our products or product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects.

WinRho SDF, HepaGam B, VARIZIG and IXINITY and all of our current product candidates are biologics. The products must be made consistently and in compliance with a clearly defined manufacturing process. Problems may arise during manufacturing for a variety of reasons, including problems with raw materials, equipment malfunction or replacement and failure to follow specific protocols and procedures. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation and contamination including from, among other things, particulates, filtration, filling, labeling, packaging, storage and shipping, and quality control testing, may result in lot failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action.

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If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, the FDA or their foreign counterparts will not approve their manufacturing facilities, which would result in significant delays in obtaining FDA or foreign marketing approvals for our product candidates.

Following the separation, we will rely on third parties to manufacture all clinical trial materials for our product candidates, and we will rely on third parties to manufacture commercial supplies, if any such product candidates are ultimately approved for commercial sale. Our product candidates, including MOR209/ES414, ES210, ES425, otlertuzumab and 5E3, will not be approved for marketing by the FDA or other foreign regulatory authorities unless the FDA or their foreign equivalents also approve the facilities used by our third-party manufacturers to produce them for commercialization. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, the FDA or their foreign counterparts will not approve their manufacturing facilities, which would result in significant delays in obtaining FDA or foreign marketing approvals for our product candidates. In order to successfully develop and commercialize our product candidates in a timely manner, we and our third-party manufacturers must be able to develop and execute on manufacturing processes, and reach agreement on contract terms, for each candidate that will:

- be approved by the FDA and/or other regulatory authorities in the countries where such candidates are to be manufactured or sold;
- provide sufficient quantities of such candidate to meet our clinical trial needs and ultimate market demand; and
- provide such amounts at a cost that will allow us to potentially make an adequate profit.

We and our third-party manufacturers may not be able to meet these manufacturing process requirements for any of our current product candidates, including MOR209/ES414, ES210, ES425, otlertuzumab and 5E3, all of which have complex manufacturing processes, which make meeting these requirements even more challenging. If we are unable to develop manufacturing processes for our clinical product candidates that satisfy these requirements, we will not be able to supply sufficient quantities of test material to conduct our clinical trials in a timely or cost effective manner, and as a result, our development programs will be delayed, our financial performance will be adversely impacted and we will be unable to meet our long-term goals.

If Emergent or other third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations or we are unable to establish or maintain such arrangements, the development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase.

Our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage or conduct our clinical trials, manufacture our products and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct all of these activities for all products and product candidates on our own and, as a result, are particularly dependent on third parties in many areas.

We may not be able to maintain our existing arrangements with respect to the commercialization or manufacture of our products or establish and maintain arrangements to develop, manufacture and commercialize our products in development on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to our products or our products in development, our results of operations would be materially and adversely affected.

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Third parties may not perform their contractual obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Our collaborative partners may develop, manufacture or commercialize, either independently or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Our collaborative partners may reevaluate their priorities from time to time, including following mergers and consolidations, and change the focus of their development, manufacturing or commercialization efforts. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third-party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to commit sufficient resources to our collaboration or conduct its activities in a timely manner, or fails to comply with regulatory requirements, such breach, termination or failure could:

- delay or otherwise adversely impact the manufacturing, development or commercialization of our products, our products in development or any additional products or product candidates that we may develop;
- require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or
- result in the termination of the development or commercialization of our products.

If we are unable to successfully develop our business infrastructure and operations, our ability to generate future product revenue will be adversely affected.

Our ability to support the sales and marketing of our products in the United States and globally will depend on our ability to properly scale our internal organization and infrastructure to accommodate the development and, upon approval, commercialization of our products and products in development. To manage our existing and planned future growth and the increasing breadth and complexity of our activities, we need to properly invest in personnel, infrastructure, information management systems and other operational resources. Developing our business infrastructure and operations may be more difficult, more expensive or take longer than we anticipate. We may also need to revise our strategy for developing the proper infrastructure and operations periodically.

Future development of our business infrastructure and operations could strain our operational, human and financial resources. In order to manage the development of our business infrastructure and global operations, we must:

- continue to improve operating, administrative, and information systems;
- accurately predict future personnel and resource needs to meet contract commitments;
- track the progress of ongoing projects; and
- attract and retain qualified management, sales, professional, scientific and technical operating personnel.

If we do not take these actions and are not able to manage our business, then our operations may be less successful than anticipated.

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We are subject to a number of risks and uncertainties associated with our international activities and operations and may not be successful in our efforts to expand internationally.

We currently have limited operations outside of the United States and Canada. However, we have manufacturing, collaboration, clinical trial and other relationships outside the United States, and our products are marketed internationally through collaborations. We may seek to grow our international operations significantly over the next several years. Our future results of operations will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Europe. Our foreign operations subject us to additional risks and uncertainties, particularly because we have limited experience in marketing, servicing and distributing our products or otherwise operating our business outside of the United States and Canada. These risks and uncertainties include:

- the fact that we have limited experience operating our business internationally;
- unexpected adverse events related to our products or product candidates that occur in foreign markets that we have not experienced in the United States;
- political and economic determinations that adversely impact pricing or reimbursement policies;
- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- compliance with complex and changing foreign legal, tax, accounting and regulatory requirements;
- cross border restrictions on the movement of cash funds and repatriation of earnings;
- language barriers and other difficulties in providing long-range customer support and service;
- longer accounts receivable collection times;
- trade restrictions and restrictions on direct investment by foreign entities;
- reduced protection of intellectual property rights in some foreign countries;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- significant foreign currency fluctuations, which could result in increased or unpredictable operating expenses and reduced revenues;
- local, economic and political conditions, including geopolitical events, such as war and terrorism; and
- compliance with foreign or U.S. laws, rules and regulations, including data privacy requirements, labor relations laws, tax laws, anti-competition regulations, anti-bribery/anti-corruption laws, including but not limited to the FCPA and the Bribery Act in the UK, which could subject us to investigation or prosecution under such foreign or U.S. laws.

Our foreign operations could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations. These and other risks associated with our international operations may materially adversely affect our business and results of operations.

Regulatory and Compliance Risks

Our long term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize our product candidates and, if we are not successful, our business and operating results may suffer.

Our product candidates and the activities associated with their development, including testing, manufacture, recordkeeping, storage and approval, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Generally, failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We

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have limited resources for use in preparing, filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

The FDA, the European Commission, the EMA, the competent authorities of the EU Member States and other comparable regulatory agencies in foreign countries impose substantial and rigorous requirements for the development, production, marketing authorization and commercial introduction of drug products. These requirements include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory authorities, including the FDA, the European Commission, the EMA and the competent authorities of the EU Member States, evolve in their staff interpretations and practices and may impose more stringent or different requirements than currently in effect, which may adversely affect our planned and ongoing drug development and/or our sales and marketing efforts.

In the United States, to obtain approval from the FDA to market any of our future biologic products, we will be required to submit a biologics license application, or BLA, to the FDA. Ordinarily, the FDA requires a sponsor to support a BLA with substantial evidence of the product's safety, purity and potency in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted.

The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Moreover, recent events, including complications experienced by patients taking FDA-approved drugs, have raised questions about the safety of marketed drugs and may result in new legislation by the U.S. Congress or foreign legislatures and increased caution by the FDA and comparable foreign regulatory authorities in reviewing applications for marketing approval.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient to support approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We have a pipeline of clinical and pre-clinical stage product candidates, including:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells. It is being developed under our collaboration with MorphoSys AG for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies;
- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease and other autoimmune and inflammatory diseases;
- otlertuzumab, a monospecific ADAPTIR protein therapeutic that is currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL;
- 5E3 mAb, a monoclonal antibody therapeutic that is currently in pre-clinical development for Alzheimer's disease;
- ES425, a bispecific immunotherapeutic ADAPTIR protein that targets ROR1 (receptor tyrosine kinase-like orphan receptor 1, a protein expressed on solid tumors, leukemias and lymphomas), which is currently in pre-clinical development for a variety of hematologic malignancies and solid tumors; and

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- other protein therapeutic product candidates primarily targeting immuno-oncology.

Developing and obtaining regulatory approval for product candidates is a lengthy process, often taking a number of years, is uncertain and is expensive. All of the product candidates that we are developing, or may develop in the future, require research and development, pre-clinical studies, nonclinical testing and clinical trials prior to seeking regulatory approval and commencing commercial sales. In addition, we may need to address a number of technological challenges in order to complete development of our product candidates. As a result, the development of product candidates may take longer than anticipated or not be successful at all.

Generally, no product can receive FDA approval, marketing authorization from the European Commission or the competent authorities of the EU Member States, or approval from comparable regulatory agencies in foreign countries unless data generated in human clinical trials demonstrates both safety and efficacy for each target indication in accordance with such authority's standards.

The large majority of product candidates that begin human clinical trials fail to demonstrate the required safety and efficacy characteristics necessary for marketing approval. Failure to demonstrate the safety and efficacy of any of our product candidates for each target indication in clinical trials would prevent us from obtaining required approvals from regulatory authorities, which would prevent us from commercializing those product candidates. Negative or inconclusive results from the clinical trials or adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that additional trials be conducted, any of which may not be clinically feasible or financially practicable, that the conduct of trials be suspended, or that a program be terminated.

Any regulatory approval we ultimately obtain may limit the indicated uses for the product or subject the product to restrictions or post-approval commitments that render the product commercially non-viable. Securing regulatory approval requires the submission of extensive non-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the regulatory authorities for each therapeutic indication to establish the product's safety and efficacy. If we are unable to submit the necessary data and information, for example, because the results of clinical trials are not favorable, or if the applicable regulatory authority delays reviewing or does not approve our applications, we will be unable to obtain regulatory approval.

Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of the products or product candidates in the jurisdiction for which approval is sought;
- diminish our competitive advantage; and
- defer or decrease our receipt of revenue.

Certain of our products in development have experienced regulatory and/or clinical setbacks in the past. For example, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; this is called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA. We plan to continue the current clinical trial under an amended protocol with

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recruitment expected to start around mid-2016. As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. Under the terms of the restructured agreement, MorphoSys' cost sharing in the years 2016 to 2018 was reduced and future milestone payments payable by MorphoSys to us were reduced to a total of up to US \$74 million. As a result of the required change in dosing regimen for MOR209/ES414, the lead RTCC candidate, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial. The requirement for further adjustments to the dosing regimen or other parts of the program could delay our development timeline or delay or prevent our ability to receive regulatory approval for MOR209/ES414.

The procedures to obtain marketing approvals vary among countries and can involve additional clinical trials or other pre-filing requirements. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all the risks associated with obtaining FDA approval, or different or additional risks. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. Accordingly, approval by the FDA does not ensure approval by the regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by the FDA or regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products and products in development in any market on a timely basis, if at all.

Biotechnology company stock prices have declined significantly in certain instances where companies have failed to obtain FDA or foreign regulatory authority approval of a product candidate or if the timing of FDA or foreign regulatory authority approval is delayed. If the FDA's or any foreign regulatory authority's response to any application for approval is delayed or not favorable for any of our product candidates, our stock price could decline significantly.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the "off-label" use of any of our products.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for IXINITY is not approved for use in patients younger than 12 years old. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines, which could result in the disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

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Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or another regulatory or enforcement authority determines that our communications regarding our marketed products are not in compliance with the relevant regulatory requirements and that we have improperly promoted off-label uses, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Even after regulatory approval is received, if we, or third parties on whom we rely to manufacture or distribute our products or product candidates, fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market.

Any drug, biologic or medical device product for which we receive FDA approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, current good manufacturing practices, or cGMP, and restrictions on advertising and promotion. Adverse events that are reported after marketing approval can result in additional limitations being placed on the product's distribution or use and, potentially, withdrawal or suspension of the product from the market. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Because of the breadth of these laws, it is possible that some of our business activities, or those of our third-party manufacturers and distributors, could be subject to challenge under one or more of such laws.

In addition, the FDA has post-approval authority to require post-approval clinical trials and/or safety labeling changes if warranted by the appearance of new safety information. In certain circumstances, the FDA may impose a Risk Evaluation and Mitigation Strategy, or REMS, after a product has been approved. Facilities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other laws. The FDA also closely monitors advertising and promotional materials we may disseminate for our products for compliance with restrictions on off-label promotion and other laws. We may not promote our products for conditions of use that are not included in the approved package inserts for our products. Certain additional restrictions on advertising and promotion exist for products that have so-called "black box warnings" in their approved package inserts, such as WinRho SDF.

Failure by Emergent or our other third-party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products or ingredients to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with the FDA's current cGMP requirements. The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. If, in connection with any future inspection, the FDA finds that any of our third-party manufacturers is not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions such manufacturer may take, the FDA may undertake certain enforcement actions, including product seizure or withdrawal of the product from the market, imposition of restrictions on the marketing or manufacturing of a product and suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements.

Similar actions may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

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If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a biotechnology company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid or other third-party payors for our products, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase, prescribing or recommendation of an item or service reimbursable under federally funded healthcare programs, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims and false statement laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other payors that are false or fraudulent or making any materially false statement in connection with the delivery or payment for healthcare benefits, items or services;
- Health Insurance Portability and Accountability Act of 1996, or HIPAA, which creates federal criminal and civil statutes that prohibit executing a scheme to defraud any healthcare benefit program; and Health Information Technology for Economic and Clinical Health, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal physician self-referral laws, such as the Stark law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral;
- the Physician Payment Sunshine Act, which imposes disclosure requirements on pharmaceutical manufacturers of payments made to physicians, healthcare providers and institutions; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Moreover, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes, so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

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Recently, several pharmaceutical and other healthcare companies have been prosecuted under the federal false claims laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations.

Further, there has been a recent trend in the increase of federal and state laws and regulations regarding financial arrangements with physicians. The Affordable Care Act imposes new requirements to report certain financial arrangements with physicians and others, including reporting any “transfer of value” made or distributed to prescribers and other healthcare providers and reporting any ownership or investment interests held by physicians and their immediate family members during each calendar year, subject to federal implementation and enforcement policies.

In addition, certain states mandate that we comply with a state code of conduct, adopt a company code of conduct under state criteria, disclose marketing payments made to physicians, and/or report compliance information to the state authorities. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and reporting requirements increase the possibility that a pharmaceutical company may violate one or more of the requirements. Any failure to comply with these reporting requirements could result in significant fines and penalties.

The risks of complying with these laws cannot be entirely eliminated. The risk of violation of such laws is also increased because many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly. If our past or present operations, or those of our distributors are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Similarly, if healthcare providers, distributors or other entities with whom we do business are found to be out of compliance with applicable laws and regulations, they may be subject to sanctions, which could also have a negative impact on us.

If we fail to comply with our obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines.

The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid rebate program will continue to increase our costs and the complexity of compliance and will be time-consuming. Changes to the definition of “average manufacturer price”, or AMP, and the Medicaid rebate amount under the Affordable Care Act and Centers for Medicare & Medicaid Services’, or CMS’s, issuance of final regulations implementing those changes also has affected and could further affect our 340B “ceiling price” calculations. Because we participate in the Medicaid rebate program, we are required to report “average sales price,” or ASP, information to CMS for certain categories of drugs that are paid for under Part B of the Medicare program, including WinRho SDF, HepaGam B, VARIZIG and IXINITY. Future statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pricing and rebate calculations vary among products and programs, involve complex calculations and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate

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amount is computed each quarter based on our submission to CMS of our current AMP and “best price” for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Price recalculations also may affect the “ceiling price” at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B/PHS drug pricing program.

In addition to retroactive rebate liability and the potential for 340B program refunds, if we are found to have made a misrepresentation in the reporting of ASP, we are subject to civil monetary penalties in an amount of up to \$10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied. If we are found to have knowingly submitted false AMP or “best price” information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification also would subject us to \$100,000 in civil monetary penalties. In addition, our failure to submit monthly/quarterly AMP or “best price” information on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

In order for our products to be reimbursed by the primary federal governmental programs, we report certain pricing data to the U.S. federal government. Compliance with reporting and other requirements of these federal programs is a pre-condition to: (i) the availability of federal funds to pay for our products under Medicaid and Medicare Part B; and (ii) procurement of our products by the Department of Veterans Affairs, or DVA, and by covered entities under the 340B/PHS program. The pricing data reported are used as the basis for establishing Federal Supply Schedule, or FSS, and 340B/PHS program contract pricing and payment and rebate rates under the Medicare Part B and Medicaid programs, respectively. Pharmaceutical companies have been prosecuted under federal and state false claims laws for submitting inaccurate and/or incomplete pricing information to the government that resulted in increased payments made by these programs. The rules governing the calculation of certain reported prices are highly complex. Although we maintain and follow strict procedures to ensure the maximum possible integrity for our federal pricing calculations, the process for making the required calculations involves some subjective judgments and the risk of errors always exists, which creates the potential for exposure under the false claims laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, and our methodologies for calculating federal prices are found to include flaws or to have been incorrectly applied, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and certain federal grantees, we also must participate in the DVA FSS pricing program. To participate, we are required to enter into an FSS contract with the DVA, under which we must make our innovator “covered drugs” available to the “Big Four” federal agencies—the DVA, the U.S. Department of Defense, or the DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard—at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the Non-Federal Average Manufacturer Price, or Non-FAMP, which

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manufacturers are required to report on a quarterly and annual basis to the DVA. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to penalties of \$100,000 for each item of false information. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to disclose the error and refund the difference to the government. The failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

For further discussions regarding the most significant governmental reimbursement programs in the United States relevant to our products, see “Business—Regulation.”

The failure to obtain or maintain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business.

We currently sell and intend to continue to sell our products outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review. We and our collaborative partners may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to commercialize our products internationally. The failure to obtain these approvals could harm our business.

Our international operations increase our risk of exposure to potential claims of bribery and corruption.

As we expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the FCPA, the U.K. Bribery Act, Canada’s Corruption of Foreign Public Officials Act, or other similar foreign laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices outside the United States are found to be in violation of the FCPA or similar foreign laws, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials.

The U.S. federal budget sequestration process may have a significant impact on our business.

On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering mandatory reductions in federal spending by as much as \$1.1 trillion from 2013 through 2021, referred to as sequestration. The Bipartisan Budget Act of 2013 and subsequent legislation provide billions in sequester relief, but also extends the 2% reduction in Medicare payments, discussed below through fiscal year 2025. Sequestration-related spending reductions may have a significant adverse impact on our business.

Sequestration spending reductions may adversely affect the FDA. While user fees can be used in the review of certain regulatory filings, including NDAs, it is possible that sequestration spending reductions will result in additional backlogs in the approval process that could adversely affect the timing of FDA review of our regulatory filings for our products and product candidates. Sequestration also includes a 2% reduction in Medicare payments, which could also have a significant negative impact on our business. These reductions impact payments to hospitals, physicians, and Medicare managed care and prescription drug plans, under Medicare Parts A, B and D, and the Medicare Advantage program. The significant magnitude of the sequestration payment reductions places additional financial pressures on Medicare providers, including hospitals with high inpatient Medicare volume, which could force these providers to take new measures to address the shortfall in previously-expected reimbursements. It is possible that these measures could result in heightened scrutiny and/or reduced purchasing of branded pharmaceuticals and any future drug product we may market.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

EU Member States, Switzerland and other countries have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the European Union, and guidance on implementation and compliance practices are often updated or otherwise revised. Our failure to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. If the currently proposed revised draft EU Data Protection Regulation is adopted in its current form it may also increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

Public concern regarding the safety of drug products could result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug approved products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products and revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. The FDAAA also significantly expands the federal

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government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional pre-clinical studies or clinical trials. If the FDA requires us to provide additional clinical or pre-clinical data for any of our product candidates, the indications for which this product candidate was approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize our product candidates may be otherwise adversely impacted.

Product Development Risks

Our business depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business would be materially and adversely affected.

We have invested significant effort and financial resources in the development of our therapeutics and product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the interest of commercial entities and non-governmental organizations and others in funding the development of certain of our product candidates, the ability to attract and establish external development partnerships and the commercial viability of our developed product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

- successful development and formulation that meets FDA requirements;
- successful completion of clinical or non-clinical development, including toxicology studies;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing and product supply arrangements;
- training of a commercial sales force for the product, whether alone or in collaboration with others;
- successful registration and maintenance of relevant patent and/or other proprietary protection; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

If we are delayed or prevented from developing or commercializing a product candidate in a profitable manner, or if doing so requires us to incur significant unanticipated costs, our growth could be materially and adversely affected.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products.

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners, where applicable, must conduct extensive pre-clinical studies and clinical trials to establish proof of concept and demonstrate the safety and efficacy of our product candidates. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

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We may experience unforeseen events or issues during, or as a result of, pre-clinical testing or clinical trials. These issues and events, which could delay or prevent our ability to receive regulatory approval for a product candidate, include, among others:

- lack of efficacy of product candidates during the trials;
- safety issues or inconclusive or incomplete testing, trial or study results;
- our inability or the inability of Emergent and our other third-party manufacturers to manufacture sufficient quantities of materials for use in trials;
- the unavailability or variability in the number and types of subjects for each study;
- government or regulatory restrictions or delays; and
- greater than anticipated costs of trials.

For example, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment.

As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, the co-development agreement with MorphoSys was restructured. As a result of the required change in dosing regimen for MOR209/ES414, the lead RTCC candidate, the termination provisions under the MorphoSys collaboration agreement were similarly amended in MorphoSys' favor. Specifically, MorphoSys, at its sole discretion, has a one-time, no notice termination right exercisable at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the current, re-started Phase 1 trial. Patients receiving weekly doses of MOR209/ES414 developed ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA. Further adverse or inconclusive clinical results could require additional adjustments to the dosing regimen or other parts of the program and could delay or prevent our ability to receive regulatory approval for MOR209/ES414.

In addition, product candidates that experience success in pre-clinical testing and early-stage clinical trials will not necessarily experience the same success in late-stage clinical trials, which are required for marketing approval. The FDA and other countries' regulatory authorities will allow us to begin clinical trials under an IND, or similar document in other countries only if we demonstrate in our submission that the potential product candidate will not expose humans to unreasonable risks and that the compound has pharmacological activity that justifies clinical development. It takes significant time and expense to generate the requisite data to support an IND or similar document. In many cases, companies spend the time and resources only to discover that the data are not sufficient to support an IND or similar document and therefore are unable to enter human clinical trials.

Even if we are successful in advancing a product candidate into the clinical development stage, before obtaining regulatory and marketing approvals, we must demonstrate through extensive human clinical trials that the product candidate is safe and effective for its intended use. Human clinical trials must be carried out under protocols that are acceptable to regulatory authorities and to the independent committees responsible for the ethical review of clinical studies. There may be delays in preparing protocols or receiving approval for them that may delay the start or completion of the clinical trials. In addition, clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global trials increasingly complex. In addition, any deficiency in the design, implementation or oversight of our

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development programs could cause us to incur significant additional costs, experience significant delays, prevent us from obtaining marketing approval for any product candidate or abandon development of certain product candidates, any of which could harm our business and cause our stock price to decline.

The FDA may designate a product as a fast track drug if it is intended for the treatment of a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for this disease or condition. Sponsors granted a fast track designation for a drug are granted more opportunities to interact with the FDA during the approval process and are eligible for FDA review of the application on a rolling basis, before the application has been completed. Receipt of Fast Track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures, and Fast Track designation may be withdrawn by the FDA at any time. In addition, Fast Track designation does not guarantee the ability to take advantage of the expedited review procedures and does not increase the likelihood of receiving any regulatory approvals.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt our manufacturing and distribution operations and could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If any of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

For example, as noted above, MOR209/ES414 is currently being tested in its first clinical trial in humans. Twelve patients have received the drug. One of the significant serious adverse events associated with the drug is infusion reactions. Infusion reactions are often associated with the infusion of a protein and are expected with this drug that activates T-cells. The events that have been reported with infusion of the drug include: fever, fatigue, hypertension, bronchospasm, chills and rigors. The severity of these reactions varied by patient and were managed medically and resolved. In addition we recently discovered that patients receiving weekly doses of our product candidate MOR209/ES414 developed ADA during use. This ADA, which was not associated with safety issues, developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. Undesirable side effects, such as this, or other unexpected adverse events or properties of any of our candidates, could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our other product candidates. If such an event occurs, a number of potentially significant negative consequences may result, including:

- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- regulatory authorities may require one or more post-market studies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

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We depend on third parties to conduct our clinical and non-clinical trials. If these third parties do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and, as a result, our business may suffer.

We do not have the ability to independently conduct the clinical and non-clinical trials required to obtain regulatory approval for our product candidates. We depend on third parties, such as independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but we do not exercise day-to-day control over their activities. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with the FDA-approved good clinical practices, or GCPs, and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under GCPs and similar regulations outside of the United States. Our failure, or the failure of our product manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would increase our development costs and delay or impact the likelihood of regulatory approval.

If third parties do not carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

In certain cases, government entities conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. These government entities have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time.

If we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may

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delay or halt the development of various product candidates. This could require changes in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

Our decisions to allocate our research and development, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also prove to be incorrect and could cause us to miss valuable opportunities.

For example, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, the parties concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of MOR209/ES414 developed ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA.

There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA. The required dosing regimen change for MOR209/ES414 may not prove successful or sufficient to allow further development of this product candidate. As MOR209/ES414 is the lead candidate for our ADAPTIR Redirected T-Cell cytotoxicity, or RTCC, bispecific platform technology, equivocal or negative outcomes may impact not only the ability to further progress this product candidate but the viability of the RTCC platform. An important part of our business strategy is to develop, partner and commercialize new product candidates using the ADAPTIR RTCC platform.

If our competitors are able to obtain orphan drug exclusivity for a product that is competitive with one or more of our product candidates and we cannot show that our product candidate is clinically superior, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including Europe and the United States, may designate drugs that target relatively small patient populations as orphan drugs. A disease or condition is considered orphan if it affects fewer than 200,000 people in the United States. Orphan drug exclusivity (afforded to the first applicant to receive approval for an orphan designated drug) prevents FDA approval of applications by others for the same drug for the designated orphan disease or condition. The FDA may approve a subsequent application from another applicant if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need.

We have received an orphan drug designation from the FDA for VARIZIG for treatment following exposure to varicella (chickenpox) in high-risk patient groups, including children with compromised immune systems, newborns and pregnant women. We have also received orphan drug designation for otlertuzumab and we may seek such status with additional product candidates.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity. VARIZIG has orphan drug exclusivity in the United States through December 2019. Our product candidate otlertuzumab was granted orphan drug designation by the FDA in November 2011 and received orphan medicinal product designation from the European Commission in December 2012 for the treatment of chronic lymphocytic leukemia. The exclusivity applies only to the indication for which each drug has been designated and approved. The applicable exclusivity period is seven years in the United States, but this period may be interrupted if a sponsor of a competitive product that is otherwise the same drug for the same use can show that

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its drug is clinically superior to our orphan drug candidate. The European exclusivity period is ten years, but may be reduced to six years if a drug no longer meets the criteria for orphan drug designation, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified.

A grant of an orphan designation is not a guarantee that a product will be approved by the FDA.

If we do not obtain orphan drug exclusivity for our drug products, which do not have patent protection, our competitors may then sell the same drug to treat the same condition.

We do not have patent protection for WinRho SDF, HepaGam B or VARIZIG. Because not all of our drugs have patent protection, orphan drug designation is particularly important for our products that are eligible for orphan drug designation. As previously noted, VARIZIG has orphan drug exclusivity in the United States for treatment following exposure to varicella (chickenpox) in high-risk patient groups through December 2019. We plan to rely on this exclusivity period under the orphan drug designation for VARIZIG to maintain a competitive position. Our product candidate otlertuzumab was granted orphan drug designation by the FDA in November 2011 and received orphan medicinal product designation from the European Commission in December 2012 for the treatment of chronic lymphocytic leukemia. Orphan designation in Europe qualifies a drug for certain development and commercial incentives, including protocol assistance, access to centralized authorization procedures, reduced fees for regulatory activities, and 10 years of market exclusivity after approval.

Intellectual Property Risks

If we are unable to protect our intellectual proprietary rights, our business could be harmed.

Our commercial success will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology, products and product candidates. Obtaining and maintaining this protection is very costly. The patentability of technology in the biotechnology field generally is highly uncertain and involves complex legal and scientific questions. We cannot be certain that our patents and patent applications, including our own and those that we have rights through licenses from third parties, will adequately protect our intellectual property. Our success protecting our intellectual property depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents, including defending those patents against adverse claims;
- secure patent term extension for the patents covering our approved products;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and
- prevent others from infringing our proprietary rights.

Our principal patent applications and trademarks are described in greater detail in “Business—Intellectual Property” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations.”

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may inadvertently lapse or be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our products. In the past, we have abandoned the prosecution and/or maintenance of patent applications related to patent families in the ordinary course of business. In the future we may choose to abandon such prosecution and/or maintenance in a similar fashion. If these patent rights are later determined to be valuable or necessary to our business, our competitive position may be adversely affected. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and in other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defensive measures.

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The cost of litigation to uphold the validity of patents, once obtained, to prevent infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subject to patent office proceedings. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume management's time and attention and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions covered by or incorporating them. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially and adversely affected.

In addition to patent litigation, we may be a party to adversarial proceedings before the Patent Trial and Appeal Board of the US Patent and Trademark Office, or the PTAB. Potential proceedings before the PTAB include inter partes review proceedings, post-grant review proceedings and interference proceedings. Depending on our level of success at the PTAB, these proceedings could adversely impact our intellectual property rights with respect to our products and technology.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. Depending on decisions by the U.S. Congress, the federal courts, and the PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Our collaborative partners and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend intellectual property rights in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties.

Our patents, once obtained, also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to market and sell our products, and therefore our business, financial condition and operating results, could be materially and adversely affected.

If the outcome of patent opposition proceedings currently pending in Europe relating to IXINITY are unsuccessful, we may need to identify an additional fill/finish manufacturer, which could result in significant production delays and additional costs associated with moving our fill/finish manufacturing activities and identifying another fill/finish manufacturer.

We are currently involved in five opposition proceedings in Europe relating to factor IX proteins such as IXINITY. Baxter International Inc. is the sole counter-party in all five proceedings and our IXINITY product currently undergoes fill-finish in Europe. Of the five European Patent Office Proceedings, three have gone before the European Patent Office Opposition Division. Of these three, two were decided in our favor (in the name of UNC, our licensor) and one was decided in favor of Baxter. Two of these oppositions have been appealed, and we expect Baxter to appeal the third. It may be several years before these oppositions go before the Boards of Appeal for a final

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decision. The remaining two oppositions have not gone before the European Patent Office Opposition Division. Depending on the final outcome of these proceedings, we may be unable to continue to conduct our current IXINITY fill/finish manufacturing activities.

Patheon UK Limited, through an affiliate, is currently the sole source third-party manufacturer that provides fill and finish services for our IXINITY product, which conducts such activities in Europe. If, as a result of an adverse outcome in these proceedings, we are required to identify an additional fill/finish manufacturer in another location, we would not be able to do so without significant delay and likely significant additional cost.

International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries we may have to expend substantial sums and management resources.

Patent and other intellectual property laws outside the United States are even more uncertain than in the United States and are continually undergoing review and revisions in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, certain countries do not grant patent claims that are directed to business methods and processes. In addition, we may have to participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts. A European Patent Opposition, for instance, is a European Patent Office proceeding that allows for an opponent to challenge the validity of an issued patent. A European Patent Opposition is a proceeding that determines only the validity of a patent and does not determine whether a party infringes a patent. To initiate an Opposition at the European Patent Office, an opponent files a notice that it wishes to oppose the patent within a nine month period following the publication of the patent grant. After the opponent files the notice, it may be a few years before the merits of the opposition are heard and decided by the European Patent Office Opposition Division and several more years before the Boards of Appeal hears and decides on any appeals.

As previously noted, we are currently involved in five opposition proceedings related to IXINITY and recombinant vitamin K dependent proteins. Depending on the final outcome of these proceedings, we may be unable to sell factor IX products in Europe relating to the subject matter claimed in the European patents we are opposing.

Although we do not have current marketing authorization for IXINITY (our only product based on recombinant vitamin K dependent proteins) in Europe, nor do we sell IXINITY in Europe, if these opposition proceedings are successful, we may never be able to obtain marketing authorization to sell IXINITY in Europe or any other recombinant vitamin K dependent products we may develop in the future. In addition, if any of the patents we own or exclusively license are invalidated during the opposition process, we may be unable to block competitors from performing certain activities in Europe currently covered by the patents.

Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations would be costly, time-consuming, distracting to management and could materially affect our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold sufficient licenses or other rights. Additionally, third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. These third parties may have substantially greater financial resources than us and could bring claims against us that could cause us to incur substantial expenses to defend against these claims and, if successful against us, could cause us to pay substantial damages. Furthermore, if a patent infringement or other similar suit were brought against us, we could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the biotechnology industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These

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licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, if at all, or if an injunction is granted against us, which could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other adversarial proceedings such as proceedings before the PTAB and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology.

Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Our Aptevo trademarks may be opposed which could have a material and adverse effect on our business.

We have applications pending that cover the APTEVO, APTEVO THERAPEUTICS, APTEVO BIOTHERAPEUTICS and APTEVO RESEARCH AND DEVELOPMENT trademarks. If a third party opposes any of these Aptevo trademarks, we may incur significant expense in the course of participating in the opposition process, which can be expensive and lengthy, and any settlement of which may result in our agreeing to be subject to restrictions on our use of the relevant Aptevo trademark. In addition, if we are unsuccessful in an opposition against an Aptevo trademark, we would lose the ability to obtain trademark registration for one or more uses of the relevant Aptevo mark.

For example, Bristol-Myers Squibb Company filed with the U.S. Patent and Trademark Office a request for a 90-day extension of time to oppose each Aptevo trademark. Specifically, unless Aptevo consents to an additional extension of time, Bristol-Myers Squibb will have until June 22, 2016 to oppose the APTEVO and APTEVO THERAPEUTICS trademarks, until July 20, 2016 to oppose the APTEVO RESEARCH AND DEVELOPMENT trademark and until July 27, 2016 to oppose the APTEVO BIOTHERAPEUTICS trademark. At this time, we are uncertain whether Bristol-Myers Squibb Company intends to oppose any of these trademarks, but any such opposition could result in our incurring of significant expenses in participating in the opposition process or attempting to negotiate a settlement agreement with Bristol-Myers Squibb Company, the loss of our ability to obtain trademark registration for one or more use of the relevant Aptevo mark or restrictions on our use of the relevant Aptevo trademark, all of which could have a material and adverse effect on our business. We have received no indication from Bristol-Myers Squibb Company that it plans to take any legal action against Aptevo other than the potential oppositions.

If a third-party files a trademark infringement claim against us, defending ourselves against such claim could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction and damages, all of which could have a material and adverse effect on our business.

If a third-party files a trademark infringement claim against us, defending ourselves against such claim could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction and damages.

At this time, we are uncertain whether Bristol-Myers Squibb Company intends to assert that our use of the Aptevo trademarks infringes its trademark rights, but defending ourselves against such claim could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction prohibiting us from using the Aptevo trademarks and damages, all which could have a material and adverse effect on our business.

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We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license in whole or in part, terminate the exclusive nature of the license and/or sue us for breach, which could cause us to not be able to market any product that is covered by the licensed patents and may be subject to damages.

Any such termination or claim, particularly relating to our agreements with respect to WinRho SDF, HepaGam B, VARIZIG or IXINITY could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, information processes and know-how. These types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants and third parties as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known, including through a potential cyber security breach, or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

Our WinRho SDF, HepaGam B and VARIZIG products are protected by Emergent's manufacturing trade secrets. There are no patents or patent applications pending that support these hyperimmune products. If Emergent fails to adequately protect the trade secrets supporting these products, competitors may be able to copy our products by reproducing the manufacturing processes.

Risks Related to Collaborations

We may not be successful in establishing and maintaining collaborations that leverage our capabilities in pursuit of developing and commercializing our product candidates.

For each of our product candidates, including otlertuzumab, we plan to evaluate the merits of entering into collaboration arrangements with third parties, including leading biotechnology companies or non-governmental organizations.

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We currently are party to a collaboration arrangement with MorphoSys AG for the joint worldwide development and commercialization of MOR209/ES414, a targeted immuno-therapeutic protein being developed for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies. In December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of MOR209/ES414 developed ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug, reduced the concentration of MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA.

We plan to continue the current clinical trial under an amended protocol with recruitment expected to start around mid-2016. As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. Under the terms of the restructured agreement, MorphoSys' cost sharing in the years 2016 to 2018 was reduced and future milestone payments payable by MorphoSys to us were reduced to a total of up to \$74 million. In addition, the amended collaboration agreement changed the total expected funding requirement for us to up to approximately \$250 million. As a result of the required change in dosing regimen for MOR209/ES414, the lead RTCC candidate, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial. Further adverse or inconclusive clinical results could lead to further renegotiation of the terms or cancellation of our collaboration agreement with MorphoSys AG.

We expect to selectively pursue collaboration arrangements with third parties that have particular technology, expertise or resources for the development or commercialization of our product candidates or for accessing particular markets. We face, and will continue to face, significant competition in seeking appropriate partners for our product candidates. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on a timely basis, on acceptable terms or at all, or if the arrangements we establish are unproductive for us, we may fail to meet our business objectives for the particular product candidate. Our ability to enter into such arrangements with respect to products in development that are subject to licenses may be limited by the terms of those licenses.

Any collaboration that we enter into may not be successful and the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborative partners. It is likely that our collaborative partners will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

The risks that we are subject to in any of our collaborations include, among others:

- our collaborative partners may not commit adequate resources to the development, marketing and distribution of any collaboration products, limiting our potential revenues from these products;
- our collaborative partners may experience financial difficulties and may therefore be unable to meet their commitments to us;
- our collaborative partners may pursue a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- our collaborative partners may terminate our relationship.

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For example, in 2011, Abbott Laboratories, or Abbott, terminated its collaboration with Emergent for the development of otlertuzumab following a portfolio reprioritization process by Abbott.

The failure of any of our future collaboration partners to perform as expected could place us at a competitive disadvantage and adversely affect us financially, including delay and increased costs of development, loss of market opportunities, lower than expected revenues and impairment of the value of the related product candidate. Collaborations are a critical part of our business strategy, and any inability on our part to establish and successfully maintain such arrangements on terms favorable to us or to work successfully with our collaborative partners could have an adverse effect on our operations and financial performance.

Financial Risks

We may seek debt financing, which may restrict the operation of our business and limit the cash available for investment in our business operations.

We may seek debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under any future indebtedness. In addition, failure to comply with the covenants under any future debt instruments could result in an event of default under those instruments. An event of default could result in the acceleration of amounts due under a particular debt instrument and a cross default and acceleration under any future debt instruments, and we may not have sufficient funds or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests, if any, in our assets securing our indebtedness.

We may not achieve profitability in future periods or on a consistent basis.

Our ability to become profitable will be substantially dependent on the receipt of the \$60 million total cash contributions from Emergent, our product sales revenues and revenues from collaboration and licensing arrangements. Accordingly, our ability to become profitable may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve or sustain profitability. In addition, we anticipate incurring significant costs associated with the separation from Emergent and making substantial expenditures to further develop and commercialize our products and product candidates. We anticipate needing to generate greater revenue in future periods from our marketed products and from our products in development in order to achieve profitability in light of our planned expenditures. If we are unable to generate greater revenue, we may not achieve profitability in future periods, and may not be able to

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maintain any profitability we do achieve. If we are unable to generate sufficient revenues, we will not become profitable and may be unable to continue operations without additional funding.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturns.

Our results of operations could be materially negatively affected by general economic conditions, both in the United States and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, and the availability and cost of credit have contributed to increased volatility and diminished expectations for the economy and the markets going forward. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds, if necessary, and our stock price may further decline.

Credit and financial market conditions may exacerbate certain risks affecting our business.

Sales of our products are made, in part, through direct sales to our customers, which include hospitals, physicians and other health care providers. As a result of adverse global credit and financial market conditions, our customers may be unable to satisfy their payment obligations for invoiced product sales or may delay payments, which could negatively affect our revenues, income and cash flow. In addition, we rely upon third parties for many aspects of our business, including our collaboration partners, wholesale distributors for our products, contract clinical trial providers, research organizations, manufacturers and third-party suppliers. Because of the tightening of global credit and the volatility in the financial markets, there may be a delay or disruption in the performance or satisfaction of commitments to us by these third parties, which could adversely affect our business.

The way that we account for our operational and business activities is based on estimates and assumptions that may differ from actual results.

The preparation of our combined financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, our management evaluates its critical estimates and judgments, including, among others: those related to revenue recognition, including product rebates, chargeback and return accruals; inventory; clinical research costs; business combinations; intangible assets and impairment; income taxes; stock-based compensation; and contingent consideration. Those critical estimates and assumptions are based on our historical experience, future projections, our observance of trends in the industry, and various other factors that are believed to be reasonable under the circumstances, and they form the basis for making judgments about the carrying values and fair values of assets and liabilities that may not be readily apparent from other sources. If actual results differ from these estimates as a result of unexpected conditions or events occurring which cause us to have to reassess our assumptions, there could be a material adverse impact on our financial results and the performance of our stock.

We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations.

The nature of our business exposes us to potential liability inherent in pharmaceutical products, including with respect to the sale of our products, any other products that we successfully develop and the testing of our product candidates in clinical trials. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise possess regulatory approval for commercial sale or study. We cannot predict the frequency, outcome or cost to defend any such claims.

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If we cannot successfully defend ourselves against future claims that our products or product candidates caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand or withdrawal of a product;
- adverse publicity and/or injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- an inability to commercialize products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition and results of operations. The cost of defending any products liability litigation or other proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability claims, regardless of merit or eventual outcome, may absorb significant management time and result in reputational harm, potential loss of revenue from decreased demand for our products and/or product candidates, withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs, and could cause our stock price to fall.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims by individuals and third-party payors. In addition, product liability claims could result in an investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, the EMA, or the competent authorities of the EU Member States. Such investigations could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension, variation, or withdrawal of approval. Any such regulatory action by the FDA, the EMA or the competent authorities of the EU Member States could lead to product liability lawsuits as well.

We rely significantly on information technology systems and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively or result in data leakage of proprietary and confidential business and employee information.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes.

We will install and implement information technology infrastructure to support our critical business functions, as discussed in greater detail in the risk factor below entitled “*As we continue to build our information technology infrastructure and transition our data to our own systems, we could incur substantial additional costs and experience temporary business interruptions.*”

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In addition, our systems are potentially vulnerable to data security breaches—whether by employee error, malfeasance or other disruption—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others.

A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to our proprietary and confidential business and employee information could result in financial, legal, business or reputational harm to us, any of which could adversely affect our business, financial condition and operating results.

Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. If we are unable to retain the services of one or more of the principal members of senior management, including our Chief Executive Officer, Marvin L. White, and Chief Financial Officer, Jeffrey G. Lamothe, and Chief Medical Officer, Scott C. Stromatt, or other key employees, our ability to implement our business strategy could be materially harmed. Our industry has experienced a high rate of turnover of management personnel in recent years. We face intense competition for qualified employees from biotechnology companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package or otherwise attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

We are subject to periodic litigation, which could result in losses or unexpected expenditure of time and resources.

From time to time, we may be called upon to defend ourselves against lawsuits relating to our business. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of any such proceedings. An unfavorable outcome in any such proceedings could have an adverse impact on our business, financial condition and results of operations. If our stock price is volatile, we may become involved in securities class action lawsuits in the future. Any litigation in the future, regardless of its merits, could result in substantial costs and a diversion of management's attention and resources that are needed to successfully run our business. For a more detailed discussion of litigation, see "Business—Legal Proceedings."

RISKS RELATED TO THE SEPARATION

Until the separation occurs, Emergent has sole discretion to change the terms of the separation in ways which may be unfavorable to us.

We expect to complete the separation from Emergent in mid-2016. Unanticipated developments, including possible delays in obtaining a tax opinion, covenant waivers or other required clearances, uncertainty of the financial markets and challenges in establishing infrastructure or processes, could delay or prevent the proposed spin-off or cause it to occur on terms or conditions that are less favorable or different than currently contemplated. Executing the proposed spin-off also requires significant time and attention from management and employees, which could distract them from other tasks in operating our business and, as a result, negatively impact our operations and our earnings.

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Until the separation occurs, we will be a wholly-owned subsidiary of Emergent. Accordingly, Emergent will effectively have the sole and absolute discretion to determine and change the terms of the separation, including the establishment of the record date for the distribution and the distribution date. These changes could be unfavorable to us. Emergent may also decide at any time not to proceed with the separation and distribution. In addition, the separation is subject to material conditions and may not be completed on the currently contemplated timeline or at all.

If the proposed separation is consummated, we may not realize some or all of the anticipated benefits due to a number of factors.

Even if the transaction is completed, we may not realize some or all of the anticipated strategic, financial or other benefits from the separation. These expected benefits include the benefits described in “The Separation and Distribution—Reasons for the Separation.” We may not achieve these and other anticipated benefits for a variety of reasons. We will be smaller, less diversified and with a narrower business focus than the currently combined company, and may be more vulnerable to changing market conditions, which could materially and adversely affect our business, financial condition and results of operations. Execution of the spin-off transaction presents a number of significant risks to our internal processes, including the failure to maintain an adequate control environment due to changes to our information technology systems and financial reporting processes, both as we execute the transaction and following consummation. There may also be dis-synergies from separating the businesses that could negatively impact the financial condition and results of operations of either or both businesses. There also can be no assurance that the separation will not adversely affect our business. Further, the combined value of the common stock of the two publicly-traded companies may not be equal to or greater than what the value of our common stock would have been had the proposed spin-off not occurred.

We have no history operating as an independent company, and our historical and pro forma financial information is not necessarily representative of the results that we would have achieved as a separate, publicly-traded company and may not be a reliable indicator of our future results.

The historical information about us in this information statement refers to our business as operated by and integrated with Emergent. Our historical and pro forma financial information included in this information statement is derived from the consolidated financial statements and accounting records of Emergent. Accordingly, the historical and pro forma financial information included in this information statement does not necessarily reflect the financial condition, results of operations or cash flows that we would have achieved as a separate, publicly-traded company during the periods presented or those that we will achieve in the future primarily as a result of the factors described below:

- Prior to the separation, our business was operated by Emergent as part of Emergent’s broader corporate organization, rather than as an independent company. Emergent or one of its affiliates performed various corporate functions for us, such as accounting, information technology, legal, human resources, regulatory, quality assurance, quality control and finance. Following the separation, Emergent will provide some of these functions to us, as described in “Certain Relationships and Related Party Transactions.” Our historical results reflect allocations of corporate expenses from Emergent for such functions. We consider the expense allocation methodology and results to be reasonable for all periods presented. However, the allocations may not be indicative of the actual expense that would have been incurred had we operated as an independent, publicly-traded company for the periods presented. We will need to make significant investments to replicate or outsource from other providers certain facilities, systems, infrastructure, and personnel to which we will no longer have access after our separation from Emergent. These initiatives to develop our independent ability to operate without access to Emergent’s existing operational and administrative infrastructure will be costly to implement. We may not be able to operate our business efficiently or at comparable costs, and our financial condition may decline;

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- Currently, our business is integrated with the other businesses of Emergent. We are able to use Emergent’s size and purchasing power in procuring various goods and services and have shared economies of scope and scale in costs, employees, vendor relationships and customer relationships. Although we will enter into a transition services agreement with Emergent, these arrangements may not fully capture the benefits we have enjoyed as a result of being integrated with Emergent and may result in us paying higher charges than in the past for these services. As a separate, independent company, we may be unable to obtain goods and services at the prices and terms obtained prior to the separation, which could increase our losses. As a separate, independent company with a distinct scope of operations, we may also not qualify for or obtain favorable tax treatments and credits. This could have an adverse effect on our results of operations and financial condition following the completion of the separation;
- Generally, our working capital requirements and capital for our general corporate purposes, including research and development and capital expenditures, have historically been satisfied as part of the corporate-wide capital allocation of Emergent. Following the completion of the separation, we may need to obtain additional financing from banks, through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements;
- After the completion of the separation, the cost of capital for our business will likely be higher than Emergent’s cost of capital prior to the separation; and
- Our historical financial information does not reflect our obligations to purchase from Emergent certain services and assets, and assume the corresponding liabilities, of our business after the distribution date. For example, prior to separation, Emergent manufactured our commercial products, with the exception of IXINITY. Following separation, our commercial products, other than IXINITY, will continue to be manufactured by Emergent under a manufacturing services agreement. Therefore, the cost of our commercial products may differ from our current pricing.

Other significant changes may occur in our cost structure, management, financing and business operations as a result of operating as an independent company. For additional information about the past financial performance of our business and the basis of presentation of the historical combined financial statements and the unaudited pro forma combined financial statements, see “Unaudited Pro Forma Combined Balance Sheet,” “Selected Historical Combined Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the historical financial statements and accompanying notes included elsewhere in this information statement.

Emergent may fail to perform under various transaction agreements that will be executed as part of the separation or we may fail to have necessary systems and services in place when certain of the transaction agreements expire.

In connection with the separation, we will enter into a separation and distribution agreement and various other agreements with Emergent, including a non-negotiable promissory note, a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian wholesaler agreement, a trademark license agreement and a product license agreement. These agreements are discussed in greater detail in the section entitled “Certain Relationships and Related Party Transactions.” Certain of these agreements will provide for the performance of services by Emergent for a period of time after the separation. We will rely on Emergent to satisfy its performance obligations under these agreements. If Emergent is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could incur operational difficulties or losses.

If we do not have in place our own systems and services, or if we do not have agreements with other providers of these services when the transition services or longer-term agreements terminate, we may not be able to operate our business effectively and our results of operations may be adversely affected. We are in the process

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of creating our own, or engaging third parties to provide, systems and services to replace many of the systems and services Emergent currently provides to us. We may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Emergent's systems to ours. These systems and services may also be more expensive or less efficient than the systems and services Emergent is expected to provide during the transition period.

As we continue to build our information technology infrastructure and transition our data to our own systems, we could incur substantial additional costs and experience temporary business interruptions.

We are continuing to install and implement our own information technology infrastructure to support our critical business functions, including accounting and reporting, customer service, inventory control and distribution. We may incur temporary interruptions in business operations if we cannot transition effectively from Emergent's existing transactional and operational systems, data centers and the transition services that support these functions as we transition these systems. We may not be successful in implementing our new systems and transitioning our data, and we may incur substantially higher costs for implementation than currently anticipated. Our failure to avoid operational interruptions as we transition systems and replace Emergent's IT services, or our failure to transition systems to replace Emergent's services successfully, could disrupt our business and have a material adverse effect on our results of operations. In addition, if we are unable to replicate or transition certain systems, our ability to comply with regulatory requirements could be impaired.

Our accounting and other management systems and resources may not be adequately prepared to meet the financial reporting and other requirements to which we will be subject as a standalone publicly-traded company following the distribution.

Our financial results previously were included within the consolidated results of Emergent, and we believe that our reporting and control systems were appropriate for those of divisions of a public company. However, we were not directly subject to the reporting and other requirements of the Exchange Act. After the distribution, we believe we will qualify as an Emerging Growth Company, or EGC. Although an EGC has certain reduced reporting and regulatory requirements, we will still be directly subject to substantial reporting and other obligations under the Exchange Act. These reporting and other obligations will place significant demands on our management and administrative and operational resources, including accounting resources. We may not have sufficient time following the separation to meet these obligations by the applicable deadlines.

Moreover, to comply with these requirements, we anticipate that we will need to migrate our systems, including information technology systems, implement additional financial and management controls, reporting systems and procedures and potentially need to hire additional accounting and finance staff. We expect to incur additional annual expenses related to these steps, and those expenses may be significant. If we are unable to upgrade our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies under the Exchange Act could be impaired. Any failure to achieve and maintain effective internal controls could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In connection with our separation from Emergent, Emergent will indemnify us for certain liabilities and we will indemnify Emergent for certain liabilities. If we are required to pay under these indemnities to Emergent, our financial results could be negatively impacted. The Emergent indemnity may not be sufficient to hold us harmless from the full amount of liabilities for which Emergent will be allocated responsibility, and Emergent may not be able to satisfy its indemnification obligations in the future.

Pursuant to the separation agreement and certain other agreements with Emergent, Emergent will agree to indemnify us for certain liabilities, and we will agree to indemnify Emergent for certain liabilities, in each case for uncapped amounts, as discussed further in "Certain Relationships and Related Party Transactions."

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Indemnities that we may be required to provide Emergent are not subject to any cap, may be significant and could negatively impact our business, particularly indemnities relating to our actions that could impact the tax-free nature of the distribution. Third parties could also seek to hold us responsible for any of the liabilities that Emergent has agreed to retain. Any amounts we are required to pay pursuant to these indemnification obligations and other liabilities could require us to divert cash that would otherwise have been used in furtherance of our operating business. Further, the indemnity from Emergent may not be sufficient to protect us against the full amount of such liabilities, and Emergent may not be able to fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from Emergent any amounts for which we are held liable, we may be temporarily required to bear these losses ourselves. Each of these risks could negatively affect our business, results of operations and financial condition.

If the distribution, together with certain related transactions, does not qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, Emergent, Aptevo, and Emergent stockholders could be subject to significant tax liabilities, and, in certain circumstances, we could be required to indemnify Emergent for taxes and related expenses resulting from the failure of the transaction to so qualify.

It is intended that the distribution, together with certain related transactions, will generally be tax-free to Emergent and its stockholders for U.S. federal income tax purposes. Emergent has received a favorable private letter ruling from the IRS regarding certain U.S. federal income tax matters relating to the distribution and certain related transactions. It is a condition to the distribution that (i) the private letter ruling from the IRS continue to be valid and in full force and effect and (ii) Emergent receive an opinion from WilmerHale LLP, in a form and substance satisfactory to Emergent, substantially to the effect that, for U.S. federal income tax purposes, the distribution and certain related transactions, taken together, will qualify as a transaction described under Sections 355(a) and 368(a)(1)(D) of the Code. The IRS private letter ruling is based upon certain facts and representations submitted by Emergent to the IRS. In addition, the opinion from WilmerHale LLP will be based upon and rely on, among other things, the IRS private letter ruling and certain facts and assumptions, as well as certain representations and covenants of Emergent and Aptevo contained in the tax matters agreement and certain representations contained in representation letters provided by Emergent, Aptevo and certain stockholders to WilmerHale LLP, including representations and covenants relating to the past and future conduct of Emergent, Aptevo and such stockholders. If any of these facts, assumptions, representations, or covenants is, or becomes, inaccurate or incomplete, the IRS private letter ruling and/or the opinion of WilmerHale LLP may be invalid and the conclusions reached therein could be jeopardized. In addition, the IRS private letter ruling only addresses certain limited matters relevant to determining whether the distribution, together with certain related transactions, qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, and the opinion of WilmerHale LLP will represent the judgment of such counsel which is not binding on the IRS or any court. Accordingly, notwithstanding the IRS private letter ruling and the opinion of WilmerHale LLP, there can be no assurance that the IRS will not assert that the distribution and/or certain related transactions should be treated as a taxable transaction for U.S. federal income tax purposes or that a court would not sustain such a challenge.

If the distribution, together with certain related transactions, does not qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, in general, (i) Emergent would recognize taxable gain on the distribution equal to the amount by which the fair market value of the Aptevo common stock distributed to Emergent stockholders exceeds Emergent's tax basis in its shares of Aptevo common stock and (ii) each Emergent stockholder would be treated as receiving a taxable distribution in an amount equal to the fair market value of the Aptevo common stock received by such stockholder. For more information, see "Material U.S. Federal Income Tax Consequences."

Under the tax matters agreement that we will enter into with Emergent, we may be required to indemnify Emergent against any tax liabilities and related expenses resulting from the failure of the distribution, together with certain related transactions, to qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code to the extent that the failure to so qualify is attributable to actions, events or transactions relating to our stock, assets or business, or a breach of the relevant representations or covenants made by us in the tax matters

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agreement or the IRS private letter ruling or in the representation letters provided to WilmerHale LLP. For a more detailed discussion, see “Certain Relationships and Related Party Transactions–Tax Matters Agreement.”

We may have received better terms from unaffiliated third parties than the terms we will receive in our agreements with Emergent.

The agreements we will enter into with Emergent in connection with the separation, including a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian wholesaler agreement, a trademark license agreement and a product license agreement, were prepared in the context of the separation while we were still a wholly-owned subsidiary of Emergent. Accordingly, during the period in which the terms of those agreements were prepared, we did not have an independent board of directors or a management team that was independent of Emergent. As a result, while we believe that the commercial agreements between Emergent and us generally reflect arm’s-length pricing and other terms, it is possible that we may have received more favorable terms had the intercompany agreements between Emergent and us been negotiated with third parties.

We expect to incur both one-time and ongoing material costs and expenses as a result of our separation from Emergent, which could adversely affect our results of operations.

We expect to incur both one-time and ongoing costs and expenses greater than those we currently incur as a result of our separation from Emergent. These increased costs and expenses may arise from various factors, including financial reporting, costs associated with complying with federal securities laws (including potential future compliance with the Sarbanes-Oxley Act of 2002), tax administration, and legal and human resources related functions, and it is possible that these costs will be material to our business.

The transfer or assignment to us of certain contracts and other assets requires the consent of a third party. If such consent is not given, we may not be entitled to the benefit of such contracts and other assets in the future.

The transfer or assignment of certain of the contracts and other assets in connection with our separation from Emergent require the consent of a third party to the transfer or assignment. In addition, in some circumstances, we are joint beneficiaries of contracts, and we will need to enter into a new agreement with the third party to replicate the existing contract or assign the portion of the existing contract related to our business. Some parties may use the consent requirement to seek more favorable contractual terms from us, which we expect would primarily take the form of price increases, which may require us to expend additional resources in order to obtain the services or assets previously provided under the contract, or to seek arrangements with new third parties. If we are unable to obtain such consents on commercially reasonable and satisfactory terms, we may be unable to obtain some of the benefits, assets and contractual commitments that are intended to be allocated to us as part of our separation from Emergent, and we may be required to seek alternative arrangements to obtain the distribution, legal, accounting, auditing, administrative and other services and assets that we would otherwise have had under such agreements. In addition, where we do not intend to obtain consent from third-party counterparties based on our belief that no consent is required, the third-party counterparties may challenge a transfer of assets to us on the basis that the terms of the applicable commercial arrangements require their consent. We may incur substantial litigation and other costs in connection with any such claims and, if we do not prevail, our ability to use these assets could be adversely impacted.

If the distribution occurs and you do not want to receive Aptevo common stock in the distribution, your sole recourse will be to divest yourself of your Emergent common stock prior to the record date.

No vote of Emergent stockholders is required in connection with the distribution. Accordingly, if the distribution occurs and you do not want to receive our common stock in the distribution, your only recourse will be to divest yourself of your Emergent common stock prior to the record date for the distribution.

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The combined post-separation value of a share of Emergent common stock and • shares of Aptevo common stock may not equal or exceed the pre-distribution value of a share of Emergent common stock.

As a result of the distribution, Emergent expects the trading price of shares of Emergent common stock immediately following the distribution to be lower than the “regular-way” trading price of such shares immediately prior to the distribution because the trading price will no longer reflect the value of the business held by Aptevo. There can be no assurance that the aggregate market value of a share of Emergent common stock and • shares of Aptevo common stock following the separation will be higher or lower than the market value of a share of Emergent common stock if the separation did not occur.

We may not be able to engage in certain corporate transactions after the separation.

To preserve the tax-free treatment to Emergent and its stockholders of the distribution, together with certain related transactions, we will be restricted, under the tax matters agreement that we will enter into with Emergent, from taking any action that prevents such transactions from being tax-free for U.S. federal income tax purposes. In particular, for a period of two years following the separation, we will be restricted from taking certain actions (including restrictions on share issuances, business combinations, sales of assets, amendments to organizational documents and similar transactions) that could cause the distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. These restrictions may limit our ability to pursue certain strategic transactions or engage in other transactions that might increase the value of our business, including use of our common stock to make acquisitions and equity capital market transactions. In addition, under the tax matters agreement, we are required to indemnify Emergent against any tax liabilities and related expenses arising from the failure of the distribution, together with certain related transactions, to be tax-free to the extent such failure is attributable to actions, events or transactions relating to our stock, assets or business, including the acquisition of our stock even if we did not participate in or otherwise facilitate the acquisition. For more information, see “Certain Relationships and Related Party Transactions—Tax Matters Agreement.”

After the separation, certain of our executive officers and/or directors may have actual or potential conflicts of interest because of their previous positions at Emergent.

The ownership by our expected executive officers and/or directors of shares of Emergent common stock, stock options or other equity awards may create, or may create the appearance of, conflicts of interest. Because of their current or former positions with Emergent, certain of our expected executive officers and/or directors own shares of Emergent common stock, stock options to purchase Emergent common stock or other equity awards. Shares of Emergent common stock, stock options to purchase Emergent common stock or other equity awards may comprise a significant portion of some of these individuals’ total personal financial assets. Following the separation, even though expected executive officers and/or directors who are currently employees of Emergent will cease to be employees of Emergent, some of our executive officers and/or directors will continue to have a financial interest in Emergent common stock, which may create, or may create the appearance of, conflicts of interest when these individuals are faced with decisions that could have different implications for Emergent than the decisions have for Aptevo.

RISKS RELATED TO APTEVO’S COMMON STOCK

We cannot be certain that an active trading market for our common stock will develop or be sustained after the separation, and following the separation, our stock price may fluctuate significantly.

A public market for our common stock does not currently exist. We anticipate that on or prior to the record date for the distribution, trading of shares of our common stock will begin on a “when-issued” basis and will continue through the distribution date. However, we cannot guarantee that an active trading market will develop or be sustained for our common stock after the separation. Nor can we predict the prices at which shares of our

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common stock may trade after the separation. Similarly, we cannot predict whether the combined market value of the shares of our common stock and Emergent's common shares will be less than, equal to or greater than the market value of Emergent's common shares prior to the separation.

The stock market in general, and the market for biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a number of factors, some of which may be beyond our control or unrelated to our operations, including, among others:

- changes in earnings estimated by securities analysts or our ability to meet those estimates;
- investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance;
- the success of competitive products or technologies;
- the timing, expenses and results of clinical and non-clinical trials of our product candidates;
- announcements regarding clinical trial results and product introductions by us or our competitors;
- announcements of acquisitions, collaborations, financings or other transactions by us;
- public concern as to the safety of our products;
- termination or delay of a development program;
- the recruitment or departure of key personnel;
- actual or anticipated variations in our product revenue and results of operations;
- the operating and stock price performance of comparable companies;
- general industry conditions and domestic and worldwide financial, economic and political instability; and
- the other factors described in this "Risk Factors" section.

In addition, when the market price of a company's common stock drops significantly, stockholders often institute securities class action lawsuits against the company. A lawsuit against us could cause us to incur substantial costs and could divert the time and attention of our management and other resources.

The public announcement of data from clinical studies or news of any developments related to our product pipeline may cause significant volatility in our stock price. If the development of any of our key pipeline products is delayed or discontinued, our stock price could decline significantly.

As we evolve into a standalone company, we will be focusing efforts and resources in building a diversified pipeline of products. We expect that investors may place heightened scrutiny on some of our products in development when making investment decisions in Aptevo compared to historic Emergent. The announcement of data from clinical studies by us or our collaborative partners or news of any developments related to our key pipeline products may cause significant volatility in our stock price. Furthermore, the announcement of any negative or unexpected data or the discontinuation of development of any of our key pipeline products, or any delay in our anticipated timelines for filing for regulatory approval, could cause our stock price to decline significantly. There can be no assurance that data from clinical studies will support a filing for regulatory approval or even if approved, that any of our key pipeline products will become commercially successful.

Your percentage of ownership in Aptevo may be diluted in the future.

In the future, your percentage ownership in Aptevo may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we will be granting to our

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directors, officers and employees. Our employees will have options to purchase shares of our common stock after the distribution as a result of conversion of their Emergent stock options to Aptevo stock options. We anticipate our compensation committee will grant additional stock options or other stock-based awards to our employees after the distribution. Such awards will have a dilutive effect on our earnings per share, which could adversely affect the market price of our common stock. From time to time, we may issue additional options or other stock-based awards to our employees under our employee benefits plans.

In addition, our restated certificate of incorporation will authorize us to issue, without the approval of our stockholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our common stock respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, we could grant the holders of preferred stock the right to elect some number of our directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock. See “Description of Aptevo’s Capital Stock.”

Fuad El-Hibri, the chairman of our Board of Directors, has significant influence over us through his substantial beneficial ownership of our common stock, including an ability to influence the election of the members of our Board of Directors, or delay or prevent a change of control of us.

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of the distribution date, Mr. El-Hibri will be the beneficial owner of approximately ●% of our outstanding common stock. As a result, Mr. El-Hibri could delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions. In addition, Mr. El-Hibri’s significant beneficial ownership of our shares could present the potential for a conflict of interest.

Provisions under Delaware law and in our restated certificate of incorporation and amended and restated by-laws may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

Certain provisions in our restated certificate of incorporation and amended and restated by-laws, and under Delaware law, may discourage, delay or prevent a merger, acquisition or other changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our incumbent directors and management.

These provisions include:

- the classification of our directors;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- advance notice requirements for stockholder nominations of candidates for election to the Board of Directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and

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- the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

The affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. The affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, Section 203 of the General Corporation Law of Delaware prohibits a corporation from engaging in a business combination with an interested stockholder, generally a person which, together with its affiliates, owns or within the last three years has owned 15% or more of the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

Several of the agreements that we will enter into with Emergent require Emergent's consent to any assignment by us of our rights and obligations under the agreements. These agreements will generally expire within two years of our separation from Emergent, except for certain agreements that will continue for longer terms and in some cases for the life of the products covered by the agreements. The consent and termination rights set forth in these agreements might discourage, delay or prevent a change of control that you may consider favorable. See "Certain Relationships and Related Party Transactions" and "Description of Aptevo's Capital Stock" for a more detailed description of these agreements and provisions.

In addition, under the tax matters agreement, for a period of two years following the separation, we will be restricted from taking certain actions (including restrictions on business combinations and share issuances) that could cause the distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. We would be required to indemnify Emergent for any taxes and related expenses resulting from the failure of the transactions to so qualify to the extent that the failure is attributable to actions, events or transactions relating our stock, assets or business, and this indemnity obligation might discourage, delay or prevent a change of control that you may consider favorable.

Our by-laws include an exclusive forum provision that could limit our stockholders' ability to obtain a judicial forum viewed by stockholders as more favorable for disputes with us or our directors, officers or other employees or certain stockholders.

Our by-laws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for: (1) any derivative action or proceeding brought on behalf of Aptevo; (2) any action asserting a claim for breach of a fiduciary duty owed by any director, officer or other employee or stockholder of Aptevo to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of General Corporation Law of the State of Delaware, which we refer to as the DGCL; (4) any action asserting a claim arising pursuant to any provision of our Certificate of Incorporation or by-laws (as they may be amended from time to time); or (5) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage lawsuits against us or our directors or officers. Alternatively, if a court outside of Delaware were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings described above, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

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Because we currently do not expect to pay dividends following the distribution, investors will benefit from an investment in our common stock only if it appreciates in value.

Prior to completion of the distribution, our Board of Directors will adopt a dividend policy with respect to the payment of dividends on our common stock following the distribution. We currently do not expect to pay dividends following the distribution. We anticipate that we will retain all our future earnings, if any, to support our operations and our proprietary drug development programs and product candidates and pursue other opportunities. Any future determination to pay dividends will be at the sole discretion of our Board of Directors and will depend upon our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments and such other factors as our Board of Directors deems relevant. For more information, see “Dividend Policy.” We cannot guarantee that we will pay any dividends in the future or continue to pay any dividend if we were to commence paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

A significant portion of our shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, in connection with the distribution or otherwise, could reduce the market price of our common stock. We are unable to predict whether large amounts of our common stock will be sold in the open market following the distribution. We are also unable to predict whether a sufficient number of buyers would be in the market at that time. Upon completion of the distribution, we expect that we will have an aggregate of approximately ● shares of our common stock issued and outstanding on ●. These shares will be freely tradeable without restriction or further registration under the U.S. Securities Act of 1933, as amended, or the Securities Act, unless the shares are owned by one of our “affiliates,” as that term is defined in Rule 405 under the Securities Act. Moreover, holders of an aggregate of approximately ● shares of our common stock immediately following the distribution will have the right to require us to register these shares of common stock under the Securities Act under specified circumstances. For a further discussion of registration rights, see “Description of Aptevo’s Capital Stock—Registration Rights.”

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This information statement and other materials Emergent and Aptevo have filed or will file with the SEC contain, or will contain, certain forward-looking statements regarding business strategies, market potential, future financial performance and other matters. The words “believe,” “expect,” “expectation,” “anticipate,” “may,” “could,” “intend,” “belief,” “estimate,” “plan,” “target,” “predict,” “likely,” “will,” “should,” “forecast,” “outlook” or other similar words or phrases, among others, generally identify “forward-looking statements,” which speak only as of the date the statements were made. The matters discussed in these forward-looking statements are subject to risks, uncertainties and other factors that could cause our actual results to differ materially from those projected, anticipated or implied in the forward-looking statements. In particular, information included under “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business” and “The Separation and Distribution” contain forward-looking statements. Where, in any forward-looking statement, an expectation or belief as to future results or events is expressed, such expectation or belief is based on the current plans and expectations of our management and expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the expectation or belief will result or be achieved or accomplished. Except as may be required by law, we undertake no obligation to modify or revise any forward-looking statements to reflect events or circumstances occurring after the date of this information statement. Factors that could cause our actual results or events to differ materially from those anticipated include the matters described under “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in addition to the following other factors, many of which are beyond our control:

- demand for and market acceptance risks for and competitive pressures related to new and existing products;
- product development risks, including satisfactory clinical performance, the ability to manufacture at appropriate scale, and the general unpredictability associated with the product development cycle;
- occurrence of manufacturing or supply difficulties;
- product quality or patient safety issues, leading to product recalls, withdrawals, launch delays, sanctions, seizures, litigation, loss of confidence or declining sales;
- future actions of FDA, EMA or any other regulatory body or government authority that could delay, limit or suspend product development, manufacturing or sale or result in seizures, recalls, injunctions, loss of customer confidence, monetary sanctions or criminal or civil liabilities;
- our ability to develop and sustain relationships with collaborative partners;
- failures with respect to the company’s compliance programs;
- global regulatory, trade and tax policies;
- the impact of competitive products and pricing, including generic competition, drug re-importation and disruptive technologies;
- our ability to identify business development and growth opportunities and to successfully execute on our business development strategy;
- our ability to realize the anticipated benefits from our joint product development and commercialization arrangements and other business development activities or to identify and enter into additional such opportunities in the future;
- future actions of third parties, including third-party payors, as healthcare reform and other similar measures are implemented in the United States and globally;
- the impact of U.S. healthcare reform and other similar actions undertaken by foreign governments with respect to pricing, reimbursement, taxation and rebate policies;

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- additional legislation, regulation and other governmental pressures in the United States or globally, which may affect pricing, reimbursement, taxation and rebate policies of government agencies and private payors or other elements of the company's business;
- the ability to protect or enforce the company's owned or in-licensed patent or other proprietary rights (including trademarks, copyrights, trade secrets and know-how) or patents of third parties preventing or restricting the company's manufacture, sale or use of affected products or technology;
- the impact of global economic conditions on us and our customers and suppliers, including foreign governments in certain countries in which we operate;
- fluctuations in foreign exchange and interest rates;
- any changes in law concerning the taxation of income, including income earned outside the United States;
- breaches or failures of the company's information technology systems;
- loss of key employees or inability to identify and recruit new employees;
- the outcomes of any litigation;
- the adequacy of our cash reserves and cash flows from operations to meet our ongoing cash obligations;
- whether the separation is completed, as expected or at all, and the timing of the separation and the distribution;
- whether the conditions to the distribution can be satisfied;
- our operations as an independent company;
- the costs and expenses related to the separation;
- Emergent's performance under various transaction agreements that will be executed as part of the separation;
- our ability to transition away from the services to be provided by Emergent pursuant to the transition services agreement and other agreements with Emergent in a timely manner;
- potential indemnification liabilities owed to Emergent after the separation;
- our ability to achieve operational, marketing and strategic benefits from the separation in a timely manner;
- our ability to access the capital markets following the separation from Emergent;
- failure of the "regular-way," "ex-distribution" or "when issued" markets to develop or other unexpected reactions to the distribution in the capital markets; and
- other factors identified elsewhere in this information statement including the risk factors described herein under the section entitled "Risk Factors."

In addition, other risks and uncertainties not presently known to us or that we consider immaterial could affect the accuracy of any such forward-looking statements. The list of factors described above is illustrative, but by no means exhaustive.

All forward-looking statements should be evaluated with the understanding of their inherent uncertainty. Additional risks and uncertainties include those detailed from time to time in our publicly-filed documents.

DIVIDEND POLICY

We currently do not expect to pay dividends following the distribution. We anticipate that we will retain all our future earnings, if any, to support our operations and our proprietary drug development programs, acquire or in-license additional products and product candidates, and pursue other opportunities, and do not intend to pay dividends in the foreseeable future. The timing, declaration, amount of, and payment of any dividends following the separation by Aptevo is within the sole discretion of its board of directors and will depend upon many factors, including Aptevo's financial condition, earnings, corporate strategy, capital requirements of its operating subsidiaries, covenants associated with any future debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets and other factors deemed relevant by Aptevo's board of directors.

CAPITALIZATION

The following table sets forth Aptevo's capitalization as of March 31, 2016 on a historical basis and on a pro forma basis to give effect to the pro forma adjustments included in Aptevo's unaudited pro forma financial information. The information below is not necessarily indicative of what Aptevo's capitalization would have been had the separation and distribution been completed as of March 31, 2016. In addition, it is not indicative of Aptevo's future capitalization. This table should be read in conjunction with "Unaudited Pro Forma Combined Balance Sheet," "Selected Historical Combined Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Aptevo's combined financial statements and notes included elsewhere in this information statement:

	As of March 31, 2016 (dollars in thousands)	
	Actual	Pro Forma
Cash and cash equivalents	\$ 3,072	\$ 40,000
Total debt	\$ —	\$ —
Equity:		
Common stock, par value \$0.001 per share	—	[●]
Additional paid-in capital	—	[●]
Note receivable from Emergent	—	(20,000)
Net investment from Emergent	334,740	—
Accumulated deficit	(244,878)	[●]
Total equity	89,862	[●]
Total Capitalization	\$ 89,862	\$ [●]

Aptevo is in the process of compiling its anticipated post-distribution capitalization. Prior to the effectiveness of the registration statement of which this information statement is a part, anticipated information regarding Aptevo's capitalization following the separation will be disclosed in accordance with the rules and regulations of the SEC in an amendment to this information statement.

SELECTED HISTORICAL COMBINED FINANCIAL DATA

Aptevo has derived the statement of operations data for the three months ended March 31, 2016 and 2015 and the balance sheet data as of March 31, 2016 from Aptevo's unaudited condensed combined financial statements which are included elsewhere in the information statement. Aptevo has derived the combined statement of operations data for the years ended December 31, 2015, 2014 and 2013 and the combined balance sheet data as of December 31, 2015 and 2014 from its audited combined financial statements, which are included in this information statement. Aptevo derived the combined statements of operations data for the years ended December 31, 2012 and 2011 and the combined balance sheet data as of December 31, 2013, 2012 and 2011 from its unaudited combined financial statements, which are not included in this information statement.

The combined financial statements have been prepared on a "carve-out" basis for the purpose of presenting Aptevo's financial position, results of operations and cash flows. Aptevo did not operate as a standalone entity in the past and accordingly the selected financial data presented herein is not necessarily indicative of Aptevo's future performance and does not reflect what Aptevo's performance would have been had Aptevo operated as an independent publicly-traded company during the periods presented.

The selected financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," the "Unaudited Pro Forma Combined Balance Sheet" and the corresponding notes included elsewhere in this information statement.

(in thousands)	Three Months Ended March 31,		Year Ended December 31,				
	2016	2015	2015	2014	2013	2012	2011
Statements of Operations Data:							
Revenue							
Product sales	\$ 7,948	\$ 6,321	\$ 27,947	\$ 30,036	\$ —	\$ —	\$ —
Collaborations	119	5,342	5,654	15,595	170	3,927	22,097
Revenues	8,067	11,663	33,601	45,631	170	3,927	22,097
Operating expenses							
Cost of product sales	3,528	3,732	16,933	16,254	—	—	—
Research and development	8,101	9,101	34,726	46,589	38,074	23,924	34,454
Selling, general and administrative	9,420	9,932	43,042	34,280	15,451	15,004	9,802
Impairment of in-process research and development	—	—	—	—	—	9,600	—
Total operating expenses	21,049	22,765	94,701	97,123	53,525	48,528	44,256
Loss from operations	(12,982)	(11,102)	(61,100)	(51,492)	(53,355)	(44,601)	(22,159)
Other (expense) income, net	80	(295)	(237)	(222)	18	29	1
Loss before benefit from income taxes	(12,902)	(11,397)	(61,337)	(51,714)	(53,337)	(44,572)	(22,158)
Benefit from income taxes	(12)	(375)	(2,020)	(599)	—	—	—
Net loss	\$ (12,890)	\$ (11,022)	\$ (59,317)	\$ (51,115)	\$ (53,337)	\$ (44,572)	\$ (22,158)

(in thousands)	As of March 31,	As of December 31,				
	2016	2015	2014	2013	2012	2011
Balance Sheet Data:						
Cash, cash equivalents and investments	\$ 3,072	\$ 4,637	\$ 3,593	\$ —	\$ —	\$ 13,491
Total assets	112,605	112,456	119,971	50,528	50,092	80,947
Total long-term liabilities	4,053	3,895	5,528	18	77	3,005
Total stockholders' equity	89,862	88,618	94,608	44,544	44,513	69,387

UNAUDITED PRO FORMA COMBINED BALANCE SHEET

The unaudited pro forma combined balance sheet discussed and presented below has been prepared from Aptevo's historical unaudited condensed combined balance sheet as of March 31, 2016. The pro forma adjustments and notes to the pro forma financial information give effect to the legal formation and capitalization of Aptevo and the contribution of the assets and liabilities of Aptevo by Emergent as described below. The unaudited pro forma combined balance sheet should be read together with the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Aptevo's historical audited combined financial statements, its unaudited condensed combined financial statements and notes related to those financial statements included elsewhere in this information statement.

The unaudited pro forma combined balance sheet as of March 31, 2016 has been prepared as if the separation had occurred on March 31, 2016. The pro forma adjustments are based on the best information available and assumptions that management believes are reasonable given the information available. While such adjustments are subject to change based upon the finalization of the terms of the separation and the underlying separation agreements, in management's opinion, the pro forma adjustments are not expected to materially differ from the final adjustments.

Aptevo's historical combined statements of operations include an allocation of expenses related to certain Emergent corporate functions, including senior management, legal, human resources, finance, investor relations, information technology and quality assurance. These expenses have been allocated to Aptevo based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, square footage, or other measures. Aptevo considers the expense allocation methodology and results to be reasonable for all periods presented. Further, the contractual agreements directly attributable to the spin-off are either not expected to have a material impact on our results of operations and/or cannot be reasonably estimated as to the incremental impact when compared to the relevant actual and/or allocated expenses noted above. Additionally, any unaudited pro forma statements of operations would not reflect certain estimated incremental expenses associated with being an independent, publicly-traded company because such amounts are not associated with the contractual agreements directly attributable to the separation and would be based on management's judgmental estimates and operating plans. Accordingly, such pro forma adjustments to revenues or expenses in the combined statement of operations for the three months ended March 31, 2016 and the year ended December 31, 2015 as if the separation had occurred on January 1, 2015 are not presented.

A significant amount of charges to effect the separation that are not ongoing in nature have been and will continue to be incurred by Emergent, such as financial, legal, tax, accounting and other advisory fees and regulatory fees. Aptevo may also incur costs in connection with the separation such as, among other things, facility and information technology system reconfiguration costs. The total amount of such separation charges to be incurred by Aptevo is not estimable at this time.

The unaudited pro forma combined balance sheet is for illustrative and information purposes only and is not intended to represent, or be indicative of, what Aptevo's financial position would have been had the separation occurred on the date indicated.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Unaudited Pro Forma Combined Balance Sheet
(in thousands)

	March 31, 2016			
	Historical	Pro Forma Adjustments		
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 3,072	\$ 36,928	(a)	\$ 40,000
Accounts receivable, net	3,458			3,458
Inventories	22,071	(12,944)	(c)	9,127
Income taxes receivable	1,387			1,387
Prepaid expenses and other current assets	5,435			5,435
Total current assets	<u>35,423</u>	<u>23,984</u>		<u>59,407</u>
Property, plant and equipment, net	4,624			4,624
In-process research and development	41,800			41,800
Intangible assets, net	16,856			16,856
Goodwill	13,902			13,902
Total assets	<u>\$ 112,605</u>	<u>\$ 23,984</u>		<u>\$ 136,589</u>
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$ 12,197	\$		\$ 12,197
Accrued compensation	2,182			2,182
Contingent consideration	233			233
Provisions for chargebacks	1,960			1,960
Deferred revenue, current portion	2,118			2,118
Total current liabilities	<u>18,690</u>			<u>18,690</u>
Deferred revenue, net of current portion	3,468			3,468
Deferred income taxes	506			506
Other liabilities	79			79
Total liabilities	<u>22,743</u>			<u>22,743</u>
Stockholders' equity:				
Common stock	—	[●]	(d)	[●]
Additional paid in capital	—	[●]	(d)	[●]
Note receivable from Emergent	—	(20,000)	(b)	(20,000)
Net investment from Emergent	334,740	(334,740)	(d)	—
Accumulated deficit	(244,878)	244,878	(d)	[●]
Total stockholders' equity	<u>89,862</u>	<u>[●]</u>		<u>[●]</u>
Total liabilities and stockholders' equity	<u>\$ 112,605</u>	<u>\$ 23,984</u>		<u>\$ [●]</u>

- (a) Reflects the effect of the planned \$40 million cash contribution from Emergent to Aptevo upon separation.
- (b) Reflects the planned capital contribution via issuance of a non-negotiable, unsecured promissory note of \$20 million upon separation. This promissory note from Emergent is payable to Aptevo within six to 12 months following the separation date and is shown as a reduction of stockholders' equity pending cash receipt.
- (c) Reflects raw materials and work-in-process inventory balances for Aptevo products remaining with Emergent. Emergent is expected to manufacture certain of the Aptevo commercial products and sell the finished products to Aptevo. Finished goods inventory on Aptevo's balance sheet will remain with Aptevo.
- (d) Reflects Emergent's net investment in Aptevo, including the impact of the pro forma adjustments herein, re-designated as Aptevo's stockholders' equity upon distribution. The allocation between common stock and paid-in capital is based on the issuance of Aptevo common stock, par value of \$0.001, as of December 31, 2015, on a pro rata basis of [●] share of Aptevo common stock for every 1 (one) share of Emergent common stock.

BUSINESS

OVERVIEW

Aptevo Therapeutics Inc. is a biotechnology company focused on novel oncology (cancer) and hematology (blood disease) therapeutics to meaningfully improve patients' lives. Our core technology is the ADAPTIR™ (modular protein technology) platform. We also have four revenue-generating products in the areas of hematology and infectious diseases, as well as various investigational stage product candidates in immuno-oncology. Aptevo was formed to own and operate certain assets from the biosciences business of Emergent BioSolutions Inc. in connection with the separation and distribution described in this information statement.

We were incorporated in the state of Delaware in February 2016. We have applied for the listing of Aptevo's common stock on the NASDAQ Global Market under the symbol "APVO." Our principal executive offices will be located at 2401 4th Ave., Suite 1050, Seattle, Washington 98121. Our telephone number following the separation will be (206) 838-0500. We will maintain an internet site at www.AptevoTherapeutics.com. Our website and the information contained on the website or connected to the website shall not be deemed to be incorporated into this information statement, and you should not rely on any such information in making an investment decision.

Our investigational stage product candidates MOR209/ES414, ES210, ES425 and otlertuzumab are built on our novel ADAPTIR™ (modular protein technology) platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. The technology can produce monospecific and multispecific immunotherapeutic proteins that specifically bind to one or more targets, for example, bispecific therapeutic molecules, which may have structural advantages over monoclonal antibodies. The mechanisms of action for MOR209/ES414, ES210, ES425 and otlertuzumab include redirected T-cell cytotoxicity, or RTCC, and targeted cytokine delivery. The structural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of other ADAPTIR immunotherapeutics that engage disease targets in a novel manner and produce a unique signaling response. We are skilled at product candidate generation, validation and subsequent pre-clinical and clinical development using the ADAPTIR platform. We have the ability to progress ADAPTIR molecules from concept to marketed product by way of our protein engineering, pre-clinical development and process development capabilities and cGMP manufacturing oversight. We also have the ability to launch, market and commercialize these product candidates upon approval.

Our marketed products are:

- WinRho® SDF [Rh₀(D) Immune Globulin Intravenous (Human)], for treatment of autoimmune platelet disorder, also called immune thrombocytopenic purpura or ITP, and, separately, for the treatment of hemolytic disease of the newborn, or HDN;
- HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)], for prevention of hepatitis-B recurrence following liver transplantation in HBsAg-positive liver transplant patients, and for treatment following exposure to hepatitis-B;
- VARIZIG® [Varicella Zoster Immune Globulin (Human)], for treatment following exposure to varicella zoster virus, which causes chickenpox, in high-risk individuals; and
- IXINITY® [coagulation factor IX (recombinant)], indicated in adults and children 12 years of age and older with hemophilia B for control and prevention of bleeding episodes, and for management of bleeding during operations;

Our investigational stage product candidates include:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells. It is being developed under our collaboration with MorphoSys AG for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies;

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- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease and other autoimmune and inflammatory diseases;
- otlertuzumab, a monospecific ADAPTIR protein therapeutic that is currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL;
- 5E3 mAb, a monoclonal antibody therapeutic that is currently in pre-clinical development for Alzheimer's disease;
- ES425 is a bispecific ADAPTIR immunotherapeutic protein that targets ROR1, an antigen found on several solid tumors and hematologic, or blood-related, malignancies. One pair of binding domains bind to ROR1 on tumors; the other pair of binding domains bind to the T-cell receptor, or TCR. ES425 employs a mechanism of action that redirects T-cell cytotoxicity, or RTCC, by which a therapeutic molecule brings T-cells into contact with tumor cells and triggers tumor killing, or targeted delivery of cytokines (or immune modulating protein) to diseased cells against tumors expressing ROR1. Initial preclinical data demonstrates redirected T-cell cytotoxicity activity. We plan to conduct animal toxicology and pharmacokinetic studies to assess the duration of time ES425 remains in circulation and how well the body tolerates its effect in the absence of tumor; and
- Other protein therapeutic product candidates primarily targeting immuno-oncology.

For information regarding revenue, profit and loss, total assets and other information concerning our results of operations for each of the last three fiscal years, please refer to "Unaudited Pro Forma Combined Balance Sheet," "Selected Historical Combined Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Aptevo's combined financial statements and notes included elsewhere in this information statement.

STRATEGY

We seek to grow our business by, among other things:

Advancing our ADAPTIR platform, initially focusing upon immuno-oncology, to develop novel treatments. We intend to focus on product development using ADAPTIR, our modular protein platform technology. We intend to develop the MOR209/ES414 program in collaboration with MorphoSys AG, with the goal of commercializing the product in North America. We plan to select and create redirected T-cell cytotoxicity, or RTCC, candidates for early development, potentially with other collaborative partners, to further validate the potential of the ADAPTIR platform and expand the pipeline. As part of the selection process, we intend to strongly favor candidates that we believe have the potential to demonstrate proof of concept early in development. We expect to continue to develop the platform to address unmet medical needs, through directed cytokine delivery via bispecifics in areas including oncology, and multispecific molecules in oncology, autoimmune disease and other therapeutic areas. Our goal is to leverage this technology to seek targeted investment in bispecific ADAPTIR therapeutics.

Continuing to develop new products. We are committed to new product development. We have expertise in molecular biology, antibody engineering and the development of protein therapeutics, including cell line development, protein purification, process development and analytical characterization. We believe that these core areas of expertise enable the development of therapeutics based on the ADAPTIR platform technology from design, pre-clinical testing, and clinical development to preparation of a Biologics License Application, or BLA.

Establishing collaborative partnerships to broaden our pipeline and provide funding for research and development. We intend to continue to develop and grow our product portfolio through internal research and development as well as through collaborations potentially with other biotechnology and pharmaceutical companies, academia and non-governmental organizations.

Successfully commercializing specialty products to create financial capacity for investment in our pipeline. We intend to continue to maximize the financial contribution of our hyperimmune products WinRho, HepaGam B and VARIZIG and expand sales of IXINITY for the purpose of funding our research and development efforts. This may require further investments.

COLLABORATIONS, LICENSES AND SUPPORT AGREEMENTS

We have entered into several significant collaborations and transactions to support our growth. These include the following:

Collaboration with MorphoSys AG to develop MOR209/ES414

In August 2014, we entered into an agreement with MorphoSys AG to co-develop and commercialize our novel oncology immunotherapeutic, MOR209/ES414, developed for treatment of metastatic castration-resistant prostate cancer. In December 2015, after a joint review of data from the ongoing Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. The decision to adjust development of MOR209/ES414 was not based on safety aspects but was driven by the high complexity and properties of this first generation ADAPTIR bispecific molecule. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; this is called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug, reduced the concentration of MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. We plan to continue the current clinical trial under the amended protocol with recruitment expected to start around mid-2016. As a result of the dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. Under the terms of the restructured agreement, MorphoSys' cost sharing in the years 2016 to 2018 was reduced and future milestone payments payable by MorphoSys to us were reduced to a total of up to \$74 million. In addition, the amended collaboration agreement changed the total expected funding requirement for us to up to approximately \$250 million. After 2018, the cost sharing returns to the rates of the original agreement. Other financial terms and the split of the commercial rights remained unchanged. The termination provisions under the MorphoSys collaboration agreement were also amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial.

Agreements with Emergent for Commercial Manufacturing Services and Transition Services

In connection with our separation from Emergent, we will enter into a manufacturing services agreement with Emergent. Under the agreement, Emergent will continue to manufacture our hyperimmune specialty plasma products WinRho SDF, HepaGam B and VARIZIG at its Winnipeg, Manitoba, Canada facilities. The expiration date of the manufacturing services agreement is five years following the date of its execution, which is expected to occur on the separation date. We will consider contract manufacturing organization relationships with third-party providers for our products and product candidates going forward and seek to finalize agreements with the party that provides the best terms and conditions in support of Aptevo's business. See "Certain Relationships and Related Party Transactions-Commercial Agreements" for further discussion of the manufacturing services agreement.

In addition, we anticipate that Emergent will also provide transition services to Aptevo for up to two years following the separation. These services may cover such functions as regulatory, pharmacovigilance,⁸ clinical research and quality assurance under our supervision.

Product License and Trademark License Agreements with Emergent

Prior to the distribution, we will enter into a product license agreement with Emergent pursuant to which Emergent will grant us a perpetual, exclusive royalty-free, nontransferable worldwide license, under certain licensed intellectual property rights, to research, develop, make, have made, use, sell, offer to sell and import WinRho SDF, HepaGam B and VARIZIG in their respective indications to support our hyperimmune products. Under the product license agreement, we will only be permitted to exercise rights with respect to Emergent’s human hyperimmune platform manufacturing know-how through a third-party contract manufacturer, and then only if the manufacturer is bound to protect the manufacturing know-how and is either approved by Emergent (in Emergent’s sole and absolute discretion) or there has been a manufacturing failure under the manufacturing services agreement. Aptevo may terminate its rights under the agreement at any time by providing written notice to Emergent. Emergent may terminate the agreement if Aptevo breaches the agreement and the breach is not cured within a specified period of time or is incurable. Each party may terminate the agreement if the other party experiences certain bankruptcy events. See “Certain Relationships and Related Party Transactions - Intellectual Property Agreements” for further discussion of the Product License Agreement.

Prior to the distribution, we will enter into a trademark license agreement with Emergent pursuant to which Emergent will grant us a non-exclusive, royalty-free, worldwide, non-sublicenseable license under certain trademarks of Emergent to distribute the physical inventory of packaging and marketing materials assigned to us as part of the distribution, solely to sell, offer to sell and otherwise commercialize the commercial products until such inventory of packaging and marketing materials is depleted but in no event after the third anniversary of the distribution. Aptevo may terminate its rights under the agreement at any time by providing written notice to Emergent. Emergent may terminate the agreement if Aptevo breaches the agreement and the breach is not cured within a specified period of time or is incurable. See “Intellectual Property Agreements - Certain Relationships and Related Party Transactions” for further discussion of the Trademark License Agreement.

License with the University of North Carolina to IXINITY intellectual property rights

Emergent has an exclusive license from the University of North Carolina to make, have made, use, offer for sale, sell and import factor IX and factor VI(a) therapeutics under certain of the University’s patents. The last of the licensed patents expire on or around September 2024. In connection with our separation from Emergent, the University has consented to the assignment of this license to us.

⁸ Pharmacovigilance refers to the drug safety evaluation process during clinical trials or after market approval where the effects of therapeutics or medical drugs are monitored to identify and evaluate adverse reactions.

PLATFORM TECHNOLOGY AND PRODUCT PORTFOLIO

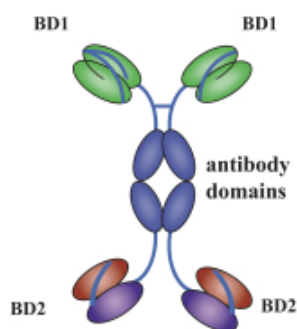
Platform Technology

ADAPTIR Platform. We believe Aptevo is well-positioned for the development of bispecific therapeutics, which are antibody-based molecules that are able to bind multiple targets of therapeutic interest, utilizing its innovative ADAPTIR™ (modular protein technology) platform. This allows Aptevo to take a novel approach to cancer immunotherapy. The platform can be used to produce monospecific and multispecific immunotherapeutic proteins that specifically bind to one or more targets, monospecific, bispecific and multispecific molecules. Structurally, monospecific ADAPTIR molecules are similar to antibodies; they are somewhat smaller than antibodies and the various functions of an antibody can be significantly modified via the ADAPTIR format. The monospecific ADAPTIR molecules are single-chain polypeptides comprising customized elements including a protein domain that binds to a specific target linked by a hinge domain to a set of antibody constant domains known as an Fc region. The Fc region is a component in antibodies that allows antibodies to direct immune responses by binding to Fc receptors found on various immune cells and also provides for an extended serum half-life, which is how long the drug remains in circulation after injection. Multispecific ADAPTIR molecules are similar in structure to monospecific ADAPTIR molecules with the exception that they have two or more customized target binding domains. Multiple targeting domains allow multispecific ADAPTIR molecules to bind multiple targets.

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The structural differences between ADAPTIR molecules and monoclonal antibodies that bind to one target allow for the development of new ADAPTIR immunotherapeutics that engage disease targets in a novel manner and produce a unique signaling response. By customizing the domains of our ADAPTIR molecules, we are able to select for desired potency, half-life, toxicity and good manufacturability. We are skilled at product candidate generation, validation and clinical development using the ADAPTIR platform. We have created various bispecific molecules that are able to redirect T-cell cytotoxicity, or RTCC. T-cells are white blood cells that fight infections and tumor cells. These bispecific ADAPTIR molecules causes T-cells to specifically kill a tumor by binding to a common component on the T-cell and then binding to a specific tumor antigen on a specific tumor, activating a T-cell to kill the tumor. We have the ability to develop ADAPTIR molecules from concept to marketed product by way of our protein engineering, pre-clinical development and process development capabilities and cGMP manufacturing oversight.

An ADAPTIR molecule is derived from a monoclonal antibody. As illustrated in the graphic below, it is composed of a pair of binding regions on either end of the molecule connected by an Fc region. The Fc region (fragment crystallizable region) in an antibody binds to complement and also to various effector cells such as Natural Killer cells (NK) which destroy bacteria and other targeted cells. In the ADAPTIR format these functions may be enhanced or eliminated depending on the function desired from the molecule. The Fc region is connected to the binding domains via a hinge region composed of amino acids. The binding domains in an ADAPTIR molecule is a single chain variable fragment (scFv), which is a fusion protein of the variable domains of the heavy and light chains of immunoglobulins or antibodies and they are connected with a short linker peptide of ten to about 25 amino acids.



Components	Functions
Binding domain 1 (scFv, ECD, Ligand)	Binds to or engages target 1
Hinge (usually IgG hinge)	Modulates binding and biological activity
Ig Fc (eg. IgG 1, IgG 2, IgG 4)	Isotype independent Retains long half life Retain ADCC, CDC activities if desired
Linker (various lengths)	Modulates binding and biological activity
Binding domain 2 (scFv, ECD, Ligand)	Binds to or engages target 2

scFv = Single Chain Fragment Variable
ECD = ExtraCellular Domain of a receptor

We believe the ADAPTIR platform is a promising platform technology within the rapidly growing field of immuno-oncology therapeutics. With the platform, we have the potential to develop products with mechanisms of action including but not limited to RTCC and targeted cytokine delivery. With targeted cytokine delivery, one end of a bispecific molecule targets a specific cell, while at the other end a cytokine “payload” is attached. This provides the capability to more precisely deliver a therapeutic cytokine and could prevent toxicity of a cytokine by limiting its delivery to other areas in the body. We believe the ADAPTIR RTCC platform may prove to have advantages over other immuno-therapeutics and other bispecific T-cell engaging technologies. In particular, in pre-clinical studies, we have gathered data indicating that the ADAPTIR therapeutic MOR209/ES414 may have

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high potency and activity at low doses, a long half-life, and reduced cytokine release. This molecule is able to be produced using standard manufacturing practices. Further clinical and preclinical studies may not confirm or establish the anticipated benefits of this platform.

Aptevo owns all ADAPTIR platform intellectual property except that Aptevo has a non-exclusive research license with Lonza to certain Chinese hamster ovary, or CHO, cell lines, which are cells derived from the ovary of a Chinese hamster and often used in biological and medical research and commercially in the production of therapeutic proteins, for use in protein expression and the GS Gene Expression System™. See section entitled “Platform Technology and Product Portfolio - Product Portfolio” for additional information about the ownership rights to ADAPTIR.

Product Portfolio

Our portfolio consists of marketed products in the areas of hematology and infectious diseases, as well as investigational stage product candidates in immuno-oncology

Marketed Products

Product	Indication(s)	Regulatory Approvals
WinRho® SDF [(Rh _o (D) Immune Globulin Intravenous (Human)]	ITP – immune thrombocytopenic purpura (described further below) HDN – hemolytic disease of the newborn (described further below) Preventing Rh _o (D) immunization in Rh _o (D)(-) women [1] Treating Rh _o (D)(-) patients after transfusions with incompatible Rh _o (D)(+) blood or erythrocyte (red blood cell) products [2]	Canada – ITP, HDN United States – ITP, HDN Portugal – [1] and [2]
HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)]	Treatment following exposure to hepatitis B Prevention of hepatitis B recurrence following liver transplantation in patients who are positive for hepatitis B surface antigen (a protein found on the surface of hepatitis B virus and in the blood or serum of hepatitis B infected individuals)	United States Canada Israel Kuwait Turkey
VARIZIG® [Varicella Zoster Immune Globulin (Human)]	Treatment following exposure to varicella (chickenpox) in high-risk patient groups, including children with compromised immune systems, newborns and pregnant women [3] Prevention and reduction of severity in maternal infections within four days of exposure to varicella zoster virus [4]	United States – [3] Canada – [4]
IXINITY [coagulation factor IX (recombinant)]	Control and prevention of bleeding episodes and for management of bleeding during operations in adults and children, 12 years of age and older, with hemophilia B.	United States

WinRho® SDF [Rh_o(D) Immune Globulin Intravenous (Human)]. WinRho SDF is made from human plasma and is comprised of purified polyclonal human immune globulins (antibodies) that bind to red blood cells that are positive for Rh_o(D) (also known as Rh_o(D)(+) red blood cells). The purified polyclonal antibodies of WinRho SDF are a collection of immunoglobulin molecules that react against Rh_o(D), each identifying a different epitope⁹ or binding site on Rh_o(D). As antibodies that are directed to the Rh_o(D) antigen on these red

⁹ An epitope, also known as antigenic determinant, is the part of an antigen that is recognized by the immune system, specifically by antibodies, B-cells, or T-cells. For example, the epitope is the specific piece of the antigen to which an antibody binds. B-cells are a type of white blood cell (called a b-lymphocyte) that produce antibodies. B-cells mature in the bone marrow before being released into the blood.

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blood cells, WinRho SDF can generally be referred to as an anti-D product, which means that it is a solution of IgG anti-RhD, which are two different types of antibodies.¹⁰ WinRho SDF is approved in the United States and Canada to treat an autoimmune platelet disorder called immune thrombocytopenic purpura, or ITP, a disease in which platelets are destroyed by a patient's own immune system, resulting in the need for an increased platelet count. Because platelets are required for blood clotting, this disorder can result in uncontrolled bleeding, either spontaneously or as a result of even minor trauma. According to a study published in 2010 in the American Journal of Hematology, U.S. incidence rates of ITP are about 3.3 cases per 100,000 people per year in adults and up to 6.4 cases per 100,000 people per year in children. WinRho SDF is also approved in the United States and Canada to prevent hemolytic disease of the newborn, or HDN, in which the mother's immune system attacks the newborn's red blood cells. HDN results from a Rho(D)(-) female giving birth to a Rho(D)(+) child.

HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)]. HepaGam B is administered intravenously and is comprised of purified polyclonal human immune globulins (antibodies) that are directed to the hepatitis B surface antigen, which is a protein found on the surface of the hepatitis B virus and in the blood or serum of hepatitis B infected individuals. In the United States, HepaGam B has been approved for two indications: for the prevention of hepatitis B reinfection after liver transplantation and for use following exposure to the hepatitis B virus. Hepatitis B is a chronic infection and a major global health concern. HepaGam B is the first hepatitis B immune globulin product to be licensed in the United States for the liver transplant-related indication. HepaGam B is also approved for both the treatment following exposure to hepatitis B and the post-liver transplantation indication in Canada, Israel, Kuwait and Turkey.

VARIZIG® [Varicella Zoster Immune Globulin (Human)]. VARIZIG is comprised of purified polyclonal human immune globulins (antibodies) directed to the varicella zoster virus, the disease agent that causes chickenpox. While most North American adults have developed immunity to chickenpox, certain at-risk patient populations may be susceptible to infection. VARIZIG is approved in the United States for treatment following exposure to varicella (chickenpox) in high-risk patient groups, including children with compromised immune systems, newborns and pregnant women. VARIZIG has orphan drug exclusivity in the United States through December 2019. In Canada, VARIZIG is approved for the prevention and reduction of severity in maternal infections within four days of exposure to varicella zoster virus.

IXINITY® (coagulation factor IX (recombinant)). IXINITY is an intravenous therapeutic comprising an active pharmaceutical ingredient of recombinant human coagulation factor IX that was approved by the U.S. Food and Drug Administration, or FDA, in April 2015 for the prevention of bleeding episodes in people with hemophilia B. Hemophilia B, also known as Christmas disease, is a rare, inherited bleeding disorder. The blood of hemophilia B patients has an impaired clotting ability, which results from its substantially reduced or missing factor IX activity. People with hemophilia B require factor IX injections to restore normal blood coagulation and to prevent frequent bleeding that could otherwise result in pain, irreversible joint damage or life-threatening hemorrhages. Prophylaxis or on-demand treatment of hemophilia B typically requires multiple injections of factor IX to maintain adequate levels of clotting factor in the blood. Current therapies are either plasma-derived or recombinant products.

Product Candidates

MOR209/ES414 . MOR209/ES414 is a targeted immunotherapeutic protein under development for metastatic castration-resistant prostate cancer. MOR209/ES414, a bispecific protein, was constructed using our ADAPTIR platform technology. It activates host T-cell immunity to specifically kill tumor cells expressing prostate specific membrane antigen, or PSMA, an enzyme that is commonly overexpressed on the surface of prostate cancer cells. MOR209/ES414 contains two pairs of binding domains, one targeting the T-cell receptor, or TCR, and one targeting PSMA on tumor cells; these binding domains are linked to opposite ends of an antibody Fc region which extends the serum half-life and enables use of a purification process typical of

¹⁰ Some individuals have red blood cells containing an antigen, known as the D antigen, on their surface, similar to a blood type antigen. Antibodies specific for the D antigen, or "anti-D", can protect pregnant women from Rh disease (a condition that occurs during pregnancy when a mother is Rh-negative and the baby is Rh-positive, which in severe cases can result in death of the fetus) by triggering an immune response to remove red blood cells with the D antigen.

antibodies. In pre-clinical studies, MOR209/ES414 has been shown to redirect T-cell cytotoxicity towards prostate cancer cells expressing PSMA. According to the American Cancer Society, prostate cancer is the most common cancer in men in the United States. Screening, radiation, surgery and hormone ablation therapy have greatly improved the detection and treatment of early stage prostate cancer. However, new therapies approved recently for patients with metastatic castration-resistant prostate cancer only improve life expectancy by a few months, and a significant medical need still exists for these individuals.

ES210. ES210 is an anti-inflammatory molecule engineered using our ADAPTIR platform technology. It is under development for the treatment of inflammatory bowel disease, including ulcerative colitis and Crohn's disease, and other autoimmune and inflammatory diseases. ES210 is a targeted cytokine therapeutic, specifically, it is designed to deliver a safer form of the anti-inflammatory cytokine, IL-10, to antigen presenting cells, or APCs, that express CD86. APCs are a therapeutic target of interest for an anti-inflammatory therapeutic such as ES210 because, as described further below, APCs play a critical role in the immune response. Structurally, ES210 contains a modified form of IL-10, coupled to binding sites specific for CD86, linked by an antibody Fc region. The mechanism of action results in suppression of T-cell responses through inhibition of antigen presentation. Antigen presenting cells play a central role in the generation and regulation of immunity; therefore, inhibiting their function represents a therapeutic opportunity to suppress immunopathological processes in autoimmune and inflammatory disease. ES210 preclinical data demonstrate potent in vitro and in vivo antagonism of T-cell proliferation in human mixed lymphocyte reactions and in a humanized¹¹ graft-versus-host disease model. The ES210 ADAPTIR molecule also has potential anti-inflammation applications in rheumatoid arthritis and in the treatment of transplant rejection. As a molecule designed using our ADAPTIR platform technology, the ES210 half-life is extended in preclinical models. Also, manufacturing benefits are realized because the platform enables use of a purification process that is typically used for making antibodies.

ES425. ES425 is a bispecific immunotherapeutic protein that targets ROR1, an antigen found on several solid tumors and hematologic malignancies. ES425 was constructed using our ADAPTIR platform; one pair of binding domains bind to ROR1 on tumors and the other pair of binding domains bind to the T-cell receptor, or TCR. Its mechanism of action is to redirect T-cell cytotoxicity against tumors expressing ROR1. Initial preclinical data demonstrate significant redirected T-cell cytotoxicity against tumors in preclinical models. We plan to conduct animal toxicology and pharmacokinetic studies (used to determine how the human body processes the drug after absorption) in order to file an investigational new drug application, or IND, with the FDA.

otlertuzumab. Otlertuzumab is a monospecific protein therapeutic intended for the treatment of chronic lymphocytic leukemia, or CLL. CLL is a type of cancer that affects the blood and bone marrow and is caused by B-cells within the blood and bone marrow that abnormally proliferate and die. Otlertuzumab is a humanized anti-CD37 monospecific protein therapeutic built using the ADAPTIR platform technology. It specifically binds to CD37, a receptor found on malignant B-cells. It functions like an antibody and engages natural killer cells, which are lymphocytes of the immune system, and other effector cells to kill the tumor cell. We believe that otlertuzumab's novel properties may provide patients with improved therapeutic options and enhanced efficacy when used in combination with chemotherapy or other targeted therapeutics.

We completed a Phase 2 clinical trial evaluating the combination of otlertuzumab and bendamustine (a chemotherapy agent) versus bendamustine alone in people with relapsed CLL (Study 16201). In that study the combination of otlertuzumab and bendamustine was superior to bendamustine alone. The combination was well tolerated with significantly increased response rate (69% vs. 39%, $p=0.003$) and prolonged progression free survival rate (15.9 months vs. 10.1 months, $p=0.0059$) over single agent bendamustine treatment. The overall incidence of adverse events was similar between the two treatment cohorts, but there was a higher incidence of fever, neutropenia (which is a low white blood cell count that could predispose a patient to infection) and thrombocytopenia (which is a low platelet count that if severe could lead to bleeding) with the combination. The addition of otlertuzumab did not appear to increase the number of serious adverse events, as there were fewer discontinuations for adverse events with the combination compared to bendamustine alone.

¹¹ Humanized refers to chemically altering animal proteins to resemble natural human amino acid sequences (or the order in which they bond).

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We are conducting a Phase 1b study to evaluate the safety and efficacy of otlertuzumab in combination with rituximab, an anti-CD20-directed biologic that binds to CD20, a receptor found primarily on the surface of immune system B-cells. We amended our Phase 1b single-arm study to include evaluating otlertuzumab in combination with obinutuzumab in people with previously untreated CLL (Study 16009). Patients began enrolling in this arm of the study mid-2015. The preliminary data showed that the combination was active and generally well-tolerated. We continue to evaluate opportunities for otlertuzumab as a product candidate in the treatment of CLL.

5E3. 5E3 is an investigational drug in preclinical development for the treatment of Alzheimer's disease and derived from a murine antibody. 5E3 is a humanized monoclonal antibody, not an ADAPTIR molecule, that selectively binds the oligomeric form of amyloid beta that have been associated with neurotoxicity. An oligomer is a type of polymer whose molecular units consist of relatively few repeating units. 5E3 targets a unique conformational epitope that is not present on the monomer or plaque forms of amyloid beta. This selective binding has been observed in pre-clinical studies and is linked to slowing the progress of neurodegeneration (the loss of nerve cells). Currently, no disease modifying therapies are available to treat this disease. According to the Alzheimer's Association, this disease affects approximately 5.3 million Americans and is anticipated to grow to 7.1 million by 2025. The technology platform licensed from University of British Columbia includes 5E3 mAb and a vaccine candidate based on an amyloid beta mimic that are being evaluated as therapeutics or diagnostics for Alzheimer's disease and with support through research grants from Brain Canada and the Canadian Institutes of Health Research, or CIHR.

ADAPTIR Therapeutic Candidates. Multiple candidates that are focused on immuno-oncology and based on the ADAPTIR platform technology are in different stages of pre-clinical development. As described above, these candidates include but are not limited to MOR209/ES414, ES210, ES425 and otlertuzumab.

Potential adverse events related to our product candidates

Experimental drugs may have a variety of adverse events related to their target, mechanism of action or off target toxicities. Clinical trials are conducted to define the efficacy and safety of a new molecule and this data is reviewed by the FDA prior to FDA approval. The majority of the drugs that we are developing are intended for the treatment of cancer. Because cancer is a serious and life threatening disease, these patients experience a number of serious adverse events as part of their disease. The risk-benefit ratio for new treatments of cancer is different than other less serious diseases. For example, for the treatment of hypertension, it is not acceptable for a drug to lower the number of white blood cells that fight infections. However, chemotherapy for the treatment of cancer frequently lowers the number of white blood cells and infections do occur, which physicians manage in the course of a patient's cancer treatment. In order to distinguish whether a new drug causes adverse events, a controlled trial is frequently conducted comparing a new drug to another therapy.

In clinical trials to date with otlertuzumab, a variety of serious adverse events have been reported. The events that have been reported with infusion of the drug include: infusion reactions, neutropenia and thrombocytopenia. Severe infusion reactions were infrequent. When these reactions are severe they lead to hypotension (low blood pressure) and bronchospasm (difficulty breathing). Neutropenia is a low white blood cell count that could predispose a patient to infection. The neutropenia observed with otlertuzumab was mild to moderate, not prolonged and did not increase the infection rate in a controlled clinical trial. Thrombocytopenia is a low platelet count that if severe could lead to bleeding. The thrombocytopenia observed with otlertuzumab was infrequent and not associated with bleeding. Any of these events or others that have not yet been experienced, could lead to serious adverse events, including death and severely limit the drug's use in the market or even its ability to be approved by a regulatory body.

MOR209/ES414 is currently being tested in its first clinical trial in humans. Twelve patients have received the drug. One of the significant serious adverse events associated with the drug is infusion reactions. Infusion reactions are often associated with the infusion of a protein and are expected with this drug that activates T-cells. The events that have been reported with infusion of the drug include: fever, fatigue, hypertension, bronchospasm, chills and rigors. The severity of these reactions varied by patient and were managed medically and resolved.

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As previously noted, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of MOR209/ES414 developed ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA. We plan to continue the current clinical trial under an amended protocol with recruitment expected to start around mid-2016. As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured.

Research and Development

We are engaged in research and development of therapeutics including the product candidates listed above and other new candidates. We incur substantial expenses for these activities. These expenses generally include the cost of inventing new technologies and products, as well as development work on new product candidates. We pursue partnerships with various third parties and these partnerships and the sales of our approved products partially offset these expenditures. Research and development expenses for the years ended December 31, 2015, 2014 and 2013 totaled approximately \$34.7 million, \$46.6 million and \$38.1 million, respectively. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Research and Development Expense” in this information statement for additional information regarding expenditures related to material research and development activities.

Distribution

Our products are sold in the United States by our commercial sales force and distributed to end-users through major U.S. distributors and wholesalers, including Cardinal Health, Inc., McKesson Corporation, AmerisourceBergen Corporation and other specialty distributors. In Canada, our products are sold to Canadian Blood Services and Héma-Québec, with Emergent acting as our exclusive Canadian wholesaler. Outside of North America, our commercial products are distributed primarily through third-party distributors. All third-party logistics (including, for instance, warehousing, inventory management, and shipping) of final drug product are provided by Emergent out of its facilities in either Winnipeg or Baltimore.

Marketing & Sales

We have biotechnology commercial operations and medical affairs teams with experience in sales, marketing, distribution, reimbursement and medical support.

The commercial operations team includes a U.S.-based field sales force that focuses its selling efforts on hemophilia treatment centers, hematology clinics, medical oncology clinics, transplant centers and public and private hospitals. Our team also has a group focused on immunology. Our teams consists of 14 representatives and two managers for hemophilia and six representatives and one manager for immunology. We have a field-based national accounts director and manager and a national sales director overseeing these functions. This team is also responsible for managing day-to-day relationships with third parties, including managed care organizations, pharmacy benefit managers, group purchasing organizations, wholesalers, specialty distributors and specialty pharmacies. Outside the United States, our products are sold through a network of regional independent distributors. The commercial operations team also includes a marketing team with experience in building pharmaceutical and biological brands across all stages of the product life cycle. Reimbursement support,

patient assistance/compassionate use and non-medical customer inquiries are handled by customer service personnel within our commercial operations team.

Our medical affairs team includes field-based medical science liaisons, who respond to customer requests for information, establish and maintain company relationships with researchers and clinicians, train our product specialists and sales personnel and interface with clinical trial investigators. Our medical affairs team also supports customers by providing medical information, drug safety and pharmacovigilance services.

Orders are filled upon receipt, and we generally have no orders on backlog.

Competition

Our products and product candidates face significant competition. Any product or product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, as well as other novel product candidates that are in development for the same indications. Specifically, the competition with respect to our products and product candidates includes the following:

- **WinRho SDF.** In the United States, the use of WinRho SDF is primarily for the immune thrombocytopenia purpura, or ITP, indication. In the U.S. ITP market, WinRho SDF competes with Rhophlac® (CSL Behring, a subsidiary of CSL Limited), Nplate® (Amgen Inc.) and Promacta® (GlaxoSmithKline plc). In Canada, the use of WinRho SDF is primarily for the HDN indication. WinRho SDF is the only anti-D product available for the prevention of HDN and treatment of ITP in Canada. The use of anti-viral drugs is also a competitive threat to this product.
- **HepaGam B.** HepaGam B competes with two products that are marketed in North America: Nabi-HB® (Biotest Pharmaceuticals Corporation) and HyperHEP B® S/D (Grifols USA, LLC). Nabi-HB® and HyperHEP B® S/D are both licensed to treat acute exposure to blood containing hepatitis B surface antigen (a protein found on the surface of hepatitis B virus and in the blood or serum of hepatitis B infected individuals) and administered via intramuscular injection. HepaGam B is currently the only intravenous hepatitis B immune globulin licensed for the liver transplantation indication in the United States and Canada. The use of anti-viral drugs is also a competitive threat to this product.
- **VARIZIG.** No other currently manufactured competitive product is licensed in the North American markets.
- **IXINITY.** Currently, IXINITY competes with five products that are marketed in North America: Rixubis (Baxter International Inc.), Benefix® (Pfizer Inc.) and Alprolix® (Biogen Idec Inc.) recombinant FIX products as well as AlphaNine® (Grifols USA, LLC) and MonoNine® (CSL Behring, a subsidiary of CSL Limited), which are FIX preparations derived from human plasma. We expect that Novo Nordisk Inc. and CSL Behring will also launch additional recombinant factor IX agents in the future.
- **MOR209/ES414.** If approved, we anticipate that MOR209/ES414 would compete with Taxotere® (Sanofi-Aventis U.S. LLC), Jevtana (Sanofi-Aventis U.S. LLC), Zytiga® (Janssen Biotech, Inc.), Xtandi® (Astellas Pharma, Inc.), Xofigo® (Bayer HealthCare Pharmaceuticals Inc.), Proveng® (Dendreon Corporation) and potentially other products currently under development. There is a potential that MOR209/ES414 could also be used in combination with these same agents.
- **ES210.** If approved, we anticipate that ES210 would compete with products indicated for inflammatory bowel diseases such as ulcerative colitis, including: HUMIRA® (AbbVie Inc.), Remicade® (Janssen Pharmaceuticals, Inc. of Johnson and Johnson) and Entyvio® (Takeda Pharmaceuticals U.S.A., Inc., a subsidiary of Takeda Pharmaceutical Company Limited). Depending on what ES210 is approved for, we anticipate that it could also compete with products indicated for moderate to severe Crohn's Disease, including: Stelara (Janssen Pharmaceuticals, Inc. of Johnson and Johnson) and Xeljanz (Pfizer Inc.).

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- **otlertuzumab.** If approved for CLL, we anticipate that otlertuzumab would compete with, or be combined with, other B-cell depleting therapies, targeted therapies and chemotherapeutics, including: Rituxan® (Genentech, Inc., a member of the Roche Group), Treanda® (Cephalon, a subsidiary of Teva Pharmaceutical Industries Ltd.), Arzerra® (GlaxoSmithKline plc and Genmab A/S), Imbruvica™ (PharmacyClics, Inc. and Johnson and Johnson), Gayzva™ (Genentech USA, Inc., a member of the Roche Group) and Zydelig® (Gilead Sciences, Inc.). In addition, Boehringer Ingelheim GmbH and ImmunoGen, Inc. are in early stage development for monoclonal antibodies directed to CD37. AbbVie Inc. is developing venetoclax ABT-199, a B-cell lymphoma 2 inhibitor, for treatment of CLL in collaboration with Genentech, Inc.
- **5E3.** The U.S. has five approved drugs for Alzheimer’s disease that temporarily improve symptoms (cholinesterase inhibitors; Aricept® (Eisai Co. Ltd.), Exelon® (Novartis Pharmaceuticals Corporation), Razadyne® (Johnson & Johnson Health Care Systems Inc.) and Cognex® (Shionogi & Co., Ltd.) and an N-methyl D-aspartate (NMDA) receptor antagonist, Namenda® (Merz Pharma GMBH & Co. KGaA)); however, none of the treatments available today alters the underlying course of this terminal disease. To date, there are no approved therapeutics for the treatment of Alzheimer’s disease, but monoclonal antibodies have figured prominently in addressing this unmet clinical need. Among the candidates are Ponezumab (Pfizer Inc., discontinued at PII), Bapineuzumab (Janssen Biotech, Inc./Pfizer Inc., discontinued), Solanezumab (Eli Lilly and Company, PIII), Crenezumab (F. Hoffmann-La Roche Ltd, PII), BAN2401 (Biogen Idec, Eisai Co. Ltd., PII) and more recently Aducanumab (Biogen Idec, PIII). Acumen Pharmaceuticals is developing an amyloid-beta oligomer specific antibody, ACU-193, and claims to be approximately one year from an Investigational New Drug Application, or IND, filing.
- **ES425.** If approved, we anticipate that ES425 may compete with other ROR1-directed protein therapeutics, including those that block the growth of cancer cells by binding to specific proteins needed for tumor formation and growth and that are under current clinical and pre-clinical development, including: KAN0439834 (Kancera AB), cirmtuzumab (University of California, San Diego and Celgene Corporation), cirmtuzumab vedotin (University of California, San Diego), and IT-4 (Magnifygen, Inc.). We also anticipate that ES425 may compete with ROR1-directed cellular therapies, such as chimeric antigen receptor-modified T-cells (T-cells collected from a patient’s own blood and genetically modified to express chimeric antigen receptors that allow the T-cells to recognize specific tumor cells), also known as CAR-T, that are under current clinical development by MD Anderson Cancer Center as well as a separate program under pre-clinical development by Juno Therapeutics, Inc.

MANUFACTURING

In connection with our separation from Emergent, we will enter into a manufacturing services agreement with Emergent. Emergent owns facilities with manufacturing and other capabilities located in Winnipeg, Manitoba, Canada, where our hyperimmune specialty plasma products WinRho SDF, HepaGam B and VARIZIG are currently manufactured. Under the agreement, Emergent will continue to manufacture our hyperimmune specialty plasma products. Under this Agreement, Emergent will also provide third-party logistics services for our hyperimmune specialty plasma products and IXINITY.

The manufacturing services agreement with Emergent will cover each step in the manufacturing process from raw materials procurement, bulk manufacturing, filing and finishing, testing, labeling, and packaging of final product, as well as third-party logistics services for delivery of such product to Aptevo customers on behalf of Aptevo. We will be reliant exclusively on Emergent for the provision of each of these services as it relates to WinRho SDF, HepaGam B and VARIZIG and as it relates to third party logistics services for IXINITY. Emergent, will also serve as our only licensed wholesaler in Canada under the Canadian wholesaler agreement we will enter with Emergent. Pursuant to this arrangement, Emergent will receive product intended for sale in Canada on our behalf and deliver it to our Canadian distributors: Canadian Blood Services and Hema-Quebec. See “Certain Relationships and Related Party Transactions – Commercial Agreements” for further discussion of the manufacturing services agreement and Canadian wholesaler agreement.

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We rely primarily on CMC for drug substance manufacture and drug substance release testing of IXINITY. Fill-finish services and associated final drug product release testing for IXINITY are provided by Emergent and various other parties. IXINITY will be delivered to Aptevo customers by Emergent as part of the third-party logistics services it provides to Aptevo under the manufacturing services agreement. For additional information, see the section entitled “Risk Factors—Risks Related to Aptevo’s Business.” Commercial packaging, packaging component procurement and release, ancillary procurement and release and distribution for IXINITY will be provided by Emergent and various other parties.

Sources and Availability of Raw Materials

We expect to rely on Emergent for all supplies and raw materials used in the production of WinRho SDF, HepaGam B and VARIZIG.

We expect to rely on CMC Biologics for all supplies and raw materials used in the production of IXINITY. Patheon UK Limited, through an affiliate, is currently the sole source third-party manufacturer that provides fill-finish services for our IXINITY product. Rovi Contract Manufacturing, S.L. is currently the sole source third-party manufacturer that supplies the syringe pre-filled with water for injection, that is packaged with and required for reconstitution of our IXINITY product.

INTELLECTUAL PROPERTY

We actively seek intellectual property protection for our products. We will own or exclusively license patent rights supporting IXINITY, the ADAPTIR platform and pipeline products including MOR209/ES414, ES210, ES425, otlertuzumab and 5E3. We practice patent life cycle management by filing patent applications to protect new inventions relating to meaningful improvements to our products and related methods. We primarily seek patent protection for inventions that support our products and product candidates, but from time to time we seek patent protection for inventions that could, for instance, support a potential business opportunity or block a competitor from designing around our existing patents.

In general and where possible, we pursue patent protection in countries where we believe there will be a significant market for the corresponding product or product candidate. We generally do not seek patent protection in countries where we have reason to believe we would not be able to enforce patents. For instance, we tend to not file in countries that are frequently listed on the Priority Watch List of the Special 301 Report prepared by the Office of the United States Trade Representative, with the exception that we occasionally file patent applications in China, Russia and India. We may also decide to take a more narrow filing approach for secondary and improvement type inventions as compared to inventions that are more foundational to our products. We do not seek patent protection in countries which are on the United Nation’s, or U.N., list of Least Developed Countries.

The term of protection for various patents associated with and expected to be associated with our marketed products and product candidates is typically 20 years from the filing date but may vary depending on a variety of factors including the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. The protection afforded by a patent varies on a product-by-product basis and country-to-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the necessity for terminal disclaimers, the availability of legal remedies in a particular country and the validity and enforceability of the patents.

In some cases, we may decide that the best way to protect our intellectual property is to retain proprietary information as trade secrets and confidential information rather than to apply for patents, which would involve disclosure of proprietary information to the public. When determining whether to protect intellectual property as

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a trade secret, we consider many factors including, for instance, our ability to maintain the trade secret, the likelihood that a competitor will independently develop the information, our ability to patent protect the intellectual property and the likelihood we would be able to enforce a resulting patent.

We are a party to a number of license agreements under which we license patents, patent applications and other intellectual property. These agreements impose various commercial diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future.

ADAPTIR Platform. Aptevo protects the ADAPTIR platform technology through a combination of patents and trade secrets. Aptevo owns all ADAPTIR platform intellectual property, except that Aptevo has a non-exclusive research license with Lonza to certain CHO cell lines, which are cells derived from the ovary of a Chinese hamster and often used in biological and medical research and commercially in the production of therapeutic proteins, for use in protein expression and the GS Gene Expression System™. The GS System is a cell transfection and protein expression system that uses a robust viral promoter and selection via glutamine metabolism to provide rapid development of high-yielding and stable mammalian cell lines that express transfected proteins of therapeutic interest. The GS System is well known in the industry, and according to Lonza, is a familiar system that has been used by over 100 global pharmaceutical and biotechnology companies. Under our Lonza research license, we have an option to take a license to use the GS System to develop and manufacture therapeutic proteins for our commercial purposes.

The intellectual property we own that supports our ADAPTIR platform was generated internally at Emergent or at Trubion Pharmaceuticals, Inc. prior to its acquisition by Emergent in 2010. One patent family which supports use of unique linkers in the homodimer (a molecule consisting of two identical halves) version of the platform was invented jointly by Trubion and Wyeth Pharmaceuticals as part of a collaboration between the two companies. Upon termination of a product license agreement between Wyeth and Trubion, Wyeth assigned the rights it had in that platform patent family to Trubion. These rights will be assigned to Aptevo in connection with the separation.

In order to differentiate our platform inventions from antibodies and other antibody-like constructs that have been publicly disclosed, many of our patents and patent applications are directed to unique aspects or components of our platform such as linkers or binding domains. Our ADAPTIR platform can be homodimeric or heterodimeric. Although most of our patent families protect both homodimeric and heterodimeric forms of the platform, we also have a patent family that is focused on the heterodimeric form of the platform.

We have filed patent applications for the ADAPTIR platform in the U.S. and in countries and territories, including Australia, Brazil, Canada, China, Egypt, Europe, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Singapore, South Africa, South Korea, United Arab Emirates and Vietnam. We plan to continue to improve our ADAPTIR platform and to file patent applications on those improvements. Our decision as to where to file any new ADAPTIR improvement inventions will be based in part on the significance of the improvement. If patents issue on the pending ADAPTIR patent applications, the patent term for those patents are estimated to expire between June 2027 and September 2036.

Hyperimmune products, WinRho, HepaGam B and VARIZIG. We rely on the confidential nature of our in-licensed manufacturing know-how as well as trade secret protection to protect our licensed products to the extent we are able to do so. In connection with our separation from Emergent, we will have received a license from Emergent under certain of its proprietary human hyperimmune platform manufacturing know-how that we may exercise under specified circumstances. We rely on this intellectual property to protect our WinRho SDF, HepaGam B and VARIZIG products. We do not have patent protection for WinRho SDF, HepaGam B or VARIZIG.

IXINITY® (coagulation factor IX (recombinant)). We license patents and patent applications from the University of North Carolina, which support the manufacture of factor IX and other Vitamin K Dependent Proteins. In addition to the patent assets licensed from the University of North Carolina, we own a patent

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portfolio with claims generally directed to factor IX pharmaceutical compositions, methods of making recombinant factor IX protein, and cell lines producing recombinant factor IX protein. This patent portfolio includes issued patents in Australia, Europe and Japan and pending patent applications in other territories including the U.S. If patents issue on our pending patent applications, the patent term for those patents is estimated to expire between December 2026 and October 2030. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

MOR209/ES414. We have patents and pending patent applications supporting the MOR209/ES414 product candidate. We have foundational patents and patent applications in countries including the U.S., Australia, Brazil, Canada, China, Egypt, Europe, Hong Kong, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Singapore, South Africa, United Arab Emirates and Vietnam. The foundational patents which grant in this patent family are estimated to expire in April 2032. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

ES210. We have patents and pending patent applications supporting our ES210 product candidate. We have foundational patents and patent applications in countries and territories, including the U.S., Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Japan, Mexico, New Zealand, Singapore, South Africa and South Korea. The foundational patents which grant in this patent family are estimated to expire in October 2029. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

ES425. We have a patent application covering our ES425 product candidate. We plan to broadly nationalize this application, and any resulting patents are estimated to expire in December 2035. In addition to the patent application family that we own, we have an exclusive license from the U.S. Department of Health and Human Services to a patent family that discloses ROR-1 antibodies that are related to the ROR-1 binding domain of ES425. The license from the U.S. Department of Health and Human Services is limited to use in the field of bispecific and multispecific therapeutic molecules with redirected T-cell cytotoxicity activity. If patent applications grant in the licensed patent family, the patents are estimated to expire in November 2031. The U.S. Department of Health and Human Services can terminate the license if we are in default in the performance of any material obligations under the agreement and do not cure the default within 90 days after receiving notice. The U.S. Department of Health and Human Services can also terminate the license if it determines that termination is necessary to meet the requirements for public use specified by federal regulations and those requirements are determined not to be adequately satisfied by our activities.

otlertuzumab. We have patents and pending patent applications supporting the otlertuzumab product candidate. We have foundational patents and patent applications in countries and territories, including the U.S., Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Russia, South Africa and South Korea. The foundational patents and patent applications which grant in these patent families are estimated to expire between July 2026 and April 2029. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

5E3. We have licensed from the University of British Columbia the right to make, have made, use, offer for sale, sell, and import products in the field of beta-amyloid disorders under certain of the University's patents. The University's patents and patent applications encompassed by the license are generally directed to antibodies that bind a specific conformational amyloid beta epitope and related pharmaceutical compositions, antigenic peptides and related pharmaceutical compositions, and methods of treating and preventing Alzheimer's disease. If patents issue on the currently pending patent applications, the projected expiration dates of the licensed patent portfolio range from March 2031 to July 2035. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

Corporate Trademarks. Where possible, we pursue registered trademarks for our marketed products in significant markets. In addition, we have pending trademark applications covering APTEVO, a graphic logo, APTEVO THERAPEUTICS, APTEVO BIOTHERAPEUTICS, APTEVO RESEARCH AND DEVELOPMENT and ADAPTIR.

REGULATION

Regulations in the United States and other countries have a significant impact on our product development, manufacturing and marketing activities.

Product Development for Therapeutics

Pre-clinical Testing. Before beginning testing of any compounds with potential therapeutic value in human subjects in the United States, stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing includes both *in vitro*, or in an artificial environment outside of a living organism, and *in vivo*, or within a living organism, laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. We perform pre-clinical testing on all of our product candidates before we initiate any human trials.

Investigational New Drug Application. Before clinical testing may begin, the results of pre-clinical testing, together with manufacturing information, analytical data and any other available clinical data or literature, must be submitted to the FDA as part of an IND. The sponsor must also include an initial protocol detailing the first phase of the proposed clinical investigation, together with information regarding the qualifications of the clinical investigators. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical studies in human volunteers. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA imposes a clinical hold within that 30-day time period.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients with the target disease or disorder under the supervision of a qualified physician (also called an investigator) pursuant to an FDA-reviewed protocol. Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another. Clinical trials must be conducted under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria, if any, to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

- Phase 1 clinical trials test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, for early evidence regarding efficacy.
- Phase 2 clinical trials involve a small sample of individuals with the target disease or disorder and seek to assess the efficacy of the drug for specific targeted indications to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.
- Phase 3 clinical trials consist of expanded, large-scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product and dosing regimen. The safety and efficacy data generated from Phase 3 clinical trials typically form the basis for FDA approval of the product candidate.
- Phase 4 clinical trials, if conducted, are conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific population. As part of a product approval, the FDA may require that certain Phase 4 studies, which are called post-marketing commitment studies, be conducted post-approval.

Good Clinical Practice. All of the phases of clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations and Good Clinical Practices, or GCP, which are ethical and scientific quality standards for conducting, recording and reporting clinical trials to assure that the data and reported results are credible and accurate and that the rights, safety and well-being of trial participants are protected.

Marketing Approval—Biologics and Drugs

Biologics License Application/New Drug Application. All data obtained from a comprehensive development program, including research and product development, manufacturing, pre-clinical and clinical trials, labeling and related information are submitted in a Biologics License Application, or BLA, to the FDA and in similar regulatory filings with the corresponding agencies in other countries for review and approval. For small molecule drugs, this information is submitted in a filing called a New Drug Application, or NDA. The submission of an application is not a guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application and request additional information rather than accept the application for filing, in which case the application must be resubmitted with the supplemental information. The FDA has two months to review an application for its acceptability for filing. Once an application is accepted for filing, the Prescription Drug User Fee Act, or PDUFA, establishes a two-tiered review system: Standard Review and Priority Review. When conducting Priority Review, the FDA has a goal to review and act on BLA and NDA submissions within six months from the date of the FDA's acceptance for filing of the application, rather than the 10-month goal under a Standard Review. The FDA gives Priority Review status to product candidates that provide safe and effective therapies where no satisfactory alternative exists or to a product candidate that constitutes a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, BLAs, NDAs and certain supplements must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug or biologic for an indication for which orphan designation has been granted.

In reviewing a BLA or NDA, the FDA may grant approval, deny the application if it determines the application does not provide an adequate basis for approval or again request additional information. Even if such additional information and data are submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. The receipt of regulatory approval often takes many years, involving the expenditure of substantial financial resources. The speed with which approval is granted often depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may also impose conditions upon approval. For example, it may require a Risk Evaluation and Mitigation Strategy, or REMS, for a product. This can include various required elements, such as publication of a medication guide, patient package insert, a communication plan to educate health care providers of the drug's risks and/or restrictions on distribution and use, such as limitations on who may prescribe or dispense the drug. The FDA may also significantly limit the indications approved for a given product and/or require, as a condition of approval, enhanced labeling, special packaging or labeling, post-approval clinical trials, expedited reporting of certain adverse events, pre-approval of promotional materials or restrictions on direct-to-consumer advertising, any of which could negatively impact the commercial success of a drug.

Fast Track Designation. The FDA may designate a product as a fast track drug if it is intended for the treatment of a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for this disease or condition. Sponsors granted a fast track designation for a drug are granted more opportunities to interact with the FDA during the approval process and are eligible for FDA review of the application on a rolling basis, before the application has been completed.

Breakthrough Therapy. Under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA may designate a product as a breakthrough therapy if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in

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clinical development. Products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Orphan Drugs. Under the Orphan Drug Act, an applicant can request the FDA to designate a product as an “orphan drug” in the United States if the drug is intended to treat an orphan, or rare, disease or condition. A disease or condition is considered orphan if it affects fewer than 200,000 people in the United States. Orphan Drug designation must be requested before submitting a BLA or NDA. Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity (afforded to the first applicant to receive approval for an orphan designated drug) prevents FDA approval of applications by others for the same drug for the designated orphan disease or condition. The FDA may approve a subsequent application from another applicant if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public’s need. A grant of an orphan designation is not a guarantee that a product will be approved. The FDA has designated VARIZIG with Orphan Drug exclusivity through December 2019 for treatment following exposure to varicella (chickenpox) in high-risk patient groups, including children with compromised immune systems, newborns and pregnant women. Our product candidate otlertuzumab was granted orphan drug designation by the FDA in November 2011 and received orphan medicinal product designation from the European Commission in December 2012 for the treatment of chronic lymphocytic leukemia. Orphan designation in Europe qualifies a drug for certain development and commercial incentives, including protocol assistance, access to centralized authorization procedures, reduced fees for regulatory activities, and 10 years of market exclusivity after approval.

Post-Approval Requirements. Any drug, biologic or medical device product for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, current good manufacturing practices, or cGMP, and restrictions on advertising and promotion. Adverse events that are reported after marketing approval can result in additional limitations being placed on the product’s distribution or use and, potentially, withdrawal or suspension of the product from the market. In addition, the FDA has post-approval authority to require post-approval clinical trials and/or safety labeling changes if warranted by the appearance of new safety information. In certain circumstances, the FDA may impose a REMS after a product has been approved. Facilities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other laws. The FDA also closely monitors advertising and promotional materials we may disseminate for our products for compliance with restrictions on off-label promotion and other laws. We may not promote our products for conditions of use that are not included in the approved package inserts for our products. Certain additional restrictions on advertising and promotion exist for products that have so-called “black box warnings” in their approved package inserts, such as WinRho SDF.

Pricing and Reimbursement

In the United States and internationally, sales of our products and our ability to generate revenues on such sales are dependent, in significant part, on the availability and level of reimbursement from third-party payors, including state and federal governments and private insurance plans. Insurers have implemented cost-cutting measures and other initiatives to enforce more stringent reimbursement standards and likely will continue to do so in the future. These measures include the establishment of more restrictive formularies and increases in the out-of-pocket obligations of patients for such products. In addition, particularly in the United States and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities.

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Various provisions of the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act), collectively referred to as the Affordable Care Act, increased the levels of rebates and discounts that we have to provide in connection with sales of such products that are paid for, or reimbursed by, certain state and federal government agencies and programs. It is possible that future legislation in the United States and other jurisdictions could be enacted, which could potentially impact the reimbursement rates for our products and also could further impact the levels of discounts and rebates we are required to pay to state and federal government entities. The most significant governmental reimbursement programs in the United States relevant to our products are described below:

Medicare Part B. Medicare Part B covers certain drug products provided in a physician's office or hospital outpatient setting under a payment methodology using "average sales price," or ASP, information. We are required to provide ASP information to the Centers for Medicare & Medicaid Services, or CMS, on a quarterly basis. Medicare payment rates using an ASP methodology are currently set at ASP plus six percent, although this rate could change in future years. If we fail to timely or accurately submit ASP, we could be subject to civil, monetary and other penalties. WinRho SDF, HepaGam B, VARIZIG and IXINITY are all eligible to be reimbursed under Medicare Part B.

Medicaid Rebate Program. For products to be covered by Medicaid, drug manufacturers must enter into a rebate agreement with the Secretary of HHS on behalf of the states and must regularly submit certain pricing information to CMS. The pricing information submitted, including information about the "average manufacturer price," or AMP, and "best price" for each of our covered drugs, determines the amount of the rebate we must pay. The total rebate also includes an "additional" rebate, which functions as an "inflation penalty." The Affordable Care Act increased the amount of the basic rebate and, for some "line extensions," increased the additional rebate. It also requires manufacturers to pay rebates on utilization by enrollees in managed care organizations. If we fail to timely or accurately submit required pricing information, we could be subject to civil, monetary and other penalties. In addition, the Affordable Care Act made changed the definition of AMP to address which manufacturer sales are to be considered, which affected the rebate liability for our products. Sales of WinRho SDF, HepaGam B, VARIZIG and IXINITY that are reimbursed through Medicaid are subject to the obligations related to this program.

340B/PHS Drug Pricing Program. The availability of federal funds to pay for WinRho SDF, HepaGam B, VARIZIG and IXINITY under the Medicaid and Medicare Part B programs requires that we extend discounts under the 340B/Public Health Service, or PHS, drug pricing program. The 340B/PHS drug pricing program requires participating manufacturers to charge no more than a statutorily-defined "ceiling" price to a variety of community health clinics and other covered entities that receive health services grants from the PHS, as well as the outpatient departments of hospitals that serve a disproportionate share of Medicaid and Medicare beneficiaries. A product's ceiling price for a quarter reflects its Medicaid AMP from two quarters earlier less its Medicaid rebate amount from two quarters earlier. Therefore, the above-mentioned revisions to the Medicaid rebate formula and AMP definition enacted by the Affordable Care Act could cause the discount produced by the ceiling price to increase. Under the Affordable Care Act, several additional classes of entities were made eligible for these discounts, increasing the volume of sales for which we must now offer the 340B/PHS discounts.

Federal Supply Schedule. We make WinRho SDF, HepaGam B, VARIZIG and IXINITY available for purchase by authorized users of the Federal Supply Schedule, or FSS, administered by the Department of Veterans Affairs, or DVA, pursuant to our FSS contract with the DVA. Under the Veterans Health Care Act of 1992, we are required to offer deeply discounted FSS contract pricing to four federal agencies—the DVA, the DoD, the Coast Guard and the PHS (including the Indian Health Service)—for federal funding to be made available for reimbursement of any of our products under the Medicaid program, Medicare Part B and for our products to be eligible to be purchased by those four federal agencies and certain federal grantees. FSS pricing to those four federal agencies must be equal to or less than the "Federal Ceiling Price," which is, at a minimum, 24% less than the Non-Federal Average Manufacturer Price for the prior fiscal year.

Foreign Regulation

Currently, we maintain a commercial presence in the United States and Canada. In the future, we may further expand our commercial presence to additional foreign countries and territories. In the European Union, medicinal products are authorized following a process similarly demanding as the process required in the United States. Medicinal products must be authorized in one of two ways, either through the decentralized procedure, which provides for the mutual recognition procedure of national approval decisions by the competent authorities of the EU Member States or through the centralized procedure by the European Commission, which provides for the grant of a single marketing authorization that is valid for all EU member states. The authorization process is essentially the same irrespective of which route is used. We are also subject to many of the same continuing post-approval requirements in the EU as we are in the United States (*e.g.*, good manufacturing practices).

Anti-Corruption Laws

We are subject to various federal and state laws pertaining to health care “fraud and abuse,” including state and federal anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a drug manufacturer to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment, to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. If we violate the kickback or false claims laws, we could be subject to civil and criminal penalties, including exclusion from participation in federal healthcare programs such as Medicare and Medicaid. Similar restrictions are imposed on the promotion and marketing of medicinal products in the European Union and other countries. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct are often strictly enforced. Even in those countries where we are not directly responsible for the promotion and marketing of our products, inappropriate activity by our international distribution partners can have implications for us. In addition, as part of the Affordable Care Act, the federal government enacted the Physician Payment Sunshine Act. Manufacturers of drugs are required to publicly report payments and transfers of value made to physicians and teaching hospitals. This information is posted on a public website. Failure to timely and accurately submit required information could subject us to civil penalties. Some states have similar laws. Many of these transparency requirements are new and uncertain and the extent to which the laws will be enforced is not always clear.

Our operations are also subject to compliance with the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits corporations and individuals from directly or indirectly paying, offering to pay, or authorizing the payment of anything of value to any foreign government official or employee, or any foreign political party or political candidate in an attempt to obtain or retain business or to otherwise influence such official, employee, party or candidate in his or her or its official capacity. We also may be implicated under the FCPA by activities taken on our behalf by our partners, collaborative partners, consultants, distributors, contract research organizations, vendors or other agents and representatives. As a public company, the FCPA also requires us to make and keep books and records that accurately and fairly reflect all of our transactions and to devise and maintain an adequate system of internal accounting controls. Our operations are also subject to compliance with the Bribery Act of 2010, which applies to activities both in the public and private sector, Canada’s Corruption of Foreign Public Officials Act and similar laws in other countries where we do business.

Other Regulation

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, export, use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents used in connection with our product development, are or may be applicable to our activities.

EMPLOYEES

Following the separation, we expect to employ approximately 140 full-time persons. The team is comprised of a dedicated group of accomplished professionals who bring a broad range of academic achievements combined with significant industry experience. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

AVAILABLE INFORMATION

The Aptevo investor website www.AptevoTherapeutics.com will be operational as of our separation date. We will make available, free of charge on our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or the Exchange Act, as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission, or SEC.

We will also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we intend to make available on our website all disclosures that are required to be posted by applicable law, the rules of the SEC or the NASDAQ listing standards regarding any amendment to, or waiver of, our code of business conduct and ethics. We have included our website address as an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of, or incorporated by reference into, this information statement.

PROPERTIES

We lease our headquarters office and laboratory space in Seattle, Washington. The Seattle facility is approximately 51,000 square feet. The Seattle lease expires in April of 2020. We also lease approximately 5,000 square feet of satellite office space in Berwyn, Pennsylvania. The Berwyn lease expires in May 2017.

LEGAL PROCEEDINGS

From time to time, we are involved in various routine legal proceedings incident to the ordinary course of our business. We believe that the outcome of all pending legal proceedings in the aggregate is unlikely to have a material adverse effect on our business, financial condition or results of operations.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion in conjunction with the audited combined financial statements and the corresponding notes and the unaudited pro forma combined balance sheet and the corresponding notes included elsewhere in this information statement. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements. The matters discussed in these forward-looking statements are subject to risk, uncertainties, and other factors that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. You should review the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this information statement for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

On August 6, 2015, Emergent BioSolutions Inc. announced its plan to separate into two independent publicly-traded companies, one a biotechnology company focused on novel oncology (cancer) and hematology (blood disease) therapeutics to meaningfully improve patients' lives and the other a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats. To accomplish this separation, Emergent created a new company, Aptevo Therapeutics Inc., to be the parent company for the development-based pharmaceuticals business focused on novel oncology and hematology therapeutics. Aptevo was incorporated in Delaware in February 2016 and is currently a wholly-owned subsidiary of Emergent. For purposes of this discussion, Aptevo refers to the development-based pharmaceuticals business focused on novel oncology and hematology therapeutics of Emergent prior to separation. To effect the separation, Emergent will make a pro rata distribution of Aptevo's common stock to Emergent's stockholders. See "The Separation and Distribution" section of this information statement for additional details on these conditions. After the distribution, Aptevo will operate as an independent, publicly-traded company.

Aptevo will consist of certain assets currently in Emergent's biosciences division, including commercial products and development programs, and the ADAPTIR platform technology. Emergent will retain the biodefense marketed products and development programs, platform technologies, including the hyperimmune specialty plasma product manufacturing platform, and manufacturing infrastructure, including the contract fill/finish business. Certain historical operations that were included by Emergent in its biosciences segment have been reallocated to Emergent's continuing operations, and as a result these financial statements differ from Emergent's historically reportable biosciences segment.

Aptevo's historical combined financial statements have been prepared on a standalone basis and are derived from Emergent's consolidated financial statements and accounting records. The combined financial statements reflect Aptevo's financial position, results of operations, and cash flows as its business was operated as part of Emergent prior to the distribution, in conformity with U.S. generally accepted accounting principles.

The combined financial statements include the allocation of certain assets and liabilities that have historically been held at the Emergent corporate level but which are specifically identifiable or allocable to Aptevo. Cash and cash equivalents held by Emergent were not allocated to Aptevo unless the cash was held by an entity that will be transferred to Aptevo in the distribution. All Aptevo intracompany transactions and accounts have been eliminated. All intercompany transactions between Aptevo and Emergent are considered to be effectively settled in the combined financial statements at the time the transaction was recorded. The total net effect of the settlement of these intercompany transactions is reflected in the combined statement of cash flows as a financing activity and in the combined balance sheet as net investment from Emergent.

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The historical financial statements do not necessarily include all of the expenses that would have been incurred had Aptevo been a separate, standalone entity and may not necessarily reflect Aptevo's results of operations, financial position and cash flows had Aptevo been a standalone company during the periods presented. Aptevo's combined financial statements include an allocation of expenses related to certain Emergent corporate functions, including senior management, legal, human resources, finance, information technology, and quality assurance. These expenses have been allocated to Aptevo based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, square footage, or other measures. Aptevo considers the expense allocation methodology and results to be reasonable for all periods presented. However, the allocations may not be indicative of the actual expense that would have been incurred had Aptevo operated as an independent, publicly-traded company for the periods presented.

Aptevo's investigational stage products MOR209/ES414, ES210, ES425 and otlertuzumab are built on our novel ADAPTIR™ (modular protein technology) platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. The technology can produce monospecific and multispecific, for example, bispecific therapeutic molecules, which may have structural advantages over monoclonal antibodies (identical antibodies from clones or copies of a unique parent cell that bind to the same target in the same way). The mechanisms of action for MOR209/ES414, ES210, ES425 and otlertuzumab include redirected T-cell cytotoxicity, or RTCC, and targeted cytokine delivery. The structural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of other ADAPTIR immunotherapeutics that engage disease targets in a unique manner and produce a unique signaling response. We are skilled at product candidate generation, validation and subsequent clinical development using the ADAPTIR platform. We have the ability to progress ADAPTIR molecules from concept to marketed product by way of our protein engineering, pre-clinical development and process development capabilities and cGMP manufacturing oversight. We also have the ability to launch, market and commercialize these product candidates upon approval.

Aptevo's marketed products are:

- WinRho® SDF [Rh₀(D) Immune Globulin Intravenous (Human)], for treatment of autoimmune platelet disorder, also called immune thrombocytopenic purpura, or ITP, and, separately, for the treatment of hemolytic disease of the newborn, or HDN;
- HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)], for prevention of hepatitis-B recurrence following liver transplantation in HBsAg-positive liver transplant patients, and for treatment following exposure to hepatitis-B;
- VARIZIG® [Varicella Zoster Immune Globulin (Human)], for treatment following exposure to varicella zoster virus, which causes chickenpox, in high-risk individuals; and
- IXINITY® [coagulation factor IX (recombinant)], indicated in adults and children 12 years of age and older with hemophilia B for control and prevention of bleeding episodes, and management of bleeding during operations.

Aptevo's investigational stage product candidates include:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells. It is being developed under our collaboration with MorphoSys AG for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies;
- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease and other autoimmune and inflammatory diseases;
- otlertuzumab, a monospecific ADAPTIR protein therapeutic that is currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL;

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- 5E3 mAb, a monoclonal antibody therapeutic that is currently in pre-clinical development for Alzheimer’s disease;
- ES425, a bispecific immunotherapeutic ADAPTIR protein that targets ROR1 (receptor tyrosine kinase-like orphan receptor 1, a protein expressed on solid tumors, leukemias, and lymphomas), which is currently in pre-clinical development for a variety of hematologic malignancies and solid tumors; and
- Other protein therapeutic product candidates primarily targeting immuno-oncology.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to revenues, accrued expenses, income taxes, stock-based compensation, inventory, intangible assets, in-process research and development and goodwill. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Aptevo recognizes revenues if four basic criteria have been met (1) there is persuasive evidence of an arrangement, (2) delivery has occurred or services have been rendered, (3) the fee is fixed or determinable and (4) collectability is reasonably assured.

Aptevo markets and sells its products through commercial wholesalers (direct customers) who purchase the products at a price referred to as the wholesale acquisition cost (“WAC”). Additionally, Aptevo may enter into separate agreements with indirect customers to acquire its products for a contracted price that is less than the product’s WAC. The indirect customers, such as group-purchasing organizations, physician practice-management groups and hospitals, continue to purchase Aptevo’s products from the wholesalers, but at their respective contractual prices. Per its wholesaler agreements, Aptevo guarantees to credit the wholesaler for the difference between the WAC and the indirect customers’ contracted price. This credit is referred to as a chargeback and revenues from product sales are recorded net of estimated chargebacks. Adjustments to the chargeback provisions are made periodically to reflect new facts and circumstances that may indicate that historical experience may not be indicative of current and/or future results.

All revenues from product sales are also recorded net of applicable allowances for sales and government rebates, special promotional programs, and discounts. These allowances are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels, contract terms, and actual discounts offered. In arriving at these estimates, Aptevo further utilizes information received from third parties including market data, inventory reports from major wholesalers, historical information and analysis. These estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates and reflect other limitations.

Aptevo defers the recognition of revenue from the sales of new product introductions until the commercial wholesalers resell the product through to healthcare providers. This is due to the inherent uncertainties in estimating normal wholesaler inventory levels of new products in addition to Aptevo provided extended payment

terms and expanded return rights that allow the wholesalers to return the product. Once Aptevco gains enough historical experience to reasonably estimate ultimate product sales, revenue from sales are no longer deferred. As of March 31, 2016, Aptevco had \$1.8 million of deferred revenue for sales related to the IXINITY product introduction.

Revenue generating collaborative research and development agreements may contain one or more provisions including licensing, research services and milestone deliverables. Aptevco analyzes its multiple element revenue generating arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. An item can generally be considered a separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a standalone basis and (2) if the arrangement includes a general right of return and delivery, the performance of the undelivered item(s) is considered probable and substantially in the control of Aptevco. Items that cannot be divided into separate units are consolidated with other units of accounting, as appropriate. Consideration to be received is allocated among the separate units based on each unit's relative selling price and is then recognized when the appropriate revenue recognition criteria are met. Aptevco deems services to be rendered if no continuing obligation exists on the part of Aptevco.

Revenue associated with non-refundable upfront license fees that can be treated as a single unit of accounting are recognized when all ongoing obligations have been delivered. Revenue associated with non-refundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting are deferred and recognized as revenue either on a straight-line basis over Aptevco's continued involvement in the research and development process or based on the proportional performance of Aptevco's expected future obligations under the contract.

Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable, (2) achievement of the milestone was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved to achieve the milestone and (4) the amount of the milestone payment appears reasonable in relation to the effort expended. If not deemed substantive, Aptevco recognizes such milestone as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process. Payments received in advance of revenue recognized are recorded as deferred revenue.

Mergers and Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, Aptevco may be required to value assets at fair value measures that do not reflect Aptevco's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in Aptevco's combined financial statements after the date of the merger or acquisition.

The fair values of intangible assets are determined utilizing information available near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, Aptevco typically obtains assistance from third-party valuation specialists for significant items. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect Aptevco's results of operations.

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The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an “income approach” through which fair value is estimated based on each asset’s discounted projected net cash flows. Aptevo’s estimates of net cash flows consider historical and projected pricing, margins and expense levels, the performance of competing products where applicable, relevant industry and therapeutic area growth drivers and factors, current and expected trends in technology and product life cycles, the time and investment that will be required to develop products and technologies, the ability to obtain marketing and regulatory approvals, the ability to manufacture and commercialize the products, the extent and timing of potential new product introductions by Aptevo’s competitors, and the life of each asset’s underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to in-process research and development (“IPR&D”) are determined using an income approach, through which fair value is estimated based on each asset’s probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, Aptevo will make a separate determination as to the then useful life of the asset and begin amortization.

Provision for Chargebacks

We record sales for our products primarily net of provisions for chargebacks, administration fees, rebates and other adjustments. These provisions are primarily estimated based on historical experience, future expectations, contractual arrangements with wholesalers and indirect customers, and other factors known to management at the time of accrual. Provisions for chargebacks, administration fees, rebates and other adjustments require varying degrees of subjectivity. While rebates generally are based on contractual terms and require minimal estimation, chargebacks require management to make more subjective assumptions.

The provision for chargebacks is a significant and complex estimate used in the recognition of revenue. We sell our products directly primarily to large commercial wholesale distributors. We also sell our products indirectly to group-purchasing organizations, physician practice-management groups and hospitals, collectively referred to as “indirect customers.” We enter into agreements with our indirect customers to establish pricing for certain of our products. The indirect customers then independently select a wholesaler from which to purchase the products. If the price paid by the indirect customers is lower than the price paid by the wholesaler, we will provide a credit, called a chargeback, to the wholesaler for the difference between the contractual price with the indirect customers and the wholesaler purchase price. The provision for chargebacks is based on expected sell-through levels by our wholesale customers to the indirect customers and estimated wholesaler inventory levels.

As sales to large wholesale customers fluctuate the reserve for chargebacks will also generally fluctuate in the same direction. However, the degree of the fluctuation depends on product mix and the amount of sales made to indirect customers with which we have specific chargeback agreements.

On a quarterly basis, management reviews actual payments for provisions, wholesaler and distributor sales to our indirect customers, inventory balances at the wholesalers and distributors, as well as any known market factors that may impact our estimate, and we make adjustments when we believe that actual expected chargebacks may differ from the actual chargeback reserve.

Financial Operations Overview

Revenues

Revenues consist primarily of product sales of our marketed products and collaboration revenues from our collaborative partners, generally in the form of upfront or milestone payments.

Cost of Product Sales

The primary expense that we incur to deliver our marketed products to our customers is manufacturing costs consisting of fixed and variable costs. Variable manufacturing costs consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing and filling operations, and sales-based royalties. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were manufactured.

Research and Development Expenses

We expense research and development costs as incurred. Our research and development expenses consist primarily of:

- personnel-related expenses;
- fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material; and
- costs of materials used in clinical trials and research and development.

We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, and the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials. These research and development costs may be partially offset by cost-sharing arrangements with collaborative partners, such as our collaboration with MorphoSys AG.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense.

Collaboration with MorphoSys AG

In August 2014, Aptevo entered into a collaboration agreement, or MorphoSys Agreement, with MorphoSys AG for the joint worldwide development and commercialization of MOR209/ES414, a targeted immunotherapeutic protein, which activates host T-cell immunity specifically against cancer cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells. MOR209/ES414 was constructed using Aptevo's proprietary ADAPTIR platform technology.

In accordance with the initial terms of the MorphoSys Agreement, Aptevo received a nonrefundable \$20.0 million upfront payment and could have received up to \$163.0 million in additional contingent payments,

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comprised of up to \$80.0 million and up to \$83.0 million, respectively, due upon the achievement of specified development and regulatory milestones. MorphoSys and Aptevo agreed to jointly fund further development of MOR209/ES414, with Aptevo responsible for 36% of the total development costs and MorphoSys responsible for the remainder, with Aptevo's funding requirement capped at \$186.0 million. Aptevo's development effort includes the performance of non-clinical, clinical, manufacturing and regulatory activities. Aptevo retains commercialization rights in the U.S. and Canada, with a tiered royalty obligation to MorphoSys, ranging from mid-single digit up to 20% of sales. MorphoSys has worldwide commercialization rights excluding the U.S. and Canada, with a low single digit royalty obligation to Aptevo.

In December 2015, after a joint review of data from the ongoing Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys decided to adjust the dosing regimen and administration of MOR209/ES414. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; this is called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. We plan to continue the current clinical trial under an amended protocol with recruitment expected to start around mid-2016. As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. In December 2015, Aptevo and MorphoSys amended the collaboration agreement to (1) decrease the additional contingent payments due Aptevo upon the achievement of specified development and regulatory milestones of up to \$32.5 million and up to \$41.5 million, respectively, (2) change the total funding requirement cap for Aptevo to up to approximately \$250.0 million and (3) change the jointly funded development cost allocation to the following:

- 2016: Aptevo is responsible for 75%; MorphoSys responsible for 25%
- 2017-2018: Aptevo is responsible for 49%; MorphoSys responsible for 51%
- 2019 and beyond: Aptevo is responsible for 36%; MorphoSys responsible for 64%

In addition, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial.

Aptevo evaluated the MorphoSys Agreement and determined that it was a revenue arrangement with multiple deliverables or performance obligations. Aptevo determined there were two units of accounting under the MorphoSys Agreement: (1) the delivered license to further develop and commercialize MOR209/ES414 and (2) undelivered items related to development services. Aptevo determined that the license had standalone value as the drug candidate has been (1) developed and is currently Phase 1 clinical trial ready, (2) MorphoSys possesses the knowledge, technology, skills, experience and infrastructure necessary to complete all further development of the drug through commercialization, and (3) MorphoSys has the right to further sublicense the product. Aptevo allocated the \$20.0 million upfront payment to the two units of accounting using the relative selling price method. Aptevo determined the estimated selling price for the license using the income approach and an appropriate discount rate. The estimated selling price includes unobservable inputs (Level 3), such as estimates of revenues and operating margins; the time and resources needed to complete the development and approval of the product candidate; and the risk related to the viability of and potential for alternative treatments. Aptevo determined the estimated selling price of the development services unit of accounting based on the estimated number of full-time equivalent personnel at the contractual rate as defined in the MorphoSys Agreement, whose rates and terms approximate those of other Emergent or Aptevo service related contracts and those observed generally through other collaboration negotiations. The allocation resulted in \$15.3 million of the

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\$20.0 million upfront payment being allocated to the license and \$4.7 million being allocated to the development services. Aptevo determined the license fee unit of accounting was delivered and completed on the date the MorphoSys Agreement was executed and thus recognized \$15.3 million of license revenue in August 2014. Revenue related to the development services is recognized as the services are performed with \$0.7 million and \$0.2 million, respectively, recognized in the years ended December 31, 2015 and 2014. The current estimated service period for the undelivered development services under the MorphoSys Agreement is through 2023.

Further, Aptevo determined that contingent payments for the achievement of the development and regulatory milestones are substantive milestones and will be accounted for as revenue in the period in which the milestones are achieved. Aptevo received a \$5.0 million milestone payment from MorphoSys reflecting the initiation of a Phase I clinical study to evaluate the safety, tolerability, and clinical activity of MOR209/ES414 in patients with metastatic castration-resistant prostate cancer. Aptevo recognized this substantive milestone achievement payment as collaborations revenue during the year ended December 31, 2015.

IXINITY

In the acquisition of Cangene Corporation, or Cangene, in February 2014, Aptevo acquired the IXINITY product candidate, an IPR&D intangible asset. As part of the purchase price allocation, Aptevo's management determined that the estimated acquisition date fair value related to the IXINITY IPR&D asset was \$8.3 million. The estimated fair value was determined using the income approach, which discounts probability-adjusted future net cash flows to present value. The projected cash flows used in determining the fair value of IXINITY were based on key assumptions, including: estimates of revenues and operating profits considering its stage of development on the acquisition date, the time and resources needed to complete the development and approval of the product candidate, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, Aptevo made a separate determination as to the then useful life of the asset and begin amortization. In April 2015, the Food and Drug Administration, or FDA, approved IXINITY for the treatment of Hemophilia B in adults and children. As a result, the \$8.3 million IXINITY IPR&D asset was reclassified as a definite-lived intangible asset and is being amortized over 10 years.

CMC ICOS Biologics, Inc., or CMC, is the exclusive manufacturer of bulk drug substance for our IXINITY product. During 2015, we ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. We continue to work with CMC to resolve the manufacturing delays, although to date in 2016 no lots of bulk drug substance have been successfully manufactured and released. Additionally, Patheon UK Limited, through an affiliate, is currently the sole source fill-finish service manufacturer for our IXINITY product. The release of drug product by Patheon may be impacted by several factors, including Patheon requiring approval from its affiliate's foreign regulatory authority of recent changes to its facility. If current efforts to proceed with the manufacturing and release of bulk drug substance and filled product are not successful, the resulting lack of supply of bulk drug substance or filled product could lead to a projected supply shortage of IXINITY requiring notification to the FDA. This inability to supply IXINITY would adversely affect its sales, market position and viability.

Results of Operations**Three Months Ended March 31, 2016 Compared to Three Months Ended March 31, 2015****Revenue***Product Sales:*

Product sales revenue increased by \$1.6 million, or 25%, to \$7.9 million for the three months ended March 31, 2016 from \$6.3 million for the three months ended March 31, 2015. This increase was primarily related to IXINITY sales of \$1.7 million for the three months ended March 31, 2016 following IXINITY's FDA approval in the second quarter of 2015. As of March 31, 2016, an additional \$1.8 million of IXINITY product sales revenue has been deferred and recorded as deferred revenue on the combined balance sheet until such time as we can reasonably estimate chargebacks and other allowances related to this new product from certain commercial wholesalers.

Collaborations:

Collaborations revenue decreased by \$5.2 million, or 98%, to \$0.1 million for the three months ended March 31, 2016 from \$5.3 million for the three months ended March 31, 2015. The decrease in collaboration revenue was from our collaboration with MorphoSys, primarily related to recognition of a \$5.0 million development milestone achievement and payment for the three months ended March 31, 2015.

Cost of Product Sales

Cost of product sales decreased by \$0.2 million, or 5%, to \$3.5 million for the three months ended March 31, 2016 from \$3.7 million for the three months ended March 31, 2015. The decrease in cost of product sales was primarily due to lower HepaGam cost of sales partially offset by the commencement of IXINITY product sales in the second quarter of 2015 after FDA approval.

Research and Development Expense

Research and development expenses decreased by \$1.0 million, or 11%, to \$8.1 million for the three months ended March 31, 2016 from \$9.1 million for the three months ended March 31, 2015. Our principal research and development expenses by program for the three months ended March 31, 2016 and 2015 are shown in the following table:

(in thousands)	Three Months Ended		Change
	March 31,		
	2016	2015	
MOR209/ES414	\$ 1,810	\$ 423	\$ 1,387
IXINITY	2,225	5,357	(3,132)
ES425	2,038	477	1,561
otlertuzumab	521	1,141	(620)
ES210	118	432	(314)
5E3	360	560	(200)
Other ADAPTIR related programs	898	651	247
Other	131	60	71
Total	\$ 8,101	\$ 9,101	\$(1,000)

The increase in expense for our MOR209/ES414 product candidate was primarily due to the timing of manufacturing activities along with decreased reimbursement from MorphoSys for development activities under our collaboration agreement. The decrease in expense for our IXINITY product candidate (which was approved by the FDA in April 2015) was primarily for manufacturing activities and the timing of clinical trial activities.

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The increase in ES425 was primarily due to lead construct selection and characterization studies. The decrease in expense for our otlertuzumab product candidate was primarily related to the timing of clinical trial activities. The decrease in ES210 was primarily due to process development along with clinical and non-clinical strategy activities. The decrease in expense for 5E3 was primarily due to early stage non-clinical activities. The increase in expense for Other ADAPTIR related programs was primarily due to characterization studies and non-clinical activities. The expenses for our Other activities were primarily due to centralized research and development activities not otherwise attributable to specific product candidates or programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by \$0.5 million, or 5%, to \$9.4 million for 2016 from \$9.9 million for 2015. This decrease was primarily due to lower costs associated with IXINITY prelaunch selling and marketing costs in 2015 partially offset by increased costs associated with Aptevo infrastructure activities in 2016.

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Revenue

Our total revenues by major product and geographic area are as follows:

<u>(in thousands)</u>	<u>Year Ended December 31,</u>	
	<u>2015</u>	<u>2014</u>
WinRho	\$ 14,218	\$ 17,192
HepaGam	10,345	10,450
Other product sales	3,384	2,395
Total product sales	27,947	30,037
Collaborations	5,654	15,594
	<u>\$ 33,601</u>	<u>\$ 45,631</u>

<u>(in thousands)</u>	<u>Year Ended December 31,</u>	
	<u>2015</u>	<u>2014</u>
United States	\$ 21,338	\$ 30,386
Canada	8,569	7,794
Rest of the world	3,694	7,451
	<u>\$ 33,601</u>	<u>\$ 45,631</u>

Revenues from our significant customers or collaboration partners as a percentage of total revenues are as follows:

	<u>Year Ended December 31,</u>	
	<u>2015</u>	<u>2014</u>
<u>Product Sales:</u>		
Canadian Blood Services	20%	13%
Cardinal Health	14%	8%
ASD Healthcare	10%	4%
<u>Collaborations:</u>		
MorphoSys	17%	34%

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Product Sales:

Product sales revenue decreased by \$2.1 million, or 7%, to \$27.9 million for 2015 from \$30.0 million for 2014. This decrease was primarily related to a decrease in non-U.S. sales of WinRho.

Product sales of IXINITY commenced in the second quarter of 2015 following FDA approval. As of December 31, 2015, \$3.3 million of IXINITY product sales revenue has been deferred and recorded as deferred revenue on the combined balance sheet until such time as we can reasonably estimate chargebacks and other allowances related to this new product.

Collaborations:

Collaborations revenue decreased by \$9.9 million, or 63%, to \$5.7 million for 2015 from \$15.6 million for 2014. The decrease in collaboration revenue was from our collaboration with MorphoSys, primarily related to recognition of \$15.3 million in revenue in 2014 related to an upfront license fee payment as compared to the achievement and recognition of a \$5.0 million research and development milestone payment in 2015.

Cost of Product Sales

Cost of product sales increased by \$0.6 million, or 4%, to \$16.9 million for 2015 from \$16.3 million for 2014. The increase in cost of product sales was primarily due to commencement of IXINITY product sales in the second quarter of 2015 after FDA approval. This increase was partially offset by the decrease in WinRho non-US sales in 2015.

Research and Development Expense

Research and development expenses decreased by \$11.9 million, or 26%, to \$34.7 million for 2015 from \$46.6 million for 2014. Our principal research and development expenses by program for 2015 and 2014 are shown in the following table:

(in thousands)	Year ended December 31,		Change
	2015	2014	
MOR209/ES414	\$ 5,765	\$ 11,914	\$ (6,149)
IXINITY	14,622	17,456	(2,834)
otlertuzumab	4,851	8,714	(3,863)
ES425	1,671	—	1,671
ES210	1,895	3,286	(1,391)
5E3	2,666	1,838	828
Other ADAPTIR related programs	2,734	2,284	450
Other	522	1,097	(575)
Total	\$34,726	\$46,589	\$(11,863)

The decrease in expense for our MOR209/ES414 product candidate was primarily due to the timing of manufacturing activities along with increased reimbursement from MorphoSys for development activities under our collaboration agreement. The decrease in expense for our IXINITY product candidate (which was approved by the FDA in April 2015) was primarily for manufacturing activities and the timing of clinical trial activities. The decrease in expense for our otlertuzumab product candidate was primarily related to the timing of clinical trial activities. The spending for ES425 was for lead construct selection and characterization studies. The decrease in ES210 was primarily due to process development along with clinical and non-clinical strategy activities. The increase in expense for 5E3 was primarily due to early stage non-clinical activities. The increase in expense for Other ADAPTIR related programs was primarily due to characterization studies and non-clinical activities. The decrease in expense for our Other activities was primarily due to centralized research and development activities not otherwise attributable to specific product candidates or programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$8.7 million, or 25%, to \$43.0 million for 2015 from \$34.3 million for 2014. This increase was primarily due to an increase in selling costs of \$5.0 million associated with a full year in 2015 of the operations acquired through the acquisition of Cangene in February 2014, including product launch costs for IXINITY in 2015, and an increase in general and administrative expense of \$3.8 million, due primarily to an increase in our provision for uncollectable accounts in 2015.

Other (Expense) Income, net

Other expense, net was \$0.2 million for both 2015 and 2014. The amount is primarily from foreign exchange losses associated with the timing of receipt of a VAT receivable in Germany.

Income Taxes

Benefit from income taxes increased by \$1.4 million, or 233%, to \$2.0 million for 2015 from \$0.6 million for 2014. The increase in the benefit was primarily due to increased Canadian scientific research and experimental development tax credits.

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013**Revenue***Product Sales:*

Product sales revenue was \$30.0 million for 2014 due to the products acquired from Cangene in February 2014. There were no product sales in 2013.

Collaborations:

Collaborations revenue increased by \$15.4 million to \$15.6 million for 2014 from \$0.2 million for 2013. The increase was primarily related to recognition of \$15.3 million in upfront license fee revenue in 2014 from MorphoSys.

Cost of Product Sales

Cost of product sales was \$16.3 million for 2014 due to the products acquired from Cangene in February 2014. There were no product sales in 2013.

Research and Development Expense

Research and development expenses increased by \$8.5 million, or 22%, to \$46.6 million for 2014 from \$38.1 million for 2013. Our principal research and development expenses by program for 2014 and 2013 are shown in the following table:

(in thousands)	Year ended December 31,		Change
	2014	2013	
MOR209/ES414	\$11,914	\$ 7,625	\$ 4,289
IXINITY	17,456	—	17,456
otlertuzumab	8,714	26,744	(18,030)
ES210	3,286	3,115	171
5E3	1,838	—	1,838
Other ADAPTIR related programs	2,284	152	2,132
Other	1,097	438	659
Total	\$46,589	\$38,074	\$ 8,515

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The increase in expense for our MOR209/ES414 product candidate was primarily due to ongoing manufacturing activities. The expense for our IXINITY product candidate, acquired from Cangene in February 2014, was primarily for clinical trial and manufacturing activities. The decrease in expense for our otlertuzumab (formerly TRU-016) product candidate was primarily related to the timing of clinical trial activities. The increase in expense for ES210 was primarily for process development along with clinical and non-clinical strategy activities. The expense for 5E3, was primarily due to early stage non-clinical activities. The increase in expense for Other ADAPTIR related programs was primarily due to characterization studies and non-clinical activities. The increase in expense for our Other activities was primarily due to centralized research and development activities not otherwise attributable to product candidates or programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$18.8 million, or 121%, to \$34.3 million for 2014 from \$15.5 million for 2013. The increase in selling general and administrative expenses was primarily due to ongoing post-acquisition selling, general and administrative costs of \$14.7 million associated with the operations of Cangene, acquired in February 2014, including selling and marketing costs for Aptevo's products.

Other (Expense) Income, net

Other expense, net was \$0.2 million for 2014, an increase of \$0.2 million from 2013. The increase was primarily due to foreign exchange losses associated with the timing of receipt of a VAT receivable in Germany.

Liquidity and Capital Resources

Sources of Liquidity

At the closing of the spin-off of Aptevo from Emergent, Emergent will provide Aptevo, from its cash reserves on hand, cash of approximately \$40 million, along with a commitment in the form of a promissory note to provide another \$20 million within six to 12 months after the separation. We expect this initial cash funding will support Aptevo's operations for at least 12 months after the completion of the spin-off, based on current operating plans and financial forecasts. Prior to the spin-off, the development-based biosciences business of Emergent was funded entirely by Emergent. In addition, Aptevo is evaluating entering into a credit facility or other debt financing arrangement with one or more financial institutions that would be entered into in connection with the completion of the spin-off.

Capital Requirements

Aptevo expects to incur losses from operations for the foreseeable future primarily due to research and development expenses, including expenses related to conducting clinical trials. Aptevo's future capital requirements will depend on a number of factors, including:

- the level, timing and cost of product sales;
- the collection of accounts receivable from customers;
- the extent to which we invest in products or technologies;
- capital improvements to new or existing facilities;
- the payment obligations under any future indebtedness;
- the scope, progress, results and costs of our development activities;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs associated with the separation from Emergent and costs associated with performance under agreements to be entered into with Emergent; and

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- the costs associated with replicating or outsourcing from other providers certain facilities, systems, operational and administrative infrastructure, including information technology infrastructure and personnel, to which we will no longer have access after our separation from Emergent.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2016 and 2015 and for the years ended December 31, 2015, 2014 and 2013.

(in thousands)	Three months ended March 31,		Year ended December 31,		
	2016	2015	2015	2014	2013
Net cash provided by (used in):					
Operating activities	\$ (14,113)	\$ (15,919)	\$(48,760)	\$(47,007)	\$(51,392)
Investing activities	(1,071)	(141)	(1,527)	(48,800)	(1,021)
Financing activities	13,619	14,383	51,331	99,400	52,413
Net decrease and increase in cash and cash equivalents	\$ (1,565)	\$ (1,677)	\$ 1,044	\$ 3,593	\$ —

Net cash used in operating activities of \$14.1 million for the three months ended March 31, 2016 was primarily due to our net loss of \$12.9 million along with an increase of \$3.1 million in prepaid expenses and other assets related to IXINITY manufacturing activities, partially offset by a decrease in accounts receivable of \$3.0 million due to the timing of collections for product sales. Net cash used in operating activities of \$15.9 million for the three months ended March 31, 2015 was primarily due to our net loss of \$11.0 million and a decrease in accrued payroll of \$2.5 million related to payment of annual bonuses during the period.

Net cash used in operating activities of \$48.8 million in 2015 was primarily due to our net loss of \$59.3 million and an increase in inventory of \$2.7 million due to the timing of sales of IXINITY, partially offset by a decrease in accounts receivable of \$3.9 million due to the timing of collection of WinRho receivables, an increase in deferred revenue of \$2.6 million due primarily to the timing of revenue recognition for IXINITY, along with a non-cash charge of \$3.5 million as a provision for uncollectible accounts.

Net cash used in operating activities of \$47.0 million in 2014 was primarily due to our net loss of \$51.1 million and an increase in accounts receivable of \$6.1 million due to the timing of collection of product sales receivables, partially offset by a decrease in inventory of \$5.0 million due to the acquisition of Cangene and an increase in deferred revenue of \$4.5 million due the timing of revenue recognition for our MorphoSys collaboration.

Net cash used in operating activities of \$51.4 million in 2013 was primarily due to our net loss of \$53.4 million.

Net cash used in investing activities for the periods presented was primarily due to the purchases of property, plant and equipment, and, in 2014, the \$47.8 million acquisition of the Aptevo related portion of Cangene.

Net cash provided by financing activities for the periods presented was principally due to the net investment from Emergent to support the operations of Aptevo.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2015:

(in thousands)	Payments due by period				
	Total	Less than 1 year	1 to 3 Years	4 to 5 Years	More than 5 years
Contractual obligations:					
Operating lease obligations	\$7,029	\$ 1,672	\$3,203	\$2,154	\$ —
Total contractual obligations	\$7,029	\$ 1,672	\$3,203	\$2,154	\$ —

MANAGEMENT

Executive Officers Following the Separation

While some of Aptevo's executive officers are currently officers and employees of Emergent, upon the separation, none of these individuals will continue to be employees or executive officers of Emergent. The following table sets forth information regarding individuals who are expected to serve as Aptevo's executive officers, including their positions after the separation. One of Aptevo's executive officers will also hold a position as a member of Aptevo's board of directors. For more information see "Board of Directors Following the Separation" below.

<u>Name</u>	<u>Age</u>	<u>Title</u>
Marvin L. White	54	Director and Chief Executive Officer
Jeffrey G. Lamothe	50	Senior Vice President and Chief Financial Officer
Scott C. Stromatt, M.D.	58	Chief Medical Officer and Senior Vice President, Clinical Development & Medical Affairs

Marvin L. White will be the Chief Executive Officer of Aptevo and will serve on Aptevo's board of directors. Mr. White served as a director of Emergent from June 2010, until his resignation from the Emergent board of directors in May 2016. Mr. White has also served as a consultant to Emergent since November 2015, under a consulting agreement with Emergent, which is discussed under "Compensation Discussion and Analysis—Marvin White Compensation." Since April 2014, Mr. White has served as president and chief executive officer of The MLW Advisory Group, LLC, a management advisory company targeting the needs of healthcare and related companies. From 2008 to March 2014, Mr. White served as system vice president and chief financial officer of St. Vincent Health, and was responsible for finance, materials management, accounting, patient financial services and managed care for all 19 hospitals and 36 joint ventures. Prior to joining St. Vincent Health in 2008, Mr. White was executive director and chief financial officer of LillyUSA, a subsidiary of Eli Lilly and Company, where he also held leadership positions in Corporate Finance and Investment Banking in the Corporate Strategy Group. He serves on the boards of CoLucid Pharmaceuticals, Inc., a public pharmaceutical company, WP Glimcher Inc., a public retail real estate investment trust, and OneAmerica Financial Insurance Partners, Inc., a private insurance and financial services company. We believe Mr. White's service as our Chief Executive Officer and his prior financial experience and service on other boards make him strongly qualified to serve on our board of directors.

Jeffrey G. Lamothe will be the Senior Vice President and Chief Financial Officer of Aptevo. He currently serves as Emergent's Vice President Finance, Biosciences Division. Mr. Lamothe assumed this role in February 2014 when Emergent concluded the acquisition of Cangene Corporation, where he was Chief Financial Officer. Mr. Lamothe assumed the role of Chief Financial Officer of Cangene in August 2012. Prior to that, Mr. Lamothe was the Chief Financial Officer for Smith Carter Architects and Engineers Incorporated, a position which he held from January 2010 until July 2012. He also previously served as President and Chief Executive Officer of Kitchen Craft Cabinetry after occupying the position of VP Finance and Chief Financial Officer with that organization. Mr. Lamothe's other past experience includes serving as Chief Financial Officer for Motor Coach Industries and he has held various roles at James Richardson & Sons, Limited and Ernst & Young LLP. Mr. Lamothe is a Chartered Accountant and a graduate of the University of Manitoba where he obtained a Bachelor of Commerce (honours) degree.

Scott C. Stromatt, M.D. will be the Chief Medical Officer and Senior Vice President, Clinical Development & Medical Affairs of Aptevo. He will continue the clinical development programs for the ADAPTIR molecules that he has designed and directed. Since 2008, Dr. Stromatt has served as Chief Medical Officer, Senior Vice President at Emergent and Chief Medical Officer, Senior Vice President at Trubion Pharmaceuticals Inc. From 2003 to 2008, Mr. Stromatt worked at Cell Therapeutics, Inc., where he held the

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positions of Executive Vice President, Clinical Development and Regulatory Affairs from 2005 to 2008, Senior Vice President, Clinical Development and Regulatory Affairs from 2004 to 2005 and Vice President, Clinical Development from 2003 to 2004. In 2002, Dr. Stromatt worked at Northwest Biotherapeutics, Inc. as Vice President Clinical Research, Chief Medical Officer. From 2000-2002, Dr. Stromatt worked as a biotechnology analyst for Wall Street investment firm C.E. Unterberg. Dr. Stromatt received his medical degree from the University of Chicago and an MBA and Bachelor of Arts from the University of Colorado.

Board of Directors Following the Separation

The following table sets forth information with respect to those persons who are expected to serve on Aptevo's board of directors following the completion of the separation, including Mr. White, whose biographical information is included above in the section entitled "Executive Officers Following the Separation." The nominees will be presented to Aptevo's sole stockholder, Emergent, for election prior to the separation. Aptevo may name and present additional nominees for election prior to the separation.

<u>Name</u>	<u>Age</u>	<u>Title</u>
Fuad El-Hibri	58	Chairman
Marvin L. White	54	Director, Chief Executive Officer
Daniel J. Abdun-Nabi	61	Director
Grady Grant, III	60	Director
Zsolt Harsanyi, Ph.D.	72	Director
Barbara Lopez Kunz	58	Director
John E. Niederhuber, M.D.	77	Director

At the time of the separation, Aptevo expects that its board of directors will consist of the directors set forth above. Upon completion of the separation, Aptevo's board of directors will be divided into three classes. Each class will be as equal in number as is possible. The directors designated as Class I directors will have terms expiring at the first annual meeting of stockholders following the distribution, which Aptevo expects to hold in 2017. The directors designated as Class II directors will have terms expiring at the following year's annual meeting of stockholders, which Aptevo expects to hold in 2018, and the directors designated as Class III directors will have terms expiring at the following year's annual meeting of stockholders, which Aptevo expects to hold in 2019. Aptevo expects that Class I will be comprised of Mr. Harsanyi and Ms. Kunz; Class II will be comprised of Mr. Abdun-Nabi and Mr. Grant; and Class III will be comprised of Mr. El-Hibri, Dr. Niederhuber and Mr. White. Commencing with the first annual meeting of stockholders following the separation, directors for each class will be elected at the annual meeting of stockholders held in the year in which the term for that class expires and thereafter will serve for a term of three years. At any meeting of stockholders for the election of directors at which a quorum is present, the election will be determined by a plurality of the votes cast by the stockholders entitled to vote in the election.

Fuad El-Hibri will be the Chairman of Aptevo's board of directors. Mr. El-Hibri is the founder and Executive Chairman of the board of directors of Emergent. Mr. El-Hibri has served as the executive chairman of Emergent's board of directors since April 2012. From June 2004 to March 2012, Mr. El-Hibri served as chief executive officer and chairman of Emergent's board of directors. Mr. El-Hibri previously served as president of Emergent from March 2006 to April 2007. Mr. El-Hibri served as chief executive officer and chairman of the board of directors of BioPort Corporation, or BioPort, from May 1998 until June 2004, when, as a result of Emergent's corporate reorganization, BioPort became a wholly-owned subsidiary of Emergent and was subsequently renamed Emergent BioDefense Operations Lansing Inc. Mr. El-Hibri is chairman of East West Resources Corporation, a venture capital and business consulting firm, a position he has held since June 1990. He served as president of East West Resources from September 1990 to January 2004. We believe Mr. El-Hibri's qualifications to serve on our board of directors include his service on other boards as well as his prior business experience, including as Emergent's chief executive officer and as an Emergent director.

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Daniel J. Abdun-Nabi is the President and Chief Executive Officer of Emergent, a position he has held since April 2012. From May 2007 to March 2012, Mr. Abdun-Nabi served as Emergent's president and chief operating officer. Mr. Abdun-Nabi previously served as Emergent's corporate secretary from December 2004 to January 2008, Emergent's senior vice president, corporate affairs and general counsel from December 2004 to April 2007 and Emergent's vice president and general counsel from May 2004 to December 2004. Mr. Abdun-Nabi served as general counsel for IGEN International, Inc., a biotechnology company, and its successor BioVeris Corporation, from September 1999 to May 2004. Prior to joining IGEN, Mr. Abdun-Nabi served as senior vice president, legal affairs, general counsel and secretary of North American Vaccine, Inc., a private vaccine company acquired by Baxter International Inc. in 2000. We believe Mr. Abdun-Nabi's qualifications to serve on our board of directors include his extensive experience in senior management positions and his demonstrated business judgment, including his long service as a senior executive of Emergent.

Grady Grant, III is the Vice President of Medical Sales for Mead Johnson Nutrition, a public company focused on pediatric nutrition. He has held this position since December 2011, preceded by 30 years of service at Eli Lilly and Company which includes his service as Vice President of Sales Neuroscience from January 2006 to December 2011. We believe Mr. Grant's qualifications to serve on our board of directors include his operating and senior management experience in the industry.

Zsolt Harsanyi, Ph.D. has served on the board of directors of Emergent since August 2004. Dr. Harsanyi has served as chairman of the board of N-Gen Research Laboratories, Inc., a privately-held biotechnology company, since March 2011. Prior to that, Dr. Harsanyi served as chief executive officer and chairman of the board of directors of Exponential Biotherapies Inc., a private biotechnology company, from December 2004 to February 2011. Dr. Harsanyi served as president of Porton International plc, or Porton International, a pharmaceutical and vaccine company, from January 1983 to December 2004. Dr. Harsanyi was a founder of Dynport Vaccine Company LLC in September 1996. Prior to joining Porton International, Dr. Harsanyi was vice president of corporate finance at E.F. Hutton, Inc. Previously, Dr. Harsanyi directed the first assessment of biotechnology for the U.S. Congress' Office of Technology Assessment, served as a consultant to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and was on the faculties of Microbiology and Genetics at Cornell Medical College. We believe Dr. Harsanyi's qualifications to serve on our board of directors include his industry experience, including his senior executive and financial positions.

Barbara Lopez Kunz is currently the Global Chief Executive of the Drug Information Association, a private health care products company. From January 2007 to March 2013, she worked as President of Health and Life Sciences at Battelle Memorial Institute, a private nonprofit applied science and technology development company. From August 2003 to December 2007, she worked as Senior VP/GM for Thermo Fisher Scientific's Fisher Biosciences and led the Latin America regional business from January 2000 to July 2003 at Uniqema, a private company acquired by Croda International plc in 2006. We believe that Ms. Kunz is qualified to serve on our board of directors because of her extensive leadership experience and knowledge of the industry.

John E. Niederhuber, M.D. is the founder, Executive Vice President, and Chief Executive Officer of the Inova Translational Medicine Institute, a not-for-profit genomics research institute. Dr. Niederhuber served as a director of Emergent from August 2010, until his resignation from the Emergent board of directors in May 2016. He previously served as the director of the National Cancer Institute (NCI), the National Institutes of Health from 2006 to 2010. Dr. Niederhuber joined the Inova Health System in August 2010 as Executive Vice President and CEO of the Inova Translational Medicine Institute. Dr. Niederhuber is also an adjunct professor of surgery and oncology at the Johns Hopkins University School of Medicine. He currently serves on the board of directors of PierianDX, a private genomics analytics company. Prior to joining NCI, Dr. Niederhuber was Director of the University of Wisconsin Comprehensive Cancer Center and professor of surgery and oncology (member of the McArdle Laboratory) at the University of Wisconsin School of Medicine from 1997 to 2005. He chaired the Department of Surgery at Stanford University School of Medicine from 1991 to 1997 and held professorships at the Johns Hopkins University School of Medicine from 1987 to 1991 and at the University of Michigan from

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1973 to 1987. We believe that Dr. Niederhuber's medical background in oncology, his laboratory research in immunology and cancer biology, and his extensive leadership experience in public and government institutions make him uniquely qualified to serve on our board of directors.

In anticipation of their appointments as chief executive officer and director of Aptevo, respectively, Mr. White and Dr. Niederhuber resigned as directors of Emergent in May 2016, prior to Emergent's 2016 annual meeting of stockholders. Messrs. El-Hibri and Abdun-Nabi and Dr. Harsanyi are expected to continue as directors of Emergent. Mr. Abdun-Nabi is expected to continue as President and Chief Executive Officer of Emergent.

On May 18, 2016, Dr. Niederhuber entered into a consulting agreement with Emergent. For further discussion of the consulting agreements entered into by Emergent in anticipation of the separation, see the section entitled "Certain Relationships and Related Party Transactions – Consulting Arrangements Entered into in Connection with the Separation."

Director Independence

It is expected that a majority of our board of directors, and the entire membership of our Audit and Compensation Committees of our Board, will consist of directors who are "independent" as defined by the applicable rules of The NASDAQ Stock Market Rules, the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the corporate governance guidelines to be adopted by our board of directors.

Rule 5605 of The NASDAQ Stock Market Rules requires a majority of a listed company's board of directors to be comprised of independent directors. In addition, The NASDAQ Stock Market Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. In addition, in affirmatively determining the independence of any director who will serve on a company's compensation committee, Rule 10C-1 under the Exchange Act requires that a company's board of directors consider all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of the director, including any consulting, advisory or other compensatory fee paid by such company to the director; and (ii) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of Mr. Grant, Dr. Harsanyi, Ms. Kunz or Dr. Niederhuber, representing four of our seven directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Rule 5605(a)(2) of the NASDAQ Marketplace Rules. Our board of directors has also determined that Mr. Grant, Dr. Harsanyi and Ms. Kunz, who will comprise our audit committee, and Mr. Grant, Ms. Kunz and Dr. Niederhuber, who will comprise our compensation committee, each satisfy the independence standards for such committees established by the SEC and the NASDAQ Marketplace Rules, as applicable.

Committees of the Board of Directors

Effective upon the completion of the separation, Aptevo's board of directors will have the following standing committees: an Audit Committee and a Compensation Committee.

Audit Committee. Mr. Grant, Dr. Harsanyi and Ms. Kunz are expected to be the members of the board's Audit Committee. Dr. Harsanyi is expected to be the Audit Committee Chairman. The board of directors is expected to determine that at least one member of the Audit Committee meets the criteria of the SEC for an "audit committee financial expert". In addition, Aptevo expects that the board of directors will determine that each of the members of the Audit Committee will be "independent" under Rule 5605 of The NASDAQ Stock Market Rules and Rule 10A-3 of the Exchange Act. The Audit Committee's responsibilities will include: (1) appointing, approving the compensation of and assessing the independence of Aptevo's independent registered public accounting firm; (2) overseeing the work of Aptevo's independent registered public accounting firm; (3) reviewing and discussing with management and the independent registered public accounting firm Aptevo's annual and quarterly financial statements and related disclosures; (4) monitoring Aptevo's internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics; (5) overseeing Aptevo's internal audit function; (6) assisting the board in overseeing Aptevo's compliance with legal and regulatory requirements; (7) periodically discussing Aptevo's risk management policies, and reviewing and commenting on a periodic risk assessment by management; (8) establishing policies regarding hiring employees from Aptevo's independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns; (9) meeting independently with Aptevo's internal auditing staff, independent registered public accounting firm and management; (10) reviewing and approving or ratifying any related party transactions; and (11) preparing audit committee reports required by SEC rules.

Compensation Committee. Mr. Grant, Ms. Kunz and Dr. Niederhuber are expected to be the members of the board's Compensation Committee. Dr. Niederhuber is expected to be the Compensation Committee Chairman. The board of directors is expected to determine that each member of the Compensation Committee will be "independent" under Rule 5605 of The NASDAQ Stock Market Rules and Rule 10A-3 of the Exchange Act. The Compensation Committee's responsibilities will include: (1) annually reviewing and approving corporate goals and objectives relevant to the compensation of Aptevo's executive officers; (2) determining the compensation of Aptevo's chief executive officer; (3) reviewing and approving the compensation of Aptevo's other named executive officers; (4) overseeing the evaluation of Aptevo's senior executives; (5) overseeing and administering Aptevo's cash and equity incentive plans; and (6) preparing the compensation committee report required by SEC rules.

The board of directors is expected to adopt a written charter for each of the Audit Committee and the Compensation Committee. These charters will be posted on Aptevo's website in connection with the separation.

Compensation Committee Interlocks and Insider Participation

During the company's fiscal year ended December 31, 2015, Aptevo was not an independent company, and did not have a compensation committee or any other committee serving a similar function. Decisions as to the compensation of Aptevo's executive officers who currently serve as Emergent's executive officers were made by Emergent, as described in the section of this information statement captioned "Compensation Discussion and Analysis."

Corporate Governance

Director Nominations

Aptevo's amended and restated by-laws will contain provisions that address the process by which a stockholder may nominate an individual to stand for election to the board of directors. We do not expect to have a standing nominating committee upon completion of the separation and distribution, though we intend to form a

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corporate governance and nominating committee as and when required to do so by law or NASDAQ rules. Accordingly, pursuant to Rule 5605(e)(1)(A) of the NASDAQ rules, director nominees will be selected, or recommended for our board's selection, by a majority of the independent directors. We believe that the independent directors can satisfactorily carry out the responsibility of properly selecting or approving director nominees without the formation of a standing nominating committee. The directors who we expect to participate in the consideration and recommendation of director nominees are Mr. Grant, Dr. Harsanyi, Ms. Kunz and Dr. Niederhuber. In accordance with Rule 5605(e)(1)(A) of the NASDAQ rules, we expect that all such directors will be independent. As there will be no standing nominating committee, we do not have a nominating committee charter in place. Aptevo expects that the board of directors will adopt a policy concerning the evaluation of stockholder recommendations of board candidates by the independent directors.

Corporate Governance Guidelines

We do not have a standing nominating and corporate governance committee, although, as discussed above, we intend to form a nominating and corporate governance committee as and when required to do so by law or NASDAQ rules. Our board of directors believes that the independent directors can satisfactorily carry out the responsibility of developing and recommending to the board of directors corporate governance principles without the formation of a standing nominating and corporate governance committee. The directors who participate in the consideration and recommendation of director nominees are Mr. Grant, Dr. Harsanyi, Ms. Kunz or Dr. Niederhuber. As there is no standing nominating and corporate governance committee, we do not have a nominating and corporate governance committee charter in place.

Aptevo's board of directors is expected to adopt a set of corporate governance guidelines in connection with the separation to assist it in guiding Aptevo's governance practices. These practices will be regularly re-evaluated by the independent directors in light of changing circumstances in order to continue serving the company's best interests and the best interests of its stockholders.

Communicating with the Board of Directors

Aptevo's board of directors will give appropriate attention to written communications that are submitted by stockholders and other interested parties and will respond if and as appropriate. The lead director, with the assistance of Aptevo's corporate secretary, will be primarily responsible for monitoring communications from stockholders and other interested parties and for providing copies or summaries to the other directors as the lead director considers appropriate.

Under procedures that will be approved by a majority of Aptevo's independent directors, communications will be forwarded to all directors if they relate to important substantive matters and include suggestions or comments that the lead director considers to be important for the directors to know. In general, communications relating to corporate governance and corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which Aptevo receives repetitive or duplicative communications.

Stockholders and other interested parties who wish to send communications on any topic to the board of directors, lead director or independent directors as a group should address such communications to the board of directors, Lead Director or Independent Directors, as applicable, c/o Corporate Secretary, Aptevo Therapeutics Inc., 2401 4th Ave., Suite 1050, Seattle, Washington 98121. The Corporate Secretary will review all such correspondence and forward to the board, lead director or independent directors a summary and/or copies of any such correspondence that deals with the functions of the board or its committees or that he otherwise determines requires their attention.

Governance Structure and Lead Director

Aptevo's corporate governance guidelines are expected to provide the board of directors flexibility in determining its leadership structure. The board of directors is expected to keep separate the positions of chief executive officer and board chairman. The board of directors believes this separate governance structure is optimal because it will enable Mr. White to focus his entire energy on running the company while affording us the benefits of continued leadership and other contributions from Mr. El-Hibri.

Aptevo's corporate governance guidelines are expected to provide that in the event the chairman of the board of directors is not an independent director, a majority of the board's independent directors may appoint an independent director, who has been nominated by a majority of our independent directors, to serve as lead director. Because Mr. El-Hibri is not expected to be an independent director, Aptevo's independent directors, based on the recommendation of a majority of our independent directors, will appoint a lead director in connection with the separation. The lead director will serve as the presiding director at all executive sessions of the non-management or independent directors, facilitate communications between Mr. El-Hibri and other members of the board of directors, determine the need for special meetings of the board of directors and consult with Mr. El-Hibri on matters relating to corporate governance and board performance.

Policies on Business Ethics

In connection with the separation, Aptevo will adopt a Code of Business Conduct and Ethics that will require all business activities to be conducted in compliance with laws, regulations and ethical principles and values. All directors, officers, and employees of Aptevo will be required to read, understand and abide by the requirements of the Code of Conduct.

The Code of Conduct will be accessible on the company's website. Any waiver of the Code of Conduct for directors or executive officers may be made only by the board of directors. Aptevo will disclose any amendment to, or waiver from, a provision of the Code of Conduct for the principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, on its website within four business days following the date of the amendment or waiver. In addition, Aptevo will disclose any waiver from the Code of Conduct for the other executive officers and for directors on its website.

Risk Oversight and Risk Management

Aptevo's board of directors will be actively engaged in oversight of risks Aptevo faces and consideration of the appropriate responses to those risks. The Audit Committee will periodically discuss risk management, including guidelines and policies to govern the process by which Aptevo's exposure to risk is handled, with senior management. The Audit Committee will also review and comment on a periodic risk assessment performed by management. After the Audit Committee performs its review and comment function, it will report any significant findings to the board of directors. The board of directors will be responsible for oversight of Aptevo's risk management programs and, in performing this function, will receive periodic risk assessment and mitigation initiatives for information and approval as necessary.

Procedures for Treatment of Complaints Regarding Accounting, Internal Accounting Controls, and Auditing Matters

In accordance with the Sarbanes-Oxley Act of 2002, Aptevo expects that its Audit Committee will adopt procedures for the receipt, retention, and treatment of complaints regarding accounting, internal accounting controls, and auditing matters and to allow for the confidential, anonymous submission by employees and others of concerns regarding questionable accounting or auditing matters.

COMPENSATION DISCUSSION AND ANALYSIS

Executive Summary

For purposes of this Compensation Discussion and Analysis and the disclosure under the various executive compensation tables included herein, the persons who we currently expect will be our named executive officers as of the distribution date have been identified. The information provided reflects summary information concerning Aptevo's executive compensation approach developed to date in connection with planning for the separation.

As a result, this Compensation Discussion and Analysis has two main parts:

- **Anticipated Aptevo Compensation Programs**—This section discusses the anticipated executive compensation programs and policies at Aptevo, including the effect of the separation on outstanding Emergent compensation awards held by our named executive officers.
- **2015 Emergent Compensation**—This section describes the compensation programs at Emergent in 2015 that applied to our named executive officers in 2015.

The persons we expect will be our named executive officers, or the Aptevo named executive officers, are as follows:

- *Marvin L. White, Aptevo Chief Executive Officer.*
- *Jeffrey G. Lamothe, Aptevo Senior Vice President and Chief Financial Officer.*
- *Scott C. Stromatt, M.D., Aptevo Chief Medical Officer and Senior Vice President, Clinical Development & Medical Affairs.*

We are currently a wholly-owned subsidiary of Emergent and not an independent company, and our compensation committee has not yet been formed. Decisions as to the past compensation of those individuals who are expected to serve as our named executive officers upon the separation have been made by Emergent. This Compensation Discussion and Analysis discusses the Emergent historical compensation and practices that applied to the Aptevo named executive officers in 2015 and attempts to outline certain aspects of Aptevo's anticipated compensation structure for the Aptevo named executive officers following the separation.

While Aptevo has discussed its anticipated programs and policies with the compensation committee of Emergent's board of directors, or the Emergent compensation committee, they remain subject to the review and approval of Aptevo's own compensation committee, which may decide to change these programs and policies following the completion of the separation.

Anticipated Aptevo Compensation Programs

Because our compensation committee has not yet been formed, Aptevo has not established its own specific set of objectives or principles for its executive compensation program. Until the separation, the Emergent compensation committee will continue to make compensation decisions and take actions regarding our compensation philosophy, principles and program design. Following the separation, these decisions will be made, and related actions taken, by our compensation committee.

Executive Compensation Principles

In anticipation of the separation, the Emergent compensation committee engaged Willis Towers Watson, its independent compensation consultant, to prepare a potential compensation philosophy for Aptevo, which includes the following:

- Pay should be linked to performance;

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- Compensation opportunities should be competitive with similarly-sized commercial and pre-commercial biopharmaceutical companies and locally based companies;
- Equity compensation programs should align employee interests with those of stockholders; and
- Supplemental benefits and perquisites should be limited and used selectively in specific circumstances to attract and retain executive officers.

Elements of Executive Compensation

In anticipation of the separation, the Emergent compensation committee reviewed competitive market data and industry surveys to assist in setting salaries, target bonus percentages and long-term incentive award guidelines. Willis Towers Watson advised Emergent in connection with this process. Compensation for Aptevo's named executive officers is expected to consist of the following elements:

- Base salary;
- Annual cash bonuses;
- Equity awards;
- Traditional benefits generally available to all employees; and
- Severance and change of control benefits.

The competitive market data reviewed by the Emergent compensation committee consisted of proxy data and published survey data, as described below:

- *2016 Radford Global Life Sciences Survey data.* The Emergent compensation committee reviewed competitive market data from a custom data sample from the Radford Global Life Sciences Survey data comprised of companies that fit the following profile:
 - A blend of commercial and pre-commercial biopharmaceutical companies (75% of the sample consisted of pre-commercial companies to reflect Aptevo's on-going business strategy);
 - R&D Long-Term strategy;
 - Companies with less than \$200 million in revenue; and
 - Employee size of between 50 and 500.

We refer to this customized data as the "Aptevo 2016 Radford Survey data."

- *2016 Proxy Peer Group.* The Emergent compensation committee also reviewed peer group data from the proxy statements of select pharmaceutical and biotechnology companies with approximately 50 to 300 employees, an R&D long-term strategy (with a handful of commercial companies to reflect the complexity of the business model), and a market capitalization of between \$65 million and \$650 million.

The Aptevo 2016 proxy peer group includes the following list of companies.

<u>2016 Aptevo Proxy Peer Group</u>
Advaxis, Inc.
Agenus Inc.
Argos Therapeutics, Inc.
Bellicum Pharmaceuticals, Inc.
BIND Therapeutics, Inc.
Caladrius Biosciences, Inc.
Curis, Inc.
Five Prime Therapeutics, Inc.
Idera Pharmaceuticals, Inc.
Immune Design Corp.
Immunomedics Inc.
Inovio Pharmaceuticals, Inc.
Omeros Corporation
OncoGenex Pharmaceuticals, Inc.
Oncothyreon Inc.
Peregrine Pharmaceuticals, Inc.
Progenics Pharmaceuticals, Inc.
Rigel Pharmaceuticals, Inc.
Sorrento Therapeutics, Inc.
Sucampo Pharmaceuticals, Inc.
TG Therapeutics, Inc.
Vanda Pharmaceuticals, Inc.
XBiotech Inc.

Base Salary. Based upon a review of the market data from the Aptevo 2016 Radford Survey data and proxy peer data and taking into account the new positions of the Aptevo named executive officers, the annual base salaries of Mr. White, Mr. Lamothe and Dr. Stromatt at the time of the separation are expected to be \$525,000, \$372,500 and \$402,500, respectively. Aptevo expects that post-separation adjustments to base salary, if any, will be made by Aptevo's compensation committee and will reflect factors such as each Aptevo named executive officer's post-separation level of responsibility as well as competitive market data for similar positions at comparable peer companies.

Annual Cash Bonuses. Based upon a review of the market data from the Aptevo 2016 Radford Survey data and proxy peer data and taking into account the new positions of the Aptevo named executive officers, the target annual cash bonus percentages for Mr. White, Mr. Lamothe and Dr. Stromatt at the time of the separation are expected to be 50%, 40% and 40% of their base salaries, respectively. Post-separation adjustments to these target annual cash bonus percentages, if any, will be made by Aptevo's compensation committee. In connection with the separation, Aptevo expects to adopt an annual bonus plan with terms to be determined by its compensation committee. Aptevo expects that its compensation committee will establish performance goals based on an incentive structure that initially will be similar to that of Emergent. See section titled "2015 Emergent Compensation—Annual Cash Bonuses" for a general overview of Emergent's incentive bonus structure and performance goals for the periods indicated. Aptevo also expects that the annual incentive objectives for the Aptevo named executive officers will be aligned with competitive market rates based on peer company comparisons.

Equity Awards. Aptevo expects its board of directors to adopt, and Emergent, as its sole stockholder prior to the distribution, to approve, the Aptevo Stock Incentive Plan, which will become effective upon Emergent's approval. The Aptevo Stock Incentive Plan will provide for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units, other stock-based awards, and cash-based awards.

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Upon effectiveness of the Aptevo Stock Incentive Plan, the number of shares of Aptevo common stock that will be reserved for issuance under the Aptevo Stock Incentive Plan will be ● shares. Aptevo's employees, officers, directors, consultants and advisors will be eligible to receive awards under the Aptevo Stock Incentive Plan; however, incentive stock options may only be granted to Aptevo's employees. The maximum number of shares of common stock with respect to which awards may be granted to any participant under the Aptevo Stock Incentive Plan is ● per calendar year. For purposes of this limit on the maximum number of shares that may be awarded to any participant, the combination of an option in tandem with a stock appreciation right will be treated as a single award. In addition, under the Aptevo Stock Incentive Plan, awards can provide for cash payments of up to ● per calendar year per individual. In addition, the Aptevo Stock Incentive Plan provides that in any calendar year, the sum of cash compensation paid to any non-employee director for service as a director and the value of awards under the Aptevo Stock Incentive Plan made to such non-employee director (calculated based on the grant date fair value for financial reporting purposes) may not exceed ●.

Pursuant to the terms of the Aptevo Stock Incentive Plan, Aptevo's board of directors (or a committee delegated by our board of directors) administers the plan and, subject to any limitations set forth in the plan, will select the recipients of awards and determine:

- The number of shares of Aptevo's common stock covered by options and the dates upon which the options become exercisable;
- The type of options to be granted;
- The duration of options, which may not be in excess of ten years;
- The exercise price of options, which price must be at least equal to the fair market value of Aptevo's common stock on the date of grant;
- The methods of payment of the exercise price of options; and
- The number of shares of Aptevo's common stock subject to and the terms and conditions of any stock appreciation rights, awards of restricted stock, restricted stock units, other stock-based awards, or cash-based awards including conditions for repurchase, measurement price, issue price and repurchase price and performance conditions (though the measurement price of stock appreciation rights must be at least equal to the fair market value of Aptevo's common stock on the date of grant and the duration of such awards may not be in excess of ten years), if any.

If Aptevo's board of directors delegates authority to one or more of Aptevo's officers to grant awards under the Aptevo Stock Incentive Plan, the executive officer will have the power to make awards to all of Aptevo's employees, except executive officers (as defined by Rule 3b-7 under the Exchange Act) and officers (as defined by Rule 16a-1(f) under the Exchange Act) and to exercise such powers under the Aptevo Stock Incentive Plan as Aptevo's board of directors may determine. However, Aptevo's board of directors will fix the terms of the awards to be granted by such officers, the maximum number of shares subject to awards that such officers may grant, and the time period in which awards may be granted. Awards to Aptevo's non-employee directors will be granted and administered by a committee of Aptevo's board of directors, all of the members of which will be independent directors under The NASDAQ Marketplace Rules.

In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Aptevo's common stock other than an ordinary cash dividend, Aptevo is required by the Aptevo Stock Incentive Plan to make equitable adjustments (or make substitute awards, if applicable), in a manner determined by Aptevo's board, to:

- The number and class of securities available under the Aptevo Stock Incentive Plan;
- The share counting rules and sublimits under the Aptevo Stock Incentive Plan;
- The number and class of securities and exercise price per share of each outstanding option;

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- The share and per-share provisions and measurement price of each outstanding stock appreciation right;
- The number of shares and repurchase price per share subject to each outstanding award of restricted stock; and
- The share and per-share related provisions and purchase price, if any, of each outstanding restricted stock unit and other stock-based award.

Upon a merger or other reorganization event (as defined in the Aptevo Stock Incentive Plan) regardless of whether such event also constitutes a change in control event (as defined in the Aptevo Stock Incentive Plan), Aptevo's board of directors may, on such terms as Aptevo's board determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and Aptevo), take any one or more of the following actions pursuant to the Aptevo Stock Incentive Plan, as to all or any (or any portion of) outstanding awards, other than awards of restricted stock:

- Provide that all outstanding awards will be assumed or substantially equivalent awards will be substituted by the acquiring or successor corporation (or an affiliate thereof);
- Upon written notice to a participant, provide that all of the participant's unexercised and/or unvested awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of such notice;
- Provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon such reorganization event;
- In the event of a reorganization event pursuant to which holders of shares of Aptevo's common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to the participants with respect to each award held by a participant equal to (1) the number of shares of Aptevo's common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, grant or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and
- Any combination of the foregoing.

Aptevo's board of directors is not obligated by the Aptevo Stock Incentive Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically. In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Notwithstanding the provisions described above and except to the extent specifically provided to the contrary in the applicable award agreement or any other agreement between the participant and Aptevo, each award (other than an award of restricted stock) will become immediately vested, exercisable or free from forfeiture, as applicable, if on or prior to the first anniversary of the date of the change in control event, the participant's service with Aptevo or the successor corporation is terminated without cause by Aptevo or the successor corporation or is terminated for good reason by the participant (as such terms are defined in the Aptevo Stock Incentive Plan).

Upon the occurrence of a reorganization event (regardless of whether such event also constitutes a change in control event), the repurchase and other rights with respect to outstanding awards of restricted stock will continue for the benefit of the successor company and will, unless Aptevo's board of directors otherwise determines, apply to the cash, securities or other property which Aptevo's common stock is converted into or exchanged for pursuant to the reorganization event. However, Aptevo's board of directors may provide for the termination or

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deemed satisfaction of such repurchase or other rights under the restricted stock award agreement or any other agreement between the participant and Aptevo, either initially or by amendment. Upon the occurrence of a change in control event (regardless of whether such event also constitutes a reorganization event), except to the extent specifically provided to the contrary in the applicable restricted stock award agreement or any other agreement between the participant and Aptevo, each award of restricted stock will become immediately vested and free from forfeiture if on or prior to the first anniversary of the date of the change in control event, the participant's service with the Aptevo or the successor corporation is terminated without cause by Aptevo or the successor corporation or is terminated for good reason by the participant.

Aptevo's board of directors will specify at the time of grant or thereafter the effect of (i) a reorganization event that is not a change in control event on any other stock-based award or cash-based award granted under the Aptevo Stock Incentive Plan and (ii) a change in control event (regardless of whether such event also constitutes a reorganization event) on any other stock-based award or cash-based award granted under the Aptevo Stock Incentive Plan.

Aptevo's board of directors may at any time provide that any award under the Aptevo Stock Incentive Plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

Aptevo's board of directors may amend, modify or terminate any outstanding award under the Aptevo Stock Incentive Plan, including but not limited to, substituting therefor another award of the same or a different type, changing the date of exercise or realization, and converting an incentive stock option into a nonstatutory stock option, subject to certain participant consent requirements. However, unless Aptevo's stockholders approve such action, the Aptevo Stock Incentive Plan provides that Aptevo may not (except as otherwise permitted in connection with a change in capitalization or reorganization event):

- Amend any outstanding stock option or stock appreciation right granted under the Aptevo Stock Incentive Plan to provide an exercise or measurement price per share that is lower than the then-current exercise or measurement price per share of such outstanding award;
- Cancel any outstanding option or stock appreciation right (whether or not granted under the Aptevo Stock Incentive Plan) and grant in substitution therefor new awards under the Aptevo Stock Incentive Plan (other than substitute awards permitted in connection with a merger or consolidation of an entity with Aptevo or Aptevo's acquisition of property or stock of another entity) covering the same or a different number of shares of Aptevo's common stock and having an exercise or measurement price per share lower than the then-current exercise or measurement price per share of the cancelled award;
- Cancel in exchange for a cash payment any outstanding option or stock appreciation right with an exercise or measurement price per share above the then-current fair market value of Aptevo's common stock; or
- Take any other action that constitutes a "repricing" within the meaning of the rules of The NASDAQ Stock Market.

No award may be granted under the Aptevo Stock Incentive Plan after 10 years from the effectiveness of the Aptevo Stock Incentive Plan but awards previously granted may extend beyond that date. Aptevo's board of directors may amend, suspend or terminate the Aptevo Stock Incentive Plan at any time, except that stockholder approval will be required to comply with Section 162(m) of the Internal Revenue Code, applicable law or stock market requirements.

In connection with the separation, the Emergent compensation committee considered long term incentive program guidelines for Aptevo, or the Aptevo LTI Guidelines. These Aptevo LTI Guidelines anticipate that:

- Aptevo will use stock option and restricted stock unit awards as the forms of long-term incentive compensation for executive officers and other employees;

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- All stock option and restricted stock unit awards to the Aptevo named executive officers will be approved by Aptevo’s compensation committee; and
- Equity awards to the Aptevo named executive officers will be determined using proxy and Radford Survey data.

Fixed share guidelines were developed to provide market competitive grants. The value of the actual grants delivered annually will depend on movements in Aptevo’s stock price. Consistent with the Aptevo LTI Guidelines, it is expected that following the separation, Aptevo’s compensation committee will make the following grants to the Aptevo named executive officers in 2017:

<u>Name</u>	<u>Shares Subject to Options</u>
Marvin L. White	267,300
Jeffrey G. Lamothe	118,800
Scott C. Stromatt, M.D.	118,800

Each stock option is expected to vest in three equal instalments on the first, second and third annual anniversaries of the date of grant and to have an exercise price equal to the closing sales price per share of Aptevo’s common stock on The NASDAQ Global Market on the trading day immediately preceding the date of grant.

Inspiration Grant. It is currently anticipated that all active Aptevo employees, except for Mr. White, will receive a restricted stock unit inspiration grant effective upon the distribution having a value equal to 40% of their base salary. Vesting will occur in two increments. The first vesting event will occur six months from the distribution date and the second vesting event will take place within 18 months of the distribution.

White Transition Grant. In lieu of receiving an annual restricted stock unit award from Emergent for his service as an Emergent director and the inspiration grant described above, Mr. White is expected to receive a transition grant of options to purchase 400,950 shares of Aptevo common stock as part of his compensation package in connection with his appointment as chief executive officer of Aptevo, which will be granted in connection with the separation. Each stock option is expected to vest in three equal instalments on the first, second and third annual anniversaries of the date of grant and to have an exercise price equal to the closing sales price per share of Aptevo’s common stock on The NASDAQ Global Market on the trading day immediately preceding the date of grant.

This grant is roughly equal to 150% of the annual grant guideline established for the Aptevo chief executive officer position.

Stromatt Retention Grant. In addition to his inspiration grant (described above), Dr. Stromatt is expected to receive a retention grant of restricted stock units with a value equal to \$229,682 based on the closing sales price per share of Aptevo’s common stock on The NASDAQ Global Market on the trading day immediately preceding the date of grant. These restricted stock units are expected to vest 12 months following the date of grant.

Following the distribution, Aptevo’s compensation committee may establish its own long-term incentive guidelines and practices, which may differ from the Aptevo LTI Guidelines initially approved.

Benefits. It is anticipated that the Aptevo named executive officers will receive benefits similar to those provided to executives of Emergent. For a summary of provisions concerning retirement, health and welfare benefits to our employees upon completion of the separation, see the section entitled “Certain Relationships and Related Party Transactions—Employee Matters Agreement.”

Executive Severance Arrangements. In connection with the separation, the Emergent board of directors is expected to adopt a senior management severance plan for Aptevo, or the Aptevo SMSP, with terms that are

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similar to those of Emergent’s Second Amended and Restated Senior Management Severance Plan, which is described below. See section titled “2015 Emergent Compensation—Executive Severance Arrangements” for a discussion regarding Emergent’s Second Amended and Restated Senior Management Severance Plan. The Aptevo SMSP will be effective upon the completion of the separation.

Effects of the Separation on Outstanding Executive Compensation Awards. For a discussion of the treatment of equity compensation awards in the separation, see the sections entitled “The Separation and Distribution—Treatment of Equity Based Compensation” and “Certain Relationships and Related Person Transactions— Employee Matters Agreement.”

2015 Emergent Compensation

This section describes the compensation programs at Emergent in 2015 that applied to the Aptevo named executive officers in 2015. None of the Aptevo named executive officers is a named executive officer of Emergent. Mr. White was a non-employee director of Emergent until his resignation from the Emergent board of directors, effective on May 18, 2016. Mr. Lamothe is currently a vice president at Emergent and Dr. Stromatt is a senior vice president at Emergent. Therefore, each Aptevo named executive officer was compensated differently from Emergent’s named executive officers in the fiscal year ending December 31, 2015. The section titled “Lamothe and Stromatt Compensation” contains a description of the compensation programs to which Mr. Lamothe and Dr. Stromatt were subject in the fiscal year ending December 31, 2015. The Section titled “Marvin White Compensation” contains a qualitative description of the compensation Mr. White received in the fiscal year ending December 31, 2015.

Lamothe and Stromatt Compensation

As employees of Emergent, Mr. Lamothe and Dr. Stromatt are compensated under Emergent’s standard compensation program, which is applicable to all senior level employees (other than the named executive officers), consisting of base salary and bonuses, which are set within a range for each position that is determined by senior management. Mr. Lamothe and Dr. Stromatt are also eligible for equity awards under the Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan.

Base Salary. Emergent generally provides base salaries to its employees that are externally competitive while appropriately recognizing individual contributions. Emergent initially used the Radford Global Life Sciences Survey data to set salaries for each Emergent role. Each Emergent role is assigned a pay grade in the salary structure based on prevailing market rates. Each pay grade consists of a minimum, a midpoint and a maximum pay rate that generally reflects the 25th, 50th and 75th percentile of the market value of the position. Salary ranges are updated annually to reflect market changes using surveys, such as Aon Hewitt and World at Work. New pay ranges are published annually and salary adjustments are recommended based on the review of the data and job performance. While Emergent attempts to target the market median, it recognizes that the percentile for any given position may vary below or above these targets based on a variety of factors, including the employee’s scope of responsibilities, individual performance and potential future contributions to Emergent. In addition, Emergent considers its overall financial performance in making decisions to adjust executive salaries.

Emergent management used the information described above in approving the annual base salaries paid to Mr. Lamothe and Dr. Stromatt for 2014 and 2015, which are described below.

<u>Name</u>	<u>2014 Base Salary</u>	<u>2015 Base Salary</u>	<u>Increase from 2014</u>
Jeffrey G. Lamothe	\$213,208	\$214,274(1)	\$ 1,066
Scott C. Stromatt, M.D.	\$378,997	\$382,803(2)	\$ 3,806

(1) Includes a 0.5% merit increase.

(2) Includes a 1% merit increase.

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Annual Cash Bonuses. Management has the authority under Emergent’s Annual Bonus Plan to award annual cash bonuses. Such cash bonuses are intended to motivate and compensate each participant for achieving financial and operational goals and individual performance objectives. At the beginning of each fiscal year, Emergent establishes objective and clear corporate goals, which may be tied to achievement of specific goals including, but not limited to, specific revenue or net income targets, business development activities, manufacturing objectives, or product development milestones. The divisional group/divisional department goals support the achievement of the corporate goals and provide a framework for development of individual goals. The individual component includes consideration of the employee’s day-to-day job performance, achievement of specific annual goals, and performance against job related behavioral competencies. Each of the three components, corporate, divisional group/divisional department and individual, is assigned a rating, from 0% to 150% that is used to calculate the bonus award. At the end of the performance year, each performance factor is assessed. The maximum payout was capped at 200% of the employee’s bonus target for bonuses payable in 2015 based on 2014 performance. Management may also award discretionary bonuses outside of the framework of the bonus plan.

The Emergent compensation committee makes an annual assessment of the level of achievement of Emergent’s corporate goals to determine the “corporate factor.” In January 2015, the Emergent compensation committee met to determine the corporate factor to be applied to bonuses paid in 2015 for 2014 performance and approved a corporate factor of 0.90. In reviewing Emergent’s performance against goals set for 2014, the committee considered both financial and non-financial achievement of goals. In its deliberations, and given that Emergent’s financial performance is a key driver of shareholder value creation, the committee determined that Emergent had achieved 90% of its overall targets.

The Emergent compensation committee reviewed the Emergent 2014 corporate goals and assessed the degree to which Emergent achieved those goals, as follows:

<u>Goal</u>	<u>Performance</u>	<u>Achievement</u>
Achieve revenue of at least \$425 million.	Achieved revenues of approximately \$450.1 million.	Achieved; the Emergent compensation committee considered the fact that Emergent exceeded this goal by approximately \$25 million, or approximately 6%.
Achieve net income of at least \$36 million.	Achieved net income of \$36.7 million.	Achieved; reported net income was \$36.7 million, or approximately 2% above the target goal.
Complete acquisition of product that will generate revenue within 12 months of acquisition.	Progressing on three potential acquisition targets that could be completed in 2015.	Goal Not Achieved.
Advance product portfolio by initiating partnered Phase 3 study for otlertuzumab.	Agreed with the Emergent board of directors to initiate Phase 2 triple drug combination studies in 2014 and Emergent is on track to initiate such studies; Emergent continues to pursue partnering discussions with third parties.	Goal Not Achieved; the Emergent compensation committee considered the fact that Emergent entered into a partnering agreement for ES414 for up to \$183 million with \$20 million upfront; financial results are comparable to the targeted otlertuzumab partnering.

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<u>Goal</u>	<u>Performance</u>	<u>Achievement</u>
Advance progress of Building 55 licensure by completing all activities to support sBLA submission in first half of 2015.	Initiated final pivotal rabbit study; Final data from ongoing non-clinical targeted to be submitted second quarter of 2015.	Achieved
Initiate factor IX US launch following FDA approval.	Agreement reached with the FDA on path to approval and complete response letter issues addressed with no financial impact; Launch targeted for first half of 2015.	Goal Not Achieved.

Lamothe Annual Bonus. Mr. Lamothe had a 30% bonus target, of which he received \$58,953, based on Emergent's 0.90 corporate factor, meeting 100% of his individual factor and exceeding 100% of his group or division level performance factor (actual was 103%). This amount also reflects 10 months proration based on the fact that Mr. Lamothe assumed his position with Emergent in late February 2014 in connection with Emergent's acquisition of Cangene Corporation.

Stromatt Annual Bonus. Dr. Stromatt had a 35% bonus target, of which he received \$119,384 based on Emergent's 0.90 corporate factor and meeting 100% of his individual and group factors.

Retention Bonus. Mr. Lamothe also received a retention bonus in the amount of \$275,586 in 2015 resulting from his decision to remain employed with Emergent in 2015 after its acquisition of Cangene Corporation in 2014.

Equity Awards. Emergent uses stock option and restricted stock unit awards as forms of long-term incentive compensation for executives and other employees. Equity awards to Mr. Lamothe and Dr. Stromatt in 2015 were valued at \$103,240 and \$212,570, respectively. Target equity award values are intended to align with the market 50th percentile, but actual grants may be positioned above or below based on individual performance, which is based on an evaluation of each participant's performance of day-to-day responsibilities, behavioral competencies, and achievement of individual goals, which were assessed by management of Emergent for Mr. Lamothe and Dr. Stromatt. The Emergent compensation committee approves equity grant guidelines that set forth a dollar value for the amount of annual equity grants that Emergent may make to executives and other employees and includes a recommended minimum, midpoint and maximum target value of equity to be awarded at each participant level.

Emergent generally makes an annual equity grant to all executives and eligible employees on the third full trading day following the release of its financial results for the prior fiscal year. Emergent generally makes an equity grant on the third full trading day following the release of its financial results for the most recently completed fiscal quarter to executives and eligible employees who have been hired or promoted since the occurrence of the last equity grant. If circumstances warrant, Emergent also may make equity grants at various other points throughout the year. Emergent's chief executive officer, chief financial officer, and executive chairman have been authorized to make awards to certain eligible employees.

The exercise price of all stock options Emergent grants is equal to the fair market value of its common stock on the date of grant, which Emergent considers to be the closing sales price of its common stock on the NYSE on the trading day immediately preceding the date of grant. Stock options and restricted stock units generally vest in three equal annual instalments beginning one year from the date of grant and stock options have a seven-year term. The vesting feature of Emergent's stock option and restricted stock unit awards is intended to aid in executive retention by providing an incentive to its eligible employees to remain in Emergent's employ during the vesting period.

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With stock options, eligible employees are rewarded if Emergent's stock price increases above the exercise price of the stock option. Emergent believes that stock option awards are an effective method of motivating employees to manage the company in a manner that is consistent with the long-term interests of Emergent's stockholders. Emergent believes that restricted stock units are another effective tool for motivating, retaining and incentivizing senior management, particularly when used in combination with stock option awards.

Benefits. Emergent maintains broad-based benefits that are generally available to all employees, including health insurance, life and disability insurance, dental insurance and, for its U.S. employees, a 401(k) plan. Senior management is eligible to participate in all of Emergent's employee benefit plans, in each case on the same basis as other employees, except that Canadian employees, such as Mr. Lamothe receive benefits that are slightly different from their U.S. counterparts. Aptevo is not expected to have any Canadian employees after the separation.

Emergent provides a matching contribution for each 401(k) plan participant of 50% of the participant's elective deferrals for the year up to 6% of the participant's eligible compensation, subject to IRS limitations. The matching contribution is fully and immediately vested.

Executive Severance Arrangements. Dr. Stromatt is a participant in Emergent's Second Amended and Restated Senior Management Severance Plan, or the Senior Management Severance Plan, which includes severance and change of control benefits. The Senior Management Severance Plan provides for payments and benefits as a result of involuntary termination without cause or termination of employment in particular circumstances in connection with a change of control (as such terms are defined in the Senior Management Severance Plan). The Senior Management Severance Plan is designed based on Emergent's understanding of market practice at comparable companies for similarly situated employees and in a manner that Emergent believes is likely to attract and help retain high quality executive talent. The Senior Management Severance Plan is described in greater detail under "Payments Upon Termination or Change of Control." Emergent does not provide any payments or benefits in the case of termination by an executive without good reason (as defined in the Senior Management Severance Plan) or in the case of termination for cause under its Senior Management Severance Plan.

With respect to Mr. Lamothe, in the event that the biosciences division of Emergent is spun-off, and in connection with such spin-off, he does not become the chief financial officer of the spin-off company, he will be entitled to \$334,771 in total severance payments in lieu of any other severance benefits to which he might otherwise be entitled, so long as Mr. Lamothe does not voluntarily decline the position of chief financial officer or the Emergent biosciences division is not acquired by another company. In the event that this severance benefit is triggered, Mr. Lamothe would continue to be covered by the Emergent medical and dental benefits plan for Emergent Canadian employees for the 24 month period commencing on the last day of his employment.

Marvin White Compensation

Marvin L. White was a non-employee director of Emergent until his resignation from its board of directors, effective on May 18, 2016. Mr. White did not receive compensation from Emergent in 2015 beyond his board and committee retainers and the compensation he received under his consulting agreement, which is described in more detail below. Consistent with Emergent's director compensation practices in 2015, Mr. White received 9,400 restricted stock units for his service as a director. Grants of restricted stock units are made by the board of directors effective on the date of Emergent's annual meeting of stockholders, provided that the director continues serving as a director after the annual meeting and has served on the board of directors for at least six months.

On November 11, 2015, Emergent and Mr. White entered into a consulting agreement pursuant to which Mr. White provides consulting services to Emergent consisting of strategy, advice and guidance in connection with the separation. In accordance with the terms of the consulting agreement, Mr. White received a consulting fee of: \$5,000 per month through December 31, 2015; \$10,000 per month through March 31, 2016; has and will

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continue to receive \$15,000 per month until completion of the spin-off and reimbursement for his reasonable out-of-pocket expenses, subject to a maximum limit of \$120,000 for total compensation and non-travel-related expense reimbursement. For fiscal year ended December 31, 2015, Mr. White earned \$8,000 in fees under this consulting agreement.

Other Executive Compensation Practices

Stock Ownership Requirements and Hedging Policies. Because Emergent believes it is important for executives to have an equity stake in the company to help align their interests with those of its stockholders, in January 2012 Emergent adopted a formal stock ownership requirement for its directors and employee executive officers. Directors and employee executive officers must directly or indirectly hold stock or restricted stock units in Emergent with a value equal to the amounts set forth in the table below. In May 2014, Emergent revised the stock ownership requirement for its non-employee directors from one to three times the base annual retainer.

<u>Position</u>	<u>Requirement</u>
Non-employee Directors	Three times the base annual retainer
Chief Executive Officer	Three times base salary
Other Executive Officers	One time base salary

Emergent's directors, chief executive officer and employee executive officers have five years to satisfy the ownership requirements, which are measured from January 2012 for all its existing directors and executive officers or from the date of appointment for newly hired directors or executive officers. Until these ownership requirements are satisfied, Emergent's directors, chief executive officer and employee executive officers must retain 50% of after-tax shares after vesting of restricted stock units or exercise of stock options. This requirement became effective beginning in 2014. Although Mr. White was subject to this policy as a director of Emergent, Mr. Lamothe and Dr. Stromatt are not.

Compensation Recovery Policy. In 2011, Emergent adopted a compensation recovery policy pursuant to which certain incentive based compensation can be recouped from a current or former executive officer if Emergent's board of directors determines that:

- Such compensation has been awarded or received by such executive officer based on financial results that were achieved or operating metrics that were satisfied, as a result of fraudulent or illegal conduct;
- Certain restatements of its financial results are required due to material noncompliance with financial reporting requirements by such executive; or
- Such executive officer engaged in intentional misconduct that contributed in any material respect to improper accounting or incorrect financial data resulting in a restatement of its financial results.

Tax and Accounting Considerations. Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, generally disallows a tax deduction for compensation in excess of \$1.0 million paid to the chief executive officer and to each other officer (other than the chief financial officer) whose compensation is required to be reported to stockholders pursuant to the Exchange Act by reason of being among the three most highly paid executive officers. Certain compensation, including qualified performance-based compensation, will not be subject to the deduction limit if certain requirements are met. Emergent periodically reviews the potential consequences of Section 162(m) of the Internal Revenue Code and it may structure the performance-based portion of its executive compensation, where feasible, to comply with exemptions in Section 162(m) so that the compensation remains tax deductible to Emergent. However, the Emergent compensation committee may, in its judgment, authorize compensation payments that do not comply with the exemptions in Section 162(m) when it believes that such payments are appropriate to attract and retain executive talent and are in the best interest of Emergent stockholders. We expect that the Aptevo compensation committee will develop its own policies and practices with respect to Section 162(m) of the Internal Revenue Code following completion of the separation.

EXECUTIVE COMPENSATION

SUMMARY COMPENSATION TABLE

The following table sets forth information for the fiscal years ended December 31, 2015, 2014 and 2013 regarding the historical compensation that the Aptevo named executive officers received from Emergent.

Name and Principal Position	Year	Salary(1)	Bonus(2)	Option Awards(3)	Stock Awards(4)	All Other Compensation(5)	Total
Marvin L. White Chief Executive Officer	2015	\$ —	\$ —	\$ —	\$ 295,066	\$ 100,921	\$ 395,987
	2014	\$ —	\$ —	\$ 68,593	\$ 96,068	\$ 120,696	\$ 285,357
	2013	\$ —	\$ —	\$ 43,301	\$ 51,300	\$ 118,500	\$ 213,101
Jeffrey G. Lamothe(6) Chief Financial Officer	2015	\$ 227,584	\$ 342,993	\$ 29,542	\$ 51,620	\$ 12,139	\$ 663,878
	2014	\$ 218,688	\$ 221,418	\$ 80,864	\$ 139,748	\$ 21,666	\$ 682,384
Scott C. Stromatt, M .D. Chief Medical Officer	2015	\$ 397,409	\$ 149,293	\$ 60,827	\$ 106,285	\$ 5,863	\$ 719,677
	2014	\$ 370,779	\$ 119,384	\$ 130,710	\$ 183,990	\$ 7,800	\$ 812,663
	2013	\$ 369,871	\$ 144,388	\$ 83,833	\$ 99,389	\$ 6,695	\$ 704,176

- (1) Includes amounts deferred at the direction of the participant to Emergent’s 401(k) plan or other retirement related plans.
- (2) Represents cash bonuses paid in February or March following the year indicated, for performance in the year indicated. For Mr. Lamothe, the bonus amount also includes retention bonuses received in 2014 and 2015.
- (3) The amounts in the “Option Awards” column reflect grant date fair value of stock option awards in the fiscal years indicated, calculated in accordance with SEC rules. For a discussion of Aptevo’s valuation assumptions, see Note 11 to the combined financial statements included in this information statement.
- (4) The amounts in the “Stock Awards” column reflect the grant date fair value of restricted stock unit awards granted in the fiscal years indicated, calculated in accordance with SEC rules. For a discussion of Aptevo’s valuation assumptions, see Note 11 to the combined financial statements included in this information statement.
- (5) Represents 401(k) or other retirement related plan matching contributions. For Mr. White, “All Other Compensation” includes his compensation as a board member of Emergent of \$92,821 in 2015, along with \$8,000 in compensation received under his consulting agreement with Emergent during 2015. For the years 2014 and 2013, “All Other Compensation” for Mr. White consists of compensation as a board member of Emergent.
- (6) Amounts for Mr. Lamothe listed above and in the “Compensation Discussion and Analysis” section are shown in dollars at an exchange rate of 0.720892 and 0.861995 U.S. dollars, respectively, for Canadian dollars for December 31, 2015 and 2014. This exchange rate represents the spot rate as of December 31, 2015 and 2014.

Employment Agreements

None of the Aptevo named executive officers has an employment agreement with Emergent.

Emergent does not have any formal or informal policy for the amount of executive salary and bonus in proportion to total compensation.

2015 GRANTS OF PLAN-BASED AWARDS

The following table sets forth information regarding each grant of an award made to each Aptevo named executive officer by Emergent during the fiscal year ended December 31, 2015 under any plan, contract, authorization or arrangement pursuant to which cash, securities, similar instruments or other property may be received.

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<u>Name</u>	<u>Grant Date</u>	<u>Number of Shares of Stock or Units(1)</u>	<u>Number of Securities Underlying Options(2)</u>	<u>Exercise Price of Option Awards (\$/sh)(3)</u>	<u>Grant Date Fair Value of Stock and Option Awards(4)</u>
Marvin L. White	3/10/2015	9,400	—	\$ —	\$ 295,066
Jeffrey G. Lamothe	3/10/2015	1,780	—	\$ 29.00	\$ 29,542
	3/10/2015	—	3,560	\$ —	\$ 51,620
Scott C. Stromatt, M.D.	3/10/2015	3,665	—	\$ 29.00	\$ 60,827
	3/10/2015	—	7,330	\$ —	\$ 106,285

- (1) Represents shares of common stock underlying a restricted stock unit award.
- (2) Represents shares of common stock issuable upon exercise of stock options.
- (3) Represents the fair market value of Emergent’s common stock on the date of grant, which is considered to be the closing sales price of Emergent’s common on the NYSE on the trading day immediately preceding the date of grant.
- (4) The amounts in the “Grant Date Fair Value of Stock and Option Awards” column reflect the grant date fair value of each equity award calculated in accordance with SEC rules. For a discussion of Aptevo’s valuation assumptions, see Note 11 to Aptevo’s combined financial statements included in this information statement.

In 2015, all equity awards granted to Emergent officers and directors were made under Emergent BioSolutions Inc. Third Amended and Restated 2006 Stock Incentive Plan, as amended, and vest in three equal instalments on the day prior to the first, second and third annual anniversaries of the grant date. All stock options have an exercise price equal to the closing sale price per share of Emergent’s common stock on the NYSE on the trading day immediately preceding the date of grant. Under the terms of the agreements governing the restricted stock unit awards granted to Emergent officers and directors in 2015, each is entitled to receive, at the time of the issuance of any shares upon vesting of the applicable restricted stock unit award, an amount of cash equal to the aggregate amount of all dividends paid by Emergent between the date of grant and the issuance of such shares, if any.

2015 OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth information regarding unexercised Emergent stock options and unvested restricted stock unit awards outstanding as of December 31, 2015 for each of the Aptevo named executive officers.

Name	2015 Outstanding Equity Awards at Fiscal Year-End				Stock Awards	
	Option Awards			Option Award Expiration Date	Unvested Stock Awards	Market Value Unvested Stock
	Exercisable	Unexercisable	Number of Securities Underlying Option Award			
Marvin White	10,800	—	\$15.75	5/31/2020	—	\$ —
	7,200	—	\$22.02	5/19/2021	—	\$ —
	7,200	—	\$14.66	5/17/2019	—	\$ —
	4,800	2,400(1)	\$14.25	5/22/2020	—	\$ —
	3,134	6,266(2)	\$20.44	5/22/2021	—	\$ —
	—	—	\$ —	—	1,200(6)	\$ 48,012(12)
	—	—	\$ —	—	3,133(7)	\$ 125,351(12)
—	—	\$ —	—	9,400(8)	\$ 376,094(12)	
Jeff Lamothe	3,317	6,633(3)	\$28.09	3/10/2021	—	\$ —
	—	3,560(4)	\$29.00	3/9/2022	—	\$ —
	—	—	\$ —	—	3,316(9)	\$ 132,673(12)
	—	—	\$ —	—	1,780(10)	\$ 71,218(12)
Scott C. Stromatt, M.D.	—	4,517(5)	\$14.67	3/11/2020	—	\$ —
	—	8,733(3)	\$28.09	3/10/2021	—	\$ —
	—	7,330(4)	\$29.00	3/9/2022	—	\$ —
	—	—	\$ —	—	2,258(11)	\$ 90,343(12)
	—	—	\$ —	—	4,366(9)	\$ 174,684(12)
	—	—	\$ —	—	3,665(10)	\$ 146,637(12)

- (1) The unexercisable portion of this stock option award vested on May 18, 2016.
- (2) Approximately one half of this stock option award vested on May 18, 2016 and the remaining unvested portion of this stock option award will vest on May 21, 2017.
- (3) Approximately one half of this stock option award vested on March 10, 2016 and the remaining unvested portion of this stock option award will vest on March 10, 2017.
- (4) Approximately one third of this stock option award vested on March 9, 2016 and approximately one third of this stock option award will vest on each of March 9, 2017 and 2018.
- (5) The unexercisable portion of this stock option award vested on March 11, 2016.
- (6) The unvested portion of this restricted stock unit award vested on May 18, 2016.
- (7) Approximately one half of this restricted stock unit award vested on May 18, 2016 and the remaining unvested portion of this restricted stock unit award will vest on May 21, 2017.
- (8) Approximately one third of this restricted stock unit award vested on May 20, 2016 and approximately one third of this restricted stock unit award will vest on each of May 20, 2017 and 2018.
- (9) Approximately one half of this restricted stock unit award vested on March 10, 2016 and the remaining unvested portion of this restricted stock unit award will vest on March 10, 2017.
- (10) Approximately one third of this restricted stock unit award vested on March 9, 2016 and approximately one third of this restricted stock unit award will vest on each of March 9, 2017 and 2018.
- (11) The unvested portion of this restricted stock unit award vested on March 11, 2016.
- (12) Represents the closing price of Emergent's common stock on December 31, 2015 multiplied by the number of shares underlying the unvested proration of the restricted stock unit award as of December 31, 2015.

2015 OPTION EXERCISES AND STOCK AWARDS VESTED

The following table sets forth information regarding the exercise of stock options and the vesting of restricted stock unit awards during the fiscal year ended December 31, 2015 for each of the Aptevo named executive officers on an aggregated basis.

Name	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise	Value Realized on Exercise(1)	Number of Shares Acquired on Vest	Value Realized on Vest(2)
Marvin L. White	—	\$ —	3,967	\$ 122,088
Jeffrey G. Lamothe	—	\$ —	1,659	\$ 48,094
Scott C. Stromatt, M.D.	28,800	\$ 893,376	6,175	\$ 178,568

- (1) The amounts in the “Value Realized on Exercise” column are calculated based on the difference between the closing market price per share of Emergent’s common stock on the date of exercise and the exercise price per share of the applicable stock option.
- (2) The amounts in the “Value Realized on Vest” column are calculated based on the closing market price per share of Emergent’s common stock on the date of vest.

PAYMENTS UPON TERMINATION OR CHANGE OF CONTROL

The Emergent Senior Management Severance Plan is for the benefit of employees with the title of executive chair, chief executive officer, president, executive vice president, senior vice president or vice president who have been designated to participate in the Senior Management Severance Plan by Emergent’s board of directors or, with the authorization of its board of directors, by Emergent’s chief executive officer. Emergent’s chief executive officer is authorized to designate the greater of 7% of the total number of its employees or 35 employees to be participants in the Senior Management Severance Plan at any particular time, on the basis of name, title, function or compensation level.

For-cause terminations. If during the term of the Senior Management Severance Plan, Emergent terminates a participant’s employment with cause, as defined in the Senior Management Severance Plan, then the participant will not be entitled to receive any compensation, benefits or rights under the Senior Management Severance Plan, and any stock options or other equity participation benefits vested on or prior to the date of the termination, but not yet exercised, will immediately terminate.

Without-cause terminations. If during the term of the Senior Management Severance Plan, Emergent terminates a participant’s employment without cause, the participant will be entitled to:

- Any unpaid base salary and accrued paid time-off through the date of termination;
- A pro rata portion of the participant’s target annual bonus in respect of the year of termination paid in equal installments for a stated period following the participant’s date of termination as indicated in the table below;
- Any bonus earned but unpaid as of the date of termination for any previously completed year paid in equal installments for a stated period following the participant’s date of termination as indicated in the table below;
- Reimbursement for any unreimbursed expenses incurred by the participant prior to the date of termination;
- An amount equal to a specified percentage of the participant’s annual base salary and target bonus, as indicated in the table below paid in installments for a stated period following the participant’s date of termination as indicated in the table below;

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- Employee and fringe benefits and perquisites, if any, to which the participant may be entitled as of the date of termination under Emergent's relevant plans, policies and programs; and
- Continued eligibility for the participant and his or her eligible dependents to receive employee benefits (such as medical, dental, life insurance (not to exceed one year), and pension benefits), for a stated period following the participant's date of termination as indicated in the table below, except when the provision of employee benefits would result in a duplication of benefits provided by any subsequent employer.

The following table sets forth the percentage of base salary and the stated period over which certain payments are made and the participant is entitled to continued employee benefits if Emergent terminates the participant's employment without cause for each of Aptevo's named executive officers who participates in the plan.

<u>Name</u>	<u>Benefits for a Termination Without Cause</u>	
	<u>Percentage of Annual Base Salary and Bonus</u>	<u>Stated Period for Continued Employee Benefits</u>
Marvin L. White	none	none
Jeffrey G. Lamothe ⁽¹⁾	none	24 months
Scott C. Stromatt, M.D.	100%	9 months

- (1) Mr. Lamothe opted out of the Senior Management Severance Plan and entered into a separate severance agreement with Aptevo.

The following table sets forth the amount of potential payments and value of benefits to which each of Aptevo's named executive officers that participates in the plan would have received if Emergent had terminated their employment without cause on December 31, 2015.

<u>Name</u>	<u>Termination without Cause</u>		
	<u>Cash Payments(1)</u>	<u>Value of Benefits(2)</u>	<u>Value of Equity</u>
Marvin L. White	\$ —	\$ —	\$ —
Jeffrey G. Lamothe	\$ 334,771	\$ 36,657	\$ —
Scott C. Stromatt, M.D.	\$ 535,924	\$ 25,393	\$ —

- (1) The amounts in this column represent the aggregate amount equal to the applicable specified percentage of the participant's annual base salary and target bonus in effect on December 31, 2015 plus 100% (the applicable pro rata portion) of the participant's target annual bonus for 2014.
- (2) The amounts in this column reflect the estimated value of future premiums under Emergent's health and welfare benefit plans and life insurance program.

Change-of-control terminations. If during the term of the Senior Management Severance Plan, Emergent terminates a participant's employment without cause or a participant resigns for good reason, as defined in the Senior Management Severance Plan, in each case within 18 months following a change of control, as defined in the Senior Management Severance Plan, then the participant will be entitled to the payments and benefits described below. If, however, Emergent terminates a participant's employment prior to a change of control at the request of a party involved in such change of control or otherwise in connection with or in anticipation of a change of control, the participant becomes entitled to the same payments and benefits described below but they are paid or distributed in the same manner as if the termination had been a without cause termination.

- A lump sum amount equal to the sum of:
 - Any unpaid base salary and accrued paid time-off through the date of termination,

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- A pro rata portion of the participant's target annual bonus in respect of the year of termination,
 - Any bonus earned but unpaid as of the date of termination for any previously completed year,
 - Any unreimbursed expenses incurred by the participant prior to the date of termination, and
 - An amount equal to a specified percentage of the sum of the participant's base salary and the participant's target bonus, as indicated in the table below;
- Employee and fringe benefits and perquisites, if any, to which the participant may be entitled as of the date of termination of employment under Emergent's relevant plans, policies and programs;
 - Any unvested stock options, stock appreciation rights, shares of restricted stock, restricted stock units and other stock-unit awards held by the participant that are outstanding on the date of termination will become fully vested as of that date. In addition, the period during which any stock options held by the participant that are outstanding on that date may be exercised shall be extended to a date that is the later of the 15th day of the third month following the termination date, or December 31 of the calendar year in which the stock option would otherwise have expired if the exercise period had not been extended, but not beyond the final date the stock option could have been exercised if the participant's employment had not terminated, in each case based on the term of the option at the original grant date;
 - Continued eligibility for the participant and his or her eligible dependents to receive employee benefits (such as medical, dental, life insurance (not to exceed one year), disability and pension benefits), for a stated period following the participant's date of termination as indicated in the table below, except when the provision of employee benefits would result in a duplication of benefits provided by any subsequent employer;
 - The retention for the maximum period permitted by applicable law of all rights the participant has to indemnification from Emergent immediately prior to the change of control and the continuation throughout the period of any applicable statute of limitations of any director's and officer's liability insurance covering the participant immediately prior to the change of control; and
 - The advancement to the participant of all costs and expenses, including attorney's fees and disbursements, incurred by the participant in connection with any legal proceedings that relate to the termination of employment or the interpretation or enforcement of any provision of the Senior Management Severance Plan, for which the participant will have no obligation to reimburse Emergent if the participant prevails in the proceeding with respect to at least one material issue or the proceeding is settled.

The following table sets forth the percentage of base salary and bonus and the stated period for continued employee benefits to which each participant is entitled under the circumstances described above in connection with a change of control.

Name	<u>Benefits for a Termination In Connection with a Change in Control</u>	
	<u>Percentage of Annual Base Salary and Bonus</u>	<u>Stated Period for Continued Employee Benefits</u>
Marvin L. White	none	none
Jeffrey G. Lamothe ⁽¹⁾	none	24 months
Scott C. Stromatt, M.D.	125%	12 months

(1) Mr. Lamothe opted out of the Senior Management Severance Plan and entered into a separate severance agreement with Aptevo.

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The following table sets forth the amount of potential payments and value of benefits that each participant would have received if Emergent had terminated their employment prior to or in connection with a change of control on December 31, 2015.

Name	Termination Prior to or in Connection with a Change of Control		
	Cash Payments(1)	Value of Benefits(2)	Value of Equity Awards(3)
Marvin L. White	\$ —	\$ —	\$ —
Jeffrey G. Lamothe(3)	\$ 334,771	\$ 36,657	\$ 322,152
Scott C. Stromatt, M.D.	\$ 669,906	\$ 19,045	\$ 710,924

- (1) The amounts in this column represent the aggregate amount equal to the applicable specified percentage of the participant's annual base salary and target bonus in effect on December 31, 2015, plus 100% (the applicable pro rata portion) of the participant's target annual bonus for 2015.
- (2) The amounts in this column reflect the estimated value of future premiums under Emergent's health and welfare benefit plans and life insurance program.
- (3) The amounts in this column reflect the value of accelerated vesting of stock options and restricted stock units. The amounts reflecting the value of accelerated vesting of stock options are calculated by multiplying the number of shares subject to accelerated vesting under outstanding stock options by the difference between \$40.01, which was the closing market price per share of Emergent common stock on December 31, 2015, and the per share exercise price of the applicable accelerated stock option. The amounts reflecting the value of accelerated vesting of restricted stock units are calculated by multiplying the number of shares subject to accelerated vesting under restricted stock unit grants by \$40.01, which was the closing market price per share of Emergent common stock on December 31, 2015.

General provisions. All payments under the Senior Management Severance Plan will be reduced by any applicable taxes required by applicable law to be paid or withheld by Emergent. If at the time a participant's employment is terminated, the participant is a specified employee within the meaning of Section 409A of the Internal Revenue Code, or Section 409A, then any payments to the participant that constitute non-qualified deferred compensation within the meaning of Section 409A will be delayed by a period of six months. All such payments that would have been made to the participant during the six-month period will be made in a lump sum on the date that is six months and one day following the date of termination, and all remaining payments will commence in the seventh month following the date of termination. Emergent's board of directors or any committee thereof designated by the Emergent board of directors is authorized to administer the Senior Management Severance Plan and has authority to adopt, amend and repeal the administrative rules, guidelines and practices relating to the Senior Management Severance Plan as it deems advisable.

As a condition to payment of any amounts payable upon a termination without cause under the Senior Management Severance Plan, the participant is required:

- For a period of 12 months (or six months for vice presidents who participate in the Senior Management Severance Plan) not to:
 - Induce, counsel, advise, solicit or encourage its employees to leave its employ or to accept employment with any other person or entity,
 - Induce, counsel, advise, solicit or encourage any person who Emergent employed within six months prior to that time to accept employment with any person or entity besides us or hire or engage that person as an independent contractor,
 - Solicit, interfere with or endeavor to cause any of its customers, clients or business partners to cease or reduce its relationship with it or induce any such customer, client or business partner to breach any agreement that such customer, client or business partner may have with Emergent, and

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- Engage in or have a financial interest in any business competing with Emergent within any state, region or locality in which Emergent is then doing business or marketing products;
- Upon reasonable notice and at Emergent’s expense, to cooperate fully with any reasonable request that may be made by Emergent in connection with any investigation, litigation or other similar activity to which Emergent is or may be a party or may otherwise be involved and for which the participant may have relevant information; and
- To sign and deliver a suitable waiver and release under which the participant will release and discharge Emergent from and on account of any and all claims that relate to or arise out of the employment relationship.

Director Compensation Following the Separation

Aptevo’s non-employee directors have not received, and will not receive, any compensation for their service on Aptevo’s board of directors prior to the completion of the distribution.

In anticipation of the separation, the Emergent compensation committee engaged Willis Towers Watson to review market practice and recommend a potential compensation structure for Aptevo’s non-employee directors. Upon this review, the Emergent board of directors approved the Aptevo Directors Compensation Program, which we expect to be effective upon the completion of the separation and distribution, subject to any adjustments by Aptevo’s compensation committee and board of directors following the distribution. Under the Aptevo Directors Compensation Program, we expect that Aptevo’s non-employee directors will receive the compensation set forth in the table below. We also expect to reimburse Aptevo’s non-employee directors for out-of-pocket expenses incurred in connection with attending our board and committee meetings.

Element	Program
Annual Cash Retainer	\$40,000
Committee Chair Retainer	\$20,000 – Audit
	\$15,000 – Compensation
Committee Member Retainer	\$10,000 – Audit
	\$7,500 – Compensation
Annual Equity Grant	25,000 options
Initial Equity Grant (including annual)	37,500 options

As indicated in the table above, we expect that the Aptevo Director Compensation Program will provide for the award of stock options upon commencement of service on Aptevo’s board of directors and for the annual award of stock options. The initial grant of stock options are expected to vest in three equal instalments on the first, second and third annual anniversaries of the date of grant. Thereafter, annual equity grants are expected to vest in four equal instalments each quarter of the year.

Director Transition Grants

It is currently anticipated that Emergent directors who will join Aptevo as directors and those Emergent directors who will serve on both boards of directors following the separation will receive additional equity grants in connection with their formal Aptevo appointments. As previously noted, Mr. White is expected to receive a transition grant of options to purchase 400,950 shares of Aptevo common stock in connection with his appointment as Aptevo’s chief executive officer. Final decisions regarding equity grants to other Emergent directors who will join the Aptevo board will be made in the future.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Agreements with Emergent

Following the separation and distribution, Aptevo and Emergent will operate separately, each as an independent public company. Aptevo will enter into a separation and distribution agreement with Emergent, which is referred to in this information statement as the “separation agreement,” to effect the separation. In connection with the separation, Aptevo will also enter into various other agreements to provide a framework for its relationship with Emergent after the separation, including a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian wholesaler agreement, a trademark license agreement and a product license agreement. These agreements will provide for the allocation between Aptevo and Emergent of Emergent’s assets, liabilities and obligations (including investments, property and employee benefits, and tax-related assets and liabilities) attributable to periods prior to, at and after Aptevo’s separation from Emergent and will govern certain relationships between Aptevo and Emergent after the separation.

The material agreements described below will be filed as exhibits to the registration statement on Form 10 of which this information statement is a part. The summaries of each of these agreements set forth the terms of the agreements that we believe are material. These summaries are qualified in their entirety by reference to the full text of the applicable agreements, which are incorporated by reference into this information statement. When used in this section, “distribution date” refers to the date on which Emergent distributes Aptevo common stock to the holders of Emergent common stock.

Separation Agreement

Transfer of Assets and Assumption of Liabilities

The separation agreement will identify the assets to be transferred, the liabilities to be assumed and the contracts to be assigned to each of Aptevo and Emergent as part of the separation of Emergent into two companies, and will provide for when and how these transfers, assumptions and assignments will occur. Certain of the necessary transfers, assumptions and assignments will be accomplished through the internal reorganization. In particular, the separation agreement will provide that, among other things, subject to the terms and conditions contained therein:

- certain assets related to Emergent’s biosciences business (and certain legacy businesses and operations of Aptevo), which we refer to as the “Aptevo Assets,” will be transferred to Aptevo or one of its subsidiaries;
- certain liabilities related to Aptevo’s business or the Aptevo Assets, which we refer to as the “Aptevo Liabilities,” will be retained by or transferred to Aptevo, including certain liabilities associated with previously consummated divestitures of assets primarily related to the biosciences business; and
- all of the assets and liabilities (including whether accrued, contingent or otherwise) other than the Aptevo Assets and Aptevo Liabilities (such assets and liabilities, other than the Aptevo Assets and the Aptevo Liabilities, we refer to as the “Excluded Assets” and “Excluded Liabilities,” respectively) will be retained by or transferred to Emergent.

Except as expressly set forth in the separation agreement or any ancillary agreement, neither Aptevo nor Emergent will make any representation or warranty as to the assets, business or liabilities transferred or assumed as part of the separation, as to any approvals or notifications required in connection with the transfers, as to the value of or the freedom from any security interests of any of the assets transferred, as to the absence or presence of any defenses or right of setoff or freedom from counterclaim with respect to any claim or other asset of either Aptevo or Emergent, or as to the legal sufficiency of any assignment, document or instrument delivered to convey title to any asset or thing of value to be transferred in connection with the separation. All assets will be

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transferred on an “as is,” “where is” basis, and the respective transferees will bear the economic and legal risks that any conveyance will prove to be insufficient to vest in the transferee good and marketable title, free and clear of all security interests, that any necessary consents or governmental approvals are not obtained, or that any requirements of law, agreements, security interests, or judgments are not complied with.

Information in this information statement with respect to the assets and liabilities of the parties following the distribution is presented based on the allocation of such assets and liabilities pursuant to the separation agreement, unless the context otherwise requires. The separation agreement will provide that, in the event that the transfer or assignment of certain assets and liabilities to Aptevo or Emergent, as applicable, does not occur prior to the separation, then until such assets or liabilities are able to be transferred or assigned, Aptevo or Emergent, as applicable, will hold such assets in trust for the other party.

The Distribution

The separation agreement will also govern the rights and obligations of the parties regarding the distribution following the completion of the separation. On the distribution date, Emergent will distribute to its stockholders that hold Emergent common stock as of the record date for the distribution all of the issued and outstanding shares of Aptevo common stock on a pro rata basis. Stockholders will receive cash in lieu of any fractional shares, if applicable.

Conditions to the Distribution

The separation agreement will provide that the distribution is subject to satisfaction (or waiver by Emergent) of certain conditions. These conditions are described under “The Separation and Distribution—Conditions to the Distribution.” Emergent will have the sole and absolute discretion to determine (and change) the terms of, and to determine whether to proceed with, the distribution and, to the extent that it determines to so proceed, to determine the record date for the distribution and the distribution date.

Claims

In general, each party to the separation agreement will assume liability for all pending, threatened and unasserted legal matters related to its own business or its assumed or retained liabilities and will indemnify the other party for any liability to the extent arising out of or resulting from such assumed or retained legal matters.

Releases

The separation agreement will provide that Aptevo and its affiliates will release and discharge Emergent and its affiliates from all liabilities assumed by Aptevo as part of the separation, from all acts and events occurring or failing to occur, and all conditions existing, on or before the distribution date relating to Aptevo’s business, and from all liabilities existing or arising in connection with the implementation of the separation, except as expressly set forth in the separation agreement. Emergent and its affiliates will release and discharge Aptevo and its affiliates from all liabilities retained by Emergent and its affiliates as part of the separation and from all liabilities existing or arising in connection with the implementation of the separation, except as expressly set forth in the separation agreement.

These releases will not extend to obligations or liabilities under any agreements between the parties that remain in effect following the separation, which agreements include, but are not limited to, a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian wholesaler agreement, a trademark license agreement and a product license agreement.

Indemnification

In the separation agreement, Aptevo will agree to indemnify, defend and hold harmless Emergent, each of Emergent's affiliates and each of Emergent and its affiliates' respective directors, officers and employees, from and against all liabilities relating to, arising out of or resulting from:

- the failure of Aptevo, any subsidiary of Aptevo, or any person controlled by Aptevo, which we refer to as the "Aptevo Group" or any other person to pay, perform or otherwise promptly discharge any Aptevo Liabilities or Aptevo Contract in accordance with its respective terms, whether prior to, on or after the distribution date;
- the business and operations of the biosciences business and related businesses and operations (except to the extent it constitutes an Excluded Liability), any Aptevo Liability or any Aptevo Contract;
- any breach by Aptevo or any other member of the Aptevo Group of the separation agreement or any of the ancillary agreements;
- except to the extent it constitutes an Excluded Liability, any guarantee, indemnification obligation, letter of credit reimbursement obligation, surety, bond or other credit support agreement, arrangement, commitment or understanding for the benefit of any member of the Aptevo Group by Emergent, any subsidiary of Emergent, any person controlled by Emergent, which we refer to as the "Emergent Group," that survives following the distribution; and
- any untrue statement or alleged untrue statement in the registration statement on Form 10, including within this information statement, of a material fact, except to the extent related exclusively to Emergent Group, Emergent Business, Emergent's intentions with respect to the distribution or terms of the distribution.

Emergent will agree to indemnify, defend and hold harmless Aptevo, each of Aptevo's affiliates and each of Aptevo's and Aptevo's affiliates' respective directors, officers and employees from and against all liabilities relating to, arising out of or resulting from:

- the failure of Emergent or any other member of the Emergent Group or any other person to pay, perform or otherwise promptly discharge any Excluded Liabilities in accordance with their terms, whether prior to, on or after the distribution date;
- the Excluded Liabilities;
- the businesses and operations of the Emergent Group other than the biosciences business (except to the extent it constitutes an Aptevo Liability and other than the conduct of business, operations or activities for the benefit of the Aptevo Group pursuant to any ancillary agreement);
- any breach by Emergent or any other member of the Emergent Group of the separation agreement or any of the ancillary agreements; and
- any untrue statement or alleged untrue statement in the registration statement on Form 10, including within this information statement, of a material fact, solely to the extent such statement or omission is related exclusively to Emergent Group, Emergent Business, Emergent's intentions with respect to the distribution or terms of the distribution.

The separation agreement will also establish procedures with respect to claims subject to indemnification and related matters.

Insurance

The separation agreement provides for the allocation between the parties of rights and obligations under existing insurance policies with respect to occurrences prior to the distribution and sets forth procedures for the administration of insured claims.

Non-competition and Non-solicitation Provisions

The separation agreement prohibits Emergent from making, manufacturing, using, selling, offering for sale, importing or otherwise exploiting protein therapeutics intended to treat oncolytic diseases during the period commencing upon completion of the distribution and ending on the earlier of the third anniversary of the completion of the distribution or a change of control of Emergent, subject to certain exceptions.

The separation agreement also prohibits, for a period of 12 months following the completion of the distribution, each of Emergent and Aptevo from soliciting the employees of the other party to leave his or her employment with the other party, or to hire such party, subject to certain exceptions.

Further Assurances

In addition to the actions specifically provided for in the separation agreement, except as otherwise set forth therein or in any ancillary agreement, both Aptevo and Emergent agree in the separation agreement to use reasonable best efforts, prior to, on and after the distribution date, to take, or cause to be taken, all actions, and to do, or cause to be done, all things necessary, proper or advisable under applicable laws, regulations and agreements to consummate and make effective the transactions contemplated by the separation agreement and the ancillary agreements.

Dispute Resolution

The separation agreement will contain provisions that govern, except as otherwise provided in any ancillary agreement, the resolution of disputes, controversies or claims that may arise between Aptevo and Emergent related to the separation or distribution. These provisions will contemplate that efforts will be made to resolve disputes, controversies and claims by negotiation by applicable local or functional representatives of Aptevo and Emergent and, if necessary, escalation of the matter to a transition committee composed of representatives of Aptevo and Emergent. If such efforts are not successful, either Aptevo or Emergent may submit the dispute, controversy or claim to binding arbitration, subject to the provisions of the separation agreement.

Expenses

Except as expressly set forth in the separation agreement or in any ancillary agreement, Emergent will be responsible for all costs and expenses incurred in connection with the separation prior to the distribution date, including costs and expenses relating to legal and tax counsel, financial advisors and accounting advisory work related to the separation. Except as expressly set forth in the separation agreement or in any ancillary agreement, or as otherwise agreed in writing by Emergent and Aptevo, all costs and expenses incurred in connection with the separation after the distribution will be paid by the party incurring such cost and expense.

Other Matters

Other matters governed by the separation agreement will include access to financial and other information, confidentiality, access to and provision of records and treatment of outstanding guarantees and similar credit support.

Termination

The separation agreement will provide that it may be terminated, and the separation and distribution may be modified or abandoned, at any time prior to the distribution date in the sole discretion of Emergent without the approval of any person, including Aptevo or Emergent stockholders. In the event of a termination of the separation agreement, no party, nor any of its directors, officers or employees, will have any liability of any kind to the other party or any other person. After the distribution date, the separation agreement may not be terminated except by an agreement in writing signed by both Emergent and Aptevo.

Transition Services Agreement

Aptevo and Emergent will enter into a transition services agreement in connection with the separation pursuant to which Emergent and its affiliates will provide to Aptevo and its affiliates, on an interim, transitional basis, various services, including, but not limited to, accounts payable administration, information technology services, regulatory and clinical support, general administrative services and other support services. The agreed-upon charges for such services are generally intended to allow Emergent to recover all direct and indirect costs. Aptevo will be provided with reasonable information that supports the charges for such transition service by Emergent.

The services will commence on the distribution date and terminate up to two years following the distribution date. Aptevo may terminate certain specified services by giving prior written notice to Emergent and paying any applicable wind-down charges.

Subject to certain exceptions, the liabilities of Emergent under the transition services agreement will generally be limited to the aggregate charges (excluding any third-party costs and expenses included in such charges) actually paid to Emergent by Aptevo pursuant to the transition services agreement. The transition services agreement also will provide that Emergent will not be liable to Aptevo for any special, indirect, incidental, punitive or consequential damages.

Tax Matters Agreement

In connection with the separation, Aptevo and Emergent will enter into a tax matters agreement that will govern the parties' respective rights, responsibilities and obligations with respect to taxes (including taxes arising in the ordinary course of business and taxes, if any, incurred as a result of any failure of the distribution and certain related transactions to qualify as tax-free for U.S. federal income tax purposes), tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings, and assistance and cooperation in respect of tax matters.

With respect to taxes arising in the ordinary course of business, Aptevo will generally be liable for all taxes relating to the biosciences business that are attributable to the period after the distribution, and Emergent will indemnify Aptevo for all taxes relating to the biosciences business that are attributable to the period prior to the distribution.

In addition, to preserve the tax-free treatment to Emergent and its stockholders of the distribution, under the tax matters agreement, Emergent and Aptevo will be restricted from taking, or failing to take, any action that could reasonably be expected to prevent the distribution, together with certain related transactions, from qualifying as a transaction described in Sections 355 and 368(a)(1)(D) of the Code. In particular, for a period of two years following the separation, Aptevo will be restricted from taking certain actions (including restrictions on share issuances, business combinations, sales of assets, amendments to organizational documents and similar transactions) that could cause the distribution, together with certain related transactions, to fail to so qualify. Aptevo may take such a restricted action if (i) it provides Emergent with an opinion from a U.S. tax counsel or accountant of recognized national standing, reasonably acceptable to Emergent, in form and substance satisfactory to Emergent, that the transaction will not affect the tax-free status of the distribution and certain related transactions, (ii) Emergent obtains, at Aptevo's request, a supplemental ruling from the IRS, in form and substance reasonably satisfactory to Emergent, that the action will not affect the tax-free status of the distribution and certain related transactions, or (iii) Emergent waives in writing the requirement to obtain such opinion or ruling.

The tax matters agreement will provide special rules that allocate tax liabilities and related expenses (including damages related to claims of Emergent stockholders) resulting from the failure of the distribution, together with certain related transactions, to qualify as a tax-free transaction under Sections 355 and 368(a)(1)(D) of the Code. In general, under the tax matters agreement, each party is expected to be responsible for any taxes

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imposed on Aptevo or Emergent that arise from the failure of the distribution, together with certain related transactions, to qualify as a transaction described under Sections 355 and 368(a)(1)(D), to the extent that the failure to so qualify is attributable to actions, events or transactions relating to such party's respective stock, assets or business, or a breach of the relevant representations or covenants made by that party in the tax matters agreement or the IRS private letter ruling or in the representation letters provided to WilmerHale LLP in connection with its providing an opinion regarding the tax consequences of the distribution and certain related transactions. This indemnification will apply with respect to an acquisition of a party's stock even if such party has not facilitated such acquisition. This indemnification will also apply even if Emergent has permitted Aptevo to take an action that would otherwise have been prohibited under the tax-related covenants described above.

Employee Matters Agreement

Aptevo and Emergent will enter into an employee matters agreement prior to the distribution to allocate liabilities and responsibilities relating to employment matters, employee compensation and benefit plans and programs and other related matters.

Generally, the employee matters agreement will provide for the transfer or assignment of employees from Emergent to Aptevo, provide for the establishment of Aptevo compensation and benefit plans and programs, which are expected to be generally comparable to those currently in place at Emergent, and allocate liabilities and responsibilities relating to their respective employees' and former employees' compensation and benefit plans and programs between Emergent and Aptevo. Among other things, the employee matters agreement will provide that, following the distribution, Aptevo's active employees generally will no longer participate in benefit plans sponsored or maintained by Emergent and will commence participation in Aptevo's benefit plans. The employee matters agreement will also provide for the treatment of outstanding Emergent equity awards (as described in the section entitled "The Separation and Distribution—Treatment of Equity Based Compensation") and certain other outstanding incentive awards. In addition, the employee matters agreement will set forth the general principles relating to employee matters, including the assumption and/or retention of liabilities and related benefit plan assets, the treatment of expense reimbursements, workers' compensation, employee leaves of absence, the provision of employee service credit, the sharing of employee information and the non-duplication or acceleration of benefits.

Intellectual Property Agreements

Product License Agreement. Aptevo will enter into a product license agreement with Emergent pursuant to which Emergent will grant to Aptevo a perpetual, exclusive royalty-free, nontransferable worldwide license, under certain licensed intellectual property rights, to research, develop, make, have made, use, sell, offer to sell and import WinRho SDF, HepaGam B and VARIZIG in their respective indications. Aptevo will only be permitted to exercise rights under the license with respect to Emergent's human hyperimmune platform manufacturing know-how through a third-party contract manufacturer, and then only if the manufacturer is bound to maintain the confidentiality of the manufacturing know-how and is either approved by Emergent, in its sole discretion, or there has been a manufacturing failure under the manufacturing services agreement. In addition, Aptevo will grant Emergent a non-exclusive, royalty-free, worldwide, perpetual, irrevocable, fully paid-up, fully sublicensable, fully transferable license to reproduce, copy, make derivative works of, use and otherwise exploit the clinical and pre-clinical data, including the related safety data, that exists on the distribution date and is related to WinRho SDF, HepaGam B and VARIZIG.

Aptevo may terminate its rights under the agreement at any time by providing written notice to Emergent. Emergent may terminate the agreement if Aptevo breaches the agreement and the breach is not cured within a specified period of time or is incurable. Each party may terminate the agreement if the other party experiences certain bankruptcy events.

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Trademark License Agreement. Aptevo will enter into a license agreement with Emergent pursuant to which Emergent will grant Aptevo a non-exclusive, royalty-free, worldwide, non-sublicenseable license under certain trademarks of Emergent to distribute the physical inventory of packaging and marketing materials assigned to Aptevo as part of the distribution, solely to sell, offer to sell and otherwise commercialize the commercial products until such inventory of packaging and marketing materials is depleted but in no event after the third anniversary of the distribution. The license will also permit Aptevo to include Emergent's trademarks on additional packaging and marketing materials created after the distribution date for WinRho SDF, HepaGam B, and VARIZIG intended for sale outside the United States, to the extent necessary to comply with regulatory requirements for so long as Emergent is providing wholesaler services for those products or manufacturing services for such products, or both. In addition, Emergent will covenant not to sue Aptevo for trade dress infringement pertaining to applicable packaging materials while Emergent is performing services for Aptevo under the manufacturing services agreement and for a specified period of time thereafter. Aptevo will grant Emergent a non-exclusive, worldwide, irrevocable, royalty-free license to use, have used, display and have displayed trademarks of Aptevo in furtherance of Emergent's performance under the agreements between Emergent and Aptevo and for incidental uses (the latter limited to two years from the distribution date).

Aptevo may terminate its rights under the agreement at any time by providing written notice to Emergent. Emergent may terminate the agreement if Aptevo breaches the agreement and the breach is not cured within a specified period of time or is incurable.

Commercial Agreements

The terms of these agreements are still being finalized and the descriptions included herein will be updated in a subsequent amendment.

Manufacturing Services Agreement. Aptevo will enter a manufacturing services agreement with Emergent prior to the distribution pursuant. The expiration date of the manufacturing services agreement is five years following the date of its execution, which is expected to occur on the separation date.

Under the manufacturing services agreement, Emergent will manufacture, fill and finish, label, package and ship the hyperimmune products for Aptevo and will provide these services, other than manufacturing and certain other services, for the IXINITY product as well. Management believes these payments approximate those that would be made in an arm's length transaction.

Canadian Wholesaler Agreement. Aptevo will enter into a Canadian wholesaler agreement with Emergent pursuant to which Emergent will make product intended for sale in Canada available to Aptevo's Canadian customers.

Funding Arrangement

At or prior to the separation, Emergent will issue a non-negotiable promissory note in the amount of \$20 million to Aptevo. This note will be unsecured, will bear no interest, will be non-transferrable and will be payable by Emergent six to 12 months after the distribution date on demand by Aptevo. For additional information, see the section entitled "Risk Factors—Risks Related to Aptevo's Business."

Consulting Arrangements Entered into in Connection with the Separation

John E. Niederhuber, M.D. On May 18, 2016, John E. Niederhuber, M.D. entered into a consulting agreement with Emergent, pursuant to which Dr. Niederhuber provides consulting services consisting of evaluative services, expert advice and guidance, general strategy recommendations, and other similar assistance

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regarding industry products, technology platforms, and research and development programs to the Emergent board of directors. In accordance with the terms of the consulting agreement, Dr. Niederhuber receives a consulting fee from Emergent of \$2,000 per calendar quarter and is reimbursed for his reasonable out-of-pocket expenses. In addition, Dr. Niederhuber was granted 2,000 Emergent restricted stock units on the effective date of his consulting agreement and will receive an additional 2,000 Emergent restricted stock units on the one-year anniversary of the effective date of the agreement. Both restricted stock unit grants will vest on the first anniversary of the date of grant. The consulting agreement has a term that expires on June 30, 2018, unless it is otherwise terminated earlier by Dr. Niederhuber, for any reason, or by Emergent for “cause” as defined in the agreement.

Marvin L. White. For a discussion of the consulting agreement entered into by and between Emergent and Mr. White in anticipation of the separation, see the section entitled “Compensation Discussion and Analysis—Marvin White Compensation.”

Procedures for Approval of Related Party Transactions

Aptevo’s board of directors will adopt a written policy regarding the review and approval or ratification of transactions involving Aptevo and its directors, nominees for directors, executive officers, immediate family members of these individuals, and stockholders owning 5% or more of our outstanding common stock, each of whom is referred to as a “related party.” The policy will cover any related party transaction, arrangement or relationship where a related party has a direct or indirect material interest and the amount involved exceeds \$120,000 in any calendar year. Under the policy, the Audit Committee of Aptevo’s Board of Directors will be responsible for reviewing and approving, or ratifying, the material terms of any related party transactions. The committee will be charged with determining whether the terms of the transaction are any less favorable than those generally available from unaffiliated third parties, and determining the extent of the related party’s interest in the transaction.

Related party transactions that will require review by the Audit Committee pursuant to this policy will be identified in:

- questionnaires annually distributed to Aptevo’s directors and officers;
- certifications submitted annually by our officers related to their compliance with Aptevo’s Code of Conduct; or
- communications made directly by the related party to Aptevo’s chief financial officer or general counsel.

In determining whether to approve or ratify a related party transaction, the Audit Committee will consider the following items, among others:

- the related party relationship with Aptevo and interest in any transaction with Aptevo;
- the material terms of a transaction with Aptevo, including the type and amount;
- the purpose of, and the potential benefits to Aptevo of, any proposed or actual transaction;
- whether a transaction was undertaken in the ordinary course of our business; and
- any information regarding the related party transaction or the related party in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

This process will be included in the written policy.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Before the distribution, all of the outstanding shares of Aptevo's common stock will be owned beneficially and of record by Emergent. The following table sets forth information with respect to the expected beneficial ownership of Aptevo's common stock, upon the distribution, by (1) each person who Aptevo believes will be a beneficial owner of 5% or more of Aptevo's outstanding common stock, (2) each expected director and named executive officer of Aptevo and (3) all of Aptevo's expected directors and named executive officers as a group. Aptevo based the share amounts on each person's beneficial ownership of Emergent's common stock and stock options or other equity awards as of ●, 2016 unless Aptevo indicates some other basis for the share amounts, and assume a distribution ratio of ● shares of Aptevo's common stock for every share of Emergent's common stock. The address of each director and executive officer shown in the table below is c/o Aptevo, ●.

Name and Address of Beneficial Owner	Beneficial Ownership of Aptevo's Common Stock	Percent of Class
Fuad El-Hibri		
Marvin L. White		*
Daniel J. Abdun-Nabi		*
Grady Grant, III		*
Zsolt Harsanyi, Ph.D.		*
Barbara Lopez Kunz		*
John E. Niederhuber, M.D.		*
Jeffrey G. Lamothe		*
Scott C. Stromatt, M.D.		*
[●]		
All directors and executive officers as a group (● persons)		

* Less than one percent

Prior to the effectiveness of the registration statement of which this information statement is a part, anticipated information regarding the Security Ownership of Certain Beneficial Owners and Management following the separation will be disclosed in accordance with the rules and regulations of the SEC in an amendment to this information statement.

THE SEPARATION AND DISTRIBUTION

Overview

On August 6, 2015, Emergent announced its intention to separate its biosciences business. The separation will occur by means of a pro rata distribution to Emergent stockholders of 100% of the shares of common stock of Aptevo, which was formed to hold certain assets of Emergent's biosciences business. In connection with this distribution, we expect that Emergent will complete an internal reorganization, which we refer to as the "internal reorganization," as a result of which Aptevo will become the parent company of those Emergent operations comprising, and the entities that will conduct, the biosciences business.

On ●, 2016, the Emergent board of directors approved the distribution of all of Aptevo's issued and outstanding shares of common stock on the basis of ● shares of Aptevo common stock for every share of Emergent common stock held as of the close of business on ●, 2016, the record date for the distribution.

At ● on ●, 2016, the distribution date, each Emergent stockholder will receive ● shares of Aptevo common stock for every share of Emergent common stock held at the close of business on the record date for the distribution, as described below. Emergent stockholders will receive cash in lieu of any fractional shares of Aptevo common stock that they would have received after application of this ratio. You will not be required to make any payment, surrender or exchange your Emergent common stock or take any other action to receive your shares of Aptevo common stock in the distribution. The distribution of Aptevo common stock as described in this information statement is subject to the satisfaction or waiver of certain conditions. For a more detailed description of these conditions, see "—Conditions to the Distribution."

Reasons for the Separation

The Emergent board of directors believes that separating the biosciences business from the biodefense business of Emergent is in the best interests of Emergent and its stockholders for a number of reasons, including the following:

- *Allocation of Capital.* The Emergent board believes that the separation will permit each company to allocate its financial resources in a manner more tailored to its own commercial and strategic priorities and eliminate the competition for capital that has arisen between the two businesses.
- *Targeted Investment Opportunities.* The Emergent board believes that the separation will (1) allow each company to target investors attracted to its business profile, (2) allow investors to separately value each company based on its unique investment identity and (3) attract investors to each company that are not willing to invest in a combined entity but are willing to invest in a distinct "pure play" company.
- *Access to Capital and Acquisition Currency.* The Emergent board believes that the separation will create an independent equity currency for each of Emergent and Aptevo that will afford each company (1) direct, standalone access to the capital markets, (2) the opportunity to capitalize on its unique growth opportunities and (3) facilitate an ability to finance future acquisitions using its capital stock.
- *Management Focus and Operational Efficiency.* The Emergent board believes that the separation will permit the management of each company to tailor business strategies to best pursue targeted opportunities for long-term growth and profitability and enhance the business focus of each company and better align resources to achieve strategic priorities.
- *Competitive Equity Compensation.* The Emergent board believes that the separation will permit Aptevo to use equity compensation to attract and retain top talent in a manner and degree consistent with its operational priorities and growth prospects and more competitive with its industry peers, and that the separation will better align the value of equity compensation with the performance of the business for which the individual is employed, which is expected to make equity compensation more attractive to potential and existing employees.

The Emergent board of directors also considered a number of potentially negative factors in evaluating the separation, including the following:

- *Increased Administrative Costs.* As a current part of Emergent, Aptevo takes advantage of certain functions performed by Emergent, such as accounting, tax, legal, human resources and other general and administrative functions. After the separation, Emergent will not perform certain of these functions for Aptevo, and, because of Aptevo's smaller scale as a standalone company, Aptevo's cost of performing such functions may be higher than the amounts reflected in Aptevo's historical financial statements, which may adversely affect Aptevo's results of operations.
- *Disruption Related to the Separation.* The actions required to separate Emergent's and Aptevo's respective businesses could disrupt Aptevo's operations.
- *Increased Impact of Certain Costs.* Certain costs and liabilities that were otherwise less significant to Emergent as a whole will be more significant for Aptevo as a standalone company due to Aptevo being smaller than Emergent.
- *Significant Separation Costs.* Emergent and Aptevo will incur costs in connection with the transition to being standalone public companies that may include accounting, tax, legal, and other professional services costs, recruiting and relocation costs associated with hiring key senior management personnel who are new to Aptevo, costs related to establishing a new brand identity in the marketplace, tax costs and costs to separate information systems.
- *Risk of Failure to Achieve Anticipated Benefits of the Separation.* Aptevo may not achieve the anticipated benefits of the separation for a variety of reasons, including, among others: (1) the separation will require significant amounts of management's time and effort, which may divert management's attention from operating and growing its business; and (2) following the separation, Aptevo may be more susceptible to market fluctuations and other adverse events than if Aptevo were still a part of Emergent because its business will be less diversified than Emergent's business prior to the completion of the separation.
- *Limitations on Strategic Transactions.* Under the terms of the tax matters agreement that Aptevo will enter into with Emergent, for a period of two years following the separation, Aptevo will be restricted from taking certain actions that could cause the distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. During this period, these restrictions may limit Aptevo's ability to pursue certain strategic transactions and equity issuances or engage in other transactions that might increase the value of its business.
- *Loss of Scale.* As a current part of Emergent, Aptevo takes advantage of Emergent's size and purchasing power in procuring certain goods and services. After the separation, as a standalone company, Aptevo may be unable to obtain these goods, services, and technologies at prices or on terms as favorable as those Emergent obtained prior to completion of the separation.
- *Loss of Joint Arrangements.* As a current part of Emergent, Aptevo takes advantage of Emergent's overall presence to procure more advantageous distribution arrangements. After the separation, as a standalone company, Aptevo may be unable to obtain similar arrangements to the same extent as Emergent did, or on terms as favorable as those Emergent obtained, prior to completion of the separation.
- *Uncertainty Regarding Stock Prices.* We cannot predict the effect of the separation on the trading prices of Aptevo or Emergent common stock or whether the combined market value of ● shares of Aptevo common stock and one share of Emergent common stock will be less than, equal to, or greater than the market value of one share of Emergent common stock prior to the distribution.

In determining to pursue the separation, the Emergent board of directors concluded that the potential benefits of the separation outweighed the potential negative factors.

Formation of Aptevo

Aptevo was formed in Delaware in February 2016 for the purpose of holding certain assets and liabilities of Emergent’s biosciences business. As part of the plan to separate the biosciences business from the remainder of its businesses, in connection with the internal reorganization, Emergent plans to transfer the equity interests of certain entities that are expected to operate the biosciences business and the assets and liabilities of the biosciences business to Aptevo prior to the distribution.

When and How You Will Receive the Distribution

With the assistance of Broadridge Financial Solutions, Inc., the distribution agent for the distribution, which we refer to as the “distribution agent,” Emergent expects to distribute Aptevo common stock at ● on ●, 2016, the distribution date, to all holders of outstanding Emergent common stock as of the close of business on ●, 2016, the record date for the distribution. The distribution agent will serve as the settlement and distribution agent in connection with the distribution and the transfer agent and registrar for Aptevo common stock.

If you own Emergent common stock as of the close of business on the record date for the distribution, Aptevo common stock that you are entitled to receive in the distribution will be issued electronically, as of the distribution date, to you in direct registration form or to your bank or brokerage firm on your behalf. If you are a registered holder, the distribution agent will then mail you a direct registration account statement that reflects your shares of Aptevo common stock. If you hold your Emergent shares through a bank or brokerage firm, your bank or brokerage firm will credit your account for the Aptevo shares. Direct registration form refers to a method of recording share ownership when no physical share certificates are issued to stockholders, as is the case in this distribution. If you sell Emergent common stock in the “regular-way” market up to and including the distribution date, you will be selling your right to receive shares of Aptevo common stock in the distribution.

Commencing on or shortly after the distribution date, if you hold physical share certificates that represent your Emergent common stock and you are the registered holder of the shares represented by those certificates, the distribution agent will mail to you an account statement that indicates the number of shares of Aptevo common stock that have been registered in book-entry form in your name.

Most Emergent stockholders hold their common stock through a bank or brokerage firm. In such cases, the bank or brokerage firm is said to hold the shares in “street name” and ownership would be recorded on the bank or brokerage firm’s books. If you hold your Emergent common stock through a bank or brokerage firm, your bank or brokerage firm will credit your account for the Aptevo common stock that you are entitled to receive in the distribution. If you have any questions concerning the mechanics of having shares held in “street name,” please contact your bank or brokerage firm.

Transferability of Shares You Receive

Shares of Aptevo common stock distributed to holders in connection with the distribution will be transferable without registration under the Securities Act of 1933, as amended, or the Securities Act, except for shares received by persons who may be deemed to be our affiliates. Persons who may be deemed to be our affiliates after the distribution generally include individuals or entities that control, are controlled by or are under common control with us, which may include certain of our executive officers, directors or principal stockholders. Securities held by our affiliates will be subject to resale restrictions under the Securities Act. Our affiliates will be permitted to sell shares of our common stock only pursuant to an effective registration statement or an exemption from the registration requirements of the Securities Act, such as the exemption afforded by Rule 144 under the Securities Act.

Number of Shares of Aptevo Common Stock You Will Receive

For every share of Emergent common stock that you own at the close of business on ●, 2016, the record date for the distribution, you will receive ● shares of Aptevo common stock on the distribution date. Emergent will not distribute any fractional shares of Aptevo common stock to its stockholders. Instead, if you are a registered holder, the distribution agent will aggregate fractional shares into whole shares, sell the whole shares in the open market at prevailing market prices and distribute the aggregate cash proceeds (net of discounts and commissions) of the sales pro rata (based on the fractional share such holder would otherwise be entitled to receive) to each holder who otherwise would have been entitled to receive a fractional share in the distribution. The distribution agent, in its sole discretion, without any influence by Emergent or Aptevo, will determine when, how, and through which broker-dealer and at what price to sell the whole shares. Any broker-dealer used by the distribution agent will not be an affiliate of either Emergent or Aptevo and the distribution agent is not an affiliate of either Emergent or Aptevo. Neither Aptevo nor Emergent will be able to guarantee any minimum sale price in connection with the sale of these shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares.

The receipt by a holder of a pro rata share of the aggregate net cash proceeds of these sales of fractional shares will be taxable to such holder for U.S. federal income tax purposes. See “Material U.S. Federal Income Tax Consequences” for additional information regarding the material U.S. federal income tax consequences of the distribution, including the receipt of cash in lieu of fractional shares. If you hold physical certificates for shares of Emergent common stock and are the registered holder, you will receive a check from the distribution agent in an amount equal to your pro rata share of the aggregate net cash proceeds of the sales. We estimate that it will take approximately two weeks from the distribution date for the distribution agent to complete the distributions of the aggregate net cash proceeds. If you hold your shares of Emergent common stock through a bank or brokerage firm, your bank or brokerage firm will receive, on your behalf, your pro rata share of the aggregate net cash proceeds of the sales and will electronically credit your account for your share of such proceeds.

Treatment of Equity Based Compensation

Generally, pursuant to the employee matters agreement, each award of Emergent restricted stock units that is held by an Emergent employee or service provider (an “Emergent Holder”) as of the effective time of the distribution will be adjusted (the “Adjusted Emergent RSUs”), and each award of Emergent restricted stock units held by an Aptevo employee or service provider (an “Aptevo Holder”) as of the effective time of the distribution will be converted to a restricted stock unit award entitling the Aptevo Holder to Aptevo common stock (the “Aptevo RSUs”). The adjustment and conversion, respectively, will be structured to reflect the effect of the distribution. The Adjusted Emergent RSUs and the Aptevo RSUs will otherwise be subject to the same terms and conditions that applied to the original Emergent restricted stock units immediately before the distribution.

Similarly, the employee matters agreement generally provides that each Emergent stock option that is held by an Emergent Holder will remain an option to purchase Emergent common stock but will be adjusted (an “Adjusted Emergent Option”), and each Emergent stock option that is held by an Aptevo Holder will be converted into an option to purchase Aptevo common stock (an “Aptevo Option”). The exercise price and the number of shares covered by each Adjusted Emergent Option and Aptevo Option will reflect the effect of the distribution. Each Adjusted Emergent Option and Aptevo Option will otherwise be subject to the same terms and conditions that applied to the original Emergent stock options immediately before the distribution.

For purposes of the equity awards, the distribution will not result in a termination of employment or service for any holder of equity awards. Rather, the date of termination of employment or service with the applicable plan sponsor following the distribution shall be the holder’s termination date for purposes of outstanding equity awards. Following the distribution each Aptevo Holder will be considered to have been employed by or have provided services to, as the case may be, Aptevo before and after the distribution for purposes of vesting of such holder’s Aptevo RSUs and/or Aptevo Options.

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Notwithstanding the foregoing and his anticipated election to the Aptevo board of directors, the employee matters agreement provides that any outstanding Emergent equity awards held by Dr. Niederhuber at the effective time of the distribution, including those recently awarded under the section entitled “Certain Relationships and Related Party Transactions – Consulting Arrangements Entered into in Connection with the Separation,” will not be converted into awards to acquire shares of Aptevo common stock. Rather, he will be treated as an Emergent Holder and receive Adjusted Emergent RSUs and Adjusted Emergent Options. The employee matters agreement further provides that his Adjusted Emergent RSUs and Adjusted Emergent Options will continue to vest in accordance with their terms while he provides consulting services to Emergent.

No award shall be adjusted or converted as described above unless such adjustment or conversion is consistent with all applicable laws, including U.S. securities laws. The adjustment or conversion of Emergent stock options and Emergent restricted stock units will be effectuated in a manner that is intended to avoid the imposition of any penalty or other taxes on the holders of such awards pursuant to Section 409A of the Code. Following the distribution, Emergent will be responsible for all liabilities associated with the Adjusted Emergent RSUs and Adjusted Emergent Options, and Aptevo will be responsible for all liabilities associated with Aptevo RSUs and Aptevo Options.

For a further discussion of the employee matters agreement, see the section entitled “Certain Relationships and Related Party Transactions–Employee Matters Agreement.”

Internal Reorganization

As part of the separation, and prior to the distribution, Emergent and its subsidiaries expect to complete an internal reorganization in order to transfer to Aptevo the biosciences business that Aptevo will hold following the separation. Among other things and subject to limited exceptions, the internal reorganization is expected to result in Aptevo owning, directly or indirectly, the operations comprising and the entities that conduct the biosciences business.

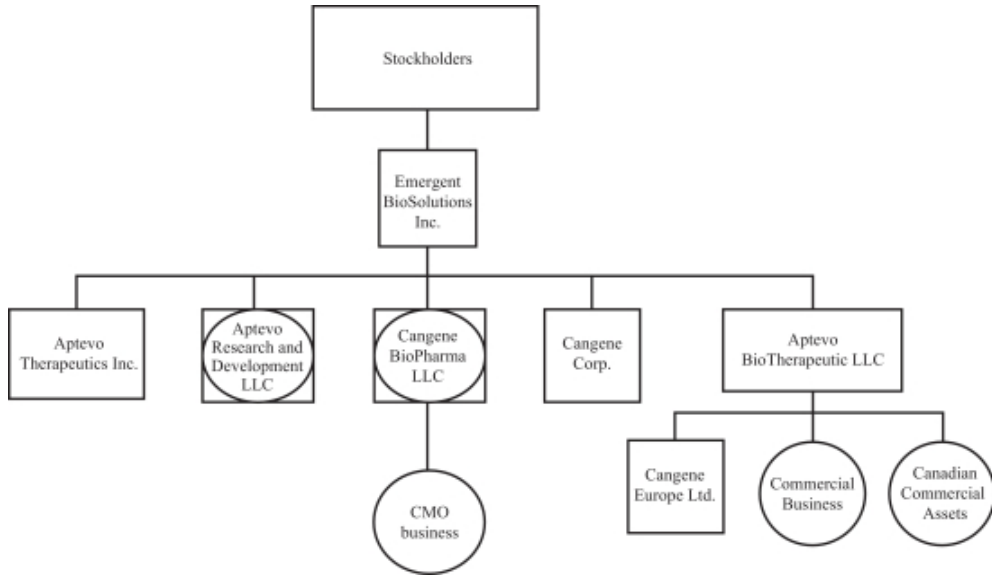
The internal reorganization is expected to include various restructuring transactions pursuant to which (1) the operations, assets and liabilities of Emergent and its subsidiaries used to conduct the biosciences business will be separated from the operations, assets and liabilities of Emergent and its subsidiaries used to conduct the biodefense business and (2) such biosciences operations, assets and liabilities will be contributed, transferred or otherwise allocated to Aptevo or one of its direct or indirect subsidiaries. Such restructuring transactions may take the form of asset transfers, mergers, demergers, dividends, contributions and similar transactions, and may involve the formation of new subsidiaries in U.S. and non-U.S. jurisdictions to own and operate the biosciences business or the biodefense business in such jurisdictions.

In the final step of the internal reorganization, Emergent will contribute to Aptevo certain assets, including all of the equity interests in the entities that are expected to conduct the biosciences business.

Following the completion of the internal reorganization and immediately prior to the distribution, Aptevo will be the parent company of the entities that are expected to conduct the biosciences business and Emergent (through subsidiaries other than Aptevo and its subsidiaries) will remain the parent company of the entities that are expected to conduct the biodefense business.

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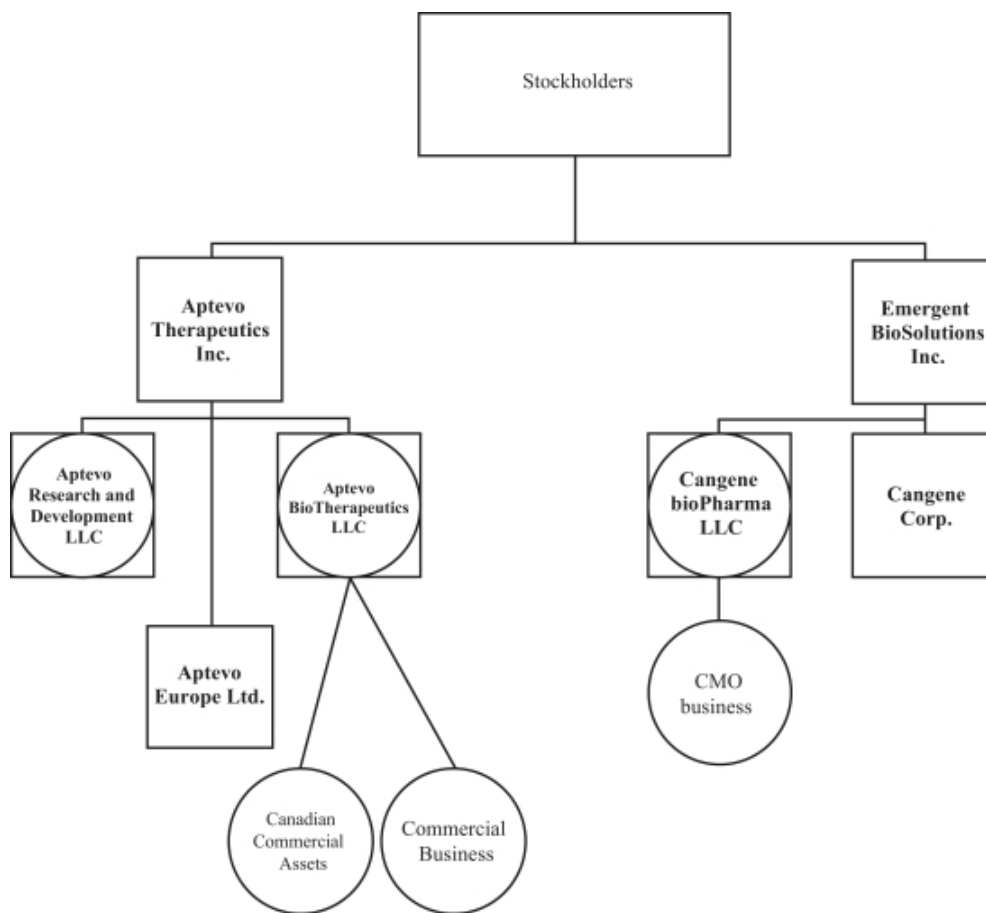
The diagram below shows the simplified current structure of the biosciences business entities of Emergent:



This diagram has been simplified for illustrative purposes and does not set forth all affiliated entities, including intermediate subsidiaries.

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The diagram below shows what we expect will be the simplified structure of each of Aptevo and Emergent after completion of the internal reorganization, the separation and the distribution:



This diagram has been simplified for illustrative purposes and does not set forth all affiliated entities, including intermediate subsidiaries.

Results of the Distribution

After the distribution, Aptevo will be an independent, publicly-traded company. The actual number of shares to be distributed will be determined at the close of business on ●, 2016, the record date for the distribution, and will reflect any exercise of Emergent options between the date the Emergent board of directors declares the distribution and the record date for the distribution. The distribution will not affect the number of outstanding shares of Emergent common stock or any rights of Emergent stockholders. Emergent will not distribute any fractional shares of Aptevo common stock.

We will enter into a separation agreement and other related agreements with Emergent before the distribution to effect the separation and provide a framework for our relationship with Emergent after the separation. These agreements will provide for the allocation between Emergent and Aptevo of Emergent’s assets, liabilities and obligations (including employee benefits, intellectual property, and tax-related assets and liabilities) attributable to periods prior to Aptevo’s separation from Emergent and will govern the relationship between Emergent and Aptevo after the separation. For a more detailed description of these agreements, see “Certain Relationships and Related Party Transactions.”

Market for Aptevo Common Stock

There is currently no public trading market for Aptevo common stock. Aptevo has applied to have its shares of common stock listed on The NASDAQ Global Market under the symbol “APVO,” subject to official notice of distribution. Aptevo has not and will not set the initial price of its common stock. The initial price will be established by the public markets.

We cannot predict the price at which Aptevo common stock will trade after the distribution. In fact, the combined trading prices, after the distribution, of the shares of Aptevo common stock that each Emergent stockholder will receive in the distribution and the Emergent common stock held at the record date for the distribution may not equal the “regular-way” trading price of the Emergent common stock immediately prior to the distribution. The price at which Aptevo common stock trades may fluctuate significantly, particularly until an orderly public market develops. Trading prices for Aptevo common stock will be determined in the public markets and may be influenced by many factors. See “Risk Factors—Risks Related to Aptevo’s Common Stock.”

Trading Between the Record Date and Distribution Date

Beginning on or shortly before the record date for the distribution and continuing up to and including through the distribution date, Emergent expects that there will be two markets in Emergent common stock: a “regular-way” market and an “ex-distribution” market. Emergent common stock that trades on the “regular-way” market will trade with an entitlement to Aptevo common stock distributed in the distribution. Emergent common stock that trades on the “ex-distribution” market will trade without an entitlement to Aptevo common stock distributed in the distribution. Therefore, if you sell shares of Emergent common stock in the “regular-way” market up to and including through the distribution date, you will be selling your right to receive shares of Aptevo common stock in the distribution. If you own Emergent common stock at the close of business on the record date and sell those shares on the “ex-distribution” market up to and including through the distribution date, you will receive the shares of Aptevo common stock that you are entitled to receive pursuant to your ownership of shares of Emergent common stock as of the record date.

Furthermore, beginning on or shortly before the record date for the distribution and continuing up to and including the distribution date, Aptevo expects that there will be a “when-issued” market in its common stock. “When-issued” trading refers to a sale or purchase made conditionally because the security has been authorized but not yet issued. The “when-issued” trading market will be a market for Aptevo common stock that will be distributed to holders of Emergent common stock on the distribution date. If you owned Emergent common stock at the close of business on the record date for the distribution, you would be entitled to Aptevo common stock distributed pursuant to the distribution. You may trade this entitlement to shares of Aptevo common stock, without trading the Emergent common stock you own, on the “when-issued” market. On the first trading day following the distribution date, “when-issued” trading with respect to Aptevo common stock will end, and “regular-way” trading will begin.

Conditions to the Distribution

The distribution will be effective at ● on ●, 2016, which is the distribution date, provided that the conditions set forth in the separation agreement have been satisfied (or waived by Emergent in its sole and absolute discretion), including, among others

- the continued validity of a private letter ruling received by Emergent from the IRS regarding certain U.S. federal income tax matters relating to the distribution and certain related transactions;
- the receipt of a tax opinion from counsel to Emergent substantially to the effect that, for U.S. federal income tax purposes, the distribution and certain related transactions, taken together, will qualify as a transaction described under Sections 355(a) and 368(a)(1)(D) of the Code;

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- the internal reorganization having been completed and the transfer of certain assets and liabilities of the biosciences business from Emergent to Aptevo having been completed in accordance with the separation agreement;
- no order, injunction, or decree issued by any government authority of competent jurisdiction or other legal restraint or prohibition preventing the consummation of the separation, distribution or any of the related transactions being in effect;
- the actions and filings necessary or appropriate under applicable U.S. federal, U.S. state or other securities laws or blue sky laws and the rules and regulations thereunder having been taken or made, and, where applicable, having become effective or been accepted;
- all governmental approvals necessary to consummate the separation, the distribution and the transactions related thereto and to permit the operation of Aptevo's business after the distribution date having been obtained and being in full force and effect;
- the separation and the distribution not violating or resulting in a breach of applicable law or any material contract of Emergent or Aptevo or any of their respective subsidiaries;
- the approval for listing on NASDAQ for the shares of Aptevo common stock to be delivered to the record holders in the distribution having been obtained, subject to official notice of issuance;
- the SEC declaring effective the Form 10, with no order suspending the effectiveness of the Form 10 in effect and no proceedings for such purposes pending before or threatened by the SEC;
- this information statement and such other information concerning Aptevo, its business, operations and management, the distribution and such other matters as Emergent shall determine in its sole and absolute discretion and as may otherwise be required by law having been mailed to the holders of record of Emergent common stock on the record date;
- Emergent's board of directors authorizing and approving the distribution and not having withdrawn such authorization and approval;
- Emergent's board of directors approving the assets and liabilities included in the Aptevo balance sheet; and
- no other events or developments existing or having occurred that, in the judgment of Emergent's board of directors, in its sole and absolute discretion, makes it inadvisable to effect the separation, the distribution or the transactions related thereto.

Emergent will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the distribution and, to the extent it determines to so proceed, to determine the record date for the distribution and the distribution date, and the distribution ratio. Emergent will also have sole and absolute discretion to waive any of the conditions to the distribution. Emergent does not intend to notify its stockholders of any modifications to the terms of the separation or distribution that, in the judgment of its board of directors, are not material. For example, the Emergent board of directors might consider material such matters as significant changes to the distribution ratio and the assets to be contributed or the liabilities to be assumed in the separation. To the extent that the Emergent board of directors determines that any modifications by Emergent materially change the material terms of the distribution, Emergent will notify Emergent stockholders in a manner reasonably calculated to inform them about the modification as may be required by law, by, for example, publishing a press release, filing a current report on Form 8-K, or circulating a supplement to this information statement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following discussion is a summary of the material U.S. federal income tax consequences of the distribution to Emergent and Emergent stockholders. This discussion is based on the Code, laws, regulations, rulings and decisions in effect on the date hereof, all of which are subject to change, possibly with retroactive effect, and to varying interpretations, which could result in U.S. federal income tax consequences different from those described below.

This discussion addresses only the U.S. federal income tax consequences to Emergent stockholders who are U.S. holders (as defined below) who hold their shares of Emergent stock as capital assets and does not address all of the U.S. federal income tax consequences that may be relevant to a particular stockholder in light of the holder's individual circumstances. This discussion does not address the tax consequences to holders who are subject to special rules, including, without limitation, financial institutions, tax-exempt organizations, insurance companies, dealers in securities or foreign currencies, persons who hold their shares as part of a straddle, hedge, conversion, constructive sale, synthetic security, integrated investment or other risk-reduction transaction for U.S. federal income tax purposes, holders who acquired their shares pursuant to the exercise of employee stock options or otherwise as compensation, or holders who did not hold their shares continuously from the record date for the distribution to the time of the distribution. In addition, this discussion does not address the tax consequences under any state, local or foreign tax laws or the alternative minimum tax or net investment income tax provisions of the Code.

For purposes of this discussion, a "U.S. holder" is a beneficial owner of Emergent common stock who is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States or any state or political subdivision thereof;
- an estate, the income of which is subject to United States federal income taxation regardless of its source; or
- a trust, if (i) a court within the United States is able to exercise primary jurisdiction over its administration and one or more U.S. persons have the authority to control all of its substantial decisions, or (ii) it has a valid election in place under applicable U.S. Treasury regulations to be treated as a U.S. person.

If a partnership (or any other entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) holds Emergent common stock, the tax treatment of a partner in the partnership generally will depend on the status of the partner and the activities of the partnership. Partnerships (or other entities or arrangements that are treated as partnerships for U.S. federal income tax purposes) that hold Emergent common stock and partners of such partnerships should consult their tax advisors regarding the tax consequences of the distribution to them.

YOU ARE URGED TO CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE SPECIFIC TAX CONSEQUENCES TO YOU OF THE DISTRIBUTION, INCLUDING THE EFFECTS OF U.S. FEDERAL, STATE, LOCAL AND FOREIGN TAX RULES AND THE EFFECT OF POSSIBLE CHANGES IN LAWS THAT MAY AFFECT THE TAX CONSEQUENCES DESCRIBED IN THIS INFORMATION STATEMENT.

Emergent has received a favorable private letter ruling from the IRS regarding certain U.S. federal income tax matters relating to the distribution and certain related transactions. It is a condition to the distribution that (i) the private letter ruling from the IRS continue to be valid and in full force and effect and (ii) Emergent receive an opinion from WilmerHale LLP, in form and substance satisfactory to Emergent, substantially to the effect

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that, for U.S. federal income tax purposes, the distribution and certain related transactions, taken together, will qualify as a transaction described under Sections 355(a) and 368(a)(1)(D) of the Code. The IRS private letter ruling is based upon certain facts and representations submitted by Emergent to the IRS. In addition, the opinion from WilmerHale LLP will be based upon and rely on, among other things, the IRS private letter ruling and certain facts and assumptions, as well as certain representations and covenants of Emergent and Aptevo contained in the tax matters agreement and certain representations contained in representation letters provided by Emergent, Aptevo and certain stockholders to WilmerHale LLP, including representations and covenants relating to the past and future conduct of Emergent, Aptevo and such stockholders. If any of these facts, assumptions, representations, or covenants is, or becomes, inaccurate or incomplete, the IRS private letter ruling and/or the opinion of WilmerHale LLP may be invalid and the conclusions reached therein could be jeopardized. In addition, the IRS private letter ruling only addresses certain limited matters relevant to determining whether the distribution, together with certain related transactions, qualifies as a transaction described under Sections 355(a) and 368(a)(1)(D) of the Code, and the opinion of WilmerHale LLP will represent the judgment of such counsel which is not binding on the IRS or any court. Accordingly, notwithstanding the IRS private letter ruling and the opinion of WilmerHale LLP, there can be no assurance that the IRS will not assert that the distribution and/or certain related transactions should be treated as a taxable transaction for U.S. federal income tax purposes or that a court would not sustain such a challenge. If the IRS were successful in any such challenge, Emergent, Aptevo, and our stockholders would be subject to the tax consequences described below under “Material U.S. Federal Income Tax Consequences if the Distribution is Taxable.”

Material U.S. Federal Income Tax Consequences if the Distribution, Together with Certain Related Transactions, Qualifies Under Sections 355 and 368(a)(1)(D) of the Code

Assuming that the distribution, together with certain related transactions, qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, the U.S. federal income tax consequences of the distribution will generally be as follows:

- subject to the discussion below regarding Section 355(e), no gain or loss will be recognized by Emergent upon the distribution of Aptevo common stock to Emergent stockholders;
- no gain or loss will be recognized by, and no amount will be included in the income of, a holder of Emergent common stock as a result of the distribution, except to the extent such holder receives cash in lieu of a fractional share of Aptevo common stock (as described below);
- an Emergent stockholder who receives shares of Aptevo common stock in the distribution will have an aggregate tax basis in the holder’s shares of Aptevo common stock received in the distribution (including any fractional share of Aptevo common stock to which the holder is entitled) and the holder’s shares of Emergent common stock immediately after the distribution equal to the holder’s aggregate tax basis in the holder’s shares of Emergent common stock immediately before the distribution, which basis will be allocated between the holder’s shares of Emergent common stock and shares of Aptevo common stock (including any fractional share of Aptevo common stock to which the holder is entitled) in proportion to their relative fair market values on the distribution date; and
- the holding period of the shares of Aptevo common stock received by an Emergent stockholder (including any fractional share of Aptevo common stock to which the holder is entitled) will include the holding period for the shares of the Emergent common stock with respect to which the shares of Aptevo common stock are received.

A stockholder of Emergent who receives cash in lieu of a fractional share of Aptevo common stock in the distribution will be treated as having sold such fractional share for cash and will recognize capital gain or loss on the sale of the fractional share equal to the difference between the cash received and the stockholder’s tax basis in the fractional share (as determined above). Such gain or loss will be long-term capital gain or loss if the stockholder’s holding period for its Emergent common stock exceeds one year at the time of the distribution.

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If a stockholder of Emergent holds different blocks of Emergent common stock (generally, shares of Emergent common stock acquired on different dates or at different prices), such holder should consult its tax advisor regarding the determination of the tax basis and holding period of shares of Aptevo common stock received in the distribution in respect of particular blocks of Emergent common stock.

Material U.S. Federal Income Tax Consequences if the Distribution is Taxable

If the distribution, together with certain related transactions, does not qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, Emergent generally would recognize taxable gain on the distribution equal to the amount by which the fair market value of the Aptevo common stock distributed to Emergent stockholders exceeds Emergent's tax basis in its shares of Aptevo common stock. In addition, each stockholder who receives shares of Aptevo common stock in the distribution would generally be treated as receiving a taxable distribution in an amount equal to the fair market value of the shares of Aptevo common stock received (including any fractional share of Aptevo common stock to which the holder is entitled),

which would be taxable as a dividend to the extent of the holder's pro rata share of Emergent's current and accumulated earnings and profits (as increased to reflect any gain recognized by Emergent on the taxable distribution). The balance of the distribution would be treated as a nontaxable return of capital to the extent of the holder's tax basis in its shares of Emergent common stock, with any remaining amount being taxed as capital gain.

Even if the distribution otherwise qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, it may be taxable to Emergent (but not to Emergent stockholders) under Section 355(e) of the Code, if the distribution is later deemed to be part of a plan (or series of related transactions) pursuant to which one or more persons acquire, directly or indirectly, stock representing a 50% or greater interest (by vote or value) in Emergent or Aptevo. For this purpose, any acquisitions (including issuances) of Emergent common stock or of Aptevo common stock within the period beginning two years before the distribution, and ending two years after the distribution, are presumed to be part of such a plan, although Emergent or Aptevo may be able to rebut that presumption. The process for determining whether an acquisition is part of a plan under these rules is complex, inherently factual, and subject to an analysis of the facts and circumstances of a particular case. If acquisitions (including issuances) of Emergent stock or Aptevo stock cause Section 355(e) of the Code to apply, Emergent would recognize taxable gain as described above, but the distribution would be tax-free to each of Emergent's stockholders (except, as described above, for cash received in respect of a fractional share of Aptevo common stock).

Depending on the circumstances, under the tax matters agreement, Aptevo may be required to indemnify Emergent for any taxes and related expenses arising from the failure of the distribution, together with certain related transactions, to qualify as tax-free under Sections 355 and 368(a)(1)(D) of the Code (including as a result of the application of Section 355(e) of the Code). In general, Aptevo is required to indemnify Emergent for such taxes and related expenses to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Aptevo's stock, assets or business, or a breach of the relevant representations or covenants made by Aptevo in the tax matters agreement or the IRS private letter ruling or in the representation letters provided to WilmerHale LLP. See "Certain Relationships and Related Party Transactions—Tax Matters Agreement" for a more detailed discussion of the tax matters agreement between Emergent and Aptevo.

Information Reporting and Backup Withholding

Payments to Emergent stockholders of cash in lieu of fractional shares of Aptevo common stock may be subject to information reporting and to backup withholding, unless such holder delivers a properly completed IRS Form W-9 certifying such holder's correct U.S. taxpayer identification number and certain other information or otherwise establishes a basis for exemption from backup withholding. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be refunded or credited against such holder's U.S. federal income tax liability, provided that the required information is timely furnished to the IRS.

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Additional Information to Help Calculate Tax Basis

After completion of the distribution, additional information will be provided to our stockholders concerning the allocation of each stockholder's basis in Emergent common stock prior to the distribution between the shares of Emergent common stock and Aptevo common stock following the distribution, including fractional shares. We intend to provide this information by making it publicly available on the investor websites of Emergent and Aptevo.

Tax Return Statement

U.S. Treasury regulations require each Emergent stockholder who receives shares of Aptevo common stock in the distribution and who, immediately before the distribution, owned at least 5% (by vote or value) of Emergent's total outstanding stock to attach to the holder's U.S. federal income tax return for the year in which the distribution occurs a statement setting forth the information required by Treasury Regulation section 1.355-5(b).

THE FOREGOING DISCUSSION IS A SUMMARY OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE DISTRIBUTION UNDER CURRENT LAW AND IS FOR INFORMATION ONLY. ALL HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES OF THE DISTRIBUTION TO THEM, INCLUDING THE APPLICATION AND EFFECT OF U.S. FEDERAL, STATE, LOCAL AND FOREIGN TAX LAWS.

DESCRIPTION OF APTEVO'S CAPITAL STOCK

The following description of our capital stock is intended as a summary only and therefore is not a complete description of our capital stock. This description is based upon, and is qualified by reference to, our certificate of incorporation and by-laws, which will be restated prior to the separation, and applicable provisions of Delaware corporate law. You should read our certificate of incorporation and by-laws, to be in effect at the time of the distribution, which are filed as exhibits to Aptevo's registration statement on Form 10, of which this information statement forms a part, for the provisions that are important to you.

Our authorized capital stock consists of 500,000,000 shares of common stock, \$0.001 par value per share, and 15,000,000 shares of preferred stock, \$0.001 par value per share. Immediately following the distribution, Aptevo expects that approximately ● shares of common stock will be issued and outstanding and no shares of preferred stock will be issued and outstanding.

Common Stock

Stockholder Meetings. Annual meetings of our stockholders will be held on the date designated in accordance with our by-laws. Written notice must be mailed to each stockholder entitled to vote not less than ten nor more than 60 days before the date of the meeting. The presence in person or by proxy of the holders of record of a majority of our issued and outstanding shares entitled to vote at such meeting constitutes a quorum for the transaction of business at meetings of the stockholders. Special meetings of the stockholders may be called for any purpose by our Board of Directors, our Chairman of the Board of Directors or our Chief Executive Officer, but such special meetings may not be called by any other person or persons. Except as may be otherwise provided by applicable law, our restated certificate of incorporation or our by-laws, all elections shall be decided by a plurality, and all other questions shall be decided by a majority, of the votes cast by stockholders entitled to vote thereon at a duly held meeting of stockholders at which a quorum is present.

Voting Rights. The holders of our common stock will be entitled to one vote per share with respect to each matter presented to our stockholders on which the holders of our common stock are entitled to vote and do not have cumulative voting rights. An election of directors by our stockholders is determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

Dividends. Holders of our common stock will be entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

Liquidation and Dissolution. In the event of our liquidation or dissolution, the holders of our common stock will be entitled to receive ratably all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Other Rights. Holders of our common stock will have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock will be subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

We will be authorized to issue "blank check" preferred stock, which may be issued in one or more series upon authorization of our board of directors. Our board of directors will be authorized to fix the designation of the series, the number of authorized shares of the series, dividend rights and terms, conversion rights, voting rights, redemption rights and terms, liquidation preferences and any other rights, powers, preferences and limitations applicable to each series of preferred stock. The authorized shares of our preferred stock will be available for issuance without further action by our stockholders, unless such action is required by applicable law

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or the rules of any stock exchange on which our securities may be listed. If the approval of our stockholders is not required for the issuance of shares of our preferred stock, our board may determine not to seek stockholder approval.

A series of our preferred stock could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt. Our board of directors will make any determination to issue preferred shares based upon its judgment as to the best interests of our stockholders. Our directors, in so acting, could issue preferred stock having terms that could discourage an acquisition attempt through which an acquirer may be able to change the composition of our board of directors, including a tender offer or other transaction that some, or a majority, of our stockholders might believe to be in their best interests or in which stockholders might receive a premium for their stock over the then-current market price of the stock.

Provisions of Our Certificate of Incorporation and By-laws and Delaware Law That May Have Anti-Takeover Effects

Our certificate of incorporation and by-laws and Delaware law will contain provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

We expect that Fuad El-Hibri, our chairman, will be the beneficial owner of approximately ●% of our outstanding common stock upon completion of the separation and distribution, based on the number of shares of Emergent common stock beneficially owned by Mr. El-Hibri as of ●, 2016. As a result, Mr. El-Hibri will have significant influence over the election of the members of our board of directors. This control could discourage others from initiating a potential merger, takeover or other change of control transaction that other stockholders may view as beneficial.

Number of Directors. Subject to the rights of holders of any series of preferred stock to elect directors, our board of directors will establish the number of directors.

Staggered Board; Removal of Directors. Our certificate of incorporation and our by-laws will divide our directors into three classes with staggered three-year terms. Each class will consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire board of directors. Our directors may be removed from office only for cause and only by the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote.

Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by the vote of a majority of our directors then in office, although less than a quorum. The classification of our board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action by Written Consent; Special Meetings. Our certificate of incorporation and our by-laws will provide that, after such time as Emergent and its subsidiaries, collectively, cease to own a majority of the voting power of all outstanding stock entitled to vote, any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Our certificate of incorporation and our by-laws also will provide that, except as otherwise required by law, special meetings of our stockholders can only be called by our board of directors, our chairman of the board or our Chief Executive Officer.

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Advance Notice Requirements. Our by-laws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Delaware Business Combination Statute. Section 203 of the DGCL is applicable to us. Section 203 of the DGCL restricts some types of transactions and business combinations between a corporation and a 15% stockholder. A 15% stockholder is generally considered by Section 203 to be a person owning 15% or more of the corporation's outstanding voting stock. Section 203 refers to a 15% stockholder as an "interested stockholder." Section 203 restricts these transactions for a period of three years from the date the stockholder acquires 15% or more of our outstanding voting stock. With some exceptions, unless the transaction is approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock of the corporation, Section 203 prohibits significant business transactions such as:

- a merger with, disposition of significant assets to or receipt of disproportionate financial benefits by the interested stockholder, and
- any other transaction that would increase the interested stockholder's proportionate ownership of any class or series of our capital stock.

The shares held by the interested stockholder are not counted as outstanding when calculating the two-thirds of the outstanding voting stock needed for approval.

The prohibition against these transactions does not apply if:

- prior to the time that any stockholder became an interested stockholder, the board of directors approved either the business combination or the transaction in which such stockholder acquired 15% or more of our outstanding voting stock, or
- the interested stockholder owns at least 85% of our outstanding voting stock as a result of a transaction in which such stockholder acquired 15% or more of our outstanding voting stock. Shares held by persons who are both directors and officers or by some types of employee stock plans are not counted as outstanding when making this calculation.

Super-Majority Voting. The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. The affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote will be required to amend or repeal the provisions of our certificate of incorporation described in this section entitled "Provisions of Our Certificate of Incorporation and By-laws and Delaware Law That May Have Anti-Takeover Effects." The affirmative vote of either a majority of the directors present at a meeting of our board of directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote will be required to amend or repeal our by-laws.

Limitation of Liability and Indemnification of Officers and Directors

Our certificate of incorporation will contain provisions permitted under the DGCL relating to the liability of directors. The provisions eliminate a director's liability for monetary damages for a breach of fiduciary duty, except in circumstances involving wrongful acts, such as the breach of a director's duty of loyalty or acts or omissions that involve intentional misconduct or a knowing violation of law. Further, our certificate of incorporation will contain provisions to indemnify our directors and officers to the fullest extent permitted by the

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DGCL. We will enter into agreements to indemnify our directors and executive officers. These agreements, among other things, will provide that we will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as a director, officer, manager, employee, agent or representative of us. The indemnification agreements will also establish the procedures that will apply in the event a director or officer makes a claim for indemnification.

Exclusive Forum

Aptevo's amended and restated by-laws will provide that unless Aptevo consents in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of Aptevo, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, other employee or stockholder of Aptevo to Aptevo or Aptevo's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim arising pursuant to any provision of Aptevo's amended and restated certificate of incorporation or by-laws or governed by the internal affairs doctrine.

Registration Rights

Holders of an aggregate of approximately ● shares of our common stock immediately following the distribution will have the right to require us to register these shares of common stock under the Securities Act under specified circumstances, including any additional shares issued or distributed by way of a dividend, stock split or other distribution in respect of these shares.

Demand Registration Rights. Subject to specified limitations, holders of these registrations rights may require that Aptevo register all or part of Aptevo common stock subject to the registration rights for sale under the Securities Act. These holders may demand registration of Aptevo common stock so long as the offering price to the public of the shares requested to be registered is at least \$25,000,000. Aptevo is required to effect only one demand registration, subject to specified exceptions.

Incidental Registration Rights. If Aptevo proposes to file a registration statement under the Securities Act either for its own account or for the account of other stockholders (other than in connection with a registration statement on Form S-8 or Form S-4 or to cover securities proposed to be issued in exchange for securities or assets of another corporation), the holders of registrable shares will be entitled to notice of the registration and Aptevo will be required to use its commercially reasonable efforts to register all or a portion of any registrable shares then held by such holders that they request that Aptevo register. In the event that any registration in which the holders of registrable shares participate pursuant to the Aptevo stockholders agreement is an underwritten public offering, Aptevo agrees to enter into an underwriting agreement containing such terms as are customary.

Limitations and Expenses. With specified exceptions, the right to include shares in a registration is subject to the right of underwriters for the offering to limit the number of shares included in the offering. Aptevo is required to pay one-half of all fees, costs and expenses of any demand registration, other than underwriting discounts and commissions.

Listing

Aptevo has applied to have its shares of common stock listed on The NASDAQ Global Market under the symbol "APVO."

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Sale of Unregistered Securities

On February 22, 2016, Aptevo issued 1,000 shares of its common stock, par value \$0.001 per share, to Emergent pursuant to Section 4(2) of the Securities Act. Aptevo did not register this issuance of the issued shares under the Securities Act because such issuance did not constitute a public offering.

Transfer Agent and Registrar

After the distribution, the transfer agent and registrar for Aptevo's common stock will be Broadridge Financial Solutions, Inc.

WHERE YOU CAN FIND MORE INFORMATION

Aptevo has filed a registration statement on Form 10 with the SEC with respect to the shares of Aptevo common stock being distributed as contemplated by this information statement. This information statement is a part of, and does not contain all of the information set forth in, the registration statement and the exhibits and schedules to the registration statement. For further information with respect to Aptevo and its common stock, please refer to the registration statement, including its exhibits and schedules. Statements made in this information statement relating to any contract or other document are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document. You may review a copy of the registration statement, including its exhibits and schedules, at the SEC's public reference room, located at 100 F Street, N.E., Washington, D.C. 20549, by calling the SEC at 1-800-SEC-0330 as well as on the Internet website maintained by the SEC at www.sec.gov. Information contained on any website referenced in this information statement is not incorporated by reference in this information statement.

As a result of the distribution, Aptevo will become subject to the information and reporting requirements of the Exchange Act and, in accordance with the Exchange Act, will file periodic reports, proxy statements and other information with the SEC.

Aptevo intends to furnish holders of its common stock with annual reports containing consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles and audited and reported on, with an opinion expressed, by an independent registered public accounting firm.

You should rely only on the information contained in this information statement or to which this information statement has referred you. Aptevo has not authorized any person to provide you with different information or to make any representation not contained in this information statement.

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**Report of Ernst & Young LLP,
Independent Registered Public Accounting Firm,
on the Audited Combined Financial Statements**

The Board of Directors and Stockholder of Aptevo Therapeutics Inc.

We have audited the accompanying combined balance sheets of Aptevo Therapeutics Inc. (as defined in Note 1, the “Company”) as of December 31, 2015 and 2014, and the related combined statements of operations, changes in stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company’s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the combined financial statements referred to above present fairly, in all material respects, the combined financial position of Aptevo Therapeutics Inc. at December 31, 2015 and 2014, and the combined results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

McLean, Virginia
April 15, 2016

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Combined Balance Sheets
(in thousands)

	December 31,	
	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,637	\$ 3,593
Accounts receivable, net	6,456	13,820
Inventories	20,322	17,625
Income taxes receivable	1,376	1,310
Prepaid expenses and other current assets	2,343	5,203
Total current assets	<u>35,134</u>	<u>41,551</u>
Property, plant and equipment, net	4,179	3,202
In-process research and development	41,800	50,100
Intangible assets, net	17,441	11,216
Goodwill	13,902	13,902
Total assets	<u>\$ 112,456</u>	<u>\$ 119,971</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,084	\$ 11,472
Accrued compensation	3,334	4,118
Contingent consideration	444	1,119
Provisions for chargebacks	2,238	2,246
Deferred revenue, current portion	3,843	880
Total current liabilities	<u>19,943</u>	<u>19,835</u>
Deferred revenue, net of current portion	3,318	3,661
Deferred income taxes	506	1,867
Other liabilities	71	—
Total liabilities	<u>23,838</u>	<u>25,363</u>
Stockholders' equity:		
Net investment from Emergent	320,606	267,279
Accumulated deficit	<u>(231,988)</u>	<u>(172,671)</u>
Total stockholders' equity	<u>88,618</u>	<u>94,608</u>
Total liabilities and stockholders' equity	<u>\$ 112,456</u>	<u>\$ 119,971</u>

The accompanying notes are an integral part of the combined financial statements.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Combined Statements of Operations
(in thousands)

	Year Ended December 31,		
	2015	2014	2013
Revenues:			
Product sales	\$ 27,947	\$ 30,036	\$ —
Collaborations	5,654	15,595	170
Revenues	33,601	45,631	170
Operating expense:			
Cost of product sales	16,933	16,254	—
Research and development	34,726	46,589	38,074
Selling, general and administrative	43,042	34,280	15,451
Loss from operations	(61,100)	(51,492)	(53,355)
Other (expense) income, net	(237)	(222)	18
Loss before benefit from income taxes	(61,337)	(51,714)	(53,337)
Benefit from income taxes	(2,020)	(599)	—
Net and comprehensive loss	<u>\$(59,317)</u>	<u>\$(51,115)</u>	<u>\$(53,337)</u>

The accompanying notes are an integral part of the combined financial statements.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Combined Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net loss	\$(59,317)	\$ (51,115)	\$(53,337)
Adjustments to reconcile to net cash provided by (used in) operating activities:			
Stock-based compensation expense	1,107	1,074	955
Depreciation and amortization	2,907	2,021	666
Deferred income taxes	(1,361)	117	—
Change in fair value of contingent obligations	214	304	—
Provision for allowance for doubtful accounts	3,481	—	—
Other	—	—	(18)
Changes in operating assets and liabilities:			
Accounts receivable	3,884	(6,134)	(8)
Inventories	(2,697)	4,954	—
Income taxes	(66)	(716)	—
Prepaid expenses and other assets	2,860	(4,246)	29
Accounts payable	(1,669)	820	121
Accrued expenses and other liabilities	69	(63)	(64)
Accrued compensation	(784)	1,223	264
Provision for chargebacks	(8)	299	—
Deferred revenue	2,620	4,455	—
Net cash used in operating activities	<u>(48,760)</u>	<u>(47,007)</u>	<u>(51,392)</u>
Cash flows from investing activities:			
Purchases of property, plant and equipment	(1,527)	(989)	(1,021)
Acquisition of Cangene Corporation, net of cash	—	(47,811)	—
Net cash used in investing activities	<u>(1,527)</u>	<u>(48,800)</u>	<u>(1,021)</u>
Cash flows from financing activities:			
Net investment from Emergent	52,220	100,104	52,413
Contingent obligation payments	(889)	(704)	—
Net cash provided by financing activities	<u>51,331</u>	<u>99,400</u>	<u>52,413</u>
Net increase in cash and cash equivalents	1,044	3,593	—
Cash and cash equivalents at beginning of year	3,593	—	—
Cash and cash equivalents at end of year	<u>\$ 4,637</u>	<u>\$ 3,593</u>	<u>\$ —</u>

The accompanying notes are an integral part of the combined financial statements.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Combined Statement of Changes in Stockholders' Equity
(in thousands)

	<u>Year Ended December 31,</u>		
	<u>2015</u>	<u>2014</u>	<u>2013</u>
Beginning Balance	\$ 94,608	\$ 44,544	\$ 44,513
Net transactions with Emergent	53,327	101,179	53,368
Net loss	(59,317)	(51,115)	(53,337)
Ending Balance	<u>\$ 88,618</u>	<u>\$ 94,608</u>	<u>\$ 44,544</u>

The accompanying notes are an integral part of the combined financial statements.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Notes to the combined financial statements

1. Nature of Business and Basis of Presentation

On August 6, 2015, Emergent BioSolutions Inc. (“Emergent”), announced its plan to separate into two independent publicly-traded companies, one a biotechnology company focused on novel oncology and hematology therapeutics to meaningfully improve patients’ lives and the other a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats. In accordance with the separation plan, Emergent will spin off certain assets and liabilities of its biosciences business into Aptevo Therapeutics Inc. (“Aptevo”) a wholly-owned subsidiary of Emergent that was incorporated in February 2016. The biosciences business of Emergent is referred to throughout these combined financial statements as “the Company” or Aptevo.

The accompanying combined financial statements include certain components of Emergent’s bioscience business as operated by Emergent during the periods presented. Certain historical operations that were included by Emergent in its bioscience segment have been reallocated to Emergent’s continuing operations, and as result these financial statements differ from Emergent’s historically reportable bioscience segment.

The accompanying combined financial statements have been prepared on a standalone basis and are derived from Emergent’s consolidated financial statements and accounting records. The combined financial statements reflect Aptevo’s financial position, results of operations, and cash flows as if its business was separately operated as part of Emergent prior to the distribution, in conformity with accounting principles generally accepted in the United States (GAAP).

The combined financial statements include the allocation of certain assets and liabilities that have historically been held at the Emergent corporate level but which are specifically identifiable or allocable to Aptevo. All Aptevo intracompany transactions and accounts have been eliminated. All intercompany transactions between Aptevo and Emergent are considered to be effectively settled in the combined financial statements at the time the transaction is recorded. The total net effect of the settlement of these intercompany transactions is reflected in the combined statement of cash flows as a financing activity and in the combined balance sheet as a net investment from Emergent.

Aptevo’s combined financial statements include an allocation of expenses related to certain Emergent corporate functions, including senior management, legal, human resources, finance, information technology, and quality assurance. These expenses have been allocated to Aptevo based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, square footage, or other measures. Aptevo considers the expense allocation methodology and results to be reasonable for all periods presented. However, the allocations may not be indicative of the actual expense that would have been incurred had Aptevo operated as an independent, publicly-traded company for the periods presented.

The income tax amounts in these combined financial statements have been calculated based on a separate return methodology and presented as if Aptevo’s operations were a standalone taxpayer in each of its tax jurisdictions.

Emergent maintains stock-based compensation plans at a corporate level. Aptevo employees participate in those programs and a portion of the cost of those plans is included in Aptevo’s combined financial statements. However, Aptevo’s combined balance sheet does not include any equity awards related to stock-based compensation.

Aptevo’s stockholders equity balances in these combined financial statements represents the excess of total assets over total liabilities, including the net due to/from balances between Aptevo and Emergent (as net investment from Emergent) and accumulated deficit. The net investment from Emergent is primarily impacted by contributions from Emergent which are the result of net funding provided to Aptevo.

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Aptevo has a history of operating losses and negative cash flows while operating as part of Emergent and, accordingly, was dependent upon Emergent for its capital funding and liquidity needs. In addition, development activities, clinical and pre-clinical testing and commercialization of Aptevo's products, if approved, will require significant additional funding. Aptevo could delay clinical trial activity or reduce funding of specific programs in order to further extend the cash burn. In accordance with the separation agreement, Emergent has committed to providing Aptevo with a total of \$60 million in cash funding, \$40 million upon the spin-off and \$20 million within six to 12 months after the separation. Management believes this funding will support Aptevo's operations for at least the next 12 months following the separation, based on current operating plans and financial forecasts. The accompanying combined financial statements are prepared on a going concern basis and the Company, post separation, is solely responsible for its financial performance and meeting its capital requirements.

2. Summary of significant accounting policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

Cash equivalents

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and include time deposits and investments in money market funds with commercial banks and financial institutions.

Fair value of financial instruments

Financial instruments include cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The carrying value of these instruments approximates their fair value due to their short term nature.

Significant customers and accounts receivable

When appropriate, Aptevo records an allowance for doubtful accounts based upon its assessment of collectability. Aptevo performs ongoing credit evaluations of its customers and generally does not require collateral.

Accounts receivable at December 31, 2015 and 2014 primarily represent amounts due to Aptevo from its commercial wholesalers. For the year ended December 31, 2014, Aptevo had one customer whose accounts receivable balance was approximately 47% of total accounts receivable. For the year ended December 31, 2015, no individual customer accounts receivable balance was a significant percentage of total accounts receivable.

Concentrations of credit risk

Financial instruments that potentially subject Aptevo to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. Aptevo places its cash and cash equivalents with high quality financial institutions and may maintain cash balances in excess of insured limits. Management believes that the financial risks associated with its cash and cash equivalents are minimal.

Inventories

Inventories, including purchased inventories, are stated at the lower of cost or market with cost being determined using a standard cost method, which approximates weighted-average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses (including allocation of fixed production-overhead costs) and includes the services and products of third-party suppliers. Aptevo analyzes its inventory

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levels quarterly and writes down, in the applicable period, inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. Aptevo also writes off, in the applicable period, the costs related to expired inventory.

Property, plant and equipment

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the following estimated useful lives:

Building improvements	10-39 years
Furniture and equipment	3-15 years
Software	3-7 years or product life
Leasehold improvements	Lesser of the asset life or the remaining lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

Income taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss and research and development tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

Aptevo's ability to realize deferred tax assets depends upon future taxable income as well as the limitations discussed below. For financial reporting purposes, a deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized prior to expiration. Aptevo considers future taxable income and ongoing tax planning strategies in assessing the need for valuation allowances. In general, if Aptevo determines that it is more likely than not to realize more than the recorded amounts of net deferred tax assets in the future, Aptevo will reverse all or a portion of the valuation allowance established against its deferred tax assets, resulting in a decrease to the provision for income taxes in the period in which the determination is made. Likewise, if Aptevo determines that it is not more likely than not to realize all or part of the net deferred tax asset in the future, Aptevo will establish a valuation allowance against deferred tax assets, with an offsetting increase to the provision for income taxes, in the period in which the determination is made.

Because tax laws are complex and subject to different interpretations, significant judgment is required. As a result, Aptevo makes certain estimates and assumptions, in (1) calculating Aptevo's income tax expense, deferred tax assets and deferred tax liabilities, (2) determining any valuation allowance recorded against deferred tax assets and (3) evaluating the amount of unrecognized tax benefits, as well as the interest and penalties related to such uncertain tax positions. Aptevo's estimates and assumptions may differ significantly from tax benefits ultimately realized.

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-17, Balance Sheet Classification of Deferred Taxes ("ASU No. 2015-17"). The amendments in ASU No. 2015-17 change the presentation requirements for deferred tax assets and liabilities, along with any related valuation allowance, to classify the balances solely as noncurrent on the balance sheet. As a result, each jurisdiction will now only have one net noncurrent deferred tax asset or liability. The amendments in ASU No. 2015-17 are effective for years beginning after December 15, 2017, and early adoption is permitted. Aptevo has elected to adopt the accounting standard for the years ended December 31, 2015 and 2014. Prior periods in Aptevo's combined financial statements were not retrospectively adjusted.

Revenue recognition

Aptevo recognizes revenues if four basic criteria have been met (1) there is persuasive evidence of an arrangement, (2) delivery has occurred or services have been rendered, (3) the fee is fixed or determinable and (4) collectability is reasonably assured.

Aptevo markets and sells its products through commercial wholesalers (direct customers) who purchase the products at a price referred to as the wholesale acquisition cost ("WAC"). Additionally, Aptevo may enter into separate agreements with indirect customers to acquire its products for a contracted price that is less than the product's WAC. The indirect customers, such as group-purchasing organizations, physician practice-management groups and hospitals, continue to purchase Aptevo's products from the wholesalers, but at their respective contractual prices. Per its wholesaler agreements, Aptevo guarantees to credit the wholesaler for the difference between the WAC and the indirect customers' contracted price. This credit is referred to as a chargeback and revenues from product sales are recorded net of estimated chargebacks. Adjustments to the chargeback provisions are made periodically to reflect new facts and circumstances that may indicate that historical experience may not be indicative of current and/or future results.

All revenues from product sales are also recorded net of applicable allowances for sales and government rebates, special promotional programs, and discounts. These allowances are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels, contract terms, and actual discounts offered. In arriving at these estimates, Aptevo further utilizes information received from third parties including market data, inventory reports from major wholesalers, historical information and analysis. These estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates and reflect other limitations.

Aptevo defers the recognition of revenue from the sales of new product introductions until the commercial wholesalers resell the product to the healthcare providers. This is due to the inherent uncertainties in estimating normal wholesaler inventory levels of new products in addition to extended payment terms and expanded return rights that allow the wholesalers to return the product. Once Aptevo gains enough historical experience to reasonably estimate allowances for chargebacks, rebates and other discounts, revenue from sales and the related allowances are recognized upon sale to the wholesaler. As of December 31, 2015, Aptevo had \$3.3 million of deferred revenue for sales related to the IXINITY product introduction during 2015.

Revenue generating collaborative research and development agreements may contain one or more provisions including licensing, research services and milestone deliverables. Aptevo analyzes its multiple element revenue generating arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. An item can generally be considered a separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a standalone basis and (2) if the arrangement includes a general right of return and delivery, the performance of the undelivered item(s) is considered probable and substantially in the control of Aptevo. Items that cannot be divided into separate units are consolidated with other units of accounting, as appropriate. Consideration to be received is allocated among the separate units based on each unit's relative selling price and is then recognized when the appropriate revenue recognition criteria are met. Aptevo deems services to be rendered if no continuing obligation exists on the part of Aptevo.

Revenue associated with non-refundable upfront license fees that can be treated as a single unit of accounting is recognized when all ongoing obligations have been delivered. Revenue associated with non-refundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue either on a straight-line basis over Aptevo's continued involvement in the research and development process or based on the proportional performance of Aptevo's expected future obligations under the contract.

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Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable, (2) achievement of the milestone was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved to achieve the milestone and (4) the amount of the milestone payment appears reasonable in relation to the effort expended. If not deemed substantive, Aptevo recognizes such milestone as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process. Payments received in advance of revenue recognized are recorded as deferred revenue.

In May 2014, the FASB issued ASU No. 2014-09, Revenue From Contracts With Customers (Topic 606) Section A—Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs—Contracts with Customers (Subtopic 340-40) (“ASU No. 2014-09”). ASU No. 2014-09 supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, as well as most industry-specific guidance, and enhances comparability of revenue recognition practices across entities and industries by providing a principles-based, comprehensive framework for addressing revenue recognition issues. In order for a provider of promised goods or services to recognize as revenue the consideration that it expects to receive in exchange for the promised goods or services, the provider should apply the following five steps: (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU No. 2014-09 also specifies the accounting for some costs to obtain or fulfill a contract with a customer and provides enhanced disclosure requirements. The FASB has deferred ASU No. 2014-09 for one year, and with that deferral, the standard will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Aptevo is permitted to use either the retrospective or the modified retrospective method when adopting ASU No. 2014-09. Aptevo is assessing the potential impact that ASU No. 2014-09 will have on its combined financial statements and disclosures.

Mergers and Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, Aptevo may be required to value assets at fair value measures that do not reflect Aptevo’s intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in Aptevo’s combined financial statements after the date of the merger or acquisition.

The fair values of intangible assets are determined utilizing information available near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, Aptevo typically obtains assistance from third-party valuation specialists for significant items. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect Aptevo’s results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an “income approach” through which fair value is estimated based on each asset’s discounted projected net cash flows. Aptevo’s estimates of net cash flows consider historical and projected pricing, margins and expense levels, the performance of competing products where applicable, relevant industry

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and therapeutic area growth drivers and factors, current and expected trends in technology and product life cycles, the time and investment that will be required to develop products and technologies, the ability to obtain marketing and regulatory approvals, the ability to manufacture and commercialize the products, the extent and timing of potential new product introductions by Aptevo's competitors, and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to in-process research and development ("IPR&D") are determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, Aptevo will make a separate determination as to the then useful life of the asset and begin amortization.

In process research and development and long-lived assets

Aptevo assesses IPR&D assets for impairment on an annual basis or more frequently if indicators of impairment are present. Aptevo's annual assessment includes a comparison of the fair value of IPR&D assets to existing carrying value, and recognizes an impairment when the carrying value is greater than the determined fair value. Aptevo believes that the assumptions used in valuing the intangible and IPR&D assets are reasonable and are based upon its best estimate of likely outcomes of sales and clinical development. The underlying assumptions and estimates used to value these assets are subject to change in the future, and actual results may differ significantly from the assumptions and estimates. Aptevo has selected October 1 as its annual impairment test date for indefinite-lived intangible assets.

Aptevo assesses the recoverability of its long-lived assets or asset groups for which an indicator of impairment exists by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If Aptevo concludes that the carrying value will not be recovered, Aptevo measures the amount of such impairment by comparing the fair value to the carrying value of the assets or asset groups.

Goodwill

Aptevo assesses the carrying value of goodwill for impairment on an annual basis or whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable. Aptevo utilizes either: (1) a two-step impairment test, which is a quantitative analysis, or (2) a step zero test, which is a qualitative analysis.

If Aptevo is required to do a two-step test, it would compare the fair value of its reporting unit to the carrying value of the reporting unit, the first step. If the carrying value of the reporting unit exceeds its fair value, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting unit's goodwill. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, an impairment loss equal to the difference is recognized. Aptevo calculates the fair value of the reporting unit utilizing the income approach. The income approach utilizes a discounted cash flow model, using a discount rate based on Aptevo's estimated weighted average cost of capital.

If Aptevo is not required to do a quantitative analysis, it will evaluate goodwill using the qualitative assessment method, which permits companies to qualitatively assess whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount. Aptevo considers developments in its operations, the industry in which it operates and overall macroeconomic factors that could have affected the fair value of the reporting unit since the date of the most recent quantitative analysis of the reporting unit's fair value.

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The determination of the fair value of a reporting unit is judgmental in nature and involves the use of significant estimates and assumptions. The estimates and assumptions used in calculating fair value include identifying future cash flows, which requires that Aptevo makes a number of critical legal, economic, market and business assumptions that reflect best estimates as of the testing date. Aptevo's assumptions and estimates may differ significantly from actual results, or circumstances could change that would cause Aptevo to conclude that an impairment now exists or that it previously understated the extent of impairment. Aptevo selected October 1 as its annual impairment test date for goodwill.

Contingent Consideration

Aptevo records contingent consideration associated with sales based royalties at fair value. The fair value model used to calculate this obligation is based on the income approach (a discounted cash flow model) that has been risk adjusted based on the probability of achievement of net sales and achievement of the milestones. The inputs Aptevo use for determining the fair value of the contingent consideration associated with sales based royalties are Level 3 fair value measurements. Aptevo re-evaluates the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the discount rates and updates in the assumed timing of or achievement of net sales. Any future increase in the fair value of the contingent consideration associated with sales based royalties are based on an increased likelihood that the underlying net sales will be achieved.

The associated payment or payments which will therefore become due and payable for sales based royalties will result in a charge to cost of product sales in the period in which the increase is determined. Similarly, any future decrease in the fair value of contingent consideration associated with sales based royalties will result in a reduction in cost of product sales.

Research and development

Research and development costs are expensed as incurred. Research and development costs primarily consist of internal labor costs, fees paid to outside service providers and the costs of materials used in clinical trials and research and development. Other research and development expenses include facility, maintenance and related support expenses.

A substantial portion of the Aptevo's pre-clinical studies and all of its clinical studies have been performed by third-party contract research organizations ("CRO"). The Company reviews the activities performed by the CRO's each period. For pre-clinical studies, the significant factors used in estimating accruals include the percentage of work completed to date and contract milestones achieved. For clinical study expenses, the significant factors used in estimating accruals include the number of patients enrolled and percentage of work completed to date. The Company's estimates are highly dependent upon the timeliness and accuracy of the data provided by its CRO's regarding the status of each program and total program spending and adjustments are made when deemed necessary.

Segment reporting

The Company has determined that it operates in a single segment: the discovery, development, commercialization and sale of novel oncology and hematology therapeutics.

3. Acquisitions

Cangene Corporation

On February 21, 2014, Emergent acquired 100% of the ownership interest of Cangene Corporation ("Cangene") for a total cash purchase price of \$221.5 million. This transaction was accounted for by Emergent under the acquisition method of accounting and the assets and liabilities of Cangene were recorded as of the

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acquisition date at their respective fair values. These combined financial statements only reflect those assets acquired and liabilities assumed associated with Aptevo's biosciences business, representing \$48.6 million of the total \$221.5 million purchase price.

The table below summarizes the allocation of the Aptevo portion of the purchase price based upon estimated fair values of the Aptevo assets acquired and liabilities assumed:

<u>(in thousands)</u>	<u>February 21, 2014</u>
Fair value of tangible assets acquired and liabilities assumed:	
Acquired assets	\$ 32,290
Assumed liabilities ⁽ⁱ⁾	<u>(12,910)</u>
Total fair value of tangible assets acquired and liabilities assumed	19,380
Acquired in-process research and development	8,300
Acquired intangible assets	12,509
Goodwill	8,399
Total purchase price	<u>\$ 48,588</u>

- (i) Assumed liabilities includes contingent purchase consideration of \$1.5 million associated with the acquisition of HepaGam B by Cangene.

The table below summarizes the fair value of intangible assets acquired and the estimated amortization periods:

<u>(in thousands)</u>	<u>Amount</u>	<u>Amortization Period in Years</u>
Corporate tradename	\$ 1,309	5
Marketed products	8,100	10
Licensed products	3,100	7
Total intangible assets	<u>\$12,509</u>	

The marketed products intangible asset consists of WinRho® SDF [Rho(D) Immune Globulin Intravenous (Human)] and VARIZIG® (Varicella Zoster Immune Globulin (Human)). The licensed products intangible asset primarily consists of HepaGam B® (Hepatitis B Immune Globulin Intravenous (Human)). In addition, as of the date of acquisition, the intangible asset associated with IPR&D acquired from Cangene was the IXINITY product candidate.

4. Fair value measurements

The fair value hierarchy under the accounting standards for fair value measurements consists of the following three levels:

Level 1—Observable inputs for identical assets or liabilities such as quoted prices in active markets;

Level 2—Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3—Unobservable inputs in which little or no market data exists, which are therefore developed by the Company's management using estimates and assumptions that reflect those that a market participant would use.

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The Company does not have any fair value measurements done on a recurring basis other than the contingent consideration acquired in the Cangene acquisition. The fair value of contingent consideration obligation associated with HepaGam B changes as a result of management's assessment of discount rates and updates to the projected and actual sales achievement of HepaGam B, which are inputs that have no observable market (Level 3). For the years ended December 31, 2015 and 2014, the contingent purchase consideration obligation increased by \$0.2 million and \$0.3 million, respectively. These adjustments are primarily due to the differences between the actual and expected timing and volume of HepaGam B sales. The incremental impact is recorded in the accompanying combined statement of operations as cost of product sales.

The following table is a reconciliation of the beginning and ending balance of the liabilities (contingent consideration) measured at fair value using significant unobservable inputs (Level 3) during the years ended December 31, 2015 and 2014.

(in thousands)	
Balance at December 31, 2013	\$ —
Expense (income) included in earnings	304
Settlements	(704)
Purchases, sales and issuances	1,519
Transfers in/(out) of Level 3	—
Balance at December 31, 2014	<u>\$1,119</u>
Expense (income) included in earnings	214
Settlements	(889)
Purchases, sales and issuances	—
Transfers in/(out) of Level 3	—
Balance at December 31, 2015	<u>\$ 444</u>

5. MorphoSys collaboration agreement

In August 2014, Aptevo entered into a collaboration agreement ("MorphoSys Agreement") with MorphoSys AG ("MorphoSys") for the joint worldwide development and commercialization of MOR209/ES414, a targeted immunotherapeutic protein, which activates host T-cell immunity specifically against cancer cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells. MOR209/ES414 was constructed using Aptevo's proprietary ADAPTIR platform technology.

In accordance with the initial terms of the MorphoSys Agreement, Aptevo received a nonrefundable \$20.0 million upfront payment and could have received up to \$163.0 million in additional contingent payments, comprised of up to \$80.0 million and up to \$83.0 million, respectively, due upon the achievement of specified development and regulatory milestones. MorphoSys and Aptevo jointly agreed to fund further development of MOR209/ES414, with Aptevo responsible for 36% of the total development costs and MorphoSys responsible for the remainder, with Aptevo's funding requirement capped at \$186.0 million. Aptevo's development effort includes the performance of non-clinical, clinical, manufacturing and regulatory activities. Aptevo retains commercialization rights in the U.S. and Canada, with a tiered royalty obligation to MorphoSys, ranging from mid-single digit up to 20% of sales. MorphoSys has worldwide commercialization rights excluding the U.S. and Canada, with a low single digit royalty obligation to Aptevo.

In December 2015, after a joint review of data from the ongoing Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys decided to adjust the dosing regimen and administration of MOR209/ES414. Aptevo plans to continue the current clinical trial under an amended protocol with recruitment to start around mid-2016. As a result of the revised dosing regimen and administration and the resultant impact to overall development timeline and technical risk, the MorphoSys Agreement was restructured.

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In December 2015, Aptevo and MorphoSys amended the collaboration agreement to (1) decrease the additional contingent payments due Aptevo upon the achievement of specified development and regulatory milestones of up to \$32.5 million and up to \$41.5 million, respectively, (2) change the total funding requirement cap for Aptevo to up to approximately \$250.0 million and (3) change the jointly funded development cost allocation to the following:

- 2016: Aptevo is responsible for 75%; MorphoSys responsible for 25%
- 2017-2018: Aptevo is responsible for 49%; MorphoSys responsible for 51%
- 2019 and beyond: Aptevo is responsible for 36%; MorphoSys responsible for 64%

In addition, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial.

Aptevo evaluated the MorphoSys Agreement and determined that it was a revenue arrangement with multiple deliverables or performance obligations. Aptevo determined there were two units of accounting under the MorphoSys Agreement: (1) the delivered license to further develop and commercialize MOR209/ES414 and (2) undelivered items related to development services. Aptevo determined that the license had standalone value as the drug candidate has been (1) developed and is currently Phase 1 clinical trial ready, (2) MorphoSys possesses the knowledge, technology, skills, experience and infrastructure necessary to complete all further development of the drug through commercialization, and (3) MorphoSys has the right to further sublicense the product. Aptevo allocated the \$20.0 million upfront payment to the two units of accounting using the relative selling price method. Aptevo determined the estimated selling price for the license using the income approach and an appropriate discount rate. The estimated selling price includes unobservable inputs (Level 3), such as estimates of revenues and operating margins; the time and resources needed to complete the development and approval of the product candidate; and the risk related to the viability of and potential for alternative treatments. Aptevo determined the estimated selling price of the development services unit of accounting based on the estimated number of full-time equivalent personnel at the contractual rate as defined in the MorphoSys Agreement, whose rates and terms approximate those of other Emergent or Aptevo service related contracts and those observed generally through other collaboration negotiations. The allocation resulted in \$15.3 million of the \$20.0 million upfront payment being allocated to the license and \$4.7 million being allocated to the development services. Aptevo determined the license fee unit of accounting was delivered and completed on the date the MorphoSys Agreement was executed and thus recognized \$15.3 million of license revenue in August 2014. Revenue related to the development services is recognized as the services are performed with \$0.7 million and \$0.2 million, respectively, recognized in the years ended December 31, 2015 and 2014. The current estimated service period for the undelivered development services under the MorphoSys Agreement is through 2023.

Further, Aptevo determined that contingent payments for the achievement of the development and regulatory milestones are substantive milestones and will be accounted for as revenue in the period in which the milestones are achieved. Aptevo received a \$5.0 million milestone payment from MorphoSys reflecting the initiation of a Phase I clinical study to evaluate the safety, tolerability, and clinical activity of MOR209/ES414 in patients with metastatic castration-resistant prostate cancer. Aptevo recognized this substantive milestone achievement payment as research and development revenue during the year ended December 31, 2015.

The MorphoSys Agreement provides for the sharing of development and clinical costs related to MOR209/ES414. In the event Aptevo's share of the total cost incurred for a given quarter exceeds its pro rata limit, Aptevo records a receivable from MorphoSys for the excess and reduces research and development expense by this amount. Accordingly, for the years ended December 31, 2015 and 2014, Aptevo has recorded a reduction to research and development expense of \$4.3 million and \$1.5 million, respectively.

As of December 31, 2015 and 2014, the MorphoSys Agreement related accounts receivable balance was \$0.5 million and \$1.0 million, respectively, and the related total deferred revenue balance was \$3.9 million and \$4.5 million, respectively.

6. Accounts receivable

For the year ended December 31, 2015, Aptevo recorded an allowance for uncollectible accounts of approximately \$3.5 million in Aptevo's combined statement of operations as selling, general and administrative expense. As of December 31, 2014, no allowance for doubtful accounts was recorded as the collection history from Aptevo's customers indicated that collection was probable.

7. Inventories

Inventories consist of the following:

(in thousands)	December 31,	
	2015	2014
Raw materials and supplies	\$ 6,520	\$ 8,252
Work-in-process	4,730	2,986
Finished goods	9,072	6,387
Total inventories	<u>\$20,322</u>	<u>\$17,625</u>

CMC ICOS Biologics, Inc., ("CMC"), is the exclusive manufacturer of bulk drug substance for the IXINITY product. During 2015, Aptevo ordered nine manufacturing lots of bulk drug substance from CMC. CMC has successfully manufactured and released only one of the nine lots of bulk drug substance ordered by Aptevo, and has not successfully manufactured or released any lots of bulk drug substance in 2016. If current efforts by CMC to manufacture and release bulk drug substance are not successful, the resulting lack of supply of bulk drug substance could lead to a projected supply shortage of IXINITY requiring notification to the FDA. The inability to supply IXINITY would negatively affect sales, market position and viability and as a result, the realizability of IXINITY related inventory. As of December 31, 2015, Aptevo had IXINITY related inventory of approximately \$2 million that may be subject to impairment if Aptevo is no longer able to sell the IXINITY product.

8. Property, plant and equipment

Property, plant and equipment consist of the following:

(in thousands)	December 31,	
	2015	2014
Buildings, building improvements and leasehold improvements	\$ 2,152	\$ 2,100
Furniture and equipment	6,826	6,246
Software	101	88
Construction-in-progress	957	94
Property, plant and equipment, gross	10,036	8,528
Less: Accumulated depreciation and amortization	(5,857)	(5,326)
Total property, plant and equipment, net	<u>\$ 4,179</u>	<u>\$ 3,202</u>

Depreciation and amortization expense was \$0.8 million, \$0.7 million and \$0.7 million for the years ended December 31, 2015, 2014 and 2013, respectively.

9. Intangible assets, in-process research and development and goodwill

As of December 31, 2015, Aptevo had \$41.8 million of IPR&D assets related to Aptevo's otlertuzumab product candidate. As of December 31, 2014, Aptevo had \$50.1 million of IPR&D comprised of \$41.8 million for the otlertuzumab product candidate and \$8.3 million related to the IXINITY product candidate. On April 29, 2015,

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the Food and Drug Administration approved IXINITY for the treatment of Hemophilia B. As a result of the approval, the \$8.3 million IXINITY IPR&D asset was reclassified to intangible assets in Aptevo's combined balance sheets and is being amortized over 10 years from the approval date.

Aptevo completed its annual impairment assessments for its IPR&D assets and goodwill as of October 1, 2015 and 2014, respectively, and determined that the fair value of the IPR&D assets and its reporting unit was in excess of carrying value.

For the years ended December 31, 2015 and 2014, Aptevo recorded \$2.1 million and \$1.3 million, respectively, of intangible asset amortization expense. As of December 31, 2015, the weighted average amortization period remaining for intangible assets was 97 months.

Intangible assets consisted of the following:

<u>(in thousands)</u>	<u>Corporate Trade name</u>	<u>Commercial Products</u>	<u>Total</u>
Cost Basis			
Balance at December 31, 2013	\$ —	\$ —	\$ —
Additions	1,309	11,200	12,509
Balance at December 31, 2014	1,309	11,200	12,509
Additions	—	8,300	8,300
Balance at December 31, 2015	<u>\$ 1,309</u>	<u>\$ 19,500</u>	<u>\$20,809</u>
Accumulated Amortization			
Balance at December 31, 2013	\$ —	\$ —	\$ —
Amortization	(224)	(1,069)	(1,293)
Balance at December 31, 2014	(224)	(1,069)	(1,293)
Amortization	(262)	(1,813)	(2,075)
Balance at December 31, 2015	<u>\$ (486)</u>	<u>\$ (2,882)</u>	<u>\$ (3,368)</u>
Net book value at December 31, 2015	<u>\$ 823</u>	<u>\$ 16,618</u>	<u>\$17,441</u>

Future amortization expense as of December 31, 2015 is as follows:

<u>(in thousands)</u>	
2016	\$ 2,345
2017	2,345
2018	2,345
2019	2,121
2020	2,083
2021 and beyond	6,202
Total remaining amortization	<u>\$17,441</u>

10. Income taxes

During the periods presented, Aptevo did not file separate tax returns as it was included in the tax returns of Emergent entities within the respective tax jurisdictions. The income tax provision included in these financial statements was calculated using a separate return basis, as if Aptevo was a separate taxpayer. Under this approach, Aptevo determines its current taxes, deferred tax assets and liabilities and related tax expense as if it were filing separate tax returns in each tax jurisdiction.

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Significant components of the provisions for income taxes attributable to operations consist of the following:

(in thousands)	Year ended December 31,		
	2015	2014	2013
Current			
International	\$ (660)	\$(716)	\$—
Total current	(660)	(716)	—
Deferred			
International	(1,360)	117	—
Total deferred	(1,360)	117	—
Total benefit from income taxes	<u>\$ (2,020)</u>	<u>\$(599)</u>	<u>\$—</u>

Aptevo's net deferred tax asset (liability) consists of the following:

(in thousands)	December 31,	
	2015	2014
Federal losses carryforward	\$ 90,121	\$ 75,276
Research and development carryforward	13,026	11,938
Scientific research and experimental development credit carryforward	3,460	4,939
Intangible assets	4,835	5,043
Stock compensation	1,167	765
Foreign deferrals	17,755	11,844
Inventory reserves	1,716	1,916
Fixed assets	1,357	1,727
Other	3,910	4,143
Deferred tax asset	<u>137,347</u>	<u>117,591</u>
Other	<u>(3,364)</u>	<u>(4,105)</u>
Deferred tax liability	<u>(3,364)</u>	<u>(4,105)</u>
Valuation allowance	<u>(134,489)</u>	<u>(115,353)</u>
Net deferred tax liabilities	<u>\$ (506)</u>	<u>\$ (1,867)</u>

Deferred assets and liabilities are a result of the separate return calculation presentation and may not represent deferred assets and liability balances after the distribution. Certain deferred items may not exist due to utilization by the Emergent group prior to the distribution, together with certain related transactions, or may hold no future value subsequent to the distribution due to Aptevo's future jurisdictional income projections. Federal net operating losses, research and development credit carryforwards, and stock compensation are examples of deferred items that have been previously utilized or will have no future value to Aptevo as the distribution, together with certain related transactions, does not result in the transfer of loss carryforwards or tax credit carryforwards to Aptevo. Aptevo has determined a valuation allowance is required for financial reporting purposes due to accumulative historic losses on a separate tax return basis as well as the expiration of certain attributes.

As of December 31, 2015 and 2014, Aptevo has recorded net operating losses of approximately \$90.1 million and \$75.3 million, respectively, and research and development credits of \$13 million and \$11.9 million, respectively. In addition, Aptevo has recorded Canadian loss carryforwards of approximately \$17.8 million and \$11.8 million, respectively, and Canadian scientific research and experimental development credits in the amount of \$3.5 million and \$4.9 million, respectively. On a separate return basis, these losses and credits would begin to expire in 2023.

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The benefit from income taxes differs from the amount of taxes determined by applying the U.S. federal statutory rate to loss before benefit from income taxes as a result of the following:

(in thousands)	Year ended December 31,		
	2015	2014	2013
US	<u>\$(41,648)</u>	<u>\$(34,143)</u>	<u>\$(53,337)</u>
International	<u>(19,689)</u>	<u>(17,571)</u>	<u>—</u>
Loss before benefit from income taxes	<u>\$(61,337)</u>	<u>\$(51,714)</u>	<u>\$(53,337)</u>
Federal tax at statutory rates	<u>\$(21,467)</u>	<u>\$(18,131)</u>	<u>\$(18,670)</u>
State taxes, net of federal benefit	419	(34)	—
Impact of foreign operations	1,828	1,962	—
Change in valuation allowance	20,563	19,756	21,790
Tax credits	(3,898)	(5,067)	(4,689)
Permanent differences	535	915	1,569
Benefit from income taxes	<u>\$ (2,020)</u>	<u>\$ (599)</u>	<u>\$ —</u>

11. Equity awards program

Emergent maintains various stock programs for the benefit of its officers, directors, and certain employees, including certain Aptevo employees. As Aptevo receives services in consideration for the participation in these plans, a share-based compensation expense for the awards has been reflected in the accompanying combined statements of operations. The following disclosures represent the Aptevo allocation of Emergent's programs. The terms and conditions of the stock programs are administered by the Emergent board of directors and the underlying equity instruments are shares of Emergent's common stock. Accordingly, the amounts presented are not necessarily indicative of future performance and do not necessarily reflect the results that Aptevo would have experienced as an independent, publicly-traded company for the periods presented.

Emergent has two stock-based employee compensation plans, the Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan" and together with the 2006 Plan, the "Emergent Plans"). Emergent has granted option awards under the Emergent Plans as well as granted restricted stock units under the 2006 Plan. The Emergent Plans have both incentive and non-qualified stock option features. Emergent no longer grants equity awards under the 2004 Plan. The exercise price of each option must be not less than 100% of the fair market value of the underlying shares on the date of grant. Awards granted generally have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the compensation committee of Emergent's board of directors, which administers the Emergent Plans.

Emergent determines the fair value of restricted stock units using the closing market price of Emergent's common stock on the day prior to the date of grant. Emergent utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. Set forth below are the assumptions used in valuing the stock options granted and a discussion of Emergent's methodology for developing each of the assumptions used:

	Year Ended December 31,		
	2015	2014	2013
Expected dividend yield	0%	0%	0%
Expected volatility	34%	35%	39-49%
Risk-free interest rate	1.35%	1.14-1.30%	0.32-0.62%
Expected average life of options	4 years	4 years	4 years

- Expected dividend yield—Emergent does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

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- Expected volatility—a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate during a period. Emergent analyzed its own historical volatility to estimate expected volatility over the same period as the expected average life of the options.
- Risk-free interest rate—the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date on which the option is granted.
- Expected average life of options — the period of time that options granted are expected to remain outstanding, based primarily on Emergent’s expectation of optionee exercise behavior subsequent to vesting of options.

The following is a summary of option award activity, specific to Aptevo employees, under the 2006 Plan:

	2006 Plan		
	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2014	212,369	\$ 21.08	\$ 1,354,845
Granted	50,320	29.00	
Exercised	(92,451)	19.30	
Forfeited	(9,688)	25.54	
Outstanding at December 31, 2015	160,550	\$ 24.38	\$ 2,509,435
Exercisable at December 31, 2015	47,391	\$ 19.12	\$ 923,206

The following is a summary of restricted stock unit award activity, specific to Aptevo employees, under the 2006 Plan:

	Number of Shares	Weighted-Average Grant Price	
			Aggregate Intrinsic Value
Outstanding at December 31, 2014	66,553	\$ 22.17	\$ 1,812,238
Granted	28,840	29.56	
Vested	(30,304)	20.22	
Forfeited	(4,843)	25.54	
Outstanding at December 31, 2015	60,246	\$ 26.43	\$ 2,410,442

Stock-based compensation expense, specific to Aptevo employees, was recorded in the following financial statement line items:

(in thousands)	Years ended December 31,		
	2015	2014	2013
Research and development	\$ 813	\$ 852	\$848
General and administrative	294	222	107
Total stock-based compensation expense	\$1,107	\$1,074	\$955

12. 401(k) savings plan

Emergent has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers substantially all U.S. employees, including certain Aptevo employees. Under the

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401(k) Plan, employees may make elective salary deferrals. Emergent currently provides for matching of qualified deferrals up to 50% of the first 6% of the employee's salary. During the years ended December 31, 2015, 2014, and 2013, the Aptevo related share of matching contributions was approximately \$0.3 million, \$0.3 million and \$0.2 million, respectively.

13. Leases and contingencies

Aptevo leases laboratory and office facilities, office equipment and vehicles under various operating lease agreements. For the years ended December 31, 2015, 2014 and 2013, total lease expense was \$1.8 million, \$1.8 million and \$1.7 million, respectively.

Future minimum lease payments under operating lease obligations, including any escalation clauses, as of December 31, 2015 were as follows:

<u>(in thousands)</u>	
2016	\$1,672
2017	1,618
2018	1,585
2019	1,611
2020	543
Total minimum lease payments	<u>\$7,029</u>

Aptevo has accrued liabilities when it is probable that a loss will be incurred and the amount of loss can be reasonably estimated.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Condensed Combined Balance Sheets (Unaudited)
(in thousands)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,072	\$ 4,637
Accounts receivable, net	3,458	6,456
Inventories	22,071	20,322
Income taxes receivable	1,387	1,376
Prepaid expenses and other current assets	5,435	2,343
Total current assets	<u>35,423</u>	<u>35,134</u>
Property, plant and equipment, net	4,624	4,179
In-process research and development	41,800	41,800
Intangible assets, net	16,856	17,441
Goodwill	13,902	13,902
Total assets	<u>\$ 112,605</u>	<u>\$ 112,456</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 12,197	\$ 10,084
Accrued compensation	2,182	3,334
Contingent consideration	233	444
Provisions for chargebacks	1,960	2,238
Deferred revenue, current portion	2,118	3,843
Total current liabilities	<u>18,690</u>	<u>19,943</u>
Deferred revenue, net of current portion	3,468	3,318
Deferred income taxes	506	506
Other liabilities	79	71
Total liabilities	<u>22,743</u>	<u>23,838</u>
Stockholders' equity:		
Net investment from Emergent	334,740	320,606
Accumulated deficit	(244,878)	(231,988)
Total stockholders' equity	<u>89,862</u>	<u>88,618</u>
Total liabilities and stockholders' equity	<u>\$ 112,605</u>	<u>\$ 112,456</u>

The accompanying notes are an integral part of the condensed combined financial statements.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Condensed Combined Statements of Operations (Unaudited)
(in thousands)

	Three months Ended	
	March 31,	
	2016	2015
Revenues:		
Product sales	\$ 7,948	\$ 6,321
Collaborations	119	5,342
Revenues	<u>8,067</u>	<u>11,663</u>
Operating expense:		
Cost of product sales	3,528	3,732
Research and development	8,101	9,101
Selling, general and administrative	9,420	9,932
Loss from operations	<u>(12,982)</u>	<u>(11,102)</u>
Other income (expense), net	80	(295)
Loss before benefit from income taxes	<u>(12,902)</u>	<u>(11,397)</u>
Benefit from income taxes	(12)	(375)
Net and comprehensive loss	<u><u>\$(12,890)</u></u>	<u><u>\$(11,022)</u></u>

The accompanying notes are an integral part of the condensed combined financial statements.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Condensed Combined Statements of Cash Flows (Unaudited)
(in thousands)

	Three Months Ended	
	March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$(12,890)	\$(11,022)
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	334	263
Depreciation and amortization	836	590
Deferred income taxes	(12)	(375)
Change in fair value of contingent obligations	(30)	215
Changes in operating assets and liabilities:		
Accounts receivable	2,998	(431)
Inventories	(1,749)	(694)
Prepaid expenses and other assets	(3,093)	(446)
Accounts payable	2,501	(1,143)
Accrued expenses and other liabilities	(4)	18
Accrued compensation	(1,151)	(2,471)
Provision for chargebacks	(278)	(81)
Deferred revenue	(1,575)	(342)
Net cash used in operating activities	<u>(14,113)</u>	<u>(15,919)</u>
Cash flows from investing activities:		
Purchases of property, plant and equipment	(1,071)	(141)
Net cash used in investing activities	<u>(1,071)</u>	<u>(141)</u>
Cash flows from financing activities:		
Net investment from Emergent	13,800	14,752
Contingent obligation payments	(181)	(369)
Net cash provided by financing activities	<u>13,619</u>	<u>14,383</u>
Net decrease in cash and cash equivalents	(1,565)	(1,677)
Cash and cash equivalents at beginning of year	4,637	3,593
Cash and cash equivalents at end of year	<u>\$ 3,072</u>	<u>\$ 1,916</u>

The accompanying notes are an integral part of the condensed combined financial statements.

Aptevo Therapeutics Inc.
(the Biosciences Business of Emergent BioSolutions Inc.)
Notes to the condensed combined financial statements

1. Nature of Business and Basis of Presentation

On August 6, 2015, Emergent BioSolutions Inc. (“Emergent”), announced its plan to separate into two independent publicly-traded companies, one a biotechnology company focused on novel oncology and hematology therapeutics to meaningfully improve patients’ lives and the other a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats. In accordance with the separation plan, Emergent formed Aptevo Therapeutics Inc. (“Aptevo”) as a wholly-owned subsidiary incorporated in February 2016. Upon completion of the separation, Emergent will transfer to and Aptevo will hold certain assets and liabilities of Emergent’s biosciences business and Aptevo will then become the standalone parent company of those biosciences business operations and entities. The biosciences business of Emergent is referred to throughout these combined financial statements as “the Company” or Aptevo.

The accompanying condensed combined financial statements include certain components of Emergent’s bioscience business as operated by Emergent during the periods presented. Certain historical operations that were included by Emergent in its bioscience segment have been reallocated to Emergent’s continuing operations, and as result these financial statements differ from Emergent’s historically reportable bioscience segment.

The accompanying condensed combined financial statements have been prepared on a standalone basis and are derived from Emergent’s consolidated financial statements and accounting records. The condensed combined financial statements reflect Aptevo’s financial position, results of operations, and cash flows as if its business was separately operated as part of Emergent prior to the distribution, in conformity with accounting principles generally accepted in the United States (GAAP).

The condensed combined financial statements include the allocation of certain assets and liabilities that have historically been held at the Emergent corporate level but which are specifically identifiable or allocable to Aptevo. All Aptevo intracompany transactions and accounts have been eliminated. All intercompany transactions between Aptevo and Emergent are considered to be effectively settled in the condensed combined financial statements at the time the transaction is recorded. The total net effect of the settlement of these intercompany transactions is reflected in the condensed combined statement of cash flows as a financing activity and in the condensed combined balance sheet as a net investment from Emergent.

Aptevo’s condensed combined financial statements include an allocation of expenses related to certain Emergent corporate functions, including senior management, legal, human resources, finance, information technology, and quality assurance. These expenses have been allocated to Aptevo based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, square footage, or other measures. Aptevo considers the expense allocation methodology and results to be reasonable for all periods presented. However, the allocations may not be indicative of the actual expense that would have been incurred had Aptevo operated as an independent, publicly-traded company for the periods presented.

The income tax amounts in these condensed combined financial statements have been calculated based on a separate return methodology and presented as if Aptevo’s operations were a standalone taxpayer in each of its tax jurisdictions.

Emergent maintains stock-based compensation plans at a corporate level. Aptevo employees participate in those programs and a portion of the cost of those plans is included in Aptevo’s condensed combined financial statements. However, Aptevo’s condensed combined balance sheet does not include any equity awards related to stock-based compensation.

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Aptevo's stockholders equity balances in these condensed combined financial statements represents the excess of total assets over total liabilities, including the net due to/from balances between Aptevo and Emergent (as net investment from Emergent) and accumulated deficit. The net investment from Emergent is primarily impacted by contributions from Emergent which are the result of net funding provided to Aptevo.

Aptevo has a history of operating losses and negative cash flows while operating as part of Emergent and, accordingly, was dependent upon Emergent for its capital funding and liquidity needs. In addition, development activities, clinical and pre-clinical testing and commercialization of Aptevo's products, if approved, will require significant additional funding. Aptevo could delay clinical trial activity or reduce funding of specific programs in order to further extend the cash burn. In accordance with the separation agreement, Emergent has committed to providing Aptevo with a total of \$60 million in cash funding, \$40 million upon the spin-off and \$20 million within six to 12 months after the separation. Management believes this funding will support Aptevo's operations for at least the next 12 months following the separation, based on current operating plans and financial forecasts. The accompanying condensed combined financial statements are prepared on a going concern basis and the Company, post separation, is solely responsible for its financial performance and meeting its capital requirements.

In the opinion of Aptevo's management, any adjustments contained in the accompanying condensed combined financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of March 31, 2016; the results of operations for the three months ended March 31, 2016 and 2015; and cash flows for the three months ended March 31, 2016 and 2015. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

2. Fair value measurements

The fair value hierarchy under the accounting standards for fair value measurements consists of the following three levels:

Level 1—Observable inputs for identical assets or liabilities such as quoted prices in active markets;

Level 2—Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3—Unobservable inputs in which little or no market data exists, which are therefore developed by Company's management using estimates and assumptions that reflect those that a market participant would use.

The Company does not have any fair value measurements done on a recurring basis other than the contingent consideration acquired in the Cangene acquisition. The fair value of contingent consideration obligation associated with HepaGam B changes as a result of management's assessment of discount rates and updates to the projected and actual sales achievement of HepaGam B, which are inputs that have no observable market (Level 3). These adjustments are primarily due to the differences between the actual and expected timing and volume of HepaGam B sales. The incremental impact is recorded in the accompanying condensed combined statement of operations as cost of product sales.

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The following table is a reconciliation of the beginning and ending balance of the liabilities (contingent consideration) measured at fair value using significant unobservable inputs (Level 3) for the three months ended March 31, 2016:

<u>(in thousands)</u>	
Balance at December 31, 2015	\$ 444
Expense (income) included in earnings	(30)
Settlements	(181)
Purchases, sales and issuances	—
Transfers in/(out) of Level 3	—
Balance at March 31, 2016	<u>\$ 233</u>

3. MorphoSys collaboration agreement

In August 2014, Aptevo entered into a collaboration agreement (“MorphoSys Agreement”) with MorphoSys AG (“MorphoSys”) for the joint worldwide development and commercialization of MOR209/ES414, a targeted immunotherapeutic protein, which activates host T-cell immunity specifically against cancer cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells. MOR209/ES414 was constructed using Aptevo’s proprietary ADAPTIR platform technology.

Revenue related to MorphoSys development services is recognized as the services are performed with \$0.1 million and \$0.2 million, respectively, recognized in the three months ended March 31, 2016 and 2015. The current estimated service period for the undelivered development services under the MorphoSys Agreement is through 2023.

Further, Aptevo determined that contingent payments for the achievement of the development and regulatory milestones are substantive milestones and will be accounted for as revenue in the period in which the milestones are achieved. Aptevo received a \$5.0 million milestone payment from MorphoSys reflecting the initiation of a Phase I clinical study to evaluate the safety, tolerability, and clinical activity of MOR209/ES414 in patients with metastatic castration-resistant prostate cancer. Aptevo recognized this substantive milestone achievement payment as research and development revenue during the three months ended March 31, 2015.

The MorphoSys Agreement provides for the sharing of development and clinical costs related to MOR209/ES414. In the event Aptevo’s share of the total cost incurred for a given quarter exceeds its pro rata limit, Aptevo records a receivable from MorphoSys for the excess and reduces research and development expense by this amount. Accordingly, for the three months ended March 31, 2016 and 2015, Aptevo has recorded a reduction to research and development expense of \$0.1 million and \$1.7 million, respectively.

As of March 31, 2016 and December 31, 2015, the MorphoSys Agreement related accounts receivable balance was \$0.1 million and \$0.5 million, respectively, and the related total deferred revenue balance was \$3.8 million and \$3.9 million, respectively.

4. Inventories

Inventories consist of the following:

<u>(in thousands)</u>	<u>March 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Raw materials and supplies	\$ 6,879	\$ 6,520
Work-in-process	6,065	4,730
Finished goods	9,127	9,072
Total inventories	<u>\$ 22,071</u>	<u>\$ 20,322</u>

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CMC ICOS Biologics, Inc., (“CMC”), is the exclusive manufacturer of bulk drug substance for the IXINITY product. During 2015, Aptevo ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. Aptevo continues to work with CMC to resolve the manufacturing delays, although to date in 2016 no lots of bulk drug substance have been successfully manufactured and released. Additionally, Patheon UK Limited (“Patheon”), through an affiliate, is currently the sole source fill-finish service manufacturer for the IXINITY product. The release of drug product by Patheon may be impacted by several factors, including Patheon requiring approval from its affiliate’s foreign regulatory authority of recent changes to its facility. If current efforts to proceed with the manufacturing and release of bulk drug substance and filled product are not successful, the resulting lack of supply of bulk drug substance or filled product could lead to a projected supply shortage of IXINITY requiring notification to the FDA. This inability to supply IXINITY would adversely affect its sales, market position and viability and as a result, the realizability of IXINITY related inventory. As of March 31, 2016, Aptevo had IXINITY related inventory of approximately \$2.5 million that may be subject to impairment if Aptevo is no longer able to sell the IXINITY product.

5. Intangible assets, in-process research and development and goodwill

As of March 31, 2016 and December 31, 2015, Aptevo had \$41.8 million of IPR&D assets related to Aptevo’s oltertuzumab product candidate.

On April 29, 2015, the U.S. Food and Drug Administration approved IXINITY for the treatment of Hemophilia B. As a result of the approval, the \$8.3 million IXINITY IPR&D asset was reclassified to intangible assets in Aptevo’s combined balance sheets and is being amortized over 10 years from the approval date.

For the three months ended March 31, 2016 and 2015, Aptevo recorded \$0.6 million and \$0.4 million, respectively, of intangible asset amortization expense. As of March 31, 2016, the weighted average amortization period remaining for intangible assets was 94 months.

Intangible assets consisted of the following:

<u>(in thousands)</u>	<u>Corporate Trade Name</u>	<u>Commercial Products</u>	<u>Total</u>
Cost Basis			
Balance at December 31, 2015	\$ 1,309	\$ 19,500	\$20,809
Additions	—	—	—
Balance at March 31, 2016	<u>\$ 1,309</u>	<u>\$ 19,500</u>	<u>\$20,809</u>
Accumulated Amortization			
Balance at December 31, 2015	\$ (486)	\$ (2,882)	\$ (3,368)
Amortization	(65)	(520)	(585)
Balance at March 31, 2016	<u>\$ (551)</u>	<u>\$ (3,402)</u>	<u>\$ (3,953)</u>
Net book value at March 31, 2016	<u>\$ 758</u>	<u>\$ 16,098</u>	<u>\$16,856</u>