

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)
 QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____

to _____

Commission File Number: 001-37746

APTEVO THERAPEUTICS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
2401 4th Avenue, Suite 1050
Seattle, Washington
(Address of principal executive offices)

81-1567056
(I.R.S. Employer
Identification No.)

98121
(Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

| | | | |
|-------------------------|--|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> (Do not check if a smaller reporting company) | Smaller reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input checked="" type="checkbox"/> |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act). Yes No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 8, 2017, the number of shares of Registrant's common stock outstanding was 21,419,356.

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In this Quarterly Report on Form 10-Q, “we,” “our,” “us,” “Aptevo,” and “the Company” refer to Aptevo Therapeutics Inc. and, where appropriate, its consolidated subsidiaries.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts, unaudited)

| ASSETS | June 30, 2017 | December 31, 2016 |
|--|------------------|-------------------|
| Current assets: | | |
| Cash and cash equivalents | \$ 22,269 | \$ 9,676 |
| Restricted cash | 400 | 400 |
| Short-term investments | 25,958 | 44,849 |
| Accounts receivable, net | 4,715 | 4,284 |
| Inventories | 7,984 | 6,639 |
| Prepaid expenses and other current assets | 5,867 | 5,566 |
| Total current assets | 67,193 | 71,414 |
| Property and equipment, net | 6,205 | 5,910 |
| Intangible assets, net | 13,493 | 14,534 |
| Total assets | <u>\$ 86,891</u> | <u>\$ 91,858</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and other accrued liabilities | \$ 5,349 | \$ 11,489 |
| Accrued compensation | 2,944 | 4,009 |
| Sales rebates and discounts | 2,146 | 3,235 |
| Deferred revenue, current portion | 1,444 | 811 |
| Total current liabilities | 11,883 | 19,544 |
| Deferred revenue, net of current portion | 2,796 | 2,896 |
| Long-term debt, net | 18,745 | 18,383 |
| Other liabilities | 2,047 | 469 |
| Total liabilities | <u>35,471</u> | <u>41,292</u> |
| Stockholders' equity: | | |
| Preferred stock: \$0.001 par value; 15,000,000 shares authorized, zero shares issued or outstanding | — | — |
| Common stock: \$0.001 par value; 500,000,000 shares authorized; 21,309,744 and 20,271,737 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively | 21 | 20 |
| Additional paid-in capital | 153,239 | 151,271 |
| Accumulated other comprehensive loss | (14) | (33) |
| Contribution receivable from former parent | — | (20,000) |
| Accumulated deficit | (101,826) | (80,692) |
| Total stockholders' equity | 51,420 | 50,566 |
| Total liabilities and stockholders' equity | <u>\$ 86,891</u> | <u>\$ 91,858</u> |

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts, unaudited)

| | <u>For the Three Months Ended June 30,</u> | | <u>For the Six Months Ended June 30,</u> | |
|---|--|-------------------|--|-------------------|
| | <u>2017</u> | <u>2016</u> | <u>2017</u> | <u>2016</u> |
| Revenues: | | | | |
| Product sales | \$ 10,750 | \$ 10,159 | \$ 18,131 | \$ 18,107 |
| Collaborations | 14 | 34 | 42 | 153 |
| Total revenues | <u>10,764</u> | <u>10,193</u> | <u>18,173</u> | <u>18,260</u> |
| Costs and expenses: | | | | |
| Cost of product sales | 5,897 | 6,544 | 6,385 | 10,072 |
| Research and development | 6,788 | 7,636 | 12,701 | 15,737 |
| Selling, general and administrative | 8,755 | 8,858 | 19,302 | 18,278 |
| Loss from operations | <u>(10,676)</u> | <u>(12,845)</u> | <u>(20,215)</u> | <u>(25,827)</u> |
| Other income (expense): | | | | |
| Other income (expense), net | (513) | (4) | (919) | 76 |
| Total other income (expense), net | <u>(513)</u> | <u>(4)</u> | <u>(919)</u> | <u>76</u> |
| Loss before income taxes | (11,189) | (12,849) | (21,134) | (25,751) |
| Benefit from income taxes | — | (11) | — | (23) |
| Net loss | <u>(11,189)</u> | <u>(12,838)</u> | <u>(21,134)</u> | <u>(25,728)</u> |
| Net loss per share - basic and diluted | <u>\$ (0.53)</u> | <u>\$ (0.63)</u> | <u>\$ (1.01)</u> | <u>\$ (1.27)</u> |
| Shares used to compute net loss per share - basic and diluted | <u>21,265,599</u> | <u>20,229,849</u> | <u>21,012,760</u> | <u>20,229,849</u> |

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aptevo Therapeutics Inc.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands, unaudited)

| | <u>For the Three Months Ended June 30,</u> | | <u>For the Six Months Ended June 30,</u> | |
|--|--|--------------------|--|--------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Net loss | \$ (11,189) | \$ (12,838) | \$ (21,134) | \$ (25,728) |
| Other comprehensive loss: | | | | |
| Unrealized losses on available-for-sale investments, net | (6) | — | (14) | — |
| Total comprehensive loss | <u>\$ (11,195)</u> | <u>\$ (12,838)</u> | <u>\$ (21,148)</u> | <u>\$ (25,728)</u> |

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands, unaudited)

| | <u>For the Six Months Ended June 30,</u> | |
|---|--|-----------------|
| | <u>2017</u> | <u>2016</u> |
| Operating Activities | | |
| Net loss | \$ (21,134) | \$ (25,728) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 2,779 | 734 |
| Depreciation and amortization | 2,175 | 1,717 |
| Income taxes | — | (23) |
| Change in fair value of contingent consideration | — | 19 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (431) | (2,058) |
| Inventories | (1,345) | 192 |
| Prepaid expenses and other current assets | (302) | (1,565) |
| Accounts payable, accrued compensation and other liabilities | (5,724) | (198) |
| Sales rebates and discounts | (1,089) | 274 |
| Deferred revenue | 533 | (3,427) |
| Net cash used in operating activities | <u>(24,538)</u> | <u>(30,063)</u> |
| Investing Activities | | |
| Purchases of property and equipment | (970) | (1,979) |
| Purchases of investments | (10,279) | — |
| Proceeds from the maturity of investments | 29,189 | — |
| Net cash provided by (used in) investing activities | <u>17,940</u> | <u>(1,979)</u> |
| Financing Activities | | |
| Payments for taxes related to net share settlement of equity awards | (809) | — |
| Settlement of contribution receivable from former parent | 20,000 | — |
| Transfer from former parent, prior to spin-off | — | 33,573 |
| Restricted cash | — | (400) |
| Contingent consideration payments | — | (272) |
| Net cash provided by financing activities | <u>19,191</u> | <u>32,901</u> |
| Increase in cash and cash equivalents | 12,593 | 859 |
| Cash and cash equivalents at beginning of period | 9,676 | 4,637 |
| Cash and cash equivalents at end of period | <u>\$ 22,269</u> | <u>\$ 5,496</u> |

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aptevo Therapeutics Inc.
Notes to Unaudited Consolidated Financial Statements

Note 1. Nature of Business and Significant Accounting Policies

Organization and Basis of Presentation

We are 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 have four revenue-generating products in the areas of hematology and infectious diseases, as well as various investigational stage product candidates in immuno-oncology.

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include normal recurring adjustments, necessary for the fair presentation of the Company's financial position.

On August 6, 2015, Emergent BioSolutions Inc., (Emergent or former parent), announced a plan to separate into two independent publicly traded companies. To accomplish this separation, Emergent created Aptevo Therapeutics Inc. or Aptevo, to be the parent company for the development-based biotechnology business focused on novel oncology and hematology therapeutics. Aptevo was incorporated in Delaware in February 2016 as a wholly owned subsidiary of Emergent. To effect the separation, Emergent made a pro rata distribution of Aptevo's common stock to Emergent's stockholders on August 1, 2016. We are currently trading on the NASDAQ Global Market under the symbol "APVO."

Prior to August 1, 2016, the consolidated financial statements were prepared on a "carve-out" basis for the purpose of presenting Aptevo's financial position, results of operations, and cash flows, and were derived from Emergent's consolidated financial statements and accounting records. 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 prior to August 1, 2016. The consolidated financial statements reflect Aptevo's financial position, results of operations, and cash flows as a separately operated business in conformity with GAAP post the August 1, 2016 spin-off.

Prior to August 1, 2016, the consolidated financial statements included an allocation of certain assets and liabilities that have historically been held at the Emergent corporate level but which were 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 consolidated financial statements at the time the transaction was recorded. The total net effect of the settlement of these intercompany transactions is reflected in the consolidated statement of cash flows as a financing activity and in the consolidated balance sheet as a net investment from Emergent. As of August 1, 2016, in connection with the separation and distribution, Emergent's investment in the Company's business was redesignated as stockholder's equity and allocated between common stock and additional paid-in capital based on the number of shares issued at the distribution date.

Prior to August 1, 2016, Aptevo's consolidated financial statements included an allocation of expenses related to certain Emergent corporate functions, including senior management, legal, human resources, finance, information technology, and quality assurance. These expenses were 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.

Prior to August 1, 2016, the income tax amounts in these consolidated financial statements were calculated based on a separate return methodology and presented as if Aptevo's operations were a standalone taxpayer in each of its tax jurisdictions.

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 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.

Revenue Recognition

We recognize revenue 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. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time as all criteria are met.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, which deferred the effective date of the new revenue standard for periods beginning after December 15, 2016 to December 15, 2017, with early adoption permitted but not earlier than the original effective date. Accordingly, the updated standard is effective for the Company in the first quarter of fiscal 2018. Aptevo has assembled a cross functional team to identify the population of contracts with customers and evaluate them under the provisions of ASU No. 2014-09. Aptevo is currently expecting to use the modified retrospective method to adopt this standard and is continuing to assess all of the potential impacts of the new standard on its consolidated financial statements and related disclosures, although we do not expect the implementation to have a material impact.

In August 2014, the FASB issued ASU No. 2014-15 Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management is required to assess an entity's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. The provisions of this standard are effective for annual periods ending after December 31, 2016, and for annual and interim periods thereafter. Aptevo adopted this guidance for the year ended December 31, 2016 and management believes that Aptevo's existing cash, cash equivalents and short-term investments will be sufficient to fund its operations through at least the third quarter of 2018.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize a lease liability and a right-of-use asset for all leases (with the exception of short term leases) at the commencement date. Lessor accounting under ASU 2016-02 is largely unchanged. ASU 2016-02 is effective for annual and interim periods beginning on or after December 15, 2018 and early adoption is permitted. Under ASU 2016-02, lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. Lessees and lessors may not apply a full retrospective transition approach. The ASU will be effective for the Company starting on January 1, 2019. Aptevo is continuing to evaluate the impact of the application of this ASU on our consolidated financial statements and disclosures. We expect to recognize right of use assets and lease liabilities.

In March 2016, the FASB issued ASU 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." ASU 2016-09 simplifies the accounting for share-based payment award transactions including the financial statement presentation of excess tax benefits and deficiencies, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. Aptevo adopted this standard effective January 1, 2017. Upon adoption of the standard, excess tax benefits and deficiencies resulting from stock-based compensation awards vesting and exercises are now recognized as discrete items in the statement of operations. Aptevo has elected to maintain its current forfeitures policy and will continue to include an estimate of forfeitures when recognizing stock-based compensation expense. Additionally, cash paid by Aptevo when directly withholding shares for tax withholding purposes will continue to be classified as a financing activity in the condensed consolidated statement of cash flows as required by the standard. The adoption of this standard did not have a material impact on Aptevo's consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments," which clarifies the classification and presentation of eight specific cash flow issues in the statement of cash flows. This standard is effective beginning January 1, 2018, with early adoption permitted. The new standard requires a retrospective transition. Aptevo is aware the adoption of this standard will have an impact for restricted cash, and evaluating further impacts on its consolidated financial statements.

Note 2. MorphoSys Collaboration Agreement

In August 2014, Aptevo entered into a collaboration agreement with MorphoSys AG (MorphoSys Agreement) 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 receive 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 I 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, no safety issues related to the development of ADA were observed. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol was amended to a continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. The MOR209/ES414 Phase I clinical trial under the amended protocol, providing continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA, commenced December 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, we and MorphoSys amended the collaboration agreement to (1) decrease the additional contingent payments due to us 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 us to up to approximately \$250 million and (3) change the jointly funded development cost allocation. 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 I 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. In December 2016, the collaboration agreement was further amended to adjust the allocation of certain manufacturing and development costs and extend MorphoSys's convenience termination rights. In June 2017, the collaboration agreement was further amended to extend the periods pertaining to the development costs. Under the amendment, we will bear 75% of all development costs with respect to MOR209/ES414, and MorphoSys will bear 25% of such costs, during the period from January 1, 2017 through August 31, 2017. During the period from September 1, 2017 through December 31, 2018, we will bear 49% of such development costs and MorphoSys will bear 51%. Beyond January 1, 2019, we would bear 36% and MorphoSys will bear 64% of such development costs.

In addition, under the revised termination rights, MorphoSys can terminate the collaboration for convenience (i) within one week following the receipt and discussion of certain test results or (ii) at any time during the last two weeks of August 2017.

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 I 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. In 2014, 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 \$0.1 million and \$0.2 million, respectively, recognized in the three months ended June 30, 2017 and 2016, and \$0.2 million and \$0.2 million in the six months ended June 30, 2017 and 2016. 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 six months ended June 30, 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. For the three months ended June 30, 2017 and June 30, 2016, Aptevo recorded a reduction to research and development expense of \$0.2 million and \$0.6 million, and for the six months ended June 30, 2017 and June 30, 2016, \$0.3 million and \$0.1 million, respectively. As of June 30, 2017, the MorphoSys Agreement related accounts receivable balance was \$0.0 million and the related total deferred revenue balance was \$3.7 million.

Note 3. Fair Value Measurements

The Company's estimates of fair value for financial assets and financial liabilities are based on the framework established in the fair value accounting guidance. The framework is based on the inputs used in valuation, gives the highest priority to quoted prices in active markets and requires that observable inputs be used in the valuations when available. The disclosure of fair value estimates in the fair value accounting guidance hierarchy is based on whether the significant inputs into the valuation are observable. In determining the level of the hierarchy in which the estimate is disclosed, the highest priority is given to unadjusted quoted prices in active markets and the lowest priority to unobservable inputs that reflect the Company's significant market assumptions. The level in the fair value hierarchy within which the fair value measurement is reported is based on the lowest level input that is significant to the measurement in its entirety. The three levels of the hierarchy are as follows:

Level 1— Quoted prices in active markets for identical assets and liabilities;

Level 2— Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3— Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial assets measured at fair value consisted of the following as of June 30, 2017 and December 31, 2016:

| (in thousands) | June 30, 2017 | | | |
|--|------------------|------------------|-------------|------------------|
| | Level 1 | Level 2 | Level 3 | Total |
| Financial Assets: | | | | |
| Money market funds | \$ 14,174 | \$ — | \$ — | \$ 14,174 |
| Corporate bonds | — | 5,979 | — | 5,979 |
| US government and agency debt securities | — | 19,979 | — | 19,979 |
| Total assets | \$ 14,174 | \$ 25,958 | \$ — | \$ 40,132 |

| (in thousands) | December 31, 2016 | | | |
|--|-------------------|------------------|-------------|------------------|
| | Level 1 | Level 2 | Level 3 | Total |
| Financial Assets: | | | | |
| Money market funds | \$ 5,215 | \$ — | \$ — | \$ 5,215 |
| Corporate bonds | — | 9,951 | — | 9,951 |
| US government and agency debt securities | — | 34,898 | — | 34,898 |
| Total assets | \$ 5,215 | \$ 44,849 | \$ — | \$ 50,064 |

If quoted market prices in active markets for identical assets are not available to determine fair value, then the Company uses quoted prices of similar instruments and other significant inputs derived from observable market data obtained from third-party data providers. These investments are included in Level 2 and consist of debt securities of U.S. government agencies and corporate bonds. There were no transfers between Levels 1 and 2 during the three and six months ended June 30, 2017.

Cash held in demand deposit accounts of \$8.1 million and \$4.4 million is excluded from our fair-value hierarchy disclosure as of June 30, 2017 and December 31, 2016, respectively. The carrying amounts for receivables, accounts payable and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Note 4. Investments

Investments are classified as available-for-sale securities and are carried at fair value with unrealized temporary holding gains and losses excluded from net income or loss and reported in other comprehensive income or loss and also as a net amount in accumulated other comprehensive income or loss until realized. Available-for-sale securities are written down to fair value through income whenever it is necessary to reflect other than temporary impairments. The Company determined that the unrealized losses on its investments as of June 30, 2017 and December 31, 2016 were temporary in nature. The Company currently has the ability and does not intend to sell these investments before recovery of their amortized cost basis. All short-term investments are limited to a final maturity of less than one year from the reporting date.

| June 30, 2017 | | | | |
|--|---------------------------|---|--|---------------------------------|
| (in thousands) | Amortized Cost | Gross Unrealized Holding Gains | Gross Unrealized Holding (Losses) | Estimated Fair Value |
| Cash equivalents: | | | | |
| Money market fund | \$ 14,174 | \$ — | \$ — | \$ 14,174 |
| Total cash equivalents | <u>\$ 14,174</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 14,174</u> |
| Short-term investments: | | | | |
| Corporate bonds | \$ 5,983 | \$ — | \$ (4) | \$ 5,979 |
| US government and agency debt securities | 19,989 | — | (10) | 19,979 |
| Total short-term investments | <u>\$ 25,972</u> | <u>\$ —</u> | <u>\$ (14)</u> | <u>\$ 25,958</u> |
| December 31, 2016 | | | | |
| (in thousands) | Amortized Cost | Gross Unrealized Holding Gains | Gross Unrealized Holding (Losses) | Estimated Fair Value |
| Cash equivalents: | | | | |
| Money market fund | \$ 5,215 | \$ — | \$ — | \$ 5,215 |
| Total cash equivalents | <u>\$ 5,215</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 5,215</u> |
| Short-term investments: | | | | |
| Corporate bonds | \$ 9,959 | \$ 1 | \$ (9) | \$ 9,951 |
| US government and agency debt securities | 34,923 | — | (25) | 34,898 |
| Total short-term investments | <u>\$ 44,882</u> | <u>\$ 1</u> | <u>\$ (34)</u> | <u>\$ 44,849</u> |

Note 5. Inventories

Inventories consist of the following:

| <u>(in thousands)</u> | <u>June 30,</u> <u>2017</u> | <u>December 31,</u> <u>2016</u> |
|----------------------------|--------------------------------|------------------------------------|
| Raw materials and supplies | \$ 249 | \$ 260 |
| Work-in-process | 1,639 | 1,165 |
| Finished goods | 6,096 | 5,214 |
| Total inventories | <u>\$ 7,984</u> | <u>\$ 6,639</u> |

CMC ICOS Biologics, Inc. (CMC) is the sole manufacturer of bulk drug substance for the 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. On October 4, 2016, we provided a Notice of Interruption in Manufacturing, or Notice, to the U.S. Food and Drug Administration (FDA), notifying the FDA of a potential interruption in the supply of IXINITY due to the ongoing manufacturing challenges with the manufacturer of the bulk drug substance. On March 15, 2017, we announced the successful manufacture of a new bulk drug substance batch of IXINITY, providing new supply of IXINITY for the commercial market in May 2017. While we do not currently anticipate or foresee a supply shortage or supply interruption occurring, any supply shortage or supply interruption of IXINITY would adversely affect its sales and could adversely affect its market position, commercial viability and the trading price of our common stock.

On June 17, 2017, the Company and CMC entered into a new non-exclusive Amended and Restated Commercial Supply, or Restated Supply Agreement, for the commercial development and manufacture of IXINITY. Pursuant to the terms of the Restated Supply Agreement, CMC agreed to manufacture IXINITY in the quantity of batches provided to CMC on a twenty-four month rolling forecast. Beginning 2018, the minimum and maximum batches will be four and ten, respectively, in a calendar year. Multiple batches ordered in succession with no changeover to another product between batches, or a campaign, shall receive an incremental discounted price.

In accordance with the Restated Supply Agreement, a \$7.0 million reserve held by CMC will be applied to, at a minimum, the next four batches manufactured through the end of 2017 as a price concession. As a result, at least the next four batches will have no raw materials or other related CMC costs associated with the inventory. Aptevo will also see an impact on the Company's statement of operations due to a lower costs of goods sold associated with this inventory, which will also result in higher gross margins as sales are recognized. Any portion of the \$7.0 million reserve held by CMC that remains unutilized as of December 25, 2017 shall be paid to the Company in cash on or before December 31, 2017. The Restated Supply Agreement has a five-year term renewable with twenty-four months' prior notice before the expiry of the term for successive two-year terms.

Note 6. Debt

Credit Facility

On August 4, 2016, we entered into a \$35.0 million Credit and Security Agreement (the Credit Agreement) with MidCap Financial Trust. The Credit Agreement provides us with up to \$35.0 million of available borrowing capacity, available (subject to certain conditions) in two tranches of \$20.0 million and \$15.0 million, respectively, through August 31, 2017. The loan repayment will include interest (no principal) through August 2018. Commencing in August 2018, the payments will include principal and interest and will be repaid in full on February 1, 2021 (54 months). Amounts drawn under the Credit Agreement bear interest at a rate of LIBOR plus 7.60% per annum. The first tranche of \$20.0 million was funded on the closing date of the Credit Agreement with the second tranche of \$15.0 million becoming available (subject to certain conditions) following the date Aptevo and its subsidiaries: (1) achieve net commercial product revenue of \$40.0 million on a trailing twelve-month basis, and (2) receive an additional \$20.0 million in cash from Emergent. Emergent made this payment on January 13, 2017. We paid debt issuance costs of \$1.9 million of which \$1.5 million remains unamortized at June 30, 2017.

The Credit Agreement contains financial covenants that require us and our subsidiaries to maintain increasing minimum net commercial product revenue for each twelve-month period ending on the last day of each calendar quarter, commencing with the twelve-month period ending September 30, 2016. As of March 31, 2017, the Company's net minimum revenue did not meet the required minimum for the twelve months ended March 31, 2017.

As a result, on May 11, 2017, we and MidCap Financial Trust entered into an amendment to the Credit Agreement to, among other things, waive the existing event of default and revise the financial covenants pertaining to the minimum required commercial product revenue for the twelve months ended March 31, 2017 and future rolling twelve month periods. As a result of the amendment, the Company was in compliance with the modified minimum net revenue covenant for the three and six months ended June 30, 2017. As such, amounts owed under the Credit Facility are classified based on their contractual maturities.

In addition, the amendment revises the provisions of the Credit Agreement to: (1) extend the time period through which the Company can draw the second tranche from August 2017 to March 2018, (2) increase the exit fee of 5.75% of the aggregate principal amount under the Credit Agreement for repayment or prepayment other than scheduled amortization payments and the final payment of principal to 6.75% and (3) permit MidCap Financial Trust to obtain an affirmative lien on the intellectual property of the Company, upon the earlier of (i) the Company's draw down of the second tranche or (ii) the Company's cash, cash equivalents, and short-term investments balance descend below a minimum cash threshold of \$25 million.

Note 7. Net Loss per Share

Net loss per share is calculated by dividing the net loss of the Company by the number of weighted shares outstanding during the period, and the number of shares issued during the spin-off for prior periods. Prior to the spin-off, Aptevo did not operate as a separate entity and as a result did not have any common stock outstanding other than 1,000 shares held by Emergent. The calculation of basic and diluted net loss per share assumes that the 20,229,849 ordinary shares issued to Aptevo stockholders in connection with the spin-off were outstanding from the beginning of the periods presented. Diluted earnings per share is calculated using the weighted average number of common shares outstanding plus dilutive common stock equivalents outstanding during the period. Common stock equivalents are excluded for the six month periods ended June 30, 2017 and 2016, respectively since the effect is anti-dilutive due to the Company's net losses. Common stock equivalents include stock options and unvested RSUs. .

The following table represents all potentially dilutive shares, which were all anti-dilutive and therefore excluded from the calculation of diluted net loss per share:

| <u>(in thousands, except for per share amounts)</u> | <u>For the Six Months Ended June 30,</u> | |
|---|--|-------------|
| | <u>2017</u> | <u>2016</u> |
| Outstanding options to purchase common stock | 3,020 | — |
| Unvested RSUs | 1,450 | — |

Note 8. Equity

Capitalization Upon Spin-off

On August 1, 2016, in connection with the spin-off of the Company from Emergent, we issued 20.2 million shares to Emergent stockholders and recorded a contribution from Emergent of \$71.2 million. The transactions recorded in 2016 included a one-time payment of \$45.0 million, and a working capital reimbursement for outstanding payments of \$1.4 million, a noncash transfer of an intangible asset of \$0.7 million, and a net transfer of cash from Emergent of \$24.2 million. In addition, in the first quarter of 2017 we received \$20.0 million as payment for a promissory note issued at the time of the spin-off.

Converted Equity Awards Incentive Plan

The Company had no stock-based compensation plans of its own prior to the spin-off from Emergent; however certain Aptevo employees participated in Emergent's stock-based compensation plans (Emergent Plans), which provided for the grants of stock options and restricted stock units (RSUs). The expense associated with Aptevo employees who participated in the Emergent Plans was allocated to the Company in the accompanying Statements of Operations for the associated periods prior to the spin off.

In connection with the spin-off the Company adopted the Converted Equity Awards Incentive Plan (the Converted Plan) and outstanding equity awards of Emergent held by Aptevo employees (the Converted Awards) were converted into or replaced with equity awards of Aptevo (the Conversion Awards) under the Converted Plan and were adjusted to maintain the economic value before and after the distribution date using the relative fair market value of the Emergent and Aptevo common stock based on the closing prices as of August 1, 2016. There was no significant incremental stock-based compensation expense recorded as a result of the equity award conversion. A total of 1.3 million shares of Aptevo common stock have been authorized for issuance under the Converted Plan. Options issued as Conversion Awards were priced according to the Converted Plan. RSUs issued as part of the Converted Plan provide for the issuance of a share of the Company's stock at no cost to the holder.

2016 Stock Incentive Plan

On August 1, 2016, the Company adopted the 2016 Stock Incentive Plan (2016 SIP). A total of 3.1 million shares of Aptevo common stock have been authorized for issuance under the 2016 SIP in the form of incentive stock options.

Stock options under the 2016 SIP generally vest pro rata over a three-year period and terminate ten years from the grant date, though the specific terms of each grant are determined individually. The Company's executive officers and certain other employees may be awarded options with different vesting criteria, and options granted to non-employee directors also vest over a three-year period. Option exercise prices for new options granted by the Company equal the closing price of the Company's common stock on the NASDAQ Global Market on the date of grant.

RSUs issued under the 2016 SIP provide for the issuance of a share of the Company's common stock at no cost to the holder. RSUs granted to employees under the 2016 SIP generally provide for time-based vesting over an eighteen-month to three-year period, although certain employees may be awarded RSUs with different time-based vesting criteria. Prior to vesting, RSUs granted under the 2016 SIP do not have dividend equivalent rights, do not have voting rights and the shares underlying the RSUs are not considered issued or outstanding.

The equity compensation awards granted by the Company generally vest only if the employee is employed by the Company (or in the case of directors, the director continues to serve on the Board) on the vesting date.

On May 31, 2017, at the 2017 Annual Meeting of Stockholders (Annual Meeting), the Company's stockholders approved the amendment and restatement of the Company's 2016 SIP (Restated 2016 Plan) to, among other things, increase the number of authorized shares issuable by 1.275 million shares of Aptevo common stock. The Restated 2016 Plan was previously approved, subject to stockholder approval, by the Board of Directors of the Company. The Restated 2016 Plan became effective immediately upon stockholder approval at the Annual Meeting.

Stock-Based Compensation Expense

Stock-based compensation expense includes amortization of stock options and RSUs granted to employees and non-employees and has been reported in our Condensed Consolidated Statements of Operations as follows:

| (in thousands) | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|---|--|---------------|--|---------------|
| | 2017 | 2016 | 2017 | 2016 |
| Research and development | \$ 544 | \$ 400 | \$ 1,236 | \$ 734 |
| General and administrative | 556 | — | 1,543 | — |
| Total stock-based compensation expense | \$ 1,100 | \$ 400 | \$ 2,779 | \$ 734 |

The Company accounts for stock-based compensation by measuring the fair value of the award as of the grant date, recognizing the compensation expense for that fair value, reduced for an estimate of forfeitures, over the vesting period.

Stock Options

Aptevo 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:

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|----------------------------------|--|-------------|--|-------------|
| | 2017 | 2016 | 2017 | 2016 |
| Expected dividend yield | 0.00% | — | 0.00% | — |
| Expected volatility | 75.00% | — | 75.00% | — |
| Risk-free interest rate | 1.88% | — | 1.91% | — |
| Expected average life of options | 6.00 years | — | 5.94 years | — |

Management applied an estimated forfeiture rate of 10%.

The following is a summary of option activity for the six months ended June 30, 2017:

| | Number of Shares | Weighted- Average Exercise Price | Weighted- Average Remaining Term | Aggregate Intrinsic Value |
|------------------------------|---------------------|--|--|---------------------------------|
| Balance at December 31, 2016 | 2,085,214 | \$ 2.57 | | \$ 164,767 |
| Granted | 993,339 | 2.07 | | — |
| Forfeited | (57,833) | 2.34 | | 3,329 |
| Outstanding at June 30, 2017 | 3,020,720 | \$ 2.41 | 7.12 | \$ 111,626 |
| Exercisable at June 30, 2017 | 1,170,395 | \$ 2.42 | 4.35 | \$ 62,765 |

As of June 30, 2017, we had \$1.9 million of unrecognized compensation expense related to options expected to vest over a weighted average period of 2.2 years.

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the closing stock price of Aptevo's common stock on the last trading day of June 30, 2017 and the exercise price, multiplied by the number of in the money options) that would have been received by the option holders had all the option holders exercised their options on June 30, 2017. The amount of aggregate intrinsic value will change based on the price of Aptevo's common stock.

Restricted Stock Units

The following is a summary of RSU activity for the six months ended June 30, 2017:

| | Number of Units | Weighted Average Fair Value per Unit | Aggregate Fair Value |
|------------------------------|--------------------|--|-------------------------|
| Balance at December 31, 2016 | 3,034,195 | \$ 2.88 | \$ — |
| Granted | 19,803 | 2.00 | — |
| Vested | (1,426,795) | 2.84 | — |
| Forfeited | (177,527) | 2.95 | — |
| Outstanding at June 30, 2017 | 1,449,676 | \$ 2.91 | \$ 3,000,829 |
| Expected to Vest | 1,333,874 | \$ 2.91 | \$ 2,761,119 |

As of June 30, 2017, we had \$2.3 million of unrecognized compensation expense related to RSUs expected to vest over a period of 0.9 years. The weighted average remaining contractual life of unvested RSUs is 3.2 years.

The fair value of each RSU has been determined to be the closing trading price of the Company's common shares on the date of grant as quoted in NASDAQ Global Market.

Note 9. Subsequent Events

On July 20, 2017, our wholly owned subsidiary, Aptevo entered into a collaboration and option agreement with Alligator Bioscience AB, or Alligator, pursuant to which Aptevo and Alligator will collaboratively develop ALG.APV-527, a lead bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a costimulatory receptor found on activated T cells, and an undisclosed tumor antigen widely overexpressed in a number of different types of cancer. This product candidate is built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. Under this collaboration agreement, Alligator also granted to Aptevo a time-limited option to enter into a second agreement with Alligator for the joint development of a separate bispecific antibody candidate simultaneously targeting 4-1BB (CD137) and an undisclosed tumor antigen that Aptevo and Alligator will collaboratively select.

In accordance with the terms of this collaboration agreement, the parties intend to develop the lead bispecific antibody candidate targeting 4-1BB (CD137) through the completion of Phase II clinical trials in accordance with an agreed upon development plan and budget. Subject to certain exceptions for Aptevo's manufacturing and platform technologies, the parties will jointly own intellectual property generated in the performance of the development activities under this collaboration agreement.

Following the completion of the anticipated development activities under this collaboration agreement, the parties intend to seek a third-party commercialization partner for this product candidate, or, in certain circumstances, may elect to enter into a second agreement granting rights to either Aptevo or Alligator to allow such party to continue the development and commercialization of this product. Under the terms of this collaboration agreement, the parties intend to share revenue received from a third-party commercialization partner equally, or, if the development costs are not equally shared under this collaboration agreement, in proportion to the development costs borne by each party.

This collaboration agreement also contains several points in development in which either party may elect to “opt-out” (i.e., terminate without cause) and, following a termination notice period, cease paying development costs for this product, which would be borne fully by the continuing party. Following an opt-out by a party, the party that did not opt-out will be granted exclusive rights to continue the development and commercialization of this product, subject to a requirement to pay a percentage of revenue received from any future commercialization partner for this product, or, if the continuing party elects to self-commercialize, tiered royalties on the net sales of this product by the continuing party ranging from the low to mid-single digits, based on the point in development during which the ‘opt-out’ occurs. The parties have also agreed on certain technical criteria or ‘stage gates’ related to the development of this product that, if not met, will cause an automatic termination and wind-down of this collaboration agreement and the activities thereunder, provided that the parties do not agree to continue.

This collaboration agreement contains industry standard termination rights, including for material breach following a specified cure period, and in the case of a party’s insolvency.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

This quarterly report on Form 10-Q includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements in this quarterly report, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives could be forward-looking statements. The words “anticipates,” “believes,” “could,” “designed,” “estimates,” “expects,” “goal,” “intends,” “may,” “plans,” “projects,” “pursuing,” “will,” “would” and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, those discussed in “Risk Factors”, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this quarterly report. Our forward-looking statements in this quarterly report are based on current expectations and we do not assume any obligation to update any forward-looking statements.

You should read the following discussion and analysis together with the financial statements and the related notes to those statements included elsewhere in this report.

Overview

We are 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.

In August 2015, Emergent BioSolutions Inc., or Emergent, announced a 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. To accomplish this separation, Emergent created a new company, Aptevo Therapeutics Inc., or Aptevo, to be the parent company for the development-based biotechnology business focused on novel oncology and hematology therapeutics. We were incorporated in Delaware in February 2016 as a wholly owned subsidiary of Emergent. To effect the separation, Emergent made a pro rata distribution of Aptevo’s common stock to Emergent’s stockholders on August 1, 2016.

In connection with the separation, we received certain assets from Emergent’s biosciences division, including commercial products and development programs, as well as the ADAPTIR platform technology. Certain historical operations that were included by Emergent in its biosciences segment have been reallocated to Emergent’s continuing operations, and as a result the financial statements and discussion and analysis contained herein differ from Emergent’s historically reportable biosciences segment.

Our historical consolidated financial statements for the periods prior to August 1, 2016 have been prepared on a standalone basis and are derived from Emergent’s consolidated financial statements and accounting records. The consolidated financial statements reflect our financial position, results of operations, and cash flows as our business was operated as part of Emergent prior to the separation, in conformity with U.S. Generally Accepted Accounting Principles (GAAP).

The consolidated 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 us. Cash and cash equivalents held by Emergent were not allocated to us unless the cash was held by an entity that was transferred to us in the distribution. All of our intracompany transactions and accounts for the periods prior to August 1, 2016 have been eliminated. Most intercompany transactions between us and Emergent for the periods prior to August 1, 2016 were considered to be effectively settled in the consolidated financial statements at the time the transaction was recorded but for those transition related services. The total net effect of the settlement of these intercompany transactions is reflected in the consolidated statement of cash flows as payment from former parent upon spin-off, net of receivable and net transfer from former parent, prior to spin-off as a financing activity and in the consolidated balance sheet as former parent investment in subsidiary.

The historical financial statements do not necessarily include all of the expenses that would have been incurred had we been a separate, standalone entity and may not necessarily reflect our results of operations, financial position and cash flows had we been a standalone company during the periods presented. Our consolidated financial statements for the periods prior to August 1, 2016 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 us 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. 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.

Net loss for the three months ended June 30, 2017, and 2016 was \$11.2 million and \$12.8 million, respectively, and net loss for the six months ended June 30, 2017 and 2016, was \$21.1 million and \$25.7 million, respectively. We had an accumulated deficit of \$101.8 million as of June 30, 2017. For the six months ended June 30, 2017, net cash used in our operating activities was \$24.5 million. We expect to experience operating losses and negative cash flows from operations for the foreseeable future. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, suspend or eliminate one or more of research and development programs. We will not generate revenues from our development stage product candidates unless and until we or our collaborators successfully complete development and obtain regulatory approval for such product candidates, which we expect will take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for one of our development stage product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such costs are not paid by collaborators. We do not have sufficient cash to complete the clinical development of any of our development stage product candidates and will require additional funding in order to complete the development activities required for regulatory approval of such product candidates.

Program Highlights

Our pipeline is composed of marketed products for hematology indications and investigational stage candidates based on our ADAPTIR™ (modular protein technology) platform. 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 and functional advantages over monoclonal antibodies. Our investigational stage product candidates otlertuzumab, MOR209/ES414, ES210, and ALG.APV-527 a bispecific antibody candidate, featuring a novel mechanism of action targeting 4-1BB (CD137). The mechanisms of action for otlertuzumab, MOR209/ES414, ES210, APVO436 and ALG.APV-527 include direct tumor cytotoxicity, antibody-dependent cell-cytotoxicity, redirected T-cell cytotoxicity (RTCC), costimulation of anti-tumor T cells and targeted cytokine delivery. The structural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of other ADAPTIR immunotherapeutics that engage immune effector cells and disease targets in a novel manner to produce unique signaling responses. 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 APVO436 (a bispecific immunotherapeutic protein targeting CD123) product by way of our protein engineering, pre-clinical development and process development capabilities, cGMP manufacturing oversight and clinical development capabilities. We also have the ability to launch, market and commercialize these product candidates upon approval. Our marketed products are:

- 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;
- WinRho® SDF Rho(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; and
- VARIZIG® Varicella Zoster Immune Globulin (Human), for treatment following exposure to varicella zoster virus, which causes chickenpox, in high-risk individuals.

Our investigational stage product candidates include:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, that simultaneously targets prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells and, CD3, a component of the T-cell receptor complex expressed on all T-cells. The mechanism of action of MOR209/ES414 is RTCC. 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.
- an immunotherapeutic protein targeting 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 CD3. Initial preclinical data demonstrates RTCC activity in vitro and killing of tumors in animal models demonstrating that ROR1 can be targeted with an ADAPTIR bispecific.
- APVO436, a bispecific ADAPTIR protein therapeutic currently in pre-clinical development targeting CD123, a cell surface receptor highly expressed on several hematological malignancies and CD3. Similar to MOR209/ES414 and the ROR1 preclinical program, APVO436 utilizes redirected RTCC to initiate killing of tumor cells.
- ALG.APV-527 a bispecific antibody candidate, featuring a novel mechanism of action designed to simultaneously target 4-1BB (CD137) and an undisclosed tumor antigen.
- Other therapeutic protein product candidates primarily targeting cancer based on mechanisms of action that modulate the immune system (immuno-oncology based mechanism of action).

Collaboration with Alligator Bioscience AB

On July 20, 2017, our wholly owned subsidiary, Aptevo Research and Development LLC, or Aptevo R&D, entered into a collaboration and option agreement with Alligator Bioscience AB, or Alligator, pursuant to which Aptevo R&D and Alligator will collaboratively develop ALG.APV-527, a lead bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a costimulatory receptor found on activated T cells, and an undisclosed tumor antigen widely overexpressed in a number of different types of cancer. This product candidate is built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. Under this collaboration agreement, Alligator also granted to Aptevo R&D a time-limited option to enter into a second agreement with Alligator for the joint development of a separate bispecific antibody candidate simultaneously targeting 4-1BB (CD137) and an undisclosed tumor antigen that Aptevo R&D and Alligator will collaboratively select.

In accordance with the terms of this collaboration agreement, the parties intend to develop the lead bispecific antibody candidate targeting 4-1BB (CD137) through the completion of Phase II clinical trials in accordance with an agreed upon development plan and budget. Subject to certain exceptions for Aptevo R&D's manufacturing and platform technologies, the parties will jointly own intellectual property generated in the performance of the development activities under this collaboration agreement.

Following the completion of the anticipated development activities under this collaboration agreement, the parties intend to seek a third-party commercialization partner for this product candidate, or, in certain circumstances, may elect to enter into a second agreement granting rights to either Aptevo R&D or Alligator to allow such party to continue the development and commercialization of this product. Under the terms of this collaboration agreement, the parties intend to share revenue received from a third-party commercialization partner equally, or, if the development costs are not equally shared under this collaboration agreement, in proportion to the development costs borne by each party.

This collaboration agreement also contains several points in development in which either party may elect to “opt-out” (i.e., terminate without cause) and, following a termination notice period, cease paying development costs for this product, which would be borne fully by the continuing party. Following an opt-out by a party, the party that did not opt-out will be granted exclusive rights to continue the development and commercialization of this product, subject to a requirement to pay a percentage of revenue received from any future commercialization partner for this product, or, if the continuing party elects to self-commercialize, tiered royalties on the net sales of this product by the continuing party ranging from the low to mid-single digits, based on the point in development during which the ‘opt-out’ occurs. The parties have also agreed on certain technical criteria or ‘stage gates’ related to the development of this product that, if not met, will cause an automatic termination and wind-down of this collaboration agreement and the activities thereunder, provided that the parties do not agree to continue.

This collaboration agreement contains industry standard termination rights, including for material breach following a specified cure period, and in the case of a party’s insolvency.

Collaboration with MorphoSys AG

In August 2014, we entered into a collaboration agreement, or MorphoSys Agreement, with MorphoSys AG, or 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 our proprietary ADAPTIR™ platform technology.

In accordance with the initial terms of the MorphoSys Agreement, we 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 agreed to jointly fund further development of MOR209/ES414, with us responsible for 36% of the total development costs and MorphoSys responsible for the remainder, with our funding requirement capped at \$186.0 million. Our development effort includes the performance of non-clinical, clinical, manufacturing and regulatory activities. We retain commercialization rights in the United States 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 United States and Canada, with a low single digit royalty obligation to us.

In December 2015, after a joint review of data from the ongoing Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, we 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; called anti-drug antibodies, or 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 administer MOR209/ES414 by continuous intravenous infusion as a way to achieve higher levels of drug and potentially prevent the development of ADA. The MOR209/ES414 Phase I clinical trial under the amended protocol commenced December 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, we and MorphoSys amended the collaboration agreement to (1) decrease the additional contingent payments due to us 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 us to up to approximately \$250 million and (3) change the jointly funded development cost allocation. 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. 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. In December 2016, the collaboration agreement was further amended to adjust the allocation of certain manufacturing and development costs and extend MorphoSys’s convenience termination rights. In June 2017, the collaboration agreement was further amended to extend the periods pertaining to the development costs. Under the amendment, we will bear 75% of all development costs with respect to MOR209/ES414, and MorphoSys will bear 25% of such costs, during the period from January 1, 2017 through August 31, 2017. During the period from September 1, 2017 through December 31, 2018, we will bear 49% of such development costs and MorphoSys will bear 51%. Beyond January 1, 2019, we would bear 36% and MorphoSys will bear 64% of such development costs.

In addition, under the revised termination rights, MorphoSys can terminate the collaboration for convenience (i) within one week following the receipt and discussion of certain test results or (ii) at any time during the last two weeks of August 2017.

We evaluated the MorphoSys Agreement and determined that it was a revenue arrangement with multiple deliverables or performance obligations. We 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. We 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. We allocated the \$20.0 million upfront payment to the two units of accounting using the relative selling price method. We 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. We 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 our 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. We 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 \$0.1 million and \$0.2 million, respectively, recognized in the three months ended June 30, 2017 and 2016, and \$0.2 and \$0.2, respectively, in the six months ended June 30, 2017 and 2016. The current estimated service period for the undelivered development services under the MorphoSys Agreement is through 2023.

Further, we 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. We 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. We 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, we acquired the IXINITY® product candidate, an IPR&D intangible asset. As part of the purchase price allocation, our 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, we 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 ten years. The clinical trial activities are associated with: (1) obtaining licensure of IXINITY for pediatric use (children under the age of 12); and (2) continued treatment of clinical subjects as part of a post-licensure extension clinical study required by the FDA. The development and qualification expenses are primarily associated with: (1) ongoing non-clinical process development studies related to the optimization of the manufacturing of drug substance (2); continuation of pre-licensure stability study commitments; (3) developing fill/finish capabilities at Emergent's Baltimore, MD fill/finish contract manufacturing facility.

CMC ICOS Biologics, Inc., or CMC, is the sole 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. During 2016, we ordered five manufacturing lots of bulk drug substance from CMC and none of these lots satisfied product release specifications. Additionally, Patheon UK Limited, through an affiliate, is currently the sole source fill-finish service manufacturer for our IXINITY product.

On October 4, 2016, we provided a Notice of Interruption in Manufacturing, or Notice, to the FDA, notifying the FDA of a potential interruption in the supply of IXINITY due to the ongoing manufacturing challenges associated with the manufacturer of the bulk drug substance. On March 15, 2017, we announced the successful manufacture of a new bulk drug substance batch of IXINITY, providing new supply of IXINITY for the commercial market in May 2017.

On June 17, 2017, the Company and CMC entered into a new non-exclusive Amended and Restated Commercial Supply, or Restated Supply Agreement, with CMC for the commercial development and manufacture of IXINITY. Pursuant to the terms of the Restated Supply Agreement, CMC agreed to manufacture IXINITY in the quantity of batches provided to CMC on a twenty-four month rolling forecast. Beginning 2018, the minimum and maximum batches will be four and ten, respectively in a calendar year. Multiple batches ordered in succession with no changeover to another product between batches, or a campaign, shall receive an incremental discounted price.

In accordance with the Restated Supply Agreement, a \$7.0 million reserve held by CMC will be applied to, at a minimum, the next four batches manufactured through the end of 2017 as a price concession. As a result, at least the next four batches will have no raw materials or other related CMC costs associated with the inventory. Aptevo will also see an impact on the Company's statement of operations due to a lower costs of goods sold associated with this inventory, which will also result in higher gross margins as sales are recognized. Any portion of the \$7 million reserve held by CMC that remains unutilized as of December 25, 2017 shall be paid to the Company in cash on or before December 31, 2017. The Restated Supply Agreement has a five-year term renewable with twenty-four months' prior notice before the expiry of the term for successive two-year terms.

While we do not currently anticipate or foresee a supply shortage or supply interruption occurring, any supply shortage interruption of IXINITY would adversely affect its sales and could adversely affect its market position, commercial viability and the trading price of our common stock.

Results of Operations

Comparison of the three and six months ended June 30, 2017 and June 30, 2016

Financial Summary

We recognized net losses of \$11.2 million and \$12.8 million for the three months ended June 30, 2017 and 2016, respectively and \$21.1 million and \$25.7 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, our accumulated deficit was \$101.8 million, and we had \$48.6 million in cash, cash equivalents and short-term investments available for general corporate use. In addition, we had restricted cash \$0.4 million that we are required to maintain in a depository as collateral for corporate credit cards.

Revenue

Product Sales

Sales by product for the three and six months ended June 30, 2017 and 2016, are shown in the following tables:

| (in thousands) | For the Three Months Ended June 30, | | Change | Percent |
|-----------------------|--|------------------|---------------|----------------|
| | 2017 | 2016 | | |
| IXINITY | \$ 3,511 | \$ 2,528 | \$ 983 | 39% |
| HepaGam | 2,773 | 2,296 | 477 | 21% |
| VARIZIG | 978 | 1,077 | (99) | -9% |
| WinRho | 3,488 | 4,258 | (770) | -18% |
| Total | \$ 10,750 | \$ 10,159 | \$ 591 | 6% |

| (in thousands) | For the Six Months Ended June 30, | | Change | Percent |
|-----------------------|--|------------------|---------------|----------------|
| | 2017 | 2016 | | |
| IXINITY | \$ 5,625 | \$ 4,772 | \$ 853 | 18% |
| HepaGam | 4,908 | 3,989 | 919 | 23% |
| VARIZIG | 1,521 | 1,637 | (116) | -7% |
| WinRho | 6,077 | 7,709 | (1,632) | -21% |
| Total | \$ 18,131 | \$ 18,107 | \$ 24 | 0% |

Product sales revenue increased by \$0.6 million, or to \$10.8 million for the three months ended June 30, 2017 from \$10.2 million for the three months ended June 30, 2016. This increase was primarily related to revenue associated with IXINITY, which increased by \$1.0 million as a result of increased sales due to the expansion of our current patient base, and from HepaGam, which had increased sales of \$0.5 million due to higher volumes related to customer incentives. These increases were offset by a decrease in revenue for WinRho of \$0.8 million, due lower sales as there is a slowing expansion of the patient base.

Product sales revenue was unchanged for the six months ended June 30, 2017, with sales of \$18.1 million for each of the six months ended June 30, 2017 and 2016. Although total sales were unchanged year-over-year, sales of HepaGam increased \$0.9 million in the current period as customer sales incentives were offered. Sales of IXINITY increased \$0.9 million due to increased product awareness in the market following the launch of IXINITY in 2015. Finally, sales of WinRho decreased by \$1.6 million due to lower sales of this product as the patient base is no longer expanding as the same rate as the prior year.

Cost of Product Sales

The primary expense 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 cost per unit.

The following table provides information regarding our cost of products sales, including gross margin for the three months and six months ended June 30, 2017 and 2016:

| | For the Three Months Ended June 30, | | Change | Percent |
|--------------------------------------|-------------------------------------|-----------|----------|---------|
| | 2017 | 2016 | | |
| Revenues: | | | | |
| Product sales | \$ 10,750 | \$ 10,159 | \$ 591 | 6% |
| Contracts, grants and collaborations | 14 | 34 | (20) | -59% |
| Total revenues | 10,764 | 10,193 | 571 | 6% |
| Costs and expenses: | | | | |
| Cost of product sales | 5,897 | 6,544 | (647) | -10% |
| Gross profit | \$ 4,867 | \$ 3,649 | \$ 1,218 | 33% |
| Gross margin percent | 45% | 36% | | |

| | For the Six Months Ended June 30, | | Change | Percent |
|--------------------------------------|-----------------------------------|-----------|----------|---------|
| | 2017 | 2016 | | |
| Revenues: | | | | |
| Product sales | \$ 18,131 | \$ 18,107 | \$ 24 | 0% |
| Contracts, grants and collaborations | 42 | 153 | (111) | -73% |
| Total revenues | 18,173 | 18,260 | (87) | 0% |
| Costs and expenses: | | | | |
| Cost of product sales | 6,385 | 10,072 | (3,687) | -37% |
| Gross profit | \$ 11,788 | \$ 8,188 | \$ 3,600 | 44% |
| Gross margin percent | 65% | 45% | | |

Cost of product sales decreased by \$0.6 million, or 10%, to \$5.9 million for the three months ended June 30, 2017 from \$6.5 million for the three months ended June 30, 2016. This decrease was due to lower sales costs associated with WinRho as the product sales also decreased, offset by increased costs associated with IXINITY and HepaGam.

Cost of product sales decreased by \$3.7 million, or 37%, to \$6.4 million for the six months ended June 30, 2017 from \$10.1 million for the six months ended June 30, 2016. This decrease was due to a one-time \$3.0 million settlement during the first six months of 2017 relating to a dispute between Aptevo and CMC in regards to certain IXINITY batches from 2015 that did not meet manufacturing specifications. Under the terms of the settlement agreement, Aptevo will not pay any additional amounts to CMC for the batches in question, as this was settled for non-cash consideration. This settlement satisfies the monies owed by Aptevo under a 2015 invoice and resolves any claims. Without the impact of this settlement, gross margin year-to-date would have been 48% compared to 45% year-to-date 2016.

Research and Development Expenses

We expense research and development costs as incurred. These expenses consist primary of personnel-related costs, 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.

Our principal research and development expenses by program for the three and six months ended June 30, 2017 and 2016 are shown in the following table:

| (in thousands) | For the Three Months Ended June 30, | | Change |
|------------------------------|-------------------------------------|-----------------|-----------------|
| | 2017 | 2016 | |
| ADAPTIR related programs (1) | \$ 2,276 | \$ 3,277 | \$ (1,001) |
| APVO436 | 1,791 | 30 | 1,761 |
| MOR209/ES414 | 795 | 825 | (30) |
| IXINITY | 619 | 1,140 | (521) |
| otlertuzumab | 413 | 830 | (417) |
| ROR1 | 867 | 1,434 | (567) |
| Other | 27 | 100 | (73) |
| Total | \$ 6,788 | \$ 7,636 | \$ (848) |

| (in thousands) | For the Six Months Ended June 30, | | Change |
|------------------------------|-----------------------------------|------------------|-------------------|
| | 2017 | 2016 | |
| ADAPTIR related programs (1) | \$ 4,539 | \$ 5,633 | \$ (1,094) |
| APVO436 | 3,158 | 34 | 3,124 |
| MOR209/ES414 | 1,367 | 2,010 | (643) |
| IXINITY | 1,437 | 4,132 | (2,695) |
| otlertuzumab | 664 | 1,278 | (614) |
| ROR1 | 1,504 | 2,506 | (1,002) |
| Other | 32 | 144 | (112) |
| Total | \$ 12,701 | \$ 15,737 | \$ (3,036) |

(1) ADAPTIR related programs also includes other non-disclosed candidates

Research and development expenses decreased by \$0.8 million, or 11%, to \$6.8 million for the three months ended June 30, 2017 from \$7.6 million for the three months ended June 30, 2016 and decreased by \$3.0 million, or 19%, to \$12.7 million for the six months ended June 30, 2017 from \$15.7 million for the six months ended June 30, 2016. This change was primarily comprised of:

- a decrease in ROR1 expenses primarily due to a reduction in the number characterization studies;
- a decrease in expense for IXINITY resulting from decreased manufacturing process development activities and the timing of clinical trial activities;
- a decrease in expense for MOR209/ES414 primarily due to the timing of manufacturing activities along with decreased reimbursement from MorphoSys for development activities under our collaboration agreement;
- a decrease in expense for otlertuzumab related to the timing of clinical trial activities;
- a decreased in the expenses for our other activities primarily related to centralized research and development activities not otherwise attributable to specific product candidates or programs;
- an increase in expense for our ADAPTIR related programs primarily due to an increase in characterization studies and non-clinical activities; and
- an increase in expense for APVO436, a new preclinical ADAPTIR molecule currently in the investigational stage.

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 expenses.

For the three months ended June 30, 2017 selling, general and administrative expenses decreased by \$0.1 million, or 1%, to \$8.8 million for 2017 from \$8.9 million for 2016. This decrease was primarily due to decreased personnel costs in the period.

For the six months ended June 30, 2017 selling, general and administrative expenses increased by \$1.0 million, or 6%, to \$19.3 million for 2017 from \$18.2 million for 2016. This increase was primarily due to increased marketing costs for IXINITY, personnel costs due to the spin-off, and consulting expenses.

Other Income (Expense), net

Other income (expense), net, consists primarily of interest on debt financing. For the three months ended June 30, 2017, other income (expense) increased to \$0.5 million from none in 2016, due to the interest on the loan entered into with Midcap Financial Trust. For the six months ended June 30, 2017, other income (expense) increased to an expense of \$0.9 million from an income of \$0.1 million in 2016, due to the interest on the loan entered into with Midcap Financial Trust in the last half of 2016.

Critical Accounting Policies and Significant Judgements and Estimates

The preparation of our condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from those estimates. An accounting policy is considered critical if it is important to a company's financial condition and results of operations and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application. Although we believe that our judgments and estimates are appropriate, actual results may differ materially from our estimates.

We believe the judgments, estimates and assumptions associated with the following critical accounting policies have the greatest potential impact on our consolidated financial statements:

- Revenue recognition;
- Collaborations;
- Research and development; and

- Stock-based compensation

For a detailed discussion of these critical accounting policies and significant judgments and estimates, refer to “Critical Accounting Policies and Significant Judgments and Estimates” within “Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2016 that was filed with the SEC on March 31, 2017. There have not been any material changes in our critical accounting policies and significant judgments and estimates as disclosed in our Annual Report Form 10-K for the year ended December 31, 2016.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of June 30, 2017.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2017, we had cash, cash equivalents and investments in the amount of \$48.6 million.

On August 1, 2016, in connection with the spin-off of the Company from Emergent, we issued 20.2 million shares of our common stock to Emergent stockholders and recorded a contribution from Emergent of \$71.2 million. The transactions recorded in 2016 included a one-time payment of \$45.0 million, and a working capital reimbursement for outstanding payments of \$1.4 million, a noncash transfer of an intangible asset of \$0.7 million, and a net transfer of cash from Emergent of \$24.2 million. In addition, in the first quarter of 2017 we received \$20.0 million as payment for a promissory note issued at the time of the spin-off.

In addition, on August 4, 2016, we entered into a \$35.0 million Credit and Security Agreement, or the Credit Agreement, with MidCap Financial Trust. The Credit Agreement provides us with up to \$35.0 million of available borrowing capacity composed of two tranches of \$20.0 million and \$15.0 million. The first tranche of \$20.0 million was made available to us, and drawn, on the closing date of the Credit Agreement and the second tranche of \$15.0 million will be available (subject to certain conditions) following the date we: (1) achieve net commercial product revenue of \$40.0 million on a trailing twelve-month basis, and (2) receive payment of the additional \$20.0 million in cash committed by Emergent. Emergent's promise to pay such \$20.0 million in cash was evidenced by a non-negotiable, unsecured promissory note issued to us and was paid in the first quarter of 2017. Once drawn, interest is paid monthly while principal will be paid on a monthly basis commencing in August 2018. The credit agreement will mature on February 1, 2021. Amounts drawn under the Credit Agreement accrue interest at a rate of LIBOR plus 7.60% per annum.

The Credit Agreement covenants require us and our subsidiaries to maintain increasing minimum net commercial product revenue for each twelve-month period ending on the last day of each calendar quarter. An event of default could result in the acceleration of the amounts owed under the Credit Agreement, 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 in our assets securing our indebtedness.

On May 11, 2017, we and MidCap Financial Trust entered into an amendment to the Credit Agreement to, among other things, waive the existing event of default and revise the financial covenants pertaining to the minimum required commercial product revenue. The amendment revises the following covenants of the Credit Agreement to: (1) extend the time period through which the Company can draw the second tranche from August 2017 to March 2018, (2) increase the exit fee of 5.75% of the aggregate principal amount under the Credit Agreement for repayment or prepayment other than scheduled amortization payments and the final payment of principal to 6.75% and (3) permit MidCap Financial Trust to obtain an affirmative lien on our intellectual property of the Company, upon the earlier of (i) the Company's draw down of the second tranche or (ii) the Company's cash balance descending below a minimum cash threshold of \$25 million.

Capital Requirements

We expect 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; and
- the costs of commercialization activities, including product marketing, sales and distribution;

We expect our cash, cash equivalents and investments along with available borrowings under our Credit Agreement, will support our operations through the third quarter of 2018, based on current operating plans and financial forecasts.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2017 and 2016:

| (in thousands) | For the Six Months Ended June 30, | |
|---------------------------------------|--|-------------|
| | 2017 | 2016 |
| Net cash provided by (used in): | | |
| Operating activities | (24,538) | (30,063) |
| Investing activities | 17,940 | (1,979) |
| Financing activities | 19,191 | 32,901 |
| Increase in cash and cash equivalents | \$ 12,593 | \$ 859 |

Net cash used in operating activities of \$24.5 million for the six months ended June 30, 2017 was primarily due to our net loss of \$21.1 million. Net cash used in operating activities of \$30.1 million for the six months ended June 30, 2016 was primarily due to our net loss of \$25.7 million.

Net cash provided by investing activities was primarily due to the maturity and redemption of investments of \$29.1 million offset by purchases of \$10.3 million in the six months ended June 30, 2017.

Net cash provided by financing activities for the periods presented includes the net proceeds received from our former parent company at the time of the spin-off in support of a promissory note to support the operations of Aptevo.

Contractual Obligations

Our future minimum contractual commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2016 that was filed with the SEC on March 14, 2017. Our future minimum contractual obligations and commitments have not changed materially from the amounts previously reported.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our exposure to market risk is primarily confined to our investment securities and notes payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and, with our current portfolio of short term investments, we are not exposed to potential loss due to changes in interest rates.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Securities Exchange Act of 1934, or the Exchange Act) required by Rules 13a-15(b) or 15d-15(b) under the Exchange Act, our Chief Executive Officer and our Chief Financial Officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We may from time to time be named as a party to legal claims, actions and complaints, including matters involving employment claims, our intellectual property or other third party claims. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors.

You should carefully consider the following risks and other information in this quarterly report on Form 10-Q in evaluating us and our 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 nine groups: operating risks, commercialization risks, regulatory and compliance risks, product development risks, intellectual property risks, risks related to collaborations, financial risks, risks related to the separation, and risks related to our common stock.

RISKS RELATED TO OUR BUSINESS

Financial Risks

We have a history of losses and may not be profitable in the future.

Our historical consolidated financial data prior to August 1, 2016 was prepared on a “carve-out” basis 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 profitability going forward.

For the three and six months ended June 30, 2017, we incurred net losses of \$11.2 million and \$21.1 million, respectively and we had an accumulated deficit of \$101.8 million as of June 30, 2017. For that same period, net cash used in our operating activities was \$24.5 million. If we cannot achieve 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 additional capital and may be unable to raise capital when needed or on acceptable terms.

As of June 30, 2017, we had cash, cash equivalents and investments in the amount of \$48.6 million. 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. Our future capital requirements will depend on many 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;
- the ability to draw down on the second tranche of \$15.0 million on our credit facility and our ability to satisfy the payment obligations and covenants under such credit facility;
- the ability to secure partnerships and/or collaborations that generate additional cash;
- capital improvements to new or existing facilities;
- the payment obligations under our current or 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 ongoing costs associated with the separation from Emergent and performance under agreements with Emergent; and
- the ongoing 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 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, a sale of commercial assets, collaboration and licensing arrangements or other strategic transactions. 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 will experience dilution. If we raise funds through collaboration and licensing arrangements with third parties or enter into other strategic transactions, 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.

Current economic conditions may make it difficult to obtain additional 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.

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. 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;
- 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 maximize the financial contribution of our marketed 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. We are constantly evaluating commercial and strategic transactions to generate revenue that include any current collaborations and collaborations or a sale of assets in the future.

We may not be able to engage in certain corporate transactions.

To preserve the tax-free treatment of the distribution related to the separation, together with certain related transactions, we are restricted under the tax matters agreement that we entered 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 are 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.

We may not achieve profitability in future periods or on a consistent basis.

Our ability to become profitable will be substantially dependent on our product sales revenues and revenues from any current collaboration and licensing arrangements and any arrangements entered into in the future. 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 profitability. In addition, we have incurred and 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, our products in development or a sale of certain assets 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 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.

The terms of our credit agreement may restrict the operation of our business and limit the cash available for investment in our business operations.

On August 4, 2016, we entered into a \$35.0 million Credit and Security Agreement, or the Credit Agreement, by and among us and certain our subsidiaries as borrowers, MidCap Financial Trust, as agent, and the lenders from time to time party thereto. The terms of the Credit Agreement, and borrowings we may make under the Credit Agreement in the future, 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 borrowings under the Credit Agreement if market rates of interest increase;
- not complying with restrictive covenants restricting, among other things, indebtedness, liens, dividends and other distributions, repayment of subordinated indebtedness, mergers, dispositions, investments (including licensing), acquisitions, transactions with affiliates and modification of organizational documents or certain other agreements;
- not complying with affirmative covenants including payment, reporting and revenue covenants; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

As of March 31, 2017, our net commercial product revenue did not meet the required minimum for the twelve months ended March 31, 2017. As a result, on May 11, 2017, we and MidCap Financial Trust entered into an amendment to the Credit Agreement to, among other things, waive the existing event of default and revise the financial covenants pertaining to the minimum required commercial product revenue. The amendment revises the following covenants of the Credit Agreement to: (1) extend the time period through which we can draw the second tranche from August 2017 to March 2018 (2) increase the exit fee of 5.75% of the aggregate principal amount under the Credit Agreement for repayment or prepayment other than scheduled amortization payments and the final payment of principal to 6.75% and (3) permit MidCap Financial Trust to obtain an affirmative lien on our intellectual property, upon the earlier of (i) our draw down of the second tranche or (ii) our cash balance descending below a minimum cash threshold of \$25 million.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under any future borrowings under the Credit Agreement. In addition, failure to comply with the covenants, including but not limited to the revenue covenants, under the Credit Agreement could result in an event of default. An event of default could result in the acceleration of amounts due under the Credit Agreement, and we may not be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests in our assets securing our indebtedness.

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 consolidated 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.

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 European Medicines Agency, or 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.

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, our Chief Financial Officer, Jeffrey G. Lamothe, and our 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. Any litigation, 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. 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.

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. Failure 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.

A key element of our strategy is to expand our product pipeline of immunotherapeutics based on our ADAPTIR platform technology. We plan to select and create 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 monospecifics and bispecifics in areas including oncology, and multispecific molecules in oncology, autoimmune disease and other therapeutic areas. Our goal is to leverage this technology to make 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.

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, research and development capabilities, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully, or more effectively negotiate third-party licensing and collaborative arrangements.

We believe that our most significant competitors in the hematology/oncology, inflammation and transplantation markets include: AbbVie Inc., Affirmed, Amgen Inc., Astellas Pharma Inc., Baxalta US Inc., Bayer AG, Biogen Idec Inc., Boehringer Ingelheim GmbH, CSL Behring, a subsidiary of CSL Limited, Dendron Corp., Genentech Inc. (a subsidiary of F. Hoffmann-La Roche Ltd.), Genmab A/S, Gilead Sciences, Inc., GlaxoSmithKline plc, Grifols USA LLC, ImmunoGen, Inc., Janssen BioTech Inc., Johnson & Johnson, MacroGenics, Inc., Novartis International AG, Pfizer Inc., Sanofi-Adventis US LLC, 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.

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.

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 IXINITY, WinRho SDF, HepaGam B, and VARIZIG, 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 United States, 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 EU review biosimilar products using a similar regulatory process. Our Biologic Products have not received marketing authorization by the European Medicines Agency, or EMA, and are not sold in Europe.

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, third-party 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; 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 and regulatory changes 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 IXINITY, WinRho SDF, HepaGam B, and VARIZIG. 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 EU, 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, 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 EU.

An inability to convince hospitals and managed care organizations to include our products on their approved formulary lists, may result in our failure to meet revenue expectations.

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 our financial condition could be adversely affected.

Our ability to sell our products, including IXINITY, WinRho SDF, HepaGam B and VARIZIG to hospitals and clinics in the United States depends in part on our relationships with group purchasing organizations, or GPOs. GPOs negotiate pricing arrangements and 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 clinics and other members. If we are not one of the providers selected by a GPO, affiliated hospitals, clinics 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. 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. If third parties do not successfully carry out their contractual duties, or if there is a delay or interruption in the distribution of our products, it could negatively impact our revenues from product sales.

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 and loss in revenue or delays in clinical development.

We do not have manufacturing capabilities and do not plan to develop such capacity in the foreseeable future. We 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 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 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.

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 or an inability to manufacture.

For example, CMC ICOS Biologics, Inc., or CMC, is the sole 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. During 2016, we ordered five manufacturing lots of bulk drug substance from CMC and none of these lots satisfied product release specifications.

On October 4, 2016, we provided a Notice of Interruption in Manufacturing, or Notice, to the FDA, notifying the FDA of a potential interruption in the supply of IXINITY due to the ongoing manufacturing challenges associated with the manufacturer of the bulk drug substance. On March 15, 2017, we announced the successful manufacture of a new bulk drug substance batch of IXINITY, providing new supply of IXINITY for the commercial market in May 2017.

On June 17, 2017, the Company and CMC entered into a new non-exclusive Amended and Restated Commercial Supply, or Restated Supply Agreement, with CMC for the commercial development and manufacture of IXINITY. Pursuant to the terms of the Restated Supply Agreement, CMC agreed to manufacture IXINITY in the quantity of batches provided to CMC on a twenty-four month rolling forecast. Beginning 2018, the minimum and maximum batches will be four and ten, respectively in a calendar year. Multiple batches ordered in succession with no changeover to another product between batches, or a campaign, should receive an incremental discounted price.

In accordance with the Restated Supply Agreement, a \$7.0 million reserve held by CMC will be applied to, at a minimum, the next four batches manufactured through the end of 2017 as a price concession in the form of no raw materials or other related costs associated with the inventory. As this reserve is utilized, Aptevo will also see an impact on the Company's income statement due to a lower costs of goods sold associated with this inventory, which will also result in higher gross margins as sales are recognized. Any remaining reserve amount outstanding as of December 25, 2017 shall be paid to the Company on or before December 31, 2017. The Restated Supply Agreement has a five-year term renewable with twenty-four months' prior notice before the expiry of the term for successive two-year terms.

While we do not currently anticipate or foresee a supply shortage or supply interruption occurring, any supply shortage or supply interruption of IXINITY would adversely affect its sales and could adversely affect its market position, commercial viability and the trading price of our common stock.

Emergent owns the manufacturing know-how necessary for the manufacture of WinRho SDF, HepaGam B and VARIZIG. An inability to manufacture these products would lead to lost revenue.

Emergent owns its human hyperimmune platform manufacturing know-how, which is necessary for the manufacture of WinRho SDF, HepaGam B, and VARIZIG. We have entered into a manufacturing services agreement with Emergent with respect to the manufacturing of these products. We also entered into a product license agreement with Emergent pursuant to which Emergent has granted us 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 are only permitted to exercise rights with respect to Emergent's human hyperimmune platform manufacturing know-how through a third-party contract manufacturer, under limited conditions, including a requirement that 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 has 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.

IXINITY, WinRho SDF, HepaGam B and VARIZIG 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. 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.

Failure of our third-party manufacturers to successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, may prevent regulatory approval of those manufacturing facilities.

We 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, otlertuzumab, APVO436, (a bispecific immunotherapeutic protein targeting CD123), 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 and ALG.APV-527 a bispecific antibody candidate, featuring a novel mechanism of action targeting 4-1BB, and tumor antigen. 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.

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, otlertuzumab, and an immunotherapeutic protein targeting ROR1, 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.

Development and commercialization of our products may be terminated or delayed.

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 and maintaining our existing arrangements with respect to the commercialization or manufacture of our products. We may 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. 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.

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.

To manage our existing and planned future growth, including our ability to support the sales and marketing of our products in the United States and globally, 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.

We are subject to a number of risks and uncertainties associated with our international activities and operations.

We currently have limited operations outside of the United States. 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: 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; export licensing requirements, political and economic instability, trade restrictions, and changes in tariffs and difficulties in staffing and managing foreign operations; cross border restrictions on the movement of cash funds and repatriation of earnings; foreign currency fluctuations; longer accounts receivable collection times; 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; 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 U.S. Foreign Corrupt Practices Act, or FCPA, and the U.K. Bribery Act of 2010, which could subject us to investigation or prosecution under such U.S. or foreign laws.

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.

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 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 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 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.

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 and, a component of the T-cell receptor complex expressed on all T-cells. The mechanism of action of MOR209/ES414 is RTCC. 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 currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL;
- an immunotherapeutic ADAPTIR protein targeting ROR1 (preclinical candidate) built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies and an antigen found on solid tumors and hematologic or blood-related, malignancies;
- APVO436, a bispecific ADAPTIR protein therapeutic currently in pre-clinical development targeting CD123, a cell surface receptor highly expressed on several hematological malignancies and CD3, a component of the T-cell receptor. Similar to MOR209/ES414 and the ROR1 preclinical program, APVO436 utilizes redirected RTCC to initiate killing of tumor cells;
- other protein therapeutic product candidates primarily targeting tumor based on mechanisms of action that modulate the immune system (immuno-oncology based mechanism of action); and
- ALG.APV-527 a bispecific antibody candidate, featuring a novel mechanism of action targeting 4-1BB (CD137) and an undisclosed tumor antigen.

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, which are called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug that 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 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.

The MOR209/ES414 Phase I clinical trial under the amended protocol, providing continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA, commenced December 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 \$74.0 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. In December 2016, the agreement was modified to adjust the allocation of certain manufacturing and development costs and extend MorphoSys' convenience termination rights. Under the amendment, the timeframe for a one-time right to terminate the collaboration agreement by MorphoSys has been extended from December 31, 2016 to June 30, 2017, or after review of clinical data from the first six patients enrolled and dosed in the MOR209/ES414 Phase I clinical trial.

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 twelve 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 civil or criminal enforcement, any of which could harm our business.

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.

Our products may face regulatory, legal or commercial challenges even after approval.

Any drug or biologic 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 boxed 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.

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.

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.

On August 2, 2011, President Obama 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.

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 IXINITY, WinRho SDF, HepaGam B and VARIZIG. 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 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 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 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.

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 EU 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 of 2010, 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.

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. The revised EU Data Protection Directive adopted in April 2016 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.

Product Development Risks

Our business depends on our success in developing and commercializing our product candidates.

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 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.

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.

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. 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. We and MorphoSys 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. This is applicable both domestically and internationally. 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.

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. Fifteen 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, in December 2015, we 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.

We depend on third parties to conduct our clinical and non-clinical trials.

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 GCPs, 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 GCPs. 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 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.

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. VARIZIG is approved in the United States to reduce the severity of varicella (chickenpox) following exposure in high-risk patient groups, including adults and children with compromised immune systems, newborns of mothers with varicella shortly before or after delivery, neonates and infants less than one year of age, and pregnant women. VARIZIG has orphan drug exclusivity in the United States 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 CLL. Orphan drug 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 ten years of market exclusivity after approval, but exclusivity 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.

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.

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.

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 outcomes 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.

A European Patent Opposition 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. We are currently involved in three opposition proceedings in Europe relating to factor IX proteins such as IXINITY. We were previously involved in five opposition proceedings in Europe relating to factor IX proteins, but two of the opposition proceedings were decided in our favor and cannot be further appealed. Baxter International Inc. (or Baxalta) is or was the sole counter-party in all proceedings. Of the five European Patent Office Proceedings, all have now gone before the European Patent Office Opposition Division. Of these oppositions, four were decided in our favor (in the name of UNC, our licensor, or Cangene Corporation when acting as an opponent) and one was decided in favor of Baxalta. Three of these oppositions have been appealed (including one which has now been settled in our favor by the Board of Appeal and can no longer be contested by Baxalta centrally at the European Patent Office), and we expect Baxalta to appeal the fourth. It may be several years before these oppositions go before the Boards of Appeal for a final decision. 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.

In addition, 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 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.

International patent protection is particularly uncertain, and if we are involved in additional 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 additional opposition proceedings, like the proceedings described above, to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts.

Third parties may choose to file patent infringement claims against us.

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. 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. 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 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. We refer to these trademarks as our house marks. If a third party opposes any of these house marks and we are unable to reach settlement prior to the commencement of an opposition proceeding, we may incur significant expense in the course of participating in the opposition process, which can be expensive and lengthy. Any settlement with a third party may result in our agreeing to be subject to restrictions on our use of the relevant house mark. In addition, if we are unsuccessful in an opposition against a house mark, we would lose the ability to obtain trademark registration for one or more uses of the relevant mark both in the United States and in other territories which could have a material and adverse effect on our business.

Synoptis Pharma Sp. z.o.o., or Synoptis, has opposed several of our house marks in the European Union. Despite efforts to initiate discussions with Synoptis regarding use of our house marks, Synoptis has refused to enter into settlement agreements. Our foreign counsel is investigating possible cancellation of Synoptis' registrations based on nonuse, which may allow the parties to enter negotiation discussions. If the event we are unsuccessful with our efforts to negotiate a settlement with Synoptis, we may lose our ability to obtain trademark registration for one or more of the house marks in the European Union, where Synoptis has opposed the marks, which could have a material and adverse effect on our business.

The Bristol Myers Squibb Company, or BMS, previously opposed several of our house marks in and outside the United States. We entered into a settlement and co-existence agreement with BMS and its licensee, Ono Pharmaceutical Co., Ltd on July 5, 2017.

BMS subsequently withdrew oppositions of our house marks. The settlement and co-existence agreement places restrictions on how we can use our house marks and how we can seek trademark protection for our house marks.

Third parties may file trademark infringement claim against us.

Defending ourselves against such trademark infringement claims could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction and damages.

Defending ourselves against claims 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.

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. 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.

Failure to comply with our obligations in our intellectual property licenses with third parties, could result in loss of license rights or other damages.

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 IXINITY, WinRho SDF, HepaGam B and VARIZIG 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. In addition, in July 2017, we entered into a collaboration agreement with Alligator Bioscience AB, or Alligator, pursuant to which Aptevo R&D and Alligator will collaboratively develop ALG.APV-527, a lead bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a costimulatory receptor found on activated T cells, and an undisclosed tumor antigen widely overexpressed in a number of different types of cancer. 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 have entered into, such as agreements with MorphoSys and Alligator, or may consider entering 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.

The failure of any of our current or 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. A loss of Aptevo's collaboration agreement with MorphoSys or Alligator would result in a burden of locating a replacement partner under potentially less favorable terms at an additional cost. 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.

Risks Related to the Separation

We may not realize some or all of the anticipated benefits of the separation from Emergent due to a number of factors.

We may not realize some or all of the anticipated strategic, financial or other benefits from the separation from Emergent. We are smaller, less diversified and with a narrower business focus than the previously consolidated company, and may be more vulnerable to changing market conditions, which could materially and adversely affect our business, financial condition and results of operations. The spin-off transactions presented 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. We may discover as a result of the separation, a negative impact on the financial condition and results of operations of our business. There also can be no assurance that the separation will not adversely affect our business.

Emergent may fail to perform under various transaction agreements that were 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 entered into a separation and distribution agreement and various other agreements with Emergent, including a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian distributor agreement, a trademark license agreement and a product license agreement. Certain of these agreements 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 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.

Our accounting and other management systems and resources may not be adequately prepared to meet the ongoing financial reporting and other requirements of a standalone publicly-traded company.

Prior to our separation from Emergent, our financial results were included within the consolidated results of Emergent. We are now directly subject to substantial reporting and other obligations under the Securities Exchange Act of 1934, or Exchange Act. These reporting and other obligations place significant demand on our management, administrative and operational resources, including accounting resources. We may not have sufficient time to meet these obligations by the applicable deadlines.

Moreover, to comply with these requirements, we have migrated our systems, including information technology systems, implement additional financial and management controls, reporting systems and procedures. 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.

If we do not continue to develop effective internal controls, we may not be able to accurately report our financial results and our business could be harmed.

We and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting as of and for the years ended December 31, 2015 and for quarters through September 30, 2016. A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Specifically, it was determined that a deferred tax liability should have been recorded associated with the difference between the book basis and the tax basis of the in-process research and development asset that was recorded as a part of an acquisition in 2010. As a result, we were required to restate our previously issued audited financial statements for the year ended December 31, 2015 and unaudited financial information for the quarter ended March 31, 2016, included in the Company's Registration Statement on Form 10, and unaudited financial information for the quarters ended June 30, 2016 and September 30, 2016 included in the Company's Quarterly Report on Form 10-Q for the quarters ended June 30, 2016 and September 30, 2016.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, beginning in 2018, Section 404 of the Sarbanes-Oxley Act, or Section 404, will require us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. As an emerging growth company, we have availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an emerging growth company. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Investor perceptions of our company may suffer if material weaknesses are found, and this could cause a decline in the market price of our common stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could harm our operating results and reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

In connection with our separation from Emergent, we and Emergent agreed to indemnify the other party for certain liabilities. 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 has agreed to indemnify us for certain liabilities, and we agreed to indemnify Emergent for certain liabilities. 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, our 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 was 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 Internal Revenue Code, or 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 was 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 represents 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 our 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.

Under the tax matters agreement that we entered 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 agreement or the IRS private letter ruling or in the representation letters provided to WilmerHale LLP.

We have incurred and 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 have incurred and expect to incur both one-time and ongoing costs and expenses 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.

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 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 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. Even though our executive officers and/or directors who were previously employees of Emergent have ceased to be employees of Emergent, some of our executive officers and/or directors 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 us.

Risks Related to Our Common Stock

We cannot be certain that an active trading market for our common stock will be sustained and our stock price may fluctuate significantly.

An active trading market for our common stock may not be sustained, nor can we predict the prices at which shares of our common stock may trade in the future.

Our stock price has fluctuated in the past and is likely to be volatile in the future. Since August 1, 2016, the reported sale price of our common stock has fluctuated between \$1.78 and \$3.33 per share. 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 management, 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 restatement of our previously issued financial statements, the misstatements that resulted in such restatement, and the material weakness that has been identified in our internal control over financial reporting, could expose us to additional risks that could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline.

As discussed in our Annual Report on Form 10-K for the year ended December 31, 2016, we restated our previously issued audited consolidated financial statements for the year ended December 31, 2015 and the unaudited financial information related to March 31, 2016 and June 30, 2016 and the three and nine months ended September 30, 2016. This restatement, along with the material weakness that were identified in our internal control over financial reporting, could expose us to potential claims and additional risks that could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline. We have implemented actions with respect to our internal controls but to the extent these steps are not successful, we could be forced to incur additional time and expense or we may not be able to produce accurate and timely financial results. As a result of the restatement and the material weakness in our internal controls, we could be subject to stockholder, governmental, or other actions in connection with the restatement or related or other matters. Any such proceedings would, regardless of the outcome, consume a significant amount of management's time and attention and would result in additional legal, accounting and other costs. If we were not to prevail in any such proceedings, we could be required to pay substantial damages or settlement costs. In addition, the restatement and related matters could impair our reputation or could lead to a loss of investor confidence.

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.

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 to our directors, officers and employees. Our employees have options to purchase shares of our common stock and we have issued significant number of restricted stock units that will vest over time. 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 authorizes 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.

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 June 30, 2017, Mr. El-Hibri was the beneficial owner of approximately 15% 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
- 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.

In addition, under the tax matters agreement, for a period of two years following the separation, we are 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 the Chancery Court of the State of Delaware will be the sole and exclusive forum for certain legal proceedings, unless we consent in writing to the selection of an alternative forum. 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.

Because we currently do not expect to pay dividends, investors will benefit from an investment in our common stock only if it appreciates in value.

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. In addition, our credit facility limits our ability to pay dividends. As a result, we currently do not expect to pay dividends for the foreseeable future. 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. 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 which could depress our stock price

If our stockholders sell a substantial number of shares of our common stock in the public market, our market price could decline. In addition, holders of an aggregate of approximately three million shares of our common stock have the right to require us to register these shares of common stock under the Securities Act of 1933, as amended, under specified circumstances.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Item 6. Exhibits

Exhibit Index

| Exhibit Number | Description |
|----------------|---|
| 4.1* | Aptevo Therapeutics Inc. 2016 Equity Incentive Plan, as amended and restated. |
| 10.2* | Amended and Restated Commercial Supply Agreement between CMC ICOS Biologics, Inc. and Aptevo Biotherapeutics LLC, dated June 16, 2017. |
| 10.3* | Fourth Amendment to License and Co-Development Agreement between MorphoSys AG and Aptevo Research and Development LLC, effective June 19, 2017. |
| 31.1* | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1* | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2* | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith.

2016 STOCK INCENTIVE PLAN1. Purpose

The purpose of this 2016 Stock Incentive Plan (the “**Plan**”) of Aptevo Therapeutics Inc., a Delaware corporation (the “**Company**”), is to advance the interests of the Company’s stockholders by enhancing the Company’s ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company’s stockholders. Except where the context otherwise requires, the term “**Company**” shall include any of the Company’s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations thereunder (the “**Code**”) and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the “**Board**”).

2. Eligibility

All of the Company’s employees, officers and directors, as well as consultants and advisors to the Company (as the terms consultants and advisors are defined and interpreted for purposes of Form S-8 under the Securities Act of 1933, as amended (the “**Securities Act**”), or any successor form) are eligible to be granted Awards (as defined below) under the Plan. Each person who is granted an Award under the Plan is deemed a “**Participant**.” The Plan provides for the following types of awards, each of which is referred to as an “**Award**”: Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Stock (as defined in Section 7), RSUs (as defined in Section 7), Other Stock-Based Awards (as defined in Section 8) and Cash-Based Awards (as defined in Section 8). Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award. All actions and decisions by the Board with respect to the Plan and any Awards shall be made in the Board’s discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

(b)Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a “**Committee**”). All references in the Plan to the “**Board**” shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board’s powers or authority under the Plan have been delegated to such Committee or officers.

(c)Delegation to Officers. Subject to any requirements of applicable law (including as applicable Sections 152 and 157(c) of the General Corporation Law of the State of Delaware), the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to employees or officers of the Company and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of Awards to be granted by such officers, the maximum number of shares subject to Awards that the officers may grant, and the time period in which such Awards may be granted; and provided further, that no officer shall be authorized to grant Awards to any “executive officer” of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”)) or to any “officer” of the Company (as defined by Rule 16a-1(f) under the Exchange Act).

(d)Awards to Non-Employee Directors. Awards to non-employee directors will be granted and administered by a Committee, all of the members of which are independent directors as defined by Section 5605(a)(2) of the NASDAQ Marketplace Rules.

(e)Minimum Vesting Requirements. Notwithstanding any other provision of the Plan, no Award granted on or after May 31, 2017 may vest (or, if applicable, be exercisable) until at least twelve (12) months following the date of grant of the Award; provided, however, that up to 5% of the share reserve set forth in Section 4(a)(1) below may be subject to Awards granted on or after May 31, 2017 that do not meet such vesting (and, if applicable, exercisability) requirements.

(f)Dividends and Dividend Equivalents. Notwithstanding any other provision of the Plan, dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to an Award other than Options or Stock Appreciation Rights, as determined by the Board and contained in the applicable Award agreement; provided, however, with respect to an Award granted on or after May 31, 2017 (i) no dividends or dividend equivalents may be paid with respect to any such shares before the date such shares have vested under the terms of such Award agreement, (ii) any dividends or dividend equivalents that are credited with respect to any such shares will be subject to all of the terms and conditions applicable to such shares under the terms of such Award agreement (including, but not limited to, any vesting conditions), and (iii) any dividends or dividend equivalents that are credited with respect to any such shares will be forfeited to the Company on the date, if any, such shares are forfeited to or repurchased by the Company due to a failure to meet any vesting conditions under the terms of such Award agreement.

4. Stock Available for Awards

(a) Authorized Number of Shares. Subject to adjustment under Section 10, Awards may be made under the Plan for up to such number of shares of common stock, \$0.001 par value per share, of the Company (the “**Common Stock**”) as is equal to the sum of:

(1) 4,341,500 shares of Common Stock (any or all of which Awards may be in the form of Incentive Stock Options (as defined in Section 5(b)); plus

(2) such additional number of shares of Common Stock as is equal to the number of shares of Common Stock subject to Awards to be granted under the Company’s Converted Equity Awards Incentive Plan which awards expire, terminate or are otherwise surrendered, canceled or forfeited (subject, however, in the case of Incentive Stock Options to any limitations of the Code).

(b) Share Counting. For purposes of counting the number of shares available for the grant of Awards under the Plan under this Section 4(a) and under the sublimits contained in Section 4(c):

(1) all shares of Common Stock covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan and against the sublimits referenced in the first clause of this Section 4(b); *provided, however*, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants an SAR in tandem with an Option for the same number of shares of Common Stock and provides that only one such Award may be exercised (a “**Tandem SAR**”), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other’s exercise will not restore shares to the Plan;

(2) if any Award (i) expires or is terminated, surrendered or cancelled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any Common Stock not being issued (including as a result of an SAR that was settleable either in cash or in stock actually being settled in cash), the unused Common Stock covered by such Award shall again be available for the grant of Awards; *provided, however*, that (A) in the case of Incentive Stock Options, the foregoing shall be subject to any limitations under the Code, (B) in the case of the exercise of an SAR, the number of shares counted against the shares available under the Plan and against the sublimits referenced in the first clause of this Section 4(b) shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and (C) the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR;

(3) shares of Common Stock delivered (either by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase shares of Common Stock upon the exercise of an Award or (ii) satisfy tax withholding obligations with respect to Awards

(including shares retained from the Award creating the tax obligation) shall not be added back to the number of shares available for the future grant of Awards; and

(4) shares of Common Stock repurchased by the Company on the open market using the proceeds from the exercise of an Award shall not increase the number of shares available for future grant of Awards.

(c) Sublimits. Subject to adjustment under Section 10, the following sublimits on the number of shares subject to Awards shall apply:

(1) Section 162(m) Per-Participant Limit. The maximum number of shares of Common Stock with respect to which Awards may be granted to any Participant under the Plan shall be 1,000,000 shares per calendar year. For purposes of the foregoing limit, the combination of an Option in tandem with an SAR shall be treated as a single Award. The per-Participant limit described in this Section 4(c)(1) shall be construed and applied consistently with Section 162(m) of the Code or any successor provision thereto, and the regulations thereunder (“**Section 162(m)**”).

(2) Limit on Awards to Non-Employee Directors. In any calendar year, the sum of the cash compensation paid to any non-employee director for service as a director and the value of Awards under the Plan made to such non-employee director (calculated based on grant date fair value for financial reporting purposes) shall not exceed \$1,000,000.

(d) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a) or any sublimits contained in the Plan, except as may be required by reason of Section 422 and related provisions of the Code.

5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an “**Option**”) and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as the Board considers necessary or advisable.

(b) Incentive Stock Options. An Option that the Board intends to be an “incentive stock option” as defined in Section 422 of the Code (an “**Incentive Stock Option**”) shall only be granted to employees of Aptevo Therapeutics Inc., any of Aptevo Therapeutics Inc.’s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. An Option that is not intended to be an Incentive Stock Option shall be designated a “**Nonstatutory Stock Option**.” The Company shall have no liability to a Participant,

or any other person, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or if the Company converts an Incentive Stock Option to a Nonstatutory Stock Option.

(c)Exercise Price. The Board shall establish the exercise price of each Option or the formula by which such exercise price will be determined. The exercise price shall be specified in the applicable Option agreement. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) on the date the Option is granted; *provided* that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Grant Date Fair Market Value on such future date. “**Grant Date Fair Market Value**” of a share of Common Stock for purposes of the Plan will be determined as follows:

(1)if the Common Stock trades on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

(2)if the Common Stock does not trade on any such exchange, the average of the closing bid and asked prices as reported by an authorized OTCBB market data vendor as listed on the OTCBB website (otcbb.com) on the date of grant; or

(3)if the Common Stock is not publicly traded, the Board will determine the Grant Date Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Grant Date Fair Market Value of a share of Common Stock for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of “closing sale price” or “bid and asked prices” if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

The Board has sole discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the participants’ agreement that the Administrator’s determination is conclusive and binding even though others might make a different determination.

(d)Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable Option agreement; *provided, however*, that no Option will be granted with a term in excess of 10 years.

(e)Exercise of Options. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with payment in full (in the manner specified in Section 5(f)) of the exercise price for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.

(f)Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) to the extent provided for in the applicable Option agreement or approved by the Board, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent provided for in the applicable Nonstatutory Stock Option agreement or approved by the Board, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;

(5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board, by payment of such other lawful consideration as the Board may determine; provided, however, that in no event may a promissory note of the Participant be used to pay the Option exercise price; or

(6) by any combination of the above permitted forms of payment.

(g)Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 10): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(d)) covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in a manner

approved by) the Board), or (4) take any other action under the Plan that constitutes a “repricing” within the meaning of the rules of the NASDAQ Stock Market (“*NASDAQ*”).

(h)No Reload Options. No Option granted under the Plan shall contain any provision entitling the Participant to the automatic grant of additional Options in connection with any exercise of the original Option.

(i)No Dividend Equivalents. No Option shall provide for the payment or accrual of dividend equivalents.

6. Stock Appreciation Rights

(a)General. The Board may grant Awards consisting of stock appreciation rights (“*SARs*”) entitling the holder, upon exercise, to receive an amount of Common Stock or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of Common Stock (valued in the manner determined by (or in a manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.

(b)Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of the Common Stock on the date the SAR is granted; *provided* that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall be not less than 100% of the Grant Date Fair Market Value on such future date.

(c)Duration of SARs. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided, however*, that no SAR will be granted with a term in excess of 10 years.

(d)Exercise of SARs. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.

(e)Limitation on Repricing. Unless such action is approved by the Company’s stockholders, the Company may not (except as provided for under Section 10): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(d)) covering the same or a different number of shares of Common Stock and having an exercise or measurement price per share lower than the then-current measurement price per share of the cancelled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board), or (4) take any other action under the Plan that constitutes a “repricing” within the meaning of the rules of the NASDAQ.

(f)No Reload SARs. No SAR granted under the Plan shall contain any provision entitling the Participant to the automatic grant of additional SARs in connection with any exercise of the original SAR.

(g)No Dividend Equivalents. No SAR shall provide for the payment or accrual of dividend equivalents.

7. Restricted Stock; RSUs

(a)General. The Board may grant Awards entitling recipients to acquire shares of Common Stock (“**Restricted Stock**”), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered at the time such Award vests (“**RSUs**”).

(b)Terms and Conditions for Restricted Stock and RSUs. The Board shall determine the terms and conditions of Restricted Stock and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c)Additional Provisions Relating to Restricted Stock.

(1)Dividends. Any dividends (whether paid in cash, stock or property) declared and paid by the Company with respect to shares of Restricted Stock (“**Unvested Dividends**”) shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Unvested Dividends will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Stock. No interest will be paid on Unvested Dividends.

(2)Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock, as well as dividends or distributions paid on such Restricted Stock, shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. “**Designated Beneficiary**” means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant’s death or (ii) in the absence of an effective designation by a Participant, the Participant’s estate.

(d)Additional Provisions Relating to RSUs.

(1)Settlement. Upon the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each RSU, the Participant shall be entitled to receive from the Company the number of shares of Common Stock specified in the Award agreement or (if so provided in the applicable Award agreement or otherwise determined by the Board) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of shares or a combination thereof. The Board may provide that settlement of RSUs shall be deferred, on a mandatory basis or at the election of the Participant, in a manner that complies with Section 409A of the Code or any successor provision thereto, and the regulations thereunder (“**Section 409A**”).

(2)Voting Rights. A Participant shall have no voting rights with respect to any RSUs.

(3)Dividend Equivalents. The Award agreement for RSUs may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of Common Stock (“**Dividend Equivalents**”). Dividend Equivalents shall be credited to an account for the Participant, may be settled in cash and/or shares of Common Stock and shall be subject to the same restrictions on transfer and forfeitability as the RSUs with respect to which paid, in each case to the extent provided in the Award agreement. No interest will be paid on Dividend Equivalents.

8. Other Stock-Based and Cash-Based Awards

(a)General. The Board may grant other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property (“**Other Stock-Based Awards**”). Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine. The Company may also grant Awards denominated in cash rather than shares of Common Stock (“**Cash-Based Awards**”).

(b)Terms and Conditions. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award or Cash-Based Award, including any purchase price applicable thereto.

(c)Dividend Equivalents. The Award agreement for an Other Stock-Based Award may provide Participants with the right to receive Dividend Equivalents. Dividend Equivalents shall be credited to an account for the Participant, may be settled in cash and/or shares of Common Stock and shall be subject to the same restrictions on transfer and forfeitability as the Other Stock-Based Award with respect to which paid, in each case to the extent provided in the Award agreement. No interest will be paid on Dividend Equivalents.

9. Performance Awards

(a)Grants. Restricted Stock, RSUs and Other Stock-Based Awards and Cash-Based Awards under the Plan may be made subject to the achievement of performance goals pursuant

to this Section 9 (“**Performance Awards**”). Performance Awards can also provide for cash payments of up to \$2,000,000 per calendar year per individual.

(b)**Committee**. Grants of Performance Awards to any Covered Employee (as defined below) intended to qualify as “performance-based compensation” under Section 162(m) (“**Performance-Based Compensation**”) shall be made only by a Committee (or a subcommittee of a Committee) comprised solely of two or more directors eligible to serve on a committee making Awards qualifying as “performance-based compensation” under Section 162(m). In the case of such Awards granted to Covered Employees, references to the Board or to a Committee shall be treated as referring to such Committee (or subcommittee). “**Covered Employee**” shall mean any person who is, or whom the Committee, in its discretion, determines may be, a “covered employee” under Section 162(m)(3) of the Code.

(c)**Performance Measures**. For any Award that is intended to qualify as Performance-Based Compensation, the Committee shall specify that the degree of granting, vesting and/or payout shall be subject to the achievement of one or more objective performance measures established by the Committee, which shall be based on the relative or absolute attainment of specified levels of one or any combination of the following, which may be determined pursuant to generally accepted accounting principles (“GAAP”) or on a non-GAAP basis, as determined by the Committee:

(1)*Earnings or Profitability Measures*, including but not limited to: (i) revenue (gross, operating or net); (ii) revenue growth; (iii) income (gross, operating, net or adjusted); (iv) earnings before interest and taxes (“EBIT”); (v) earnings before interest, taxes, depreciation and amortization (“EBITDA”); (vi) earnings growth, (vii) profit margins or contributions; and (viii) expense levels or ratios;

(2)*Return Measures*, including, but not limited to: return on (i) investment; (ii) assets; (iii) equity; or (iv) capital (total or invested);

(3)*Cash Flow Measures*, including but not limited to: (i) operating cash flow; (ii) cash flow sufficient to achieve financial ratios or a specified cash balance; (iii) free cash flow; (iv) cash flow return on capital; (v) net cash provided by operating activities; (vi) cash flow per share; and (vii) working capital or adjusted working capital;

(4)*Stock Price and Equity Measures*, including, but not limited to: (i) return on stockholders’ equity; (ii) total stockholder return; (iii) stock price; (iv) stock price appreciation; (v) market capitalization; (vi) earnings per share (basic or diluted) (before or after taxes); and (vii) price-to-earnings ratio;

(5)*Strategic Metrics*, including, but not limited to: (i) acquisitions or divestitures; (ii) collaborations, licensing or joint ventures; (iii) product research and development; (iv) clinical trials; (v) regulatory filings or approvals; (vi) patent application or issuance; (vii) manufacturing or process development; (viii) sales or net sales; (ix) sales growth, (x) market share; (xi) market penetration; (xii) inventory control; (xiii) growth in assets; (xiv) key hires; (xv) business expansion; (xvi) achievement of milestones under a third-party agreement; (xvii) financing; (xviii) resolution of significant litigation; (xix) legal compliance or

risk reduction; (xx) improvement of financial ratings; or (xxi) achievement of balance sheet or income statement objectives;

(6) In each case such performance measures may be adjusted to exclude any one or more of (i) extraordinary items, (ii) gains or losses on the dispositions of discontinued operations, (iii) the cumulative effects of changes in accounting principles, (iv) the impairment or writedown of any asset or assets, (v) charges for restructuring and rationalization programs or (vi) other extraordinary or non-recurring items, as specified by the Committee when establishing the performance measures. Such performance measures: (i) may vary by Participant and may be different for different Awards; (ii) may be particular to a Participant or the department, branch, line of business, subsidiary or other unit in which the Participant works and may cover such period as may be specified by the Committee; and (iii) shall be set by the Committee within the time period prescribed by, and shall otherwise comply with the requirements of, Section 162(m). Awards that are not intended to qualify as Performance-Based Compensation may be based on these or such other performance measures as the Board may determine.

(d) Adjustments. Notwithstanding any provision of the Plan, with respect to any Performance Award that is intended to qualify as Performance-Based Compensation, the Committee may adjust downwards, but not upwards, the cash or number of shares payable pursuant to such Award, and the Committee may not waive the achievement of the applicable performance measures except in the case of the death or disability of the Participant or a change in control of the Company.

(e) Other. The Committee shall have the power to impose such other restrictions on Performance Awards as it may deem necessary or appropriate to ensure that such Awards satisfy all requirements for Performance-Based Compensation.

10. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. 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 Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under the Plan set forth in Section 4(a), (ii) the share counting rules and sublimits set forth in Sections 4(b) and 4(c), (iii) the number and class of securities and exercise price per share of each outstanding Option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding award of Restricted Stock and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding RSU and each Other Stock-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise,

notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Reorganization and Change in Control Events.

(1) Definitions.

(i) A “**Reorganization Event**” shall mean:

- (A) any merger or consolidation of the Company with or into another entity as a result of which the Common Stock is converted into or exchanged for the right to receive cash, securities or other property or is canceled; or
- (B) any exchange of shares of Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction.

(ii) A “**Change in Control Event**” shall mean:

- (A) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a “**Person**”) of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d 3 promulgated under the Exchange Act) 50% or more of either (x) the aggregate number of shares of Common Stock then-outstanding (the “**Outstanding Company Common Stock**”) or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the “**Outstanding Company Voting Securities**”); provided, however, that for purposes of this subsection (A), the following acquisitions shall not constitute a Change in Control Event: (I) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (II) any acquisition by any employee benefit plan (or related trust) sponsored

or maintained by the Company or any corporation controlled by the Company, or (III) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (C) of this definition;

- (B) such time as the Continuing Directors (as defined below) do not constitute a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term “**Continuing Director**” means at any date a member of the Board (x) who was a member of the Board on the date of the initial adoption of this Plan by the Board or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or
- (C) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a “**Business Combination**”), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business

Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "**Acquiring Corporation**") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(D) the complete liquidation or dissolution of the Company.

- (iii) "**Cause**" shall, unless otherwise specified in the applicable Award agreement or another agreement between the Participant and the Company, mean any (A) willful failure by the Participant, which failure is not cured within 30 days of written notice to the Participant from the Company, to perform his or her material responsibilities to the Company, (B) willful misconduct by the Participant which affects the business reputation of the Company, (C) material breach by the Participant of any employment, consulting, confidentiality, non-competition or non-solicitation agreement with the Company, (D) conviction or plea of nolo contendere (no contest) by the Participant to a felony, or (E) commission by the Participant of any act involving fraud, theft or dishonesty with respect to the Company's business or affairs. The Participant shall be considered to have been discharged for "Cause" if the Company determines, within 30 days after the Participant's resignation, that discharge for Cause was warranted.
- (iv) "**Good Reason**" shall, unless otherwise specified in the applicable Award agreement or another agreement between the Participant and the Company, mean any significant diminution in the Participant's authority, or responsibilities from and after such

Reorganization Event or Change in Control Event, as the case may be, or any material reduction in the annual cash compensation payable to the Participant from and after such Reorganization Event or Change in Control Event, as the case may be, or the relocation of the place of business at which the Participant is principally located to a location that is greater than 50 miles from its location immediately prior to such Reorganization Event or Change in Control Event.

(2) Effect on Awards other than Restricted Stock.

- (i) Reorganization Event. Upon the occurrence of a Reorganization Event (regardless of whether such event also constitutes a Change in Control Event), the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Stock on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (A) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (B) 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, (C) provide that outstanding Awards shall become exercisable, realizable, or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (D) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "*Acquisition Price*"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (X) the number of shares of 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 (Y) the excess, if any, of (I) the Acquisition Price over (II) the exercise, grant or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, and (E) any combination of the foregoing. In taking any of the actions permitted under this Section 10(b)(2)(i), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

- (ii) Notwithstanding the terms of Section 10(b)(2)(i)(A), in the case of outstanding Restricted Stock Units that are subject to Section 409A of the Code: (A) if the applicable Restricted Stock Unit agreement provides that the Restricted Stock Units shall be settled upon a “change in control event” within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a “change in control event”, then no assumption or substitution shall be permitted pursuant to Section 10(b)(2)(i)(A) and the Restricted Stock Units shall instead be settled in accordance with the terms of the applicable Restricted Stock Unit agreement; and (B) the Board may only undertake the actions set forth in clauses (C), (D) or (E) of Section 10(b)(2)(i) if the Reorganization Event constitutes a “change in control event” as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A of the Code; if the Reorganization Event is not a “change in control event” as so defined or such action is not permitted or required by Section 409A of the Code, and the acquiring or succeeding corporation does not assume or substitute the Restricted Stock Units pursuant to clause (A) of Section 10(b)(2)(i), then the unvested Restricted Stock Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.
- (iii) For purposes of Section 10(b)(2)(i)(A), an Award (other than Restricted Stock) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each share of Common Stock subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determined to be equivalent in value (as of the date of such determination or another date specified by the Board) to

the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

- (iv) Change in Control Event. Notwithstanding the provisions of Section 10(b)(2)(i), except to the extent specifically provided to the contrary in the instrument evidencing the Award or any other agreement between the Participant and the Company, each Award (other than Restricted Stock) shall become immediately vested, exercisable, or free from forfeiture, as applicable, if on or prior to the first anniversary of the date of the consummation of a Change in Control Event, the Participant's service with the Company or a successor corporation is terminated without Cause by the Company or the successor corporation or is terminated for Good Reason by the Participant.

(3) Effect on Restricted Stock.

- (i) Reorganization Event. Upon the occurrence of a Reorganization Event (regardless of whether such event also constitutes a Change in Control Event), the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Stock; *provided, however*, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, either initially or by amendment.
- (ii) Change in Control Event. 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 instrument evidencing the Award or any other agreement between the Participant and the Company, each Award of Restricted Stock shall become immediately vested and free from forfeiture if on or prior to the first anniversary of the date of the consummation of a Change in Control Event, the Participant's service with the Company or a successor corporation is terminated without Cause by the Company or the successor corporation or is terminated for Good Reason by the Participant.

(4) Effect on Other Awards.

- (i) Reorganization Event that is not a Change in Control Event. The Board shall specify at the time of grant or thereafter the effect of a Reorganization Event that is not a Change in Control Event on any Other Stock-Based Award or Cash-Based Award granted under the Plan.
- (ii) Change in Control Event. The Board shall specify at the time of grant or thereafter the effect of 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 Plan.

(5) Treatment of Performance-Based Awards. Notwithstanding any other provision of this Plan, with respect to an Award granted on or after May 31, 2017 that vests based on the attainment of performance goals, any acceleration of vesting and/or exercisability pursuant to this Section 10 shall be calculated (i) based on actual performance or, if such actual performance cannot be determined, target performance; and (ii) on a pro rata basis based on the fractional performance period.

11. General Provisions Applicable to Awards

(a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by a Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; *provided, however*, that, except with respect to Awards subject to Section 409A, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the Common Stock subject to such Award to such proposed transferee; *provided further*, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 11(a) shall be deemed to restrict a transfer to the Company.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator,

guardian or Designated Beneficiary, may exercise rights, or receive any benefits, under an Award.

(d)Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Board, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their fair market value (determined by (or in a manner approved by) the Company; *provided, however*, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain shares of Common Stock having a fair market value (determined by (or in a manner approved by) the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of shares of Common Stock (up to the number of shares having a fair market value equal to the maximum individual statutory rate of tax (determined by (or in a manner approved by) the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(e)Amendment of Award. Except as otherwise provided in Sections 5(g) and 6(e), the Board may amend, modify or terminate any outstanding Award, 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 to a Nonstatutory Stock Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 10.

(f)Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and

delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(g)Limits on Acceleration of Vesting. The Board may at any time provide that any Award shall become immediately exercisable in full or in part, free from some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be (become “Accelerated”); provided, however, that, notwithstanding any other provision of the Plan, an Award granted on or after May 31, 2017 may be Accelerated only (i) upon a Participant’s death or disability or (ii) as set forth in Section 10 hereof.

12. Miscellaneous

(a)No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b)No Rights As Stockholder; Clawback. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be issued with respect to an Award until becoming the record holder of such shares. In accepting an Award under the Plan, a Participant shall agree to be bound by any clawback policy the Company may adopt in future.

(c)Effective Date and Term of Plan. The Plan shall become effective on the date the Plan is approved by the Company’s stockholders (the “*Effective Date*”). No Awards shall be granted under the Plan after the expiration of 10 years from the Effective Date, but Awards previously granted may extend beyond that date.

(d)Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that (i) to the extent required by Section 162(m), no Award granted to a Participant that is intended to comply with Section 162(m) after the date of such amendment shall become exercisable, realizable or vested, as applicable to such Award, unless and until the Company’s stockholders approve such amendment in the manner required by Section 162(m); (ii) no amendment that would require stockholder approval under the rules of the national securities exchange on which the Company then maintains its primary listing may be made effective unless and until the Company’s stockholders approve such amendment; and (iii) if the national securities exchange on which the Company then maintains its primary listing does not have rules regarding when stockholder approval of amendments to equity compensation plans is required (or if the Company’s Common Stock is not then listed on any national securities exchange), then no amendment to the Plan (A) materially increasing the number of shares authorized under the Plan (other than pursuant to Sections 4(d) or 10), (B) expanding the types of Awards that may be granted under the Plan, or (C) materially expanding the class of participants eligible to participate in the Plan shall be effective unless and until the Company’s stockholders approve such amendment. In addition, if at any time the approval of the Company’s stockholders is required as to any other modification or amendment under Section 422 of the

Code or any successor provision with respect to Incentive Stock Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 12(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan. No Award shall be made that is conditioned upon stockholder approval of any amendment to the Plan unless the Award provides that (i) it will terminate or be forfeited if stockholder approval of such amendment is not obtained within no more than 12 months from the date of grant and (2) it may not be exercised or settled (or otherwise result in the issuance of Common Stock) prior to such stockholder approval.

(e) Authorization of Sub-Plans (including for Grants to non-U.S. Employees). The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Section 409A of the Code. Except as provided in individual Award agreements initially or by amendment, if and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A) (the "**New Payment Date**"), except as Section 409A may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A but do not to satisfy the conditions of that section.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally

liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h)Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

**Amended and Restated
COMMERCIAL SUPPLY
AGREEMENT**

BETWEEN

CMC ICOS BIOLOGICS, INC.

and

APTEVO BIOTHERAPEUTICS LLC.

DISCLAIMER

THIS DOCUMENT IS ISSUED BY CMC FOR DISCUSSION PURPOSES ONLY. IT IS NOT INTENDED TO CONSTITUTE ANY OFFER OR CREATE ANY LEGAL RELATIONS.

THE SUPPLY OF THIS DOCUMENT IN ELECTRONIC FORM IS STRICTLY ON THE UNDERSTANDING THAT NO AMENDMENTS WILL BE MADE TO IT WHICH ARE NOT EXPLICITLY DRAWN TO CMC'S ATTENTION EITHER BY MARKING THE CHANGES IN THE TEXT ITSELF OR OTHERWISE

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APPENDIX ONE47

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APPENDIX THREE50

COMMERCIAL SUPPLY AGREEMENT



THIS AMENDED AND RESTATED COMMERCIAL SUPPLY AGREEMENT ("Agreement") is made as of June 16, 2017 (the "**Restatement 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 Ave SE, Bothell, Washington, USA (hereinafter referred to as "**CMC**"); and,
- (2) **APTEVO BIOTHERAPEUTICS LLC.**, duly incorporated under the laws of the state of Delaware and having its principal place of business at 2401 4th Avenue, Suite 1050, Seattle, WA 98121 (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 research, development, manufacture and sale of pharmaceuticals and biologics, including the product designated by Customer as recombinant factor IX product as described in BB-IND 13552 ("**IB-1001**");
- (B) CMC and Customer entered into a Commercial Supply (Manufacturing Services) Agreement (the "**Original CSA**") on June 17, 2011 (the "**Original Effective Date**") for the commercial development and manufacture of the Product as well as a Letter Agreement dated April 13, 2017 (the "**Letter Agreement**");
- (C) The Parties now wish to amend and restate the Original CSA in its entirety as set forth below and for this Agreement to supersede, restate and replace, as of the Restatement Date, the Original CSA.

NOW THEREFORE, THE PARTIES AGREE as follows:

COMMERCIAL SUPPLY AGREEMENT

1. DEFINITIONS AND INTERPRETATION

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

"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 a Party. For the purpose of this definition control means the direct or indirect beneficial ownership of more than fifty percent (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 company, partnership or entity;

"Agreement" this Agreement including all Appendices and any amendments to the foregoing made in accordance with this Agreement;

"Appendix" one or more of the Appendices to this Agreement;

or

"Appendices"

"Applicable Laws" all applicable ordinances, rules, regulations, laws, guidelines, requirements and court orders of any kind whatsoever of any national (e.g., the FDA, EPA, etc.), supra-national (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity of the US or EU applicable to the Services;

"Authority Submission" has the meaning set out in **Clause 8.3**;

- "Batch"** BDS that is intended to be of uniform character and quality, within specific limits, and is produced in one cell culture run using the Cell Line at a specified bioreactor scale, and such purification, analytical and further processing steps as described in a Work Statement applicable to the BDS harvested from that run resulting in one lot of BDS
- "Batch Minimum"** Minimum number of Batches of Product Customer is required to purchase and has financial obligation for each twelve (12) month period, commencing January and ending December ("Calendar Year")
- "Batch Maximum"** Maximum number of Batches of Product Customer may order as per the process set out in Section 5 and CMC must provide for each Calendar Year under this Agreement. Customer may increase Batch Maximum, in which case CMC shall use best efforts to meet expectations.
- "Batch Price"** the price payable for each Batch as initially described in the Appendix Two and as may be amended by agreement between the Parties or by operation of **Clause 7**;
- "Binding Batch"** has the meaning set out in **Clause 5.7**;
- "BLA"** a Biologics License Application and any amendments or supplements thereto filed with the FDA pursuant to 21 C.F.R. Part 601 or any other application required for the purpose of marketing and selling a biological product filed with a Regulatory Authority outside the United States, including with respect to the EU a Marketing Authorization Application;
- "Bulk Drug Substance or BDS"** means the Product in bulk, as expressed by the Cell Line and harvested and purified in bulk from a cell culture run pursuant to the applicable Process;
- "Business Day"** any day which is not a Saturday, a Sunday or a U.S. public holiday;
any day;
- "Calendar Day"** a 3-month period beginning on January 1, April 1, July 1, or October 1 of each year;
- "Calendar Quarter"**
- "Campaign"** Multiple batches of Product produced in succession with no changeover to another product between batches;
- "Cancellation Fee"** has the meaning set out in **Clause 5.9**;
- "Cell Line"** the mammalian cell line designated 122-8H6 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;

"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, 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; (c) the ICH guide Q7 "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients;" and (d) any other laws, regulations and statutes set forth by a Government Authority applicable to the manufacture of compounds and products by CMC under this Agreement;

"Change of Control" in relation to a body corporate, the occurrence of an event or circumstance where a person who is not presently able to do any of the following things becomes able to do one of the following things (whether directly or indirectly or through one or more intervening persons, companies or trusts):
(a) control the composition of more than one half of the body's board of directors;
(b) be in a position to cast, or control the casting of, more than one half of the maximum number of votes that might be cast at a general meeting of the members of the body; or
(c) hold or have a beneficial interest in more than one half of the issued share capital of the body;

"CHEF1 Technology" the Chinese Hamster Ef-1 regulatory DNA ("CHEF1") as further describe in US Patent Number 5,888,809 and the technology described in US Patent Number 5,888,809.

"CMC Facility" CMC's manufacturing facility in Bothell, Washington or another facility agreed on by the Parties in writing;

"CMC Failure" has the meaning set out in **Clause 13.3**;

"CMC Intellectual Property Rights" Intellectual Property rights and CMC Know-How (excluding the CHEF1 Technology) owned by CMC and used in the Services;

"CMC How" **Know-**all information, techniques, trade secrets, data and technical information known to CMC which is not of general public knowledge, other than provided to CMC by Customer, or developed during the Services;

"Commencement Date" in respect of a cGMP Batch the date on which (i) an ampoule of cells is thawed for the cell culture for manufacture of BDS, or (ii) CMC's manufacturing suite has been configured specifically for that cGMP Batch; whichever is the earlier;

"Commercial Quality Agreement" (QA) the agreement between the Parties defining the quality responsibilities, including cGMP standards, regarding the performance of the Services;

"Commercially Reasonable Efforts" with respect to CMC, such level of efforts and resources that would be typically and ordinarily expended, in accordance with generally accepted biological manufacturing industry standards, by companies that provide manufacturing and related services in the biopharmaceutical industry, as applicable, of comparable size and resources to CMC, for a similar activity with respect to the scope of Services to be provided under this Agreement, the profit earned under this Agreement and the strategic value of the Agreement to the business of CMC;

"Committee Member" has the meaning set out in **Clause 4.8**;

"Confidential Information" means all information disclosed by, or on behalf of, the Disclosing Party to Recipient Party relating to this Agreement and includes:

(I) information disclosed in writing, orally or by any other means;

(II) information disclosed before, after or on the date of this Agreement; and

(iii) information relating to the Disclosing Party's operations, processes, plans, intentions, production information, know how, data, formulae, expertise, methodology, drawings, specifications, design rights, trade secrets, market opportunities and business affairs, and any new and novel combinations thereof;

"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, Cell Line, BDS or materials, techniques or processes used in the Services;

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| "Customer Know-How" | all information, techniques, trade secrets, data and technical information known to Customer in connection with the Cell Line, Customer Materials, Process and Product which are (i) not known to CMC prior to being provided to CMC by or on behalf of Customer; or (ii) not of general public knowledge; |
| "Customer Materials" | the Cell Line, vectors, plasmids and all other materials and equipment supplied by Customer, its Affiliate or agent to CMC or made available to CMC by or on behalf of Customer or purchased by CMC on behalf of Customer; |
| "Defect" | has the meaning in Clause 6.7 ; |
| "Defect Notice" | has the meaning in Clause 6.7 ; |
| "Deliverables" | the data, results and materials generated from the performance of the Services including Drug History Record and Product; |
| "Delivery" or "Delivered" | has the meaning in Clause 6.4 ; |
| "Delivery Date" | means, as applicable, the date a Batch is to be delivered or is actually Delivered; |
| "Deposit" | sum payable to CMC prior to the start of manufacturing of Batch. Deposits shall be applied to the cost of delivered Batches, in accordance with Appendix 2. |
| "Disputed Deliverable" | has the meaning in Clause 6.13 ; |
| "Drug History Record" | all lot disposition documentation relevant to a cGMP Batch to be provided to Customer with the Product from that cGMP Batch, including but not limited to manufacturing batch records, Certificates of Compliance and Certificates of Analysis; |
| "EMA" | European Medicines Agency or any successor agency; |
| "Exceptional Batches" | has the meaning in Clause 5.6 ; |
| "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 ; |
| "Forecast" | has the meaning set out in Clause 5.1 ; |

"Fundamental Change" means a Change of Control, merger, acquisition or change of management of CMC or Affiliates;

"Group" in respect of the relevant Party, its Affiliates and holding companies and the Affiliates of those holding companies;

"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 4.8**;

"Non-Fault Delays" has the meaning set out in **Clause 4.1**;

"Order" a Firm Order or a Semi-Firm Order;

"Other Customers" has the meaning set out in **Clause 5.10**;

"Permitted Recipients" (a) 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 of the other Party for the purpose of enabling the relevant Party to perform its obligations under this Agreement; and (b) in communications with existing or prospective licensees, sublicensees or collaborators, and consultants and advisors of each Party in connection with transactions or prospective transactions or pursuant to the conduct of such Party's business; provided that in the case of (a) and (b), such Persons are under obligations of confidence no less onerous than those set out in **Clause 10** imposed on the recipient Party;

- "Person(s)"** any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein;
- "Process"** the method for manufacture, harvesting and purification of the Product as defined in Customer approved manufacture batch records;
- "Product"** Customer's biologic known as IB-1001 manufactured in Batch form as Bulk Drug Substance;
- "Project Manager"** has the meaning set out in **Clause 4.8**;
- "Project Team"** has the meaning set out in **Clause 4.9**;
- "Purchase Order"** has the meaning set out in **Clause 5.5.1**;
- "Raw Materials"** media, resins, chemicals, solvents, filters, membranes, disposable analytical test kits, disposable bags, and other items consumed for the manufacture of Products in accordance with this Agreement 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;
- "Regulatory Approval Submission"** the earlier of the first submission of a Biologics License Application or Market Authorization Application for the Product;
- "Regulatory Obligations"** those mandatory regulatory requirements applicable in Europe and the United States of America to the manufacture of cGMP Product for human use;
- "Regulatory Authority"** the FDA in the United States or any health regulatory authority in another country that is a counterpart to the FDA and holds responsibility for allowing development of the Product and/or granting Regulatory Approval for a Product, including the EMA, and any successor(s) thereto;

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| "Release Further Processing" | Forhas the meaning set out in Clause 6.8; |
| "Representative(s)" | has the meaning set out in Clause 4.9; |
| "Semi-Firm Order" | Has the meaning set out in Clauses 5.3.2; |
| "Services" | manufacturing of the Product by CMC and all activities to be conducted by CMC related to the manufacturing of the Product under this Agreement; |
| "Shipping Company" | a shipping company or other agent designated by Customer to receive a Delivery on behalf of Customer; |
| "Shipping Guidelines" | the storage and transport guidelines for the Product that are determined by mutual written agreement of the Parties; |
| "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 cGMP documentation, as otherwise set forth in Appendix One or as may otherwise be agreed between the Parties or modified in accordance with Clause 4.5 which includes (i) specifications for BDS and Raw Materials, (ii) manufacturing, testing and packaging instructions and specifications for Product in accordance with the Process, (iii) storage and shipping requirements, and (iv) any other technical information necessary to manufacture a Batch; |
| "Standard Operating Procedures" or "SOPs" | the standard operating procedures of CMC which define CMC's methods of performing activities applicable to the Services; |
| "Storage Cost" | has the meaning set out in Clause 7.8; |
| "Supply Failure" | has the meaning set out in Clause 5.14; |
| "Term" | has the meaning set out in Clause 14.1; |
| "Testing Laboratories" | the Third Parties 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; |

- “**Timelines**” collectively and individually the dates to manufacture Product and render other Services to Deliver Product according to the Forecast and/or each accepted Commencement Date and Delivery Date; or
- “**Third Party(ies)**” any person, company, organization or entity other than CMC, Customer or their Affiliates.

1.2 Additional Definitions. Each of the following definitions is set forth in the clause of this Agreement indicated below:

| <u>Definition:</u> | <u>Clause:</u> |
|-----------------------------|-----------------------|
| <u>Binding Batches</u> | 5.7 |
| <u>Reserve Payment</u> | 7.1 |
| <u>Producer Price Index</u> | 7.3 |

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

- 1.3.1 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;
- 1.3.2 the table of contents and clause headings are included for convenience only and shall not affect the interpretation of this Agreement;
- 1.3.3 use of the singular includes the plural and vice versa and use of any gender includes the other genders;
- 1.3.4 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);
- 1.3.5 a reference to "writing" does not include email;
- 1.3.6 a reference to "records", "data", "documents" and "information" refers to such items in tangible, and electronic and visual mediums unless specified to the contrary; and
- 1.3.7 any phrase introduced by the terms "including", "include", "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

1.4 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.

1.5 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 use Commercially Reasonable Efforts to manufacture Product: (a) that meets Specifications; (b) in compliance with Applicable Laws and Regulatory Obligations; and (c) in accordance with the terms of this Agreement and the Commercial Quality Agreement.

2.2 During the Term, CMC shall use Commercially Reasonable Efforts to manufacture Product in the quantity of Batches that are the subject of each Firm Order and Semi-Firm Order pursuant to the forecast mechanism set out in **Clause 5** and in accordance with the terms and requirements set out in this Agreement. Customer shall purchase from CMC and CMC shall supply to Customer the Product in the quantity of Batches in accordance with the terms of this Agreement.

2.3 CMC shall maintain a completed Drug History Record and such other records as specified in the Commercial Quality Agreement for the period of time specified in the Commercial Quality Agreement. CMC shall retain and store samples of all cGMP Product released by CMC's quality department with a Certificate of Analysis for such period as may be required by Applicable Laws and Regulatory Obligations and the Commercial Quality Agreement, which in the absence of a definitive time period shall be fifteen (15) years from the date of release or Delivery. If the Parties agree, CMC shall retain such samples for a longer period at the Customer's cost.

- 2.4 Third Party Subcontractors
CMC may subcontract:
- 2.4.1 to its Affiliates, any part of the Services (provided that the Affiliates may not further subcontract those parts of the Services), with the prior written consent of Customer (such consent not to be unreasonably withheld, delayed or conditioned);
 - 2.4.2 to Testing Laboratories, with the prior written consent of Customer (such consent not to be unreasonably withheld, delayed or conditioned) and;
 - 2.4.3 to any other reputable qualified Third Party, any part(s) of the Services (provided CMC identifies the specific Services to be performed) with the prior written consent of Customer (such consent not to be unreasonably withheld, delayed or conditioned).

CMC shall remain responsible for the Services to be rendered by Third Parties to whom it subcontracts and shall ensure such Third Parties perform such subcontracted Services in compliance with the terms and conditions of this Agreement.

- 2.5 Totality of Services
The manufacture of Binding Batches 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 and price for such supplemental services.

3. RAW MATERIALS, CUSTOMER MATERIALS, AND EQUIPMENT

- 3.1 CMC shall be responsible for obtaining Raw Materials required for the manufacture of Product in reasonable quantities consistent with the Forecast and Purchase Orders. CMC shall ensure that all Raw Materials (i) conform to their respective Specifications; and (ii) are stored and handled in accordance with cGMP, Applicable Laws and Regulatory Obligations and the Commercial Quality Agreement.
- 3.2 All Raw Materials purchased by CMC for the Services will be the property of the Customer and deemed Customer Materials. Customer hereby grants to CMC a security interest in all Raw Materials to secure the payment of any and all undisputed amounts due to CMC. If Customer fails to pay such amounts to CMC within forty-five (45) Business Days after the due date as defined in Appendix Two, CMC shall be entitled to use the Raw Materials for which Customer has not paid for any purposes after notifying Customer and without any compensation or liability to Customer. Customer shall no longer owe CMC the cost incurred by CMC for the purchase of any specific Raw Materials used by CMC under this **Clause 3.2** upon such use by CMC.
- 3.3 All equipment acquired by CMC to perform Services shall be owned by CMC. CMC shall charge customer(s) a one-time "commissioning" fee for such equipment and be responsible for all delivery, installation, maintenance and storage costs associated with such equipment. In the event such equipment is used for additional CMC customer(s), Customer shall only

be responsible for a proportionate amount of the 'commissioning' fee, unless otherwise agreed to by the Parties. In the event the same equipment is used for two CMC customers, Customer shall only be responsible for fifty-percent (50%) of the "commissioning" fee. For clarity, should the equipment be used for another customer, a portion of the commissioning fee, equal to fifty-percent (50%) shall be credited to the Customer against outstanding or future invoices. CMC shall use such equipment to render the Services and in accordance with Customer's instructions.

4. **TIMELINE, SPECIFICATION AND PROJECT MANAGEMENT**

Timeline

4.1 CMC shall use Commercially Reasonable Efforts to maintain the Timeline. Notwithstanding that obligation, the Parties acknowledge and agree that the Timeline may be varied as agreed by CMC and the Customer in writing 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 the Services; and/or (iii) Force Majeure Situations or other circumstances beyond CMC's reasonable control ("**Non-Fault Delays**").

4.2 In the event of any Non-Fault Delays, CMC shall update the Timeline as agreed with the Customer and, shall endeavour to 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 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. Circumstances that occur beyond CMC's control, such as circumstances referenced in 4.1(iii), such as Force Majeure, shall not require a writing.

4.4 Where the Timeline has been amended in accordance with this **Clause 4**, it shall be binding upon the Parties upon mutual agreement. 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 progress of the Services compared to the current Timeline.

Specification, Process & Quantities

4.5 The Specifications shall be amended only as agreed upon in writing by the Parties and signed by an authorized representative of each Party. For the avoidance of doubt, where the Parties cannot agree to modify, amend or update the Specification, the previous Specification as agreed to by the Parties shall apply.

4.6 For clarity 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 derived from a Batch, unless such low or unexpected yield of Product is due to CMC's failure to execute a written process agreed upon by the Parties, thereby resulting in a substantial loss of 50% or more of the fair market value of the Product. The Parties shall use good faith efforts to discuss and agree as to what constitutes substantial loss.

- 4.7 CMC shall not make any change to the Process, except by prior written approval of Customer for such change. The Parties agree to cooperate to amend or supplement the Process to the extent reasonably necessary to comply with changes in Applicable Laws and/or Regulatory Obligations. CMC shall follow the change control procedures set forth in the Commercial Quality Agreement for any proposed changes in the Process.
- Project Manager, Joint Steering Committee and Project Team**
- 4.8 Each Party shall, within thirty (30) days after the Restatement Date, appoint an individual as a project leader ("**Project Manager**") who shall be responsible for leading and co-ordinating the day to day operation of the Services. In addition, within thirty (30) days after the Restatement Date, each Party shall select a maximum of three of their senior technical staff (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**" or "**JSC**").
- 4.9 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 Forecast, Timeline, the Services and communicating between the Parties ("**Project Team**"). Any disputes or issues that cannot be readily resolved by the Project Team shall be referred to the Joint Steering Committee for resolution.
- 4.10 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 Managers shall meet upon reasonable request either in person or by telephone or video-conference and each Party shall bear its own costs for attending such meetings.
- 4.11 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, (iv) providing a forum to discuss any technical difficulties or changes to Services or Batch 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**, and (v) ensure that intent of this Agreement is maintained throughout the Term. The Joint Steering Committee shall meet on a reasonably regular basis during the Term.
- 4.12 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 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.

- 4.13 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 **Clause 18.3** and **18.4**.

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

Forecasts

- 5.1 Commencing on the Restatement Date, and thereafter at the beginning of each subsequent Calendar Quarter, Customer shall, subject to the provisions of this clause, deliver to CMC a rolling twenty-four (24) month forecast of Customer's requirements for CMC to manufacture Product for the following twenty-four (24) months ("**Forecast**").

- 5.2 Each Forecast shall set out the number of Batches of Product to be manufactured for Customer during each Calendar Quarter covered by the Forecast together with the requested Commencement Date and Delivery Date for each Batch covered by the Forecast. CMC shall fulfil Customer Purchase Orders with Batches in accordance with its current 2017 forecast for the remainder of Calendar Year 2017 (Restatement Date until December 31, 2017), including GMP 78 and GMP 79.

- 5.3 In respect of each Forecast:

5.3.1 the first three Calendar Quarter periods covered by the Forecast shall be a definitive and binding order on Customer (a "**Firm Order**");

5.3.2 the fourth Calendar Quarter covered by the Forecast shall be seventy-five percent (75%) binding, the fifth Calendar Quarter shall be fifty percent (50%) binding and the sixth Calendar Quarter shall be twenty-five (25%) percent binding on Customer (a "**Semi-Firm Order**") and the seventh and eighth Calendar Quarters shall be zero percent (0%) binding.

5.3.3 Beginning with the 2018 Calendar Year and for each entire Calendar Year thereafter, the Batch Minimum shall be four (4) Batches. The Batch Maximum shall be ten (10) Batches. Both parties shall use Commercially Reasonable Efforts review the Batch Maximum on a quarterly basis to ensure adequate capacity is made available by CMC. The Batch Maximum may be increased as Customer requires and is mutually agreed to by the parties.

5.3.4 The terms of this Section 5.3 shall not become effective until January 1, 2018.

5.3.5 CMC shall reserve the Slots for the Batch Minimum as described in **Clause 5.3.2** and **5.3.3**. Customer shall be entitled to reserve additional Slots and CMC shall reserve the Slots to meet the rolling forecast up to the annual Batch Maximum.

- 5.3.6 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:
- 5.3.7 The quantity of Product set out in the second, third and fourth Calendar Quarter of the immediately preceding Forecast shall, respectively, in the next Forecast, become the first three Calendar Quarters of the Firm Order without any variation (other than with CMC's prior written consent);
- 5.3.8 The quantity of Product set out in the fifth (5th) Calendar Quarter of the immediately preceding Forecast shall, respectively, in the next Forecast, become the (i) fourth Calendar Quarter in the next Forecast and a Semi-Firm Order for such fourth Calendar Quarter; and the quantity of Product set out in the sixth (6th) Calendar Quarter of the immediately preceding Forecast shall, respectively, in the next Forecast, become the fifth (5th) Calendar Quarter in the next Forecast and a Semi-Firm Order and may be varied by Customer by a maximum of twenty five percent (25%) in whole Batches or three (3) Batch, whichever is the greater;
- 5.3.9 Customer shall provide a new projection for the sixth (6th) Calendar Quarter in accordance with the principles set out in **Clause 5.3**.

5.4 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 by Customer where:

- 5.4.1 The effective forecast will be shifted forward by one quarter; and
- 5.4.2 The preferred delivery dates for the newly effective forecast shall reflect the previously effective forecast plus three (3) months.

Orders

5.5 Orders for Product shall be provided by Customer and accepted by CMC as follows:

- 5.5.1 Customer shall provide written or electronic purchase orders (each, a "**Purchase Order**") for each Firm Order in conformance with the relevant Forecast within fifteen (15) Business Days after each Forecast submitted by Customer under **Clause 5.1** and CMC shall confirm receipt of each Purchase Order within fifteen (15) Business Days. Each Purchase Order shall be in a form reasonably acceptable to CMC and Customer.
- 5.5.2 Each Purchase Order shall include a requested delivery date no earlier than nine (9) months from the submission date of the Purchase Order for each Batch subject to such Purchase Order, unless otherwise agreed by CMC.
- 5.5.3 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.

- 5.6 Notwithstanding the limits on ordering under a Forecast, CMC may, in response to Customer's written request, elect to manufacture additional Batches of Product in a Calendar Quarter beyond the quantity submitted in a Firm Order for that same Calendar Quarter ("**Exceptional Batches**"). CMC's obligation to manufacture Exceptional Batches shall only arise upon CMC's written acceptance whereby the Exceptional Batches accepted by CMC shall be deemed part of the Firm Order(s) for the relevant Calendar Quarter(s).
- 5.7 All quantities of Batches that are the subject of a Firm Order or a Semi-Firm Order (i.e., the binding portion of a Semi-Firm Order) shall (i) be binding ("**Binding Batches**") upon Customer and CMC and (ii) may not be delayed or cancelled by Customer or CMC except as provided for in this Agreement. Partial Batches subject of a Firm or Semi-Firm Order shall be rounded up to the nearest whole Batch.
- 5.8 Should Customer fail to order the Batch Minimum in any Calendar Year, then Customer shall pay to CMC a sum calculated as the difference between Binding Batches and the Batch Minimum multiplied by the Batch Price. CMC shall be entitled to invoice in December of each Calendar Year, and Customer shall pay such invoice within thirty (30) Calendar Days of receipt of invoice in accordance with the provisions of **Clause 7**.
- 5.9 Should Customer delay or cancel a Binding Batch in any Calendar Year, then Customer shall pay to CMC a sum calculated as the number of cancelled or delayed Binding Batches multiplied by the Batch Price ("**Cancellation Fee**"). CMC shall be entitled to invoice the cancelled or delayed Batch no earlier than the Delivery Date, and Customer shall pay such invoice within thirty (30) Calendar Days of receipt of invoice, subject to Clause 5.10 and in accordance with the provisions of **Clause 7**. For the purposes of determining the Batch Minimum, any cancelled Batch for which Customer has paid a Cancellation Fee shall be counted toward the Batch Minimum.
- 5.10 Notwithstanding the provisions of **Clause 5.9** CMC shall undertake Commercially Reasonable Efforts to fill any cancelled Slots with the manufacture of products of another customer ("**Other Customer**") who has not previously reserved a Slot. If CMC sells to such Other Customer GMP manufacturing capacity not previously reserved or contemplated by that Other Customer at the time of the cancellation or delay using the Slot that would have been used for Customer had the cancelled Batch not occurred, then CMC shall credit Customer with the savings achieved through this mitigation (after accounting for out-of-pocket costs incurred by CMC to accomplish such mitigation) and apply this amount against any outstanding or future invoice. Notwithstanding the foregoing CMC shall not be obliged to credit any sum greater than the Cancellation Fees actually paid by Customer. Any Slot filled by such Other Customer, shall count towards the Batch Minimum obligation under **Clause 5.9**.

- 5.11 In the case of cancelled Batches for which Raw Materials have been purchased by CMC and paid by Customer and which cannot be used to manufacture future Batches subject to the Forecast, Customer shall be entitled to elect to either (i) request CMC to arrange shipment of those Raw Materials to Customer, such shipping fees to be paid by Customer or (ii) offer the Raw Materials to CMC for purchase for use with other customers and CMC will reimburse/credit Customer for such quantity of Raw Materials.
- 5.12 CMC shall use the Forecasts to plan for and, as appropriate, reserve Slots in its cGMP manufacturing suite for those Batches to be manufactured under Firm Orders and Semi-Firm Orders according to the then current Timeline.
- 5.13 Where a 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 the entire CMC Facility, shall be reserved as near in time to the existing vacated Slots as CMC's then current schedule will permit.
- 5.14 Supply Failure
Should CMC become aware or conclude that it will be unable to meet the Timeline for manufacture or Delivery of one or more Binding Batch(es) resulting in a halting of manufacture of the Product ("**Supply Failure**"), then CMC shall provide notification in writing to Customer within fifteen (15) Calendar Days of such circumstances, identify the Batches that may be affected by such Supply Failure, identify what CMC believes will cause such Supply Failure and explain what efforts CMC is taking to minimize such Supply Failure (a "**Supply Failure Notification**"). In the event that Customer receives a Supply Failure Notification or a Supply Failure occurs, CMC and Customer shall work collaboratively through the JSC to discuss and find ways for CMC to promptly minimize such prospective or actual Supply Failure and ensure supply of Product as soon as practicable in accordance with the current Forecast and any Purchase Orders accepted by CMC for Batches that may be or are affected by such Supply Failure.
- 5.15 If the Supply Failure results solely from CMC's breach of its obligations under this Agreement, the following shall apply until the Supply Failure is resolved:
- 5.15.1 The Forecast and Customer's obligations thereunder will be suspended such that no additional Batches become Firm Orders and **Clause 5.4** will not apply until Customer agrees the Supply Failure has been resolved and manufacturing resumes.
- 5.15.2 Provided that Customer is not in material or continuous breach of this Agreement and the Supply Failure is not due to or contributed by Customer's acts or omission, Customer shall be entitled to engage an alternate supplier to manufacture the Batches. CMC shall support the transfer of the Process and test methods to such alternate supplier (including conducting a technology transfer consistent with the transfer of information described in **Clause 15**);

- 5.15.3 CMC will reserve capacity for the remaining aggregate Batch Minimum in the year such that when the Supply Failure ends and manufacturing resumes, the remaining Batch Minimum is to be allocated to the subsequent twelve (12) month period or as agreed to by CMC and Customer.
 - 5.15.4 If Customer engages an alternate supplier, the Minimum Batches obligation shall be reduced by an equivalent number of Batches manufactured by the alternate supplier.
 - 5.15.5 Customer shall not be charged under **Clause 5.9** for any failure to meet the Batch Minimum where such failure results from a Supply Failure.
 - 5.15.6 Customer shall not be obligated to pay a Cancellation Fee for Batches that cannot be manufactured or Delivered due to such Supply Failure and Customer shall not be charged under **Clause 5.9** for any failure to meet the Batch Minimum where such failure results from a Supply Failure.
 - 5.15.7 At Customer's sole option, any prepayments for Raw Materials or Batches that cannot be manufactured due to a Supply Failure shall be credited against other payments owed by Customer to CMC under this Agreement.
- 5.16 Notwithstanding any other provision in this Agreement, CMC shall not, while it is seeking to remedy a Supply Failure and achieve supply reinstatement be deemed in breach of its obligations under this Agreement with respect to the supply of Product, except as set forth in Section 5.15.

6. **PACKAGING, STORAGE, DELIVERY AND EXAMINATION**

Packaging, Storage and Transport

- 6.1 Unless otherwise agreed, all Product and Deliverables shall be packaged by CMC in accordance with its applicable packaging SOPs and Applicable Laws. Customer shall inform CMC in advance of any special packaging and labeling requirements and CMC shall accommodate reasonable customer specific packaging requests.

Storage

- 6.2 CMC shall store at the CMC Facility any such Deliverable for a period of forty-five (45) Business Days after Delivery on behalf of Customer. Storage of a Deliverable at CMC's premises after Delivery shall be at Customer's sole risk and liability except that CMC shall be responsible for damage to such Deliverables to the extent any damage is caused during such storage solely by an act of CMC's negligence, willful misconduct and/or illegal conduct. If Deliverables have not been collected by Customer or Customer's Shipping Company forty-five (45) Business Days after Delivery, CMC shall notify Customer of the outstanding collection. CMC shall be entitled five (5) Business Days after such reminder to continue to store it at a cost to Customer of Five Thousand U.S. dollars (\$5,000) per week, unless the

Parties have previously negotiated for longer term storage or Customer informs CMC in writing to dispose of such Deliverables.

Delivery

- 6.3 CMC shall provide Customer with advance written notice of each anticipated Delivery Date and, in any event, shall provide at least twenty (20) Business Days advance written notice of each Delivery Date.
- 6.4 Except as set out in **Clause 6.5** or in the Specifications, the Product that CMC manufactures pursuant to this Agreement shall be released to Customer Ex Works (Incoterms 2010) at the CMC Facility at 9.00 am on the date specified on CMC's notification to Customer that the Product is available for collection. The Deliverables will be deemed to have been delivered upon the date Product is so released in accordance with the Quality Agreement ("**Deliver**", "**Delivery**" or "**Delivered**"). Collection may be arranged at any time during normal business hours on Business Days or such other time as may be agreed by the Parties. 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.
- 6.5 Data, results, Batch records and Drug History Records shall be delivered by courier with registered delivery or by other electronic means agreed by Customer.
- 6.6 Customer shall, prior to the collection of the Deliverables, inform CMC of its Shipping Company. Customer shall coordinate with such Shipping Company for the shipment of the Product and CMC shall not be responsible for any shipping costs of the Shipping Company. Upon collection, Customer shall be responsible for ensuring that the Deliverables are stored and transported in accordance with the Shipping Guidelines.
- 6.7 Following their Delivery, Customer shall promptly examine and/or test the Deliverables for any defect or non-conformity, including in the case of Product non-conformity with the Specifications and cGMP standards which Deliverables are specified to meet (a "**Defect**" or "Defective). Where any alleged 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 and, in the case of Product, the receipt of both the Product and Drug History Records.
- 6.8 Release For Further Processing
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:
- 6.8.1 not be administered to any living organism;
- 6.8.2 be handled by Customer with utmost care and attention and treated with caution as if it were an unknown substance;

6.8.3 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 negligence, gross negligence or wilful misconduct.

Title and Risk

6.9 Subject to **Clause 6.6**, title and risk in the Deliverables shall pass to Customer on Delivery.

Examination of Deliverables for Defects

6.10 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, (iii) reasonable detail, including, as applicable, test results, 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) confirmation that the Deliverables have been stored and transported in accordance with applicable Shipping Guidelines, and (vi) where the Customer asserts that the Defect is due to CMC, the reasons why the Customer makes that assertion. If a Defect in any Deliverable is not notified to CMC in accordance with the provisions and time limits stipulated in **Clause 6.6** the Deliverable shall be deemed accepted and free of Defect and Customer shall have no further remedy against CMC in respect of that Deliverable.

Consequences of Defective Product

6.11 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 fifteen (15) Business Days of receipt of the Defect Notice whether it accepts responsibility for the Defect in full, in part or not.

6.12 If a Defect is primarily due to CMC's fault, and not as a result of any Customer action or inaction or any Third Party (other than an agent of CMC performing Services) then CMC shall replace or rework the Defective Deliverables at no charge to Customer. CMC shall use Commercially Reasonable Efforts having regard to its other obligations and commercial commitments to third parties and subject to availability of Raw Materials in the timing of such replacement, to replace such Defective Deliverables within one hundred and eighty (180) Calendar Days.

6.13 If there is a dispute regarding whether or not a Deliverable is Defective ("**Disputed Deliverable**"), then (a) appropriate persons from both Parties will work together to confirm that any method of analysis used to identify the defect in question was performed correctly and in accordance with the regulatory license for the Product. The Parties will use good faith efforts for a period of thirty (30) days after completing such confirmation to resolve whether the Disputed Deliverable is Defective due to CMC's failure to manufacture in accordance with this Agreement.

6.14 In the event the Parties cannot resolve their dispute, in the manner described, a mutually agreed-upon independent laboratory, acting as an expert and not as an arbitrator, 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. During the further dispute resolution described above in this section, at Customer's request, CMC shall use Commercially Reasonable Efforts to supply Customer with replacement Product subject to availability of Raw Materials and capacity in CMC's Facility, which replacement Product Customer shall purchase on the same terms as Product that is the subject of the independent testing. With respect to all Product that Customer properly rejects, Customer shall destroy all remaining unused Product as soon as possible after CMC's request and at CMC's expense. 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 Customer shall indemnify CMC for all liabilities, costs and damages incurred by CMC resulting from Customer's breach of this limitation on use).

6.15 **The remedies and obligations under Clause 6.12 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.**

7. BATCH PRICE, PAYMENT TERMS AND MILESTONE PAYMENTS

Reserve Payment and Batch Price

- 7.1 Pursuant to a Settlement & Amendment agreement dated November 20, 2012 between CMC and Customer and related amendments ("**Settlement Agreement**"), a fund was established in the amount of \$10 million (the "**Fund**") to part finance the performance of the Services under the Original CSA. Pursuant to the Letter Agreement, the Parties agreed to apply \$3 million from the Fund to settle a disputed invoice issued by CMC on March 25, 2016, leaving \$7 million remaining within the Fund as of the Restatement Date, which will serve as a Reserve Payment under this Agreement. The Reserve Payment of \$7 million shall be applied to the Price of four (4) Binding Batches manufactured by CMC during 2017 ("2017 Batches"), including the price of Raw Materials and other related Services related to Binding Batches. Any portion of the \$7 million Fund not used by close of business, Seattle time by December 25, 2017 shall be paid to the Company on or before December 31, 2017; provided however that any portion of the Fund that can be applied to the Batch Price and any other costs related to any pending 2017 Batches that are in the process of being manufactured shall be retained by CMC.
- 7.2 The Batch Price in Appendix Two is stated in U.S. Dollars and is exclusive of all taxes, duties, or other fees imposed by or under the authority of any state, government or public authority of any nature (other than taxes on CMC's income) or any external costs, Raw Materials or shipping and associated costs that CMC incurs to provide the Services, which Customer agrees to pay in addition to the Batch Price in accordance with the terms herein.
- 7.3 The Batch Price stated in Appendix Two may be adjusted on an annual basis, commencing with the first anniversary of the Restatement Date and thereafter on each anniversary of the Restatement Date in an amount not to exceed the annual percentage change in the latest published version of the *Producer Price Index* for the most recent twelve (12) month period

ending on the date of the anniversary of the Restatement Date or 3% of the Batch Price of the prior twelve (12) month period, whichever is less. The "**Producer Price Index**" means the Producer Price Index for Biological Products for human use (PPI Series ID PCU325414325414T) published by the Bureau of Labor Statistics (or if such index is discontinued, the successor index or, if none, such other similar index mutually agreed upon by the Parties). For the avoidance of doubt, if the annual percentage change is negative, the Batch Price will not change (annual percentage change of 0.0% will be applied). For example, the Batch Price stated in Appendix Two shall apply for the first year of manufacture after the Restatement Date. In the second year following the Restatement Date, the Batch Price shall be the Batch Price stipulated in Appendix Two adjusted by one application of the annual percent change in Producer Price Index as applicable for the 12-month period between the Restatement Date and the 1-year anniversary of the Restatement Date. The adjustment to the Batch Price shall be a compound adjustment based on the immediately preceding Batch Price. The Batch Price applicable to any particular Batch shall be determined by the Commencement Date. CMC shall give written notice to the Customer of the new Batch Price schedule at any time the latest version of the applicable Producer Price Index for the anniversary Restatement Date has been published. Any "true-up" for change in Batch Price due to application of the annual Batch Price adjustment will be invoiced upon release of the Batch to the Customer.

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; or

7.4.2 which result in the financial returns under this Agreement being substantially affected to CMC's detriment other than by the acts or omissions of CMC,

then the Parties shall negotiate in good faith a way to continue the Services while overcoming such financial investment or detriment. For purposes of clarity, CMC shall bear one hundred percent (100%) of the costs of any changes necessary to comply with changes in cGMP or manufacturing regulations promulgated pursuant to enabling legislation under a statute that are not specific to the Product and relate to a general requirement for biologics contract manufacturing services.

Invoicing & Payment Terms

7.5 All invoices will be in U.S. Dollars and Customer agrees to pay all sums due hereunder in U.S. Dollars.

7.6 CMC will issue invoices in accordance with the provisions of Appendix Two.

7.7 All invoices shall be paid by wire transfer to the following account:

ACCOUNT DETAILS:

Silicon Valley Bank



3003 Tasman Drive
Santa Clara, CA 95054
Routing & Transit #: 121140399
Account #: 3300585916

Unless expressly stated on an invoice to the contrary, all invoices are issued net and if not disputed in good faith in writing before the due date, will be paid in full without any deductions, deferment or set off by Customer within forty-five (45) Calendar Days after issuance of invoice to Customer. If Customer disputes an invoice, Customer shall notify CMC in writing of the dispute before the due date, which notice must include a description of the dispute. The Parties shall use Commercially Reasonable Efforts to resolve the dispute as quickly as possible. If the dispute is not resolved within fifteen (15) Calendar Days after the date of Customer's notice, the CEOs of the parties shall meet and resolve the dispute. Customer shall, subject to the other terms and conditions of this Agreement, pay amounts due that are not in dispute.

7.8 Raw Materials costs for all Services will be invoiced to Customer as set forth in Appendix Two. If Customer requests CMC purchase Raw Materials in excess of what is needed to meet the Forecast ("**Excess Raw Materials**"), Customer shall pay to CMC, a sum in respect of CMC's reasonable storage fees for the Excess Raw Materials purchased by CMC ("**Storage Cost**"). CMC shall invoice Customer on a monthly basis for the Storage Cost.

7.9 All shipping costs will be charged with actual shipping fee (if paid by CMC), plus five hundred U.S. dollars (\$500) handling fee for domestic shipping destinations and two thousand U.S. dollars (\$2,000) handling fee for international shipping destinations. CMC shall use Commercially Reasonable Efforts to issue one (1) invoice for the cost of all Services and external costs, including Raw Materials, Storage Cost, shipping costs and associated costs, unless otherwise agreed to by the parties.

Late Payments

7.10 If the undisputed portion of an invoice is not settled by Customer in full in accordance with this Agreement and after providing the Customer with thirty (30) Calendar Days prior written notice to settle such undisputed portion of an invoice, CMC may, at its discretion:

7.10.1 charge Customer, which Customer will pay, interest at a rate of two percent (2%) per month on the sums overdue on a compounded basis until payment is received in full and/or;

7.10.2 until the portion of the invoice is received in full, and with ten (10) Business Days prior written notice to Customer, suspend the performance of the Services. Where performance is suspended, CMC shall have no liability to Customer for such suspension or delay in the Timeline and the Batch Price for any Batches that are the subject of a Firm Order or a Semi-Firm Order which are delayed or cancelled as a result of the suspension shall become due and payable by Customer.

- 7.11 Payments due to Customer
Where any payment, credit or refund is properly due to the Customer under this Agreement, the Customer can elect to:
- 7.11.1 have that amount refunded to it by CMC on thirty (30) Calendar Days' notice; or
 - 7.11.2 have that amount set-off against any further amount payable by the Customer under this Agreement or any future agreement the Parties enter into.
- 7.12 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 thirty (30) Calendar Days of the Customer requesting CMC refund that amount.

8. CUSTOMER AUDITS, REGULATORY INSPECTIONS & MATTERS

- 8.1 Audits
Customer's audit rights are as set forth in the Commercial Quality Agreement.
- 8.2 Regulatory Inspections
CMC shall permit, upon reasonable notice and during reasonable times, a competent governmental or regulatory authority body to enter those areas of CMC's premises 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. Such inspections are subject to:
- 8.2.1 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.
- During any regulatory inspection, CMC shall provide reasonable assistance as requested by the relevant government or Regulatory Authority and shall promptly permit access to, copy and verify records and reports in CMC's possession, custody or control relating to the cGMP Stages of the Services. If the regulatory inspection is related to the manufacture of the Product, with the exception of inspections associated with maintaining the regulatory license (i.e., E.G., FDA biennial inspections), or Customer specific, CMC shall be entitled to charge Customer for such work associated with such visits.
- 8.3 Regulatory Filings and Standards
During the preparation for filing with any Regulatory Authority of any documentation for the Product which is or is equivalent to the Regulatory Authority's Chemistry and Manufacturing Controls portion of an approval application, including any BLA ("**Authority Submission**"), 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 Process that

CMC will perform pursuant to this Agreement. CMC shall provide Customer with its comments within thirty (30) Business Days from receipt of the documents. For clarity, CMC's thirty (30) Business Day review period applies to the first review of the document. Subsequent minor reviews and comments shall be provided by CMC to the Customer within ten (10) Business Days from receipt of the documents.

- 8.4 For clarity, the Parties agree that in reviewing the documents referred to in **Clause 8.3** above, CMC's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by CMC hereunder. As such, CMC shall not assume responsibility or liability for the accuracy of the filings with Regulatory Authorities other than for information provided by CMC in writing and intended for inclusion in regulatory filings. The sole responsibility of the preparation and filing of all regulatory documents with the Regulatory Authorities with respect to the Product shall be borne by Customer.
- 8.5 Customer shall provide to CMC all documents relating to the Product and services performed hereunder by CMC that are reasonably requested by CMC and required to comply with any Regulatory Authority's pre-approval inspection of the CMC Facility, including but not limited to, development reports, Chemistry and Manufacturing Controls documentation and stability data, subject to Customer being able to legally provide such documents to CMC.
- 8.6 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 related to the CMC-generated data.
- 8.7 CMC will provide Customer with information and data regarding the manufacture of Product to the extent reasonably requested by Customer or necessary for Customer to prepare and defend any inquiries from the FDA or other Regulatory Authorities to satisfy regulatory requirements with respect to Product. Without limiting the foregoing,
- 8.7.1 CMC shall provide regulatory support to Customer for a Regulatory Authority's pre-approval inspection of the CMC Facility and during review of any Authority Submission at a cost specified in Appendix Two.
- 8.7.2 Customer will inform CMC of requests for information from Regulatory Authorities during review of an Authority Submission for which CMC support is needed. CMC will use diligent efforts to adhere with the turn-around times requested by Customer to support such regulatory responses.

9. WARRANTIES

Customer Warranties

- 9.1 Customer warrants and represents to CMC that:

- 9.1.1 to the best of its knowledge, it 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 for use in the performance of the Services and the manufacture of Product pursuant to this Agreement;
- 9.1.2 to the best of its knowledge, the Materials and Safety Data Sheet for the BDS and Cell Line is accurate and 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 accordance with the recommendations and guidelines in the Materials and Safety Data Sheet supplied by Customer will not cause a health hazard or biohazard;
- 9.1.3 to the best of its knowledge the use of any of the Cell Line, Customer Materials, 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 the Product according to the Specification and it knows of no reason (suspected or otherwise) why the Objective cannot be achieved or the Services successfully performed and the information regarding the Cell Line and the Process provided to CMC by or on behalf of the Customer is complete and accurate.
- 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 it has the necessary permits, facilities, Third Party contractors and skilled personnel necessary of a biologics contract manufacturer for the regular provision of manufacturing and development services of biologic material and required for performance of the Services in accordance with this Agreement;
- 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 and the performance of 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 the Services are to be performed according to cGMP, CMC shall apply the appropriate cGMP standards to the performance of such Services and perform the Services in accordance with the Commercial Quality Agreement; and
- 9.2.5 the Product when Delivered to Customer and released with a Certificate of Analysis by CMC, shall comply with the Specifications 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; and
- 9.2.7 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.

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 and the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;
- 9.3.2 it shall obtain and during the Term maintain in force all appropriate permits and regulatory licenses required in connection with such Party's handling, transport and storage of the Cell Line and Product; and
- 9.3.3 neither Party shall perform any actions that are prohibited by local and other anti-corruption laws (including the U.S. Foreign Corrupt Practices Act, collectively "**Anti-Corruption Laws**") that may be applicable to one or both Parties. Without limiting the foregoing, neither Party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other third party related to the transaction in a manner that would violate Anti-Corruption Laws.

Exclusion of other express and implied warranties

9.4 Except as provided in this Agreement, 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 of the Disclosing Party;
 - 10.1.2 use the Confidential Information of the Disclosing Party only during the Term for those purposes reasonably necessary to perform its obligations or exercise its rights under this Agreement and without prejudice to the generality of the foregoing, not use any Confidential Information of the Disclosing Party to obtain any commercial advantage over the Disclosing Party;
 - 10.1.3 ensure the proper and secure storage of all Confidential Information of the Disclosing Party applying standards of care reasonably expected and no less stringent than standards applied to protection of Recipient Party's own confidential information; and
 - 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 of the Disclosing Party 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 such 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;
- 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;
 - 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, including 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 was independently discovered or developed by the Recipient Party without the use of or reference to the Disclosing Party's Confidential Information as evidenced by written records.

- 10.3 In addition, notwithstanding **Clause 10.1**, the Recipient Party may disclose Confidential Information to the extent the disclosure is required by Applicable Law or a valid order of a court or other governmental body having jurisdiction; *provided, however,* that the Recipient Party gives reasonable prior written notice to the Disclosing Party of such required disclosure and makes a reasonable effort to assist the Disclosing Party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation requires, or for which the order was issued. Notwithstanding anything to the contrary herein, Customer may use and disclose Confidential Information of CMC in preparing and submitting BLAs to Regulatory Authorities or marketing Products with CMC's prior written consent, which shall not be unreasonably withheld.
- 10.4 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.
- 10.5 If the Recipient Party or any of its Permitted Recipients is/are compelled to disclose any Confidential Information in the circumstances described in **Clause 10.3** 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.
- 10.6 Each Party shall be permitted to disclose the terms of this Agreement, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement, to any actual or potential acquirers, merger partners, licensees, sublicensees, investors and professional advisors on a need to know basis and to its board of directors in connection with the corporate governance of such Party. Except as otherwise provided for in this Agreement (including this **Clause 10.6**) 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.
- 10.7 At the request of the Disclosing Party, the Recipient Party shall promptly destroy (on request) or 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 copies of any document containing the Disclosing Party's Confidential Information solely for the purpose of determining the scope of the obligations under this Agreement or to comply with regulatory obligations. Further, the Recipient Party shall not be required to

return or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by their automatic or routine archiving and back-up procedures.

- 10.8 The Parties acknowledge that they have received Confidential Information under other agreements between each other. 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 or exercising rights under this Agreement.
- 10.9 The provisions of this **Clause 10** shall survive expiration or termination of the Agreement for a period of 10 years.
- 10.10 For the avoidance of doubt, the provisions of this **Clause 10** do not restrict the Customer's right to disclose or otherwise deal with the Deliverables after such Deliverables have been Delivered to the Customer.

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 Restatement 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 Pre-Existing IPR. Nothing in this Agreement shall act as any assignment or 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.

CHEF1 Technology

- 11.2 Notwithstanding anything to the contrary in this Agreement, CMC retains sole ownership of all right, title and interest in (a) the CHEF1 Technology; (b) any polynucleotides or vectors comprising any CHEF1 Technology and any host cells transfected with those polynucleotides or vectors; (c) all Intellectual Property rights in any of (a) or (b); and (d) all improvements or modifications to any of (a), (b) or (c) (collectively, "**CHEF1 Property**"). Nothing in this Agreement grants or obligates CMC to grant any rights in the CHEF1 Property to Customer or any third party.

Customer's grant of Intellectual Property License for the Services

- 11.3 The Customer hereby grants to CMC for the Term a non-exclusive, royalty-free, sublicensable to Affiliates, limited license in respect of Customer Intellectual Property Rights solely to the extent the same is required and necessary for the proper performance of the Services. This license:

11.3.1 does not prevent the Customer from granting a license to or making any use of its Pre-Existing IPR; and

11.3.2 terminates automatically upon the expiry or termination of this Agreement, whichever is the earlier.

Intellectual Property created in the course of the Services

11.4 Without affecting **Clauses 11.1** and **11.2**, all data, results, information, processes, materials, trade secrets, know-how and corresponding Intellectual Property newly generated by CMC exclusively in its performance of the Services and which is related to the Product and is not useful for general biologics manufacturing activities shall be owned by Customer ("**Customer Agreement IPR**"). CMC shall cooperate with Customer and execute any appropriate documents to fully effect the foregoing.

11.5 All Intellectual Property other than Customer IPR generated by CMC under the Services shall be owned by CMC ("**CMC IPR**").

License to CMC IPR

11.6 CMC hereby grants to Customer a general, royalty free, sub-licensable, worldwide license to use CMC Intellectual Property Rights or CMC IPR to the extent that the same is necessary or useful for the exploitation (including to make, have made, use, sell, offer for sale, distribute or import) of the Product or use of the Cell Line or Process to manufacture Product. Except to Permitted Recipients or as otherwise provided in this Agreement, 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 Agreement IPR.

Right to file for protection

11.7 Each Party may file patent protection on any Intellectual Property it owns in accordance with this **Clause 11** above 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

11.8 Except as otherwise provided for in this Agreement or required by Applicable Law, 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, publication or other without the prior consent of the other Party, which shall not be unreasonably withheld or delayed.

12. INDEMNITIES AND LIABILITY

CMC's Indemnity

12.1 Customer shall indemnify, defend and hold harmless CMC and each of its directors and officers and Testing Laboratories (the "**CMC Parties**") against any and all losses, demands, 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) ("**Losses**") arising out of any claim, action or proceeding ("**Claims**") that the CMC Parties may or have suffered or incurred directly as a result of the following:

12.1.1 any third party claim of infringement or alleged infringement or breach of any Third Party Intellectual Property rights by CMC's use of the Cell Line, Process, Customer

Intellectual Property Rights, Customer Materials in the performance of the Services or manufacture of Product hereunder;

- 12.1.2 any third party claims resulting from the use, handling, distribution, marketing, safety or sale of the Product or BDS, including any derivative, conjugated form or formulation of the same, by or on behalf of Customer;
- 12.1.3 Any Recall other than one for which CMC is responsible pursuant to Clause 13.3;
- 12.1.4 any contamination or damage to CMC's operations or CMC Facility caused by the Cell Line or Customer Materials except to the extent such Cell Line and Customer Materials were not handled in accordance with this Agreement or the guidelines set out in the Materials and Safety Data Sheets;
- 12.1.5 any use, handling, distribution, marketing, safety or sale by or on behalf of Customer of Product which was the subject of a Release for Further Processing in accordance with **Clause 6.13**; or
- 12.1.6 any acts or omissions of an auditor of Customer while on CMC's premises.

The foregoing indemnities shall not apply to the extent the Losses or Claims arose from CMC's or any of its representatives or contractors (including Testing Laboratories) negligence, gross negligence, breach of this Agreement, or wilful misconduct or are covered by an indemnity under **Clause 12.2**.

Customer's Indemnity

12.2 CMC shall promptly indemnify, defend and hold harmless Customer and each of its directors and officers, employees, agents, contractors or representatives ("**Customer Parties**") against any and all Losses arising out of any Claim that the Customer Parties may or have suffered or incurred directly as a result of the following:

- 12.2.1 third party claim due to a material inaccuracy in a Certificate of Analysis such that certified Product at the time of Delivery does not meet Specification when certified to meet Specification;
- 12.2.2 third party claim to the extent caused by CMC's failure to manufacture Product or BDS according to cGMP, the Process or the Specifications; or
- 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, but excluding claims where such use is in combination with the Cell Line, Customer Materials, Process or Customer Intellectual Property Rights.

The foregoing indemnities shall not apply to the extent the Losses or Claims arose from the Customer or any of the Customer Parties' negligence, gross negligence, breach of this Agreement or wilful default or are covered by an indemnity under **Clause 12.1**.

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 twenty-one (21) Calendar Days of it receiving notice of the Claim, threat or action, notify the other Party (the "**Indemnitor**") in writing in general terms of any 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 Claims;
 - 12.3.2 not prejudice any defence to any 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 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).
- 12.5 In the event of a claim under **Clause 12.2.3**, 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 the Claim. In the event that legal proceedings are commenced by a Third Party, the Parties shall use their best endeavours to conduct such discussions as

expeditiously as possible. If the Parties are unable to agree to a solution to avoid the infringement within thirty (30) days of good faith negotiations, CMC may, upon written notice to Customer, suspend the infringing Services without liability.

Insurance

- 12.6 Customer shall procure from a reputable insurance carrier commercial general liability insurance including coverage for product liability with a combined single limit of no less than fifteen million dollars (\$15,000,000) per occurrence and fifteen million dollars (\$15,000,000) in the aggregate pursuant to a claims made policy. Customer will maintain such insurance during the Term of this Agreement and for three (3) years after the last sale of a Commercial Product. Upon reasonable request, Customer will deliver a certificate of insurance evidencing such coverage and an endorsement of additional insured in favour of CMC.
- 12.7 CMC shall maintain, at its expense comprehensive general liability insurance and workers compensation insurance, including product liability insurance, in the amount of five million dollars (\$5,000,000) 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 Customer upon reasonable request. Notwithstanding the preceding sentence, CMC shall be obligated to maintain product liability insurance obtained by it pursuant to this **Clause 12.7** during the Term and after expiration or termination of this Agreement for a period three (3) years following the Commercial Product expiration date for the last lot of Commercial Product delivered hereunder.
- 12.8 Each Party will provide the other Party evidence of such coverage upon request. Each Party will provide the other Party with at least thirty (30) days' written notice prior to non-renewal, termination or modification of their respective insurance coverage as described above.

Limitation of Liability

- 12.9 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 16, 12.10** and **12.11**, 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 shall be limited to the lesser of the total Price of the Services actually paid to CMC in the twelve (12) month period preceding the occurrence of the event giving rise to the claim or five million dollars (\$5,000,000 USD).
- 12.10 Without prejudice to **Clause 12.11** 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:

12.10.1 loss of indirect profits, business, business opportunities or revenue; and

12.10.2 special, indirect or consequential loss.

12.11 Nothing in this Agreement shall purport or attempt or serve to exclude or restrict any liability for (i) gross negligence; (ii) liability for any fraud or fraudulent misrepresentation; (iii) amounts owed by a Party under Appendix Two; or (iv) claims indemnified by Customer under Section 12.1.

13. PRODUCT RECALL

13.1 Subject to **Clause 13.3.1**, 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. 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 as a result of CMC's failure to manufacture Product in accordance with the terms of this Agreement or cGMP ("**CMC Failure**"), then CMC shall, subject to **Clause 12**, reimburse Customer for all reasonable expenses incurred by Customer in undertaking the Recall of those specific Products which are the subject of a CMC Failure. Such payment shall be made within forty-five (45) days after Customer providing CMC with an invoice for such costs. If CMC 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 CMC Failure, then the Parties shall mutually select an independent laboratory to evaluate whether the Product is defective due to CMC's CMC 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). If such evaluation substantially supports CMC's basis(es) for the dispute, then CMC shall not be responsible for any costs of the Recall. Subject to Clauses 9 and 12, any payment by CMC under this Clause 13.3 shall be Customer's sole remedy for the costs of the Recall.

- 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 The Original CSA governed the relationship between the Parties from the Original Effective Date to the Restatement Date. **This Agreement shall commence on the Restatement Date and will, subject to earlier termination in accordance with this Clause 14** or otherwise, continue for a term of five (5) years from the Restatement Date (the "Term"). The term of this Agreement may be extended beyond the then current Term for two-year periods with no less than twenty – four (24) month notice before the expiry of the Term.

14.2 Upon Customer reaching a decision not to extend the Term with an Additional Term (i) it shall within ten (10) Business Days of that decision provide written notice to CMC of its intention; and (ii) Customer shall not be entitled to seek extension of the Term under the provisions of **Clause 14**.

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 undisputed sum payable under this Agreement within sixty (60) Calendar 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 thirty (30) Calendar Days starting on the date of receipt of notice from the Non-Defaulting Party generally identifying the breach and requiring it to be remedied, or (ii) if the breach is CMC's breach in the manufacture or performance of a Batch (including but not limited to a Supply Failure as per Clause **5.15**), CMC fails to commence manufacture of a replacement Batch within twelve (12) months of receipt of notice from the Non-Defaulting Party generally identifying the breach and requiring it to be remedied;
- 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;

14.2.4 any material permit or regulatory license is permanently revoked preventing the performance of the Services by the Defaulting Party.

For purposes of this Agreement and, without limitation, the assessment of a material breach under this Clause 14.2.4 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 under this Agreement.

14.2.5 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.

Effect of Termination

14.1 Upon termination of this Agreement, Customer shall pay to CMC:

14.1.1 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 for the cancelled Services (fairly determined by the Project Team having regard to man hours, materials, profit element and irreversible commitments incurred by CMC);

14.1.2 according to Customer being the Defaulting Party under **Clause 14.3**:

14.1.2.1 in respect of Firm Orders and Semi-Firm Orders in existence at the date of termination, a payment calculated as (i) the total Batch Price in respect of all pending, outstanding and undelivered Binding Batches (including the binding portion of a Semi-Firm Order) that have not been Delivered at the time of termination, provided, that in no event shall such amount to be paid to CMC be less than the total price of three (3) full batches, and CMC shall deliver to Customer all such Batches dispositioned but not Delivered as of the effective date of termination and paid for by Customer pursuant to this clause;

14.1.3 payments due at the time of termination pursuant to **Clauses 5.9, 5.10, 7.5, 14** and/or **Appendix Two** are to be made within ninety (90) days;

14.2 Upon termination of this Agreement for any reason, provided the Customer has paid all undisputed sums outstanding and which are properly due under this Agreement, CMC shall, within forty-five (45) Calendar Days of the date of termination of this Agreement, 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 where the Customer has not paid CMC all sums

properly due within forty-five (45) Business Days of the date of termination of this Agreement.

Survival

- 14.3 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 1.1., 1.2, 1.3, 3, 6.10 – 6.15, 7.4, 7.10, 9 – 12, 13.3 and 14 - 18** shall survive termination or expiry and remain in full force and effect.

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 for material breach by Customer or (ii) on expiry of this Agreement; Customer may by written notice to CMC seek assistance from CMC with respect to the transfer to another manufacturer of the then-current Process and test methods solely for the purpose of manufacturing and testing the Product ("**Technology Transfer**"). Following CMC's receipt of such notice, the Parties will establish, in good faith, a schedule and plan for effecting such transfer and CMC will thereafter co-operate with Customer in implementing such plan as agreed by the Parties. As part of the Technology Transfer, CMC will make available for collection, subject to any Regulatory Obligations, all Customer Materials, Cell Line and one copy of all documentation (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 and validation reports and production process documentation, test method SOPs and method development and validation reports.
- 15.2 The obligations on CMC in respect of the Technology Transfer shall only be exercisable by Customer within a period of nine (9) months after the date of termination by either party or expiry (whichever is the earlier) and CMC shall not be obliged to commit any greater human resources in the Technology Transfer than sixty (60) FTE days. In the event Customer engages a second source of supply, CMC agrees to work jointly with Customer in the Technology Transfer to that second source of supply. Customer shall pay, CMC's costs providing the Technology Transfer at a daily FTE rate set out in the Work Statement executed for the Technology Transfer. The Customer will not, and CMC will not be obliged to, transfer any CMC Know-How pursuant to this Technology Transfer until the contract manufacturer to whom the process is transferred enters into a limited royalty-free license and confidentiality agreement reasonably acceptable to and with CMC in order to protect CMC's Know-How and Confidential Information.

16. FORCE MAJEURE

- 16.1 CMC shall not be held liable or responsible to Customer nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this 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 (a "**Force Majeure Situation**").

- 16.2 CMC shall notify Customer in writing of any Force Majeure Situation which prevents CMC from complying with an obligation under this Agreement. If a Force Majeure Situation continues for more than three (3) months after notice of such Force Majeure Situation is served, and is adversely affecting the performance of this Agreement, each Party which is will have the right, on thirty (30) days' advance written notice 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 for which Services have been rendered or any claim for damages solely as a result of the termination of this Agreement or non-performance of the Services due to such Force Majeure Situation. 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 Situation 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 of termination where CMC has been able to undertake the Services or parts thereof notwithstanding the Force Majeure Situation. This **Clause 16.2** shall not apply to excuse either Party's payment obligations under this Agreement nor relieve Customer from the payment of Firm Orders.

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, 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) days of the Dispute Notice being given the Parties shall each refer the Dispute to their respective Chief Executive Officers who shall meet in order to attempt to resolve the dispute. If within thirty (30) 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 Dispute may be submitted to and finally be settled by the Courts of or sitting in the State of New York. Nothing in this MSA shall prohibit (nor force) the Parties to submit to any other dispute resolution forums as they may between themselves subsequently agree to or discuss.

18. MISCELLANEOUS

Fundamental Change

- 18.1 The occurrence of a Fundamental Change shall not relieve CMC of its responsibility for performance of its obligations under this Agreement. CMC must promptly:
- 18.1.1 notify Customer as soon as CMC is aware that a Fundamental Change has occurred or is reasonably likely to occur;
- 18.1.2 upon request, provide to Customer such further information and written assurances, from CMC and its successors that there will be no adverse consequences to the supply of Product to Customer or the performance of CMC obligations under this Agreement resulting from the occurrence of the Fundamental Change. Without prejudice to the generality of this **Clause 18.1.2**, Customer may seek written assurances from CMC and its successors relating to CMC's ongoing corporate and management culture, capacity, capability and financial viability.
- 18.2 Neither CMC nor its successor shall be entitled to terminate this Agreement as a result of a Fundamental Change.

Amendment

- 18.3 Other than as provided for elsewhere in this Agreement in respect of the Timeline, 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.
- 18.4 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

- 18.5 This Agreement may not be assigned by either Party without the prior written consent of the other Party except that a Party may otherwise assign its respective rights and transfer its respective duties to any assignee of all or substantially all of its business (or that portion thereof to which this Agreement relates) or in the event of its merger or consolidation or similar transaction.
- 18.6 An assignment by either Party will not release that Party of any obligation to the other Party under the terms of this Agreement.

18.7 Entire 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 subject matter of this Agreement. If any term of this Agreement conflicts with any term of the Commercial Quality Agreement, the conflicting term of this Agreement shall prevail.

18.8 Waiver and Amendment
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.

18.9 Severability
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 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.

18.10 Notices
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 18.10** (or as otherwise notified by that Party hereunder). Any such notice shall be deemed to have been received:

18.10.1 if hand delivered or sent by prepaid recorded or special delivery post or prepaid international recorded airmail, at the time of delivery;

18.10.2 if sent by post (other than by prepaid recorded or special delivery post), 5 (five) Business Days from the date of posting; or

18.10.3 if sent by airmail (other than by prepaid international recorded airmail), 5 (five) Business 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 5.00p.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 9.00a.m. on the next Business Day.

The addresses of the Parties for the purposes of this **Clause 18.10** are:

CMC ICOS Biologics, Inc.
22021 20th Avenue SE
Bothell, WA, USA 98021

For the attention of:
Legal Department
Aptevo Biotherapeutics LLC.
2401 4th Avenue, Suite 1050
Seattle, WA, USA 98121

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 (5) 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

18.11 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

18.12 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 authorise 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.



THIS AGREEMENT has been executed by or on behalf of the Parties on the Restatement Date.

Signed on behalf of)
CMC ICOS BIOLOGICS, INC.)
by)
Name: _____)
Position: _____)
)

Signed on behalf of)
APTEVO BIOTHERAPEUTICS LLC.)
by)
Name: _____)
Position: _____)
)
)
)
)

COMMERCIAL SUPPLY AGREEMENT

APPENDIX ONE

Product specification and list of relevant quality documents

APPENDIX TWO

Batch Price and Payment Terms

Pricing

Batch Prices for incremental orders in a given year are based on the table below and shall be implemented on January 1, 2018. The price is adjusted by the US Producer Price Index for Biological Products for human use (PPI Series ID PCU325414325414T) published by the US Bureau of Labor Statistics on an annual basis or 3%, whichever is less.

| Incremental Batch # in a Campaign | Price for incremental orders in a Campaign |
|-----------------------------------|--|
| 1-2 | \$ 1.30M |
| 3-5 | \$ 1.261M |
| 6-8 | \$ 1.235M |
| 9+ | \$ 1.170M |

Example: The Batch Price for six back to back Batches in a Campaign shall be as follows – Batches 1-2 charged at \$1.30M/Batch, Batches 3-5 charged at \$1.26M/Batch, Batch 6 charged at \$1.235M/Batch.

- Orders of a single Batch or multiple Batches ordered during a Calendar Year not in a Campaign shall be is at Full Price.

Payment Terms

Payment terms shall not become effective and no payment shall be due until January 1, 2018.

- 15% of Batch Price as a Deposit nine (9) months prior to vial thaw.
- 35% of Batch Price at vial thaw.
- 25% of Batch Price upon release of each Batch by CMC Quality.
- 25% of Batch Price upon Batch release by Customer Quality.

Raw Materials:



Customer Owned Raw Materials: For the following Raw Materials, CMC will order these Raw Materials in advance of manufacturing as needed to maintain reasonable inventory for anticipated manufacturing. The cost of these Raw Materials will be billed to the Customer, plus ten percent (10%), when the Raw Materials are ordered, with payment due within thirty (30) days from the invoice date.

Customer Owned Materials:

- Soy Powder
- Basal Media 18 Powder 100L
- Basal Media 18 Powder 10L
- Basal Media 19 Powder 100L
- Resins

Estimated Bill of Materials Invoice: Estimated cost of the Bill of Materials, excluding Customer Owned Raw Materials, and consumables to be used in each Batch, plus ten percent (10%), shall be submitted to Customer ninety (90) days prior to the forecasted batch thaw date (the "Estimated Materials Invoice") and shall be due and payable within thirty (30) Business Days.

Final Invoice: CMC shall provide Customer with a final itemized invoice of all costs associated with each Batch within thirty (30) Business Days from fill date (the "Final Invoice"). Any difference between the Final Invoice and the Estimated Materials Invoice owed to CMC shall be payable within thirty (30) days from the date of the Final Invoice. Any difference between the Estimated Materials Invoice and the Final Invoice owed to Customer shall be credited to the Customer within thirty (30) days from the date of the Final Invoice. After the Final Invoice has been submitted to Customer, no other costs shall be billed to Customer for a completed Batch.

Project Management:

- A project management fee shall be charged in accordance with the Forecast and the following tiered fee schedule, commencing at Batch Minimum as defined herein:

| # of Forecasted Batches for the Calendar Year | Project Management Fee per Month |
|---|----------------------------------|
| 4 | \$5,000 |
| 5 | \$6,250 |
| 6 | \$7,500 |
| 7 | \$8,750 |
| 8 + | \$10,000 * |

* Project management fee shall be charged only after July 1, 2017 and shall not exceed \$10,000 per month for the duration of this Agreement.

Other Activities:

- Other activities (i.e., stability testing, etc.) will be performed by CMC upon request by Customer with the scope of work and pricing agreed in writing by the Parties in a Project Change Order (PCO).

APPENDIX THREE

First Forecast

[To be Provided by Customer]

**FOURTH AMENDMENT
TO LICENSE AND CO-DEVELOPMENT AGREEMENT**

THIS FOURTH AMENDMENT ("**Fourth Amendment**") effective as of June 19, 2017 ("**Effective Date**"), is made by and between **MorphoSys AG**, a German corporation (registered at the District Court of Munich, HRB121023) having an office and place of business at Semmelweisstrasse 7, 82152Planegg, Germany, (collectively with its affiliates, "**Morphosys**") and **Aptevo Research and Development LLC** (previously Emergent Product Development Seattle, LLC), a US corporation (registered in Delaware, N° 4858233) having an office and place of business at 2401 Fourth Avenue, Suite 1050, Seattle, Washington, USA ("**Aptevo**").

WHEREAS, Aptevo and MorphoSys entered into that License and Co-Development Agreement dated as of August 19, 2014, as amended by first amendment effective as of July 8, 2015, by second amendment effective as of December 7, 2015 and by third amendment effective as of December 8, 2016 ("**Agreement**"); and

WHEREAS, Aptevo and MorphoSys now desire to further amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Aptevo and MorphoSys hereby agree as follows:

1. **Incorporation of Recitals; Capitalized Terms.** The Recitals set forth above are deemed to be true and accurate in all respects and are hereby incorporated into this Fourth Amendment by reference. Capitalized terms used herein shall have the same meanings ascribed to them in the Agreement unless otherwise expressly defined herein.

2. **Section 4.4.1 (a) of the Agreement shall be deleted in its entirety and replaced as follows:**

4.4.1 General.

(a)

- (i) Calendar Year 2016. Aptevo shall bear seventy-five percent (75%) of all Development Costs for the Calendar Year 2016 and MorphoSys shall bear twenty-five percent (25%) of all Development Costs for the Calendar Year 2016 (whether incurred by Aptevo or MorphoSys or their respective Affiliates, sublicensees or subcontractors) set forth in the Development Budget for the Calendar Year 2016 with respect to any Development Activities for the Calendar Year 2016 (including Manufacturing Development Activities); *provided, however*, that Development Costs for the Calendar Year 2016 incurred by Aptevo or its Affiliates, sublicensees or subcontractors (and shared by MorphoSys twenty-five percent (25%)), will be limited to Four Million Four Hundred Seventy Five Thousand Dollars (\$4,475,000) in 2016 and Development Costs for the Calendar Year 2016 incurred by MorphoSys or its Affiliates, sublicensees or subcontractors (and shared by Aptevo seventy-five (75%)) will be limited to One Million Five Hundred Eight Thousand Euros

(\$1'508,000). If expenses incurred by either Party in Calendar Year 2016 exceed those listed above, then the additional expenses shall be paid by the Party incurring them—unless the other Party agrees in advance to share the additional expenses according to the percentages given above.

- (ii) Calendar Year 2017.
 - (x) Aptevo shall bear seventy-five percent (75%) of all Development Costs from January 1, 2017 to August 31, 2017 and MorphoSys shall bear twenty-five percent (25%) of all Development Costs from January 1, 2017 to August 31, 2017 (whether incurred by Aptevo or MorphoSys or their respective Affiliates, sublicensees or subcontractors) as set forth in the Development Budget for the Calendar Year 2017 (including Manufacturing Development Activities).
 - (y) Aptevo shall bear forty-nine percent (49%) of all Development Costs from September 1, 2017 to December 31, 2017 and MorphoSys shall bear fifty-one percent (51%) of all Development Costs from September 1, 2017 to December 31, 2017 (whether incurred by Aptevo or MorphoSys or their respective Affiliates, sublicensees or subcontractors) as set forth in the Development Budget for the Calendar Year 2017 (including Manufacturing Development Activities).
- (iii) Calendar Year 2018. Aptevo shall bear forty-nine percent (49%) of all Development Costs for the Calendar Year 2018 and MorphoSys shall bear fifty-one percent (51%) of all Development Costs for the Calendar Year 2018 (whether incurred by Aptevo or MorphoSys or their respective Affiliates, sublicensees or subcontractors) set forth in the Development Budget for the Calendar Year 2018 (including Manufacturing Development Activities).
- (iv) Calendar Years 2019 and beyond. Aptevo shall bear thirty-six percent (36%) of all Development Costs for the Calendar Year 2019 and all subsequent Calendar Years and MorphoSys shall bear sixty-four percent (64%) of all Development Costs for the Calendar Year 2019 and all subsequent Calendar Years (whether incurred by Aptevo or MorphoSys or their respective Affiliates, sublicensees or subcontractors) set forth in the applicable Development Budget with respect to any Development Activities for the Calendar Year 2019 and all subsequent Calendar Years (including Manufacturing Development Activities). Notwithstanding the foregoing, beginning in Calendar Year 2019 Aptevo's obligation to bear its thirty-six percent (36%) share of all Development Costs is subject to the Development Cost Cap.

3. Article 13.2 b) of the Agreement shall be deleted in its entirety and replaced as follows:

13.2 b)

MorphoSys shall also have the right to terminate the Agreement at its sole unfettered discretion by written notice either: (i) with immediate effect (i.e. with no

notice period) within one week after the ADA test results from six (6) subjects participating under the ES414 Protocol 401 Amendment 2 of the Phase I/II Clinical Trial Dose Escalation Phase that have been treated for three (3) twenty-eight (28) day cycles (or the relevant number of cycles and days on treatment foreseen in ES414 Protocol 401 Amendment 2), have been obtained and have been discussed at a JSC meeting, or (ii) at any time during the last two (2) weeks of August 2017 with effect as of August 31, 2017, but regardless whether (i) or (ii) occurs first. For the avoidance of doubt continuous payment obligations from MorphoSys to Aptevo pursuant to Article 14.1.2 shall not apply if MorphoSys terminates the Agreement pursuant to this Article 13.2 (b).

4. Interpretation; Full Force And Effect; Counterparts. Except as expressly amended hereby, the Agreement shall continue in full force and effect. This Fourth Amendment is incorporated and made a part of the Agreement between MorphoSys and Aptevo. In the event of any conflict or inconsistency between the Agreement and this Fourth Amendment, the latter shall prevail. This Fourth Amendment may be executed by the Parties hereto in one or more counterparts, all of which shall be valid and binding on the Party or Parties executing them and all counterparts shall constitute one and the same document for all purposes. Each Party hereto represents and warrants that this Fourth Amendment has been duly authorized, executed and delivered by or on behalf of such Party.

IN WITNESS WHEREOF, Aptevo and MorphoSys have entered into this Fourth Amendment as of the Effective Date.

Aptevo Research and Development LLC

By: _____

Name: _____

Title: _____

Date: _____

MorphoSys AG

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jeff Lamothe, certify that:

1. I have reviewed this Quarterly Report on form 10-Q of Aptevo Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and
5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: August 10, 2017

By: _____ /s/ Jeff Lamothe
Jeff Lamothe
Senior Vice President, Chief Financial Officer, and
Treasurer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Aptevo Therapeutics Inc. on Form 10-Q for the period ending June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 10, 2017

By: _____ /s/ Marvin White
Marvin White
President and Chief Executive Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Aptevo Therapeutics Inc. on Form 10-Q for the period ending June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 10, 2017

By: _____ /s/ Jeff Lamothe

Jeff Lamothe
Senior Vice President, Chief Financial Officer,
and Treasurer