

**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 March 31, 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, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

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 May 10, 2017, the number of shares of Registrant's common stock outstanding was 21,199,794.

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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	<u>March 31, 2017</u>	<u>December 31, 2016</u>
Current assets:		
Cash and cash equivalents	\$ 14,014	\$ 9,676
Restricted cash	400	400
Short-term investments	46,877	44,849
Accounts receivable, net	1,926	4,284
Inventories	8,063	6,639
Prepaid expenses and other current assets	6,116	5,566
Total current assets	<u>77,396</u>	<u>71,414</u>
Property and equipment, net	6,384	5,910
Intangible assets, net	14,013	14,534
Total assets	<u>\$ 97,793</u>	<u>\$ 91,858</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 8,766	\$ 11,489
Accrued compensation	2,505	4,009
Sales rebates and discounts	2,310	3,235
Deferred revenue, current portion	878	811
Total current liabilities	<u>14,459</u>	<u>19,544</u>
Deferred revenue, net of current portion	2,802	2,896
Long-term debt, net	18,435	18,383
Other liabilities	611	469
Total liabilities	<u>36,307</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; 21,219,950 and 20,271,737 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	21	20
Additional paid-in capital	152,143	151,271
Accumulated other comprehensive loss	(41)	(33)
Contribution receivable from former parent	—	(20,000)
Accumulated deficit	(90,637)	(80,692)
Total stockholders' equity	<u>61,486</u>	<u>50,566</u>
Total liabilities and stockholders' equity	<u>\$ 97,793</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)

	For the Three Months Ended March 31,	
	2017	2016
Revenues:		
Product sales	\$ 7,381	\$ 7,948
Collaborations	28	119
Total revenues	7,409	8,067
Costs and expenses:		
Cost of product sales	488	3,528
Research and development	5,913	8,101
Selling, general and administrative	10,547	9,419
Loss from operations	(9,539)	(12,981)
Other income (expense):		
Other income (expense), net	(406)	80
Total other income (expense), net	(406)	80
Loss before income taxes	(9,945)	(12,901)
Benefit from income taxes	—	12
Net loss	(9,945)	(12,889)
Net loss per share - basic and diluted	\$ (0.48)	\$ (0.64)
Shares used to compute net loss per share - basic and diluted	20,757,111	20,229,849

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 March 31,</u>	
	<u>2017</u>	<u>2016</u>
Net loss	\$ (9,945)	\$ (12,889)
Other comprehensive loss:		
Unrealized losses on available-for-sale investments, net	(8)	—
Total comprehensive loss	<u>\$ (9,953)</u>	<u>\$ (12,889)</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)

	For the Three Months Ended March 31,	
	2017	2016
Operating Activities		
Net loss	\$ (9,945)	\$ (12,889)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,678	334
Depreciation and amortization	990	836
Income taxes	—	(12)
Change in fair value of contingent consideration	—	(31)
Changes in operating assets and liabilities:		
Accounts receivable	2,358	2,998
Inventories	(1,424)	(1,749)
Prepaid expenses and other current assets	(550)	(3,093)
Accounts payable, accrued compensation and other liabilities	(4,182)	1,347
Sales rebates and discounts	(925)	(278)
Deferred revenue	(27)	(1,575)
Net cash used in operating activities	<u>(12,027)</u>	<u>(14,112)</u>
Investing Activities		
Purchases of property and equipment	(794)	(1,071)
Purchases of investments	(10,138)	—
Proceeds from the sale and maturities of investments	8,102	—
Net cash used in investing activities	<u>(2,830)</u>	<u>(1,071)</u>
Financing Activities		
Payments for taxes related to net share settlement of equity awards	(805)	—
Proceeds from former parent	20,000	—
Transfer from former parent, prior to spin-off	—	13,800
Contingent consideration payments	—	(181)
Net cash provided by financing activities	<u>19,195</u>	<u>13,619</u>
Increase (decrease) in cash and cash equivalents	4,338	(1,564)
Cash and cash equivalents at beginning of period	9,676	4,636
Cash and cash equivalents at end of period	<u>\$ 14,014</u>	<u>\$ 3,072</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). In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only 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 is continuing to evaluate the effect that the standard will have on its consolidated financial statements and related disclosures including the areas of variable consideration and new disclosure requirements. Aptevo is currently expecting to use the modified retrospective method to adopt this standard.

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 and cash equivalents will be sufficient to fund its operations through at least the second 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 currently evaluating the impact of the application of this ASU on our consolidated financial statements and disclosures.

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 currently evaluating the impact of the new standard 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, Aptevo and MorphoSys amended the collaboration agreement to decrease the additional contingent payments due to Aptevo upon the achievement of specified development and regulatory milestones of up to \$32.5 million and up to \$41.5 million, respectively and change the total funding requirement cap for Aptevo to up to approximately \$250.0 million. 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. 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 June 30, 2017. During the period from July 1, 2017 through December 31, 2018, we will bear 49% of such development costs and MorphoSys will bear 51%. Beyond January 1, 2019, we will bear 36% and MorphoSys will bear 64% of such development costs. In addition, 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 within one week following the receipt and discussion of clinical data from the first six patients enrolled and dosed in the MOR209/ES414 Phase I clinical trial.

Aptevo evaluated the MorphoSys Agreement and determined that it was a revenue arrangement with multiple deliverables or performance obligations. Aptevo determined there were two units of accounting under the MorphoSys Agreement: (1) the delivered license to further develop and commercialize MOR209/ES414, and (2) undelivered items related to development services. Aptevo determined that the license had standalone value as the drug candidate has been: (1) developed and is currently Phase 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 \$0.0 million and \$0.1 million, respectively, recognized in the three months ended March 31, 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 March 31, 2017 Aptevo recorded a reduction to research and development expense of \$0.1 million and for the three months ended March 31, 2016 Aptevo recorded a reduction to research and development expense of \$0.1 million.

As of March 31, 2017, the MorphoSys Agreement related accounts receivable balance was \$0.1 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 March 31, 2017 and December 31, 2016:

(in thousands)	March 31, 2017			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	\$ 7,154	\$ —	\$ —	\$ 7,154
Corporate bonds	—	11,943	—	11,943
US government and agency debt securities	—	34,934	—	34,934
Total assets	\$ 7,154	\$ 46,877	\$ —	\$ 54,031

(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-months ended March 31, 2017.

Cash held in demand deposit accounts of \$6.9 and \$4.4 million is excluded from our fair-value hierarchy disclosure as of March 31, 2017 and December 31, 2016, respectively. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets 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 marketable securities as of March 31, 2017 and December 31, 2016 were temporary in nature, and the Company currently has the ability and intent to not sell these securities 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.

	March 31, 2017			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding (Losses)	Estimated Fair Value
Cash equivalents:				
Money market fund	\$ 7,154	\$ —	\$ —	\$ 7,154
Total cash equivalents	\$ 7,154	\$ —	\$ —	\$ 7,154
Short-term investments:				
Corporate bonds	\$ 11,957	\$ —	\$ (14)	\$ 11,943
US government and agency debt securities	34,961	—	(27)	34,934
Total short-term investments	\$ 46,918	\$ —	\$ (41)	\$ 46,877
	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	\$ 5,215	\$ —	\$ —	\$ 5,215
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	\$ 44,882	\$ 1	\$ (34)	\$ 44,849

Note 5. Inventories

Inventories consist of the following:

	March 31, 2017	December 31, 2016
(in thousands)		
Raw materials and supplies	\$ 224	\$ 260
Work-in-process	1,571	1,165
Finished goods	6,268	5,214
Total inventories	\$ 8,063	\$ 6,639

CMC ICOS Biologics, Inc. (CMC) is the exclusive 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® coagulation factor IX (recombinant) due to the ongoing manufacturing challenges with the manufacturer of the bulk drug. On March 15, 2017, we announced the successful manufacture of a recent bulk drug substance batch of IXINITY and we anticipate that the new supply will be available beginning in May 2017, after the completion of routine final drug product (FDP) manufacturing activities. 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.

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 \$1.6 million remains unamortized at March 31, 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 quarter ended March 31, 2017 and expects to be in compliance with all future net revenue covenants. As such, amounts owed under the Credit Facility are classified based on their contractual maturities.

In addition, 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.

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 on March 31, 2017, 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 three-month periods ended March 31, 2017 and 2016, 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:

(in thousands, except for per share amounts)	For the Three Months Ended March 31,	
	2017	2016
Outstanding options to purchase common stock	2,510	—
Unvested RSUs	1,588	—

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.

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	
	March 31,	
	2017	2016
Research and development	\$ 691	\$ 2,693
General and administrative	987	—
Total stock-based compensation expense	<u>\$ 1,678</u>	<u>\$ 2,693</u>

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 March 31,	
	2017	2016
Expected dividend yield	0.00%	—
Expected volatility	75.00%	—
Risk-free interest rate	1.94%	—
Expected average life of options	6 years	—

Management applied an estimated forfeiture rate of 10%.

The following is a summary of option activity for the three months ended March 31, 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	470,839	1.98		
Forfeited	(45,594)	2.36		2,785
Outstanding at March 31, 2017	2,510,459	\$ 2.46	6.78	\$ 105,631
Exercisable at March 31, 2017	1,115,990	\$ 2.43	4.61	\$ 50,062

As of March 31, 2017, we had \$1.5 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 March 31, 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 March 31, 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 three months ended March 31, 2017:

	Number of Units	Weighted Average Fair Value per Unit	Aggregate Fair Value
Balance at December 31, 2016	3,034,195	\$ 2.88	\$ —
Granted	18,512	1.99	—
Vested	(1,324,833)	2.85	—
Forfeited	(139,788)	2.96	—
Outstanding at March 31, 2017	1,588,086	\$ 2.90	\$ 3,271,457
Expected to Vest	1,427,553	\$ 2.90	\$ 2,940,759

As of March 31, 2017, we had \$3.2 million of unrecognized compensation expense related to RSUs expected to vest over a period of 1.1 years. The weighted average remaining contractual life of unvested RSUs is 3.5 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 April 13, 2017, Aptevo and CMC agreed to settle a dispute between the two parties related 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 a non-cash consideration. This \$3.0 million settlement is reflected as a reduction in Aptevo's cost of product sales for the quarter ended March 31, 2017. The related liability balance is no longer reflected in the accompanying balance sheet as of March 31, 2017 as upon the execution of this agreement all open claims have been resolved.

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 the Spin-Off, 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.

For the three months ended March 31, 2017, we incurred a net loss of \$9.9 million and we had an accumulated deficit of \$97.8 million as of March 31, 2017. For that same period, net cash used in our operating activities was \$12.0 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. Our investigational stage product candidates otlertuzumab, MOR209/ES414, ES210, APVO436 and a proof of concept bispecific immunotherapeutic protein targeting ROR1 are built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. The technology can produce monospecific and multispecific immunotherapeutic proteins that specifically bind to one or more targets, for example, bispecific therapeutic molecules, which may have structural and functional advantages over monoclonal antibodies. The mechanisms of action for otlertuzumab, MOR209/ES414, ES210, APVO436 and a proof of concept bispecific immunotherapeutic protein targeting ROR1 include direct tumor cytotoxicity, antibody-dependent cell-cytotoxicity, redirected T-cell cytotoxicity (RTCC) 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 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, 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, RTCC against tumors expressing ROR1. 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.
- a proof of concept bispecific 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, an invariant component of the T-cell receptor complex. 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, 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 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 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; this is 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 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 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. 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.

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 \$0.0 million and \$0.1 million, respectively, recognized in the three months ended March 31, 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 exclusive manufacturer of bulk drug substance for our IXINITY product. During 2015, we ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. During 2016, we ordered five manufacturing lots of bulk drug substance from CMC and none of these lots satisfied product release specifications. We continue to work with CMC toward the successful release of product. 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® coagulation factor IX (recombinant) due to the ongoing manufacturing challenges with the manufacturer of the bulk drug. On March 15, 2017, we announced the successful manufacture of a recent bulk drug substance batch of IXINITY and we anticipate that the new supply will be available beginning in May 2017, after the completion of routine final drug product (FDP) manufacturing activities.

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

Three Months Ended March 31, 2017 Compared to Three Months Ended March 31, 2016

Financial Summary

We recognized net losses of \$9.9 million and \$12.9 million for the three months ended March 31, 2017 and 2016, respectively. As of March 31, 2017, our accumulated deficit was \$97.8 million, and we had \$61.3 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 months ended March 31, 2017 and 2016 are shown in the following table:

(in thousands)	For the Three Months Ended		Change	Percent
	March 31,			
	2017	2016		
WinRho	\$ 2,589	\$ 3,451	\$ (862)	-25%
IXINITY	2,114	1,693	421	25%
HepaGam	2,135	2,244	(109)	-5%
VARIZIG	543	560	(17)	-3%
Total	\$ 7,381	\$ 7,948	\$ (567)	-8%

Product sales revenue decreased by \$0.6 million, or 7%, to \$7.4 million for the three months ended March 31, 2017 from \$7.9 million for the three months ended March 31, 2016. This decrease was primarily related to revenue associated with WinRho which decreased by \$0.9 million due to lower sales in the first three months of 2017 following higher sales at the end of 2016. In addition, we experienced a decrease in revenue for HepaGam B as a greater percentage of sales of this product occurred overseas where the price is lower due to contractual pricing agreements. This was slightly offset by an increase in unit sales of our IXINITY product.

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 ended March 31, 2017 and 2016:

	For the Three Months Ended March 31,		Change	Percent
	2017	2016		
Revenues:				
Product sales	\$ 7,381	\$ 7,948	\$ (567)	-7%
Contracts, grants and collaborations	28	119	(91)	-76%
Total revenues	7,409	8,067	(658)	-8%
Costs and expenses:				
Cost of product sales	488	3,528	(3,040)	-86%
Gross profit	\$ 6,921	\$ 4,539	\$ 2,382	52%
Gross margin percent	93%	56%		

Cost of product sales decreased by \$3.0 million, or 86%, to \$0.5 million for the three months ended March 31, 2017 from \$3.5 million for the three months ended March 31, 2016. This decrease was due to a one-time \$3.0 million settlement 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 and reflected as a reduction in Aptevo's cost of product sales for the quarter ended March 31, 2017. This settlement satisfies the monies owed under the 2015 invoice and resolves any claims. Without this transaction, gross margin for the first quarter of 2017 would have been 53% compared to 56% for the first quarter of 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 months ended March 31, 2017 and 2016 are shown in the following table:

(in thousands)	For the Three Months Ended March 31,		Change
	2017	2016	
ADAPTIR related programs (1)	\$ 4,311	\$ 898	\$ 3,413
APVO436	588	—	588
MOR209/ES414	462	1,810	(1,348)
IXINITY	197	2,225	(2,028)
otlertuzumab	192	521	(329)
ROR1	158	2,038	(1,880)
Other	5	609	(604)
Total	\$ 5,913	\$ 8,101	\$ (2,188)

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

Research and development expenses decreased by \$2.2 million, or 27%, to \$5.9 million for the three months ended March 31, 2017 from \$8.1 million for the three months ended March 31, 2016. This change was primarily comprised of:

- a decrease in expense for our IXINITY product candidate (which was approved by the FDA in April 2015) due to a decrease in manufacturing process development activities and the timing of clinical trial activities
- a decrease in expense for our MOR209/ES414 product candidate primarily due to the timing of manufacturing activities along with decreased reimbursement from MorphoSys for development activities under our collaboration agreement;
- a decrease in ROR1 primarily due to a decrease in characterization studies;
- a decrease in expense for our otlertuzumab product candidate related to the timing of clinical trial activities; and
- the expenses for our other activities, which decreased, primarily related to centralized research and development activities not otherwise attributable to specific product candidates or programs;
- an increase in expense for ADAPTIR related programs primarily due to an increase in characterization studies and non-clinical activities;
- an increase in expense for CD123, a new preclinical ADAPTIR candidate now 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 March 31, 2017 selling, general and administrative expenses increased by \$1.2 million, or 13%, to \$10.6 million for 2017 from \$9.4 million for 2016. This increase was primarily due to increased marketing, 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 March 31, 2017, other income (expense) increased to an expense of \$0.4 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 March 31, 2017.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2017, we had cash, cash equivalents and marketable securities in the amount of \$61.3 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.

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 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 the proceeds from our Credit Agreement, will support our operations through the second quarter of 2018, based on current operating plans and financial forecasts.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2017 and 2016.

<i>(in thousands)</i>	For the Three Months Ended March 31,	
	2017	2016
Net cash provided by (used in):		
Operating activities	(12,027)	(14,112)
Investing activities	(2,830)	(1,071)
Financing activities	19,195	13,619
Increase (decrease) in cash and cash equivalents	\$ 4,338	\$ (1,564)

Net cash used in operating activities of \$12.0 million for the three months ended March 31, 2017 was primarily due to our net loss of \$9.9 million. Net cash used in operating activities of \$14.1 million for the three months ended March 31, 2016 was primarily due to our net loss of \$12.9 million.

Net cash used in investing activities for the periods presented was primarily due to the purchase of securities investment of \$10.0 million offset by maturities of \$8.0 million in the three months ended March 31, 2017.

Net cash provided by financing activities for the periods presented includes the net proceeds received from our former parent company 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 March 31, 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.

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 months ended March 31, 2017, we incurred a net loss of \$9.9 million and we had an accumulated deficit of \$97.8 million as of March 31, 2017. For that same period, net cash used in our operating activities was \$12.0 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 March 31, 2017, we had cash, cash equivalents and marketable securities in the amount of \$61.3 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 could include 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 collaboration and licensing arrangements. Accordingly, our ability to become profitable may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve 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 of 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 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.

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 exclusive manufacturer of bulk drug substance for our IXINITY product. During 2015, we ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. 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® coagulation factor IX (recombinant) due to the ongoing manufacturing challenges with the manufacturer of the bulk drug. On March 15, 2017, we announced the successful manufacture of a recent bulk drug substance batch of IXINITY and we anticipate that the new supply will be available beginning in May 2017, after the completion of routine final drug product (FDP) manufacturing activities. 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 and proof of concept bispecific immunotherapeutic protein targeting ROR1, will not be approved for marketing by the FDA or other foreign regulatory authorities unless the FDA or their foreign equivalents also approve the facilities used by our third-party manufacturers to produce them for commercialization. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, the FDA or their foreign counterparts will not approve their manufacturing facilities, which would result in significant delays in obtaining FDA or foreign marketing approvals for our product candidates. In order to successfully develop and commercialize our product candidates in a timely manner, we and our third-party manufacturers must be able to develop and execute on manufacturing processes, and reach agreement on contract terms.

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 a proof of concept bispecific 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;
- a proof of concept bispecific 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; and
- other protein therapeutic product candidates primarily targeting tumor based on mechanisms of action that modulate the immune system (immuno-oncology based mechanism of action).

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 in the amount of \$100,000 per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification also would subject us to \$100,000 in civil monetary penalties. In addition, our failure to submit monthly/quarterly AMP or “best price” information on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

In order for our products to be reimbursed by the primary federal governmental programs, we report certain pricing data to the U.S. federal government. Compliance with reporting and other requirements of these federal programs is a pre-condition to: (i) the availability of federal funds to pay for our products under Medicaid and Medicare Part B; and (ii) procurement of our products by the Department of Veterans Affairs, or DVA, and by covered entities under the 340B/PHS program. The pricing data reported are used as the basis for establishing Federal Supply Schedule, or FSS, and 340B/PHS program contract pricing and payment and rebate rates under the Medicare Part B and Medicaid programs, respectively. Pharmaceutical companies have been prosecuted under federal and state false claims laws for submitting inaccurate and/or incomplete pricing information to the government that resulted in increased payments made by these programs. The rules governing the calculation of certain reported prices are highly complex. Although we maintain and follow strict procedures to ensure the maximum possible integrity for our federal pricing calculations, the process for making the required calculations involves some subjective judgments and the risk of errors always exists, which creates the potential for exposure under the false claims laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, and our methodologies for calculating federal prices are found to include flaws or to have been incorrectly applied, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and certain federal grantees, we also must participate in the DVA FSS pricing program. To participate, we are required to enter into an FSS contract with the DVA, under which we must make our innovator “covered drugs” available to the “Big Four” federal agencies—the DVA, the U.S. Department of Defense, or the DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard—at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the Non-Federal Average Manufacturer Price, or Non-FAMP, which 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.

The Bristol-Myers Squibb Company, or BMS, has opposed several of our house marks in and outside the United States. At this time, we are in discussions with BMS regarding our use of our house marks. We and BMS have agreed to delay opposition proceedings to allow the parties to negotiate a resolution. In the event these discussions are not concluded to BMS's satisfaction, we may lose our ability to obtain trademark registration for one or more of its house marks both in the United States and in other territories where BMS has opposed or may still oppose the marks, which could have a material and adverse effect on our business.

Third party 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.

At this time, we received no indication from BMS that it plans to take any legal action against Aptevo, but defending ourselves against such claim could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction prohibiting us from using the Aptevo trademarks and damages, all which could have a material and adverse effect on our business.

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.

We expect to selectively pursue collaboration arrangements with third parties that have particular technology, expertise or resources for the development or commercialization of our product candidates or for accessing particular markets. We face, and will continue to face, significant competition in seeking appropriate partners for our product candidates. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on a timely basis, on acceptable terms or at all, or if the arrangements we establish are unproductive for us, we may fail to meet our business objectives for the particular product candidate. Our ability to enter into such arrangements with respect to products in development that are subject to licenses may be limited by the terms of those licenses.

Any collaboration that we enter into may not be successful and the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborative partners. It is likely that our collaborative partners will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

The risks that we are subject to in any of our collaborations include, among others:

- our collaborative partners may not commit adequate resources to the development, marketing and distribution of any collaboration products, limiting our potential revenues from these products;
- our collaborative partners may experience financial difficulties and may therefore be unable to meet their commitments to us;
- our collaborative partners may pursue a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- our collaborative partners may terminate our relationship.

The failure of any of our future collaboration partners to perform as expected could place us at a competitive disadvantage and adversely affect us financially, including delay and increased costs of development, loss of market opportunities, lower than expected revenues and impairment of the value of the related product candidate. A loss of Aptevo's collaboration agreement with MorphoSys 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 March 31, 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.

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. The above description of the terms of the amendment to the Credit Agreement is a summary and is qualified in its entirety by the terms of the amendment, which is filed as exhibit 10.1 to this Quarterly Report on Form 10-Q.

Item 6. Exhibits

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Aptevo Therapeutics Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on August 2, 2016).
3.2	Amended and Restated Bylaws of Aptevo Therapeutics Inc. incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed on August 2, 2016).
4.1	Registration Rights Agreement, dated as of August 1, 2016, by and among Aptevo Therapeutics Inc. and certain of its stockholders incorporated by reference to Exhibit 4.0 to the Company's Current Report on Form 8-K, filed on August 2, 2016).
10.1*	Amendment No.1 to the Credit and Security Agreement, dated May 11, 2017, by and among Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC and MidCap Financial Trust, as agent and the lenders from time to time thereto.
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.

AMENDMENT NO. 1 TO CREDIT AND SECURITY AGREEMENT

This AMENDMENT NO. 1 TO CREDIT AND SECURITY AGREEMENT (this “**Agreement**”) is made as of this 11th day of May, 2017, by and among **APTEVO THERAPEUTICS INC.**, a Delaware corporation (“**Aptevo Therapeutics**”), **APTEVO BIOTHERAPEUTICS LLC**, a Delaware limited liability company (“**Aptevo BioTherapeutics**”), **APTEVO RESEARCH AND DEVELOPMENT LLC**, a Delaware limited liability company (“**Aptevo R&D**”), and Aptevo R&D together with Aptevo Therapeutics and Aptevo BioTherapeutics, each individually, a “**Borrower**” and collectively, the “**Borrowers**”), **MIDCAP FINANCIAL TRUST**, a Delaware statutory trust, as Agent (in such capacity, together with its successors and assigns, “**Agent**”) and the other financial institutions or other entities from time to time parties to the Credit Agreement referenced below, each as a Lender.

RECITALS

A. Agent, Lenders and Borrowers have entered into that certain Credit and Security Agreement, dated as of August 4, 2016 (the “**Original Credit Agreement**” and as the same is amended hereby and as it may be further amended, modified, supplemented and restated from time to time, the “**Credit Agreement**”), pursuant to which the Lenders have agreed to make certain advances of money and to extend certain financial accommodations to Borrowers in the amounts and manner set forth in the Credit Agreement.

B. Pursuant to Section 6.2 of the Original Credit Agreement, Borrowers are required to maintain a minimum Net Commercial Product Revenue for each applicable Defined Period and Borrowers failed to comply with such requirement for the Defined Period ending March 31, 2017 which failure constitutes an Event of Default under Section 10.1(a)(ii) of the Credit Agreement (the “**Specified Event of Default**”).

C. Borrowers have requested, and Agent and Lenders have agreed, to waive, *ab initio*, the Specified Event of Default and to amend certain provisions of the Original Credit Agreement to, among other things, modify the conditions to the availability of Term Loan Tranche 2, grant a springing lien in the Borrower’s Intellectual Property, and amend the Net Commercial Product Revenue covenant, all in accordance with the terms and subject to the conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Agent, Lenders and Borrowers hereby agree as follows:

1. **Recitals.** This Agreement shall constitute a Financing Document and the Recitals and each reference to the Credit Agreement, unless otherwise expressly noted, will be deemed to reference the Credit Agreement as amended hereby. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Credit Agreement (including those capitalized terms used in the Recitals hereto).

2. **Limited Waiver.**

(a) At the request of and as an accommodation to the Borrowers and subject to the satisfaction of the conditions to effectiveness set forth in Section 5 hereof, Agent and Required Lenders hereby waive, *ab initio*, the Specified Event of Default in accordance with the terms hereof.

(b) The limited waiver set forth in this Section 2 is effective solely for the purposes set forth herein and shall be limited precisely as written and shall not, except as expressly provided herein, be deemed to (a) be a consent to any other amendment, waiver or modification of any term or condition of the Credit Agreement or of any other Financing Document; (b) prejudice any right that Agent or Lenders have or may have in the future under or in connection with the Credit Agreement or any other Financing Document (other than in respect of the Specified Event of Default); (c) constitute a consent to or waiver of any past, present or future Default or Event of Default (other than the Specified Event of Default) or other violation of any provisions of the Credit Agreement or any other Financing Documents; (d) create any obligation to forbear from taking any enforcement action, or to make any further extensions of credit (other than in respect of the Specified Event of Default); or (e) establish a custom or course of dealing among any of the Credit Parties, on the one hand, or Agent or any Lender, on the other hand.

3. **Amendments to Original Credit Agreement.** Subject to the satisfaction of the conditions to effectiveness set forth in Section 5 below, the Original Credit Agreement is hereby amended as follows:

(a) The definition of “Collateral” in Section 1.1 of the Original Credit Agreement is hereby amended by adding the following words at the end thereof:

“but excluding any Excluded Property”

(b) Clause (b) of the definition of “Excluded Property” in Section 1.1 of the Original Credit Agreement is hereby amended by adding the following parenthetical after the words “property right” in the first line thereof:

“(including without limitation any jointly owned or jointly developed Intellectual Property rights)”

(c) Clause (c) of the definition of “Excluded Property” in Section 1.1 of the Original Credit Agreement is hereby amended and restated in its entirety as follows:

“(c) prior to the occurrence of a Springing IP Event, Intellectual Property except to the extent that it is necessary under applicable law to have a Lien and security interest in any such Intellectual Property in order to have a perfected Lien and security interest in and to IP Proceeds (*provided* that, for avoidance of doubt, neither Agent nor any Lender shall have any right to transfer or dispose of any Intellectual Property as a result of this clause (c)), and for the avoidance of any doubt, the Collateral shall include, and Agent shall have a Lien and security interest in, (i) all IP Proceeds, (ii) all payments with respect to IP Proceeds that are received after the commencement of a bankruptcy or insolvency proceeding and (iii) except to the extent excluded by clause (b) above, all license and sublicense agreements to which any Borrower is a party and all rights granted to such Borrower thereunder, including without limitation, the license and sublicense agreements entered into between any Borrower and Emergent in connection with the Emergent Spinoff Transaction; *provided, however,* that, upon the occurrence of a Springing IP Event and continuing at all times thereafter (whether or not the Springing IP Event continues), Intellectual Property shall no longer constitute “Excluded Property” pursuant to this clause (c) (but may, for the avoidance of doubt, be excluded by other clauses of this definition to the extent applicable) and the Collateral shall immediately include all Intellectual Property of each Borrower (including, for the avoidance of doubt, all IP Proceeds but excluding Intellectual Property excluded by other clauses of this definition) automatically and without notice or any further action by Agent, any Lender or any Credit Party; and”

(d) The definition of “Excluded Property” in Section 1.1 of the Original Credit Agreement is hereby amended by adding a new clause (d) immediately following clause (c) thereof and prior to the words “*provided, however*” as follows:

“(d) intent to use trademark applications.”

(e) The following definitions in Section 1.1 of the Original Credit Agreement are hereby amended and restated in their entirety as follows:

“**“Fee Letter”** means each agreement between Agent and Borrower relating to fees payable to Agent, for its own account, in connection with the execution of this Agreement, including, without limitation, any amendments and restatements thereof.”

“**“Security Document”** means this Agreement, the Intellectual Property Security Agreement and any other agreement, document or instrument executed concurrently herewith or at any time hereafter pursuant to which one or more Credit Parties or any other Person either (a) Guarantees payment or performance of all or any portion of the Obligations, and/or (b) provides, as security for all or any portion of the Obligations, a Lien on any of its assets in favor of Agent for its own benefit and the benefit of the Lenders, as any or all of the same may be amended, supplemented, restated or otherwise modified from time to time in accordance with the terms hereof.”

“**“Term Loan Tranche 2 Activation Date”** means the date, if any, on which the Agent receives a Compliance Certificate delivered in accordance with Section 4.1, and such other documentation and information relating to the following conditions as Agent may reasonably request, evidencing to Agent’s reasonable satisfaction that (a) Borrower’s consolidated Net Commercial Product Revenue for the twelve (12) month period immediately preceding such date is greater than or equal to \$40,000,000, and (b) Agent has received all documents, instruments and other agreements from Borrower and Borrower has taken such other actions as reasonably requested by Agent to perfect and maintain Agent’s first priority perfected security interest (subject to Permitted Liens), for the ratable benefit of Lenders, in Borrower’s Intellectual Property (other than Excluded Property).”

“**“Term Loan Tranche 2 Commitment Termination Date”** means March 31, 2018.

(f) Section 1.1 of the Original Credit Agreement is hereby amended by adding the following definitions in the appropriate alphabetical order therein:

“**“First Amendment”** means that certain Amendment No. 1 to Credit and Security Agreement, dated as of May 11, 2017, by and among Borrowers, Agent and the Lenders.”

“**“First Amendment Effective Date”** means the first date that all of the conditions in Section 5 of the First Amendment are satisfied.”

“**“Intellectual Property Security Agreement”** means an Intellectual Property Security Agreement in the form attached hereto as Exhibit G, which agreement shall become effective in accordance with the terms of Section 4.16(f).

“**“Springing IP Event”** means that, on any date, (a) the Borrowers have allowed, as of the close of business on any day, the aggregate amount of unrestricted cash and cash equivalents held by the Borrowers in Deposit Accounts or Securities Accounts that are

subject to a first priority perfected Lien (subject to Permitted Liens) in favor of the Agent to be less than \$25,000,000 or (b) a borrowing of the Term Loan Tranche 2 has occurred.”

(g) Clause (b) of Section 4.16 of the Original Credit Agreement is hereby amended and restated in its entirety as follows:

“(b) If Borrower obtains any Registered Intellectual Property (other than copyrights, mask works and related applications, which are addressed below), Borrower shall notify Agent on a quarterly basis and execute such documents and provide such other information (including, without limitation, copies of applications) and take such other actions as Agent shall request in its good faith business judgment to perfect and maintain a first priority perfected security interest (subject to Permitted Liens) in favor of Agent, for the ratable benefit of Lenders, in (x) prior to the occurrence of a Springing IP Event, the IP Proceeds or (y) upon the occurrence of a Springing IP Event, the Registered Intellectual Property (other than Excluded Property and any security interest that is not required to be perfected under the terms of this Agreement). Upon the occurrence of a Springing IP Event, Borrower shall take such actions as Agent shall request in its good faith business judgment to perfect and maintain a first priority perfected security interest (subject to Permitted Liens) in favor of Agent, for the ratable benefit of Lenders, in the Registered Intellectual Property (other than Excluded Property and any security interest that is not required to be perfected under the terms of this Agreement).”

(h) Section 4.16 of the Original Credit Agreement is hereby amended by adding the following new clauses (f) through (h) thereto:

“(f) On the First Amendment Effective Date, each Borrower will execute and deliver to Agent the Intellectual Property Security Agreement. The Intellectual Property Security Agreement shall be held in escrow by Agent, and shall not be in force and effect, unless and until the occurrence of the Springing IP Event, at which time (i) the Intellectual Property Security Agreement shall immediately and automatically become effective without any further action or consent by any Borrower and (ii) Agent shall be automatically authorized to file the Intellectual Property Security Agreement (including any updated schedules thereto delivered pursuant to Section 4.16(h)) with the United States Patent and Trademark Office and/or United States Copyright Office, as applicable.

(g) Upon the occurrence of a Springing IP Event and continuing at all times thereafter (whether or not the Springing IP Event continues), then automatically and without notice or any further action by Agent, any Lender or any Borrower (i) Agent shall be authorized to file UCC financing statements, financing statement amendments and security agreements (including any Intellectual Property Security Agreement) necessary or desirable to perfect such security interest in the Intellectual Property (other than Excluded Property and any security interest that is not required to be perfected under the terms of this Agreement), and (ii) each Borrower shall execute such other agreements and take such other actions as Agent may reasonably request to establish, perfect or protect Agent’s security interest in the Intellectual Property (other than Excluded Property and any security interest that is not required to be perfected under the terms of this Agreement).

(h) Borrowers shall promptly (and in any event within three (3) Business Days of the occurrence thereof) provide Agent and each Lender with written notice of the occurrence of a Springing IP Event, which notice shall be accompanied by a certificate from an authorized executive officer from each Borrower (A) acknowledging that the Springing IP Event has occurred, (B) specifying the date on which the Springing IP Event

occurred, and (C) acknowledging that Agent may exercise any rights it may have under this Agreement or any other Financing Document with respect to the Springing IP Event. Without limiting the foregoing, Borrowers shall promptly (and in any event within ten (10) days of the occurrence of a Springing IP Event) provide Agent a supplement to the Intellectual Property Security Agreement certifying to and attaching true, correct and complete copies of updated schedules to the Intellectual Property Security Agreement and certifying that all Intellectual Property owned by each Borrower and registered in the United States as of the date of such certification is reflected on such schedules (other than Excluded Property).”

(i) Section 9.2(c) of the Original Credit Agreement is hereby amended and restated in its

entirety as follows:

“(c) Without limiting the generality of Section 3.2, except with respect to any rights of any Borrower as a licensee under any license of Intellectual Property owned by another Person, and except for (x) the filing of financing statements under the UCC, (y) any change of ownership filings applications, authorizations, consents or other actions that may be required with respect to Permits and (z) after the Springing IP Event, the filing of the Intellectual Property Security Agreement, duly completed with scheduled attached, with the United States Patent and Trademark Office and/or the United States Copyright Office (as the case may be), no authorization, approval or other action by, and no notice to or filing with, any Governmental Authority or consent of any other Person is required for (i) the grant by each Borrower to Agent of the security interests and Liens in the Collateral provided for under this Agreement and the other Security Documents (if any), or (ii) the exercise by Agent of its rights and remedies with respect to the Collateral provided for under this Agreement and the other Security Documents or under any applicable Law, including the UCC and neither any such grant of Liens in favor of Agent or exercise of rights by Agent shall violate or cause a default under any agreement between any Borrower and any other Person relating to any such collateral, including any license constituting Collateral to which a Borrower is a party, whether as licensor or licensee, with respect to any Intellectual Property, whether owned by such Borrower or any other Person.”

(j) Section 9.2(g)(ix) of the Original Credit Agreement is hereby amended by replacing the words “the foregoing” in the first line thereof with the words “this Agreement or any other Financing Document”.

(k) Section 9.2(g) of the Original Credit Agreement is hereby amended by adding a new clause (x) at the end thereof as follows:

“(x) If, after the First Amendment Effective Date, any Borrower desires to enter into a Permitted License and the proposed licensee under such Permitted License requests that Agent enter into a non-disturbance agreement (or similar agreement) in connection with such Permitted License, Agent hereby agrees to negotiate in good faith and on a commercially reasonable basis with such Borrower and such licensee to enter into such a non-disturbance and attornment agreement with respect to the proposed Permitted License and the Intellectual Property that is the subject thereof, which shall provide (among other things) (A) that, notwithstanding any exercise of rights and/or remedies by the Agent under this Agreement after a Springing IP Event in respect of the Intellectual Property that is the subject of such Permitted License, such licensee shall continue to have the rights and licenses set forth in its license agreement to the extent that such licensee is in compliance with the terms thereof; *provided* that in the case of any bankruptcy or insolvency proceeding with respect to such Borrower the rights of such licensee and the Agent shall

be determined in accordance with the Bankruptcy Code (or other Laws applicable to such proceeding), (B) an acknowledgement and consent by such licensee of Agent's security interest in the Collateral (including, to the extent applicable, such Permitted License and the Intellectual Property that is the subject thereof), and (C) that such Permitted License shall attach to the owner of such Intellectual Property after such exercise of rights and remedies."

(l) Schedule 6.2 of the Original Credit Agreement is hereby replaced in its entirety by a new Schedule 6.2 attached hereto as Exhibit A.

(m) The Original Credit Agreement is hereby amended by adding the attached Exhibit G as Exhibit G thereto, in appropriate alphabetical order therein.

4. **Representations and Warranties; Reaffirmation of Security Interest.** Each Borrower hereby confirms that each of the representations and warranties set forth in the Credit Agreement is true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) with respect to such Borrower as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (without duplication of any materiality qualifier in the text of such representation or warranty). Each Borrower confirms and agrees that all security interests and Liens granted to Agent continue in full force and effect, and that all Collateral remains free and clear of any Liens, other than those granted to Agent and Permitted Liens. Nothing herein is intended to impair or limit the validity, priority or extent of Agent's security interests in and Liens on the Collateral. Each Borrower acknowledges and agrees that the Credit Agreement, the other Financing Documents and this Agreement constitute the legal, valid and binding obligation of such Borrower, and are enforceable against such Borrower in accordance with their terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws relating to the enforcement of creditors' rights generally and by general equitable principles.

5. **Conditions to Effectiveness.** This Agreement shall become effective as of the date on which each of the following conditions has been satisfied (or waived in writing by the Agent and the Required Lenders), as determined by Agent in its sole discretion:

(a) Borrowers, Agent and Required Lenders shall have delivered to Agent this Agreement, executed by an authorized officer of each such Person;

(b) Borrowers shall have delivered to Agent a duly executed copy of the Amended and Restated Fee Letter, in form and substance reasonably satisfactory to Agent;

(c) Borrowers shall have delivered to Agent a duly executed Intellectual Property Security Agreement to be held in escrow, in form and substance reasonably satisfactory to Agent;

(d) Agent shall have filed UCC-3 amendment statements necessary to reflect the amendments set forth in this Agreement;

(e) Agent shall have received (i) reasonably satisfactory diligence of the Borrowers' Intellectual Property, including without limitation customary intellectual property searches and (ii) lien searches and other searches as Agent determines necessary and as otherwise permitted by Section 7.3 of the Credit Agreement;

(f) all representations and warranties of Borrowers contained herein shall be true and correct in all material respects (without duplication of any materiality qualifier in the text of such

representation or warranty) as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (without duplication of any materiality qualifier in the text of such representation or warranty) (and such parties' delivery of their respective signatures hereto shall be deemed to be its certification thereof); and

(g) prior to and after giving effect to the agreements set forth herein, no Default or Event of Default (other than the Specified Event of Default) shall exist under any of the Financing Documents.

6. **Release.** In consideration of the agreements of Agent and Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Borrower, voluntarily, knowingly, unconditionally and irrevocably, with specific and express intent, for and on behalf of itself and all of its respective parents, subsidiaries, affiliates, members, managers, predecessors, successors, and assigns, and each of their respective current and former directors, officers, shareholders, agents, and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Releasing Parties**") does hereby fully and completely release, acquit and forever discharge each of Agent, Lenders, and each their respective parents, subsidiaries, affiliates, members, managers, shareholders, directors, officers and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Released Parties**"), of and from any and all actions, causes of action, suits, debts, disputes, damages, claims, obligations, liabilities, costs, expenses and demands of any kind whatsoever, at law or in equity, whether matured or unmatured, liquidated or unliquidated, vested or contingent, choate or inchoate, known or unknown that the Releasing Parties (or any of them) has against the Released Parties or any of them (whether directly or indirectly), based in whole or in part on facts, whether or not now known, existing on or before the date hereof (and not, for the avoidance of doubt, arising at any time hereafter). Each Borrower acknowledges that the foregoing release is a material inducement to Agent's and each Lender's decision to enter into this Agreement and agree to the modifications contemplated hereunder, and has been relied upon by Agent and Lenders in connection therewith.

7. **No Waiver or Novation.** The execution, delivery and effectiveness of this Agreement shall not, except as expressly provided in this Agreement, operate as a waiver of any right, power or remedy of Agent, nor constitute a waiver of any provision of the Credit Agreement, the Financing Documents or any other documents, instruments and agreements executed or delivered in connection with any of the foregoing. Nothing herein is intended or shall be construed as a waiver of any existing Defaults or Events of Default under the Credit Agreement or the other Financing Documents (other than as expressly set forth in Section 2 hereof with respect to the Specified Event of Default) or any of Agent's rights and remedies in respect of such Defaults or Events of Default (other than as expressly set forth in Section 2 hereof with respect to the Specified Event of Default). This Agreement (together with any other document executed in connection herewith) is not intended to be, nor shall it be construed as, a novation of the Credit Agreement.

8. **Affirmation.** Except as specifically amended pursuant to the terms hereof, each Borrower hereby acknowledges and agrees that the Credit Agreement and all other Financing Documents (and all covenants, terms, conditions and agreements therein) shall remain in full force and effect, and are hereby ratified and confirmed in all respects by such Borrower. Each Borrower covenants and agrees to comply with all of the terms, covenants and conditions of the Credit Agreement and the Financing Documents, notwithstanding any prior course of conduct, waivers, releases or other actions or inactions on Agent's or any Lender's part which might otherwise constitute or be construed as a waiver of or amendment to such terms, covenants and conditions.

9. **Miscellaneous.**

(a) **Reference to the Effect on the Credit Agreement.** Upon the effectiveness of this Agreement, each reference in the Credit Agreement to “this Agreement,” “hereunder,” “hereof,” “herein,” or words of similar import shall mean and be a reference to the Credit Agreement, as amended by this Agreement.

(b) **Incorporation of Credit Agreement Provisions.** The provisions contained in Section 11.6 (Indemnification) of the Credit Agreement are incorporated herein by reference to the same extent as if reproduced herein in their entirety.

(c) THIS AGREEMENT AND ALL DISPUTES AND OTHER MATTERS RELATING HERETO OR ARISING THEREFROM (WHETHER SOUNDING IN CONTRACT LAW, TORT LAW OR OTHERWISE), SHALL BE GOVERNED BY, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO CONFLICTS OF LAWS PRINCIPLES.

(d) EACH BORROWER HEREBY CONSENTS TO THE JURISDICTION OF ANY STATE OR FEDERAL COURT LOCATED IN THE STATE OF NEW YORK IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, AND IRREVOCABLY AGREES THAT, SUBJECT TO AGENT’S ELECTION, ALL ACTIONS OR PROCEEDINGS ARISING OUT OF OR RELATING TO THIS AGREEMENT SHALL BE LITIGATED IN SUCH COURTS. EACH BORROWER EXPRESSLY SUBMITS AND CONSENTS TO THE JURISDICTION OF THE AFORESAID COURTS AND WAIVES ANY DEFENSE OF FORUM NON CONVENIENS. EACH BORROWER HEREBY WAIVES PERSONAL SERVICE OF ANY AND ALL PROCESS AND AGREES THAT ALL SUCH SERVICE OF PROCESS MAY BE MADE UPON SUCH BORROWER BY CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED, ADDRESSED TO SUCH BORROWER AT THE ADDRESS SET FORTH IN THIS AGREEMENT AND SERVICE SO MADE SHALL BE COMPLETE TEN (10) DAYS AFTER THE SAME HAS BEEN POSTED.

(e) EACH BORROWER, AGENT AND THE LENDERS HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY AND AGREES THAT ANY SUCH ACTION OR PROCEEDING SHALL BE TRIED BEFORE A COURT AND NOT BEFORE A JURY. EACH BORROWER, AGENT AND EACH LENDER ACKNOWLEDGES THAT THIS WAIVER IS A MATERIAL INDUCEMENT TO ENTER INTO A BUSINESS RELATIONSHIP, THAT EACH HAS RELIED ON THE WAIVER IN ENTERING INTO THIS AGREEMENT, AND THAT EACH WILL CONTINUE TO RELY ON THIS WAIVER IN THEIR RELATED FUTURE DEALINGS. EACH BORROWER, AGENT AND EACH LENDER WARRANTS AND REPRESENTS THAT IT HAS HAD THE OPPORTUNITY OF REVIEWING THIS JURY WAIVER WITH LEGAL COUNSEL, AND THAT IT KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS.

(f) **Headings.** Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose.

(g) **Counterparts.** This Agreement may be signed in any number of counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same instrument. Delivery of an executed counterpart of this Agreement by facsimile or by electronic mail delivery of an electronic version (e.g., .pdf or .tif file) of an executed signature page shall be effective as delivery of an original executed counterpart hereof and shall bind the parties hereto.

(h) Entire Agreement. This Agreement constitutes the entire agreement and understanding among the parties hereto and supersedes any and all prior agreements and understandings, oral or written, relating to the subject matter hereof.

(i) Severability. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any applicable jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(j) Successors/Assigns. This Agreement shall bind, and the rights hereunder shall inure to, the respective successors and assigns of the parties hereto, subject to the provisions of the Credit Agreement and the other Financing Documents.

[SIGNATURES APPEAR ON FOLLOWING PAGES]

IN WITNESS WHEREOF, intending to be legally bound, the undersigned have executed this Agreement as of the day and year first hereinabove set forth.

AGENT:

MIDCAP FINANCIAL TRUST,
as Agent

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: /s/ Maurice Amsellem

Name: Maurice Amsellem

Title: Authorized Signatory

LENDER:

MIDCAP FINANCIAL TRUST,
as a Lender

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: /s/ Maurice Amsellem

Name: Maurice Amsellem

Title: Authorized Signatory

LENDER:

APOLLO INVESTMENT CORPORATION

By: Apollo Investment Management, L.P., as Advisor

By: ACC Management, LLC, as its General Partner

By: /s/ Tanner Powell

Name: Tanner Powell

Title: Authorized Signatory

MidCap / Aptevo / Amendment No. 1 to Credit Agreement
\\DC - 036639/000031 - 10303807

LENDER:

FLEXPOINT MCLS HOLDINGS LLC

By: /s/ Daniel Edelman

Name: Daniel Edelman

Title: Authorized Signatory

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LENDER:

ELM 2016-1 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By: /s/ Adam Day

Name: Adam Day

Title: Authorized Signatory

MidCap / Aptevo / Amendment No. 1 to Credit Agreement
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BORROWERS:

APTEVO THERAPEUTICS INC.

By: /s/ Jeffrey G. Lamothe
Name: Jeffrey G. Lamothe
Title: Chief Financial Officer

APTEVO BIOTHERAPEUTICS LLC

By: /s/ Jeffrey G. Lamothe
Name: Jeffrey G. Lamothe
Title: Chief Financial Officer

APTEVO RESEARCH AND DEVELOPMENT LLC

By: /s/ Jeffrey G. Lamothe
Name: Jeffrey G. Lamothe
Title: Chief Financial Officer

Exhibit A

Schedule 6.2 – Minimum Net Commercial Product Revenue Schedule

Defined Period Ending	Minimum Net Commercial Product Revenue Amount
30-Sep-16	\$34,847,470
31-Dec-16	\$35,000,000
31-Mar-17	\$34,000,000
30-Jun-17	\$33,250,000
30-Sep-17	\$34,000,000
31-Dec-17	\$36,500,000
31-Mar-18	\$38,000,000
30-Jun-18	\$39,000,000
30-Sep-18	\$40,000,000
31-Dec-18	\$41,000,000
31-Mar-19	\$42,000,000
30-Jun-19	\$43,000,000
30-Sep-19	\$44,000,000
31-Dec-19	\$45,000,000
31-Mar-20	\$45,500,000
30-Jun-20	\$46,000,000
30-Sep-20	\$46,500,000
31-Dec-20 and the last day of each calendar quarter occurring thereafter	\$47,000,000

Exhibit G to Credit Agreement (Form of Intellectual Property Security Agreement)

MidCap / Aptevo / Amendment No. 1 to Credit Agreement
\\DC - 036639/000031 - 10303807

**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, Marvin White, 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: May 12, 2017

By: _____ /s/ Marvin White

Marvin White
President and Chief Executive Officer

**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: May 12, 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 March 31, 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: May 12, 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 March 31, 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: May 12, 2017

By: _____ /s/ Jeff Lamothe

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