
**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 September 30, 2016

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. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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 November 1, 2016, 20,248,824 shares of the registrant's common stock were outstanding.

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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	September 30, 2016	December 31, 2015
Current assets:		
Cash and cash equivalents	\$ 10,894	\$ 4,637
Restricted cash	400	—
Short-term investments	49,785	—
Accounts receivable, net	2,958	6,456
Inventories	11,574	20,322
Income tax receivable, net	—	1,376
Prepaid expenses and other current assets	3,818	2,343
Total current assets	79,429	35,134
Property and equipment, net	6,139	4,179
In-process research and development	—	41,800
Intangible assets, net	15,055	17,441
Goodwill	—	13,902
Total assets	\$ 100,623	\$ 112,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 8,951	\$ 10,084
Accrued compensation	3,429	3,334
Contingent consideration, current portion	183	444
Provisions for chargebacks	2,030	2,238
Deferred revenue, current portion	640	3,843
Total current liabilities	15,233	19,943
Deferred revenue, net of current portion	3,096	3,318
Long-term debt, net	18,111	—
Deferred income taxes	—	506
Other liabilities	433	71
Total liabilities	36,873	23,838
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; 20,246,355 and zero shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	20	—
Additional paid-in capital	149,493	—
Accumulated other comprehensive loss	(17)	—
Contribution receivable from former parent	(20,000)	—
Former parent investment in subsidiary	—	320,606
Accumulated deficit	(65,746)	(231,988)
Total stockholders' equity	63,750	88,618
Total liabilities and stockholders' equity	\$ 100,623	\$ 112,456

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

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts, unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenues:				
Product sales	\$ 9,405	\$ 6,441	\$ 27,512	\$ 19,704
Contracts, grants and collaborations	—	121	153	5,611
Total revenues	<u>9,405</u>	<u>6,562</u>	<u>27,665</u>	<u>25,315</u>
Costs and expenses:				
Cost of product sales	6,163	3,525	16,235	11,696
Research and development	7,114	7,712	22,851	27,319
Selling, general and administrative	11,680	8,513	29,958	28,900
Impairment of goodwill and intangible assets	55,702	—	55,702	—
Loss from operations	<u>(71,254)</u>	<u>(13,188)</u>	<u>(97,081)</u>	<u>(42,600)</u>
Other income (expense):				
Other income (expense), net	(493)	84	(417)	(230)
Total other income (expense), net	<u>(493)</u>	<u>84</u>	<u>(417)</u>	<u>(230)</u>
Loss before income taxes	(71,747)	(13,104)	(97,498)	(42,830)
Benefit from income taxes	6	424	29	1,411
Net loss	<u>(71,741)</u>	<u>(12,680)</u>	<u>(97,469)</u>	<u>(41,419)</u>
Unrealized loss on available-for-sale investments	(17)	—	(17)	—
Comprehensive loss	<u>\$ (71,758)</u>	<u>\$ (12,680)</u>	<u>\$ (97,486)</u>	<u>\$ (41,419)</u>
Net loss per share - basic and diluted	<u>\$ (3.55)</u>	<u>\$ (0.63)</u>	<u>\$ (4.82)</u>	<u>\$ (2.05)</u>
Shares used to compute net loss per share - basic and diluted	<u>20,235,987</u>	<u>20,229,849</u>	<u>20,231,910</u>	<u>20,229,849</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)

	Nine Months Ended September 30,	
	2016	2015
Operating Activities		
Net loss	\$ (97,469)	\$ (41,419)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,067	822
Depreciation and amortization	2,912	2,099
Impairment of goodwill and intangible assets	55,702	—
Income taxes	(506)	(694)
Change in fair value of contingent consideration	(261)	66
Changes in operating assets and liabilities:		
Accounts receivable	3,497	(1,986)
Inventories	8,748	(4,093)
Income taxes	1,376	594
Prepaid expenses and other current assets	(1,475)	1,619
Accounts payable, accrued compensation and other liabilities	(1,155)	244
Provision for chargebacks	(208)	(296)
Deferred revenue	(3,425)	1,968
Net cash used in operating activities	<u>(30,197)</u>	<u>(41,076)</u>
Investing Activities		
Purchases of property and equipment	(1,933)	(1,012)
Purchases of investments	(49,802)	—
Net cash used in investing activities	<u>(51,735)</u>	<u>(1,012)</u>
Financing Activities		
Proceeds from exercise of stock options	2	—
Proceeds from long-term debt, net of issuance costs	18,038	—
Restricted cash	(400)	—
Payment from former parent upon spin-off, net of receivable	45,000	—
Net transfer from former parent, prior to spin-off	25,549	42,650
Contingent consideration payments	—	(678)
Net cash provided by financing activities	<u>88,189</u>	<u>41,972</u>
Increase (decrease) in cash and cash equivalents	6,257	(116)
Cash and cash equivalents at beginning of period	4,637	3,593
Cash and cash equivalents at end of period	<u>\$ 10,894</u>	<u>\$ 3,477</u>
Supplemental disclosures:		
Contribution receivable from former parent	\$ 20,000	\$ —
Cash paid for interest	\$ 261	\$ —

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

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
(in thousands, except share amounts, unaudited)

	Common Stock		Former Parent Investment in Subsidiary	Additional Paid-In Capital	Accumulated Deficit	Contribution Receivable from Former Parent	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount						
Balance at December 31, 2015	—	\$ —	\$ 320,606	\$ —	\$ (231,988)	\$ —	\$ —	\$ 88,618
Capitalization upon spinoff	20,229,849	20	—	66,374	—	(20,000)	—	46,394
Net transfers from former parent	—	—	(288,883)	81,050	231,988	—	—	24,155
Unrealized losses on available-for-sale investments	—	—	—	—	—	—	(17)	(17)
Common stock issued upon exercise of stock options	6,675	—	—	1	—	—	—	1
Common stock issued upon vesting of restricted stock units	9,831	—	—	1	—	—	—	1
Stock-based compensation	—	—	—	2,067	—	—	—	2,067
Net loss for the period	—	—	(31,723)	—	(65,746)	—	—	(97,469)
Balance at September 30, 2016	<u>20,246,355</u>	<u>\$ 20</u>	<u>\$ 0</u>	<u>\$ 149,493</u>	<u>\$ (65,746)</u>	<u>\$ (20,000)</u>	<u>\$ (17)</u>	<u>\$ 63,750</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 Changes

Organization and Basis of Presentation

Aptevo Therapeutics Inc. (Aptevo or the Company) is a biotechnology company focused on novel oncology and hematology therapeutics to meaningfully improve patients' lives. On August 1, 2016 the Company became an independent publicly traded company through a pro-rata distribution of Aptevo's common stock to Emergent BioSolutions Inc. (Emergent) stockholders. Each Emergent stockholder of record as of the close of business on August 1, 2016 received one share of Aptevo common stock for every two shares of Emergent common stock held on the record date. Aptevo's common stock began "regular way" trading on the NASDAQ global stock market under the ticker symbol "APVO" on August 1, 2016.

In connection with the spin-off, on August 1, 2016, Aptevo and Emergent entered into a separation and distribution agreement as well as various other related agreements (collectively the Agreements) that govern the separation and the relationships between the parties going forward, including a transition services agreement, a manufacturing services agreement, an employee matters agreement, and a tax matters agreement. Prior to the separation, Aptevo was dependent upon Emergent for all of its working capital and financing requirements.

At the closing of the spin-off of Aptevo from Emergent, Emergent provided Aptevo cash in the amount of \$45.0 million, along with a commitment in the form of a promissory note to provide another \$20.0 million within six to twelve months after the separation. In addition, on August 4, 2016, we entered into a \$35.0 million Credit and Security Agreement, or the Credit Agreement, by and among us and certain our subsidiaries as borrowers, MidCap Financial Trust, as agent, and the lenders from time to time party thereto. The Credit Agreement provides us with up to \$35.0 million of available borrowing capacity, which will be available (subject to certain conditions) to us in two tranches of \$20.0 million and \$15.0 million, respectively, through August 31, 2017. See Note 6 — Debt.

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.

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 U.S. 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 is 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.

Principles of Consolidation

The consolidated financial statements include the accounts of the company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

Revenue Recognition

Aptevo recognizes 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.

Chargebacks, Rebates, and other Discounts

Aptevo markets and sells its products through commercial wholesalers (direct customers) who purchase the products at a price referred to as the wholesale acquisition cost (WAC). Additionally, Aptevo may enter into separate agreements with indirect customers to acquire its products for a contracted price that is less than the product's WAC. The indirect customers, such as group-purchasing organizations, physician practice-management groups and hospitals, continue to purchase Aptevo's products from the wholesalers, but at their respective contractual prices. Per its wholesaler agreements, Aptevo guarantees to credit the wholesaler for the difference between the WAC and the indirect customers' contracted price. This credit is referred to as a chargeback and revenues from product sales are recorded net of estimated chargebacks. Adjustments to the chargeback provisions are made periodically to reflect new facts and circumstances, therefore historical experience may not be indicative of current and/or future results.

All revenues from product sales are also recorded net of applicable allowances for sales and government rebates, special promotional programs, and discounts. These allowances are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels, contract terms, and actual discounts offered. In arriving at these estimates, Aptevo further utilizes information received from third parties including market data, inventory reports from major wholesalers, historical information and analysis. These estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates and reflect other limitations.

Collaborations

Revenue generating collaborative research and development agreements may contain one or more provisions including licensing, research services and milestone deliverables. Aptevo analyzes its multiple element revenue generating arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. An item can generally be considered a separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a standalone basis, and (2) if the arrangement includes a general right of return and delivery, the performance of the undelivered item(s) is considered probable and substantially in the control of Aptevo. Items that cannot be divided into separate units are consolidated with other units of accounting, as appropriate. Consideration to be received is allocated among the separate units based on each unit's relative selling price and is then recognized when the appropriate revenue recognition criteria are met. Aptevo deems services to be rendered if no continuing obligation exists on the part of Aptevo.

Revenue associated with non-refundable upfront license fees that can be treated as a single unit of accounting is recognized when all ongoing obligations have been delivered. Revenue associated with non-refundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue either on a straight-line basis over Aptevo's continued involvement in the research and development process or based on the proportional performance of Aptevo's expected future obligations under the contract.

Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable, (2) achievement of the milestone was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved to achieve the milestone and (4) the amount of the milestone payment appears reasonable in relation to the effort expended. If not deemed substantive, Aptevo recognizes such milestone as revenue on a percent of completion basis over the remaining expected term of continued involvement in the research and development process. Payments received in advance of revenue recognized are recorded as deferred revenue.

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.

Cash Equivalents

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and include time deposits and investments in money market funds with commercial banks and financial institutions.

Investments

Investments are classified as available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are reported as a separate component of shareholders' equity. Amortization, accretion, interest and dividends, realized gains and losses and declines in value judged to be other-than-temporary are included in other income (expense). The cost of securities sold is based on the specific-identification method. Investments in securities with maturities of less than one year, or those for which management intends to use the investments to fund current operations, are included in current assets. We evaluate whether an investment is other-than-temporarily impaired based on the specific facts and circumstances. Factors that are considered in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the investee; and the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment.

Fair Value of Financial Instruments

The Company measures and records cash equivalents and investment securities considered available-for-sale at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value include:

Level 1—Observable inputs for identical assets or liabilities such as quoted prices in active markets;

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

Level 3—Unobservable inputs in which little or no market data exists, which are therefore developed by the Company's management using estimates and assumptions that reflect those that a market participant would use.

The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair value due to their short maturities.

Accounts Receivable

When appropriate, Aptevo records an allowance for doubtful accounts based upon its assessment of collectability. Aptevo performs ongoing credit evaluations of its customers and generally does not require collateral. Aptevo recorded an allowance for doubtful accounts of \$3.5 million in the fourth quarter of 2015 and \$0.0 for the nine month periods ended September 30, 2016.

Concentrations of Credit Risk

Financial instruments that potentially subject Aptevo to concentrations of credit risk consist primarily of cash and cash equivalents, certain investments and accounts receivable. Aptevo places its cash and cash equivalents with high quality financial institutions and may maintain cash balances in excess of insured limits. Management believes that the financial risks associated with its cash and cash equivalents are minimal.

Inventories

Inventories, including purchased inventories, are stated at the lower of cost or market with cost being determined using a standard cost method, which approximates weighted-average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses (including allocation of fixed production-overhead costs) and includes the services and products of third-party suppliers. Aptevo analyzes its inventory levels quarterly and writes down, in the applicable period, inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. Aptevo also writes off, in the applicable period, the costs related to expired inventory.

Debt Issuance Costs

We defer costs related to debt issuance and amortize these cost to interest expense over the term of the debt, using the effective interest method. Debt issuance costs are presented in the balance sheet as a reduction of the carrying amount of the debt liability.

Property and Equipment

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the following estimated useful lives:

Building improvements	10-39 years
Furniture and equipment	3-15 years
Software	3-7 years or product life
Leasehold improvements	Lesser of the asset life or the remaining lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss and research and development tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

Aptevo's ability to realize deferred tax assets depends upon future taxable income as well as the limitations discussed below. For financial reporting purposes, a deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized prior to expiration. Aptevo considers future taxable income and ongoing tax planning strategies in assessing the need for valuation allowances. In general, if Aptevo determines that it is more likely than not to realize more than the recorded amounts of net deferred tax assets in the future, Aptevo will reverse all or a portion of the valuation allowance established against its deferred tax assets, resulting in a decrease to the provision for income taxes in the period in which the determination is made. Likewise, if Aptevo determines that it is not more likely than not to realize all or part of the net deferred tax asset in the future, Aptevo will establish a valuation allowance against deferred tax assets, with an offsetting increase to the provision for income taxes, in the period in which the determination is made.

Because tax laws are complex and subject to different interpretations, significant judgment is required. As a result, Aptevo makes certain estimates and assumptions, in (1) calculating Aptevo's income tax expense, deferred tax assets and deferred tax liabilities, (2) determining any valuation allowance recorded against deferred tax assets and (3) evaluating the amount of unrecognized tax benefits, as well as the interest and penalties related to such uncertain tax positions. Aptevo's estimates and assumptions may differ significantly from tax benefits ultimately realized.

Mergers and Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, Aptevo may be required to value assets at fair value measures that do not reflect Aptevo's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in Aptevo's consolidated financial statements after the date of the merger or acquisition.

The fair values of intangible assets are determined utilizing information available near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, Aptevo typically obtains assistance from third-party valuation specialists for significant items. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect Aptevo's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an "income approach" through which fair value is estimated based on each asset's discounted projected net cash flows. Aptevo's estimates of net cash flows consider historical and projected pricing, margins and expense levels, the performance of competing products where applicable, relevant industry and therapeutic area growth drivers and factors, current and expected trends in technology and product life cycles, the time and investment that will be required to develop products and technologies, the ability to obtain marketing and regulatory approvals, the ability to manufacture and commercialize the products, the extent and timing of potential new product introductions by Aptevo's competitors, and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to in-process research and development ("IPR&D") are determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, Aptevo will make a separate determination as to the then useful life of the asset and begin amortization.

In-Process Research and Development and Long-lived Assets

Aptevo assesses IPR&D assets for impairment on an annual basis or more frequently if indicators of impairment are present. Aptevo's annual assessment includes a comparison of the fair value of IPR&D assets to existing carrying value, and recognizes an impairment when the carrying value is greater than the determined fair value. Aptevo believes that the assumptions used in valuing the intangible and IPR&D assets are reasonable and are based upon its best estimate of likely outcomes of sales and clinical development. The underlying assumptions and estimates used to value these assets are subject to change in the future, and actual results may differ significantly from the assumptions and estimates. Aptevo has selected October 1 as its annual impairment test date for indefinite-lived intangible assets.

Aptevo assesses the recoverability of its long-lived assets or asset groups for which an indicator of impairment exists by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If Aptevo concludes that the carrying value will not be recovered, Aptevo measures the amount of such impairment by comparing the fair value to the carrying value of the assets or asset groups. See Note 7 — Impairment of Intangible Assets, In Process Research and Development and Goodwill.

Goodwill

Aptevo assesses the carrying value of goodwill for impairment on an annual basis or whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable. Aptevo utilizes either: (1) a two-step impairment test, which is a quantitative analysis, or (2) a step zero test, which is a qualitative analysis.

If Aptevo is required to do a two-step test, it would first compare the fair value of its reporting unit to the carrying value of the reporting unit. If the carrying value of the reporting unit exceeds its fair value, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting unit's goodwill. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, an impairment loss is recognized. Aptevo calculates the fair value of the reporting unit utilizing the income approach.

We generally base our measurement of fair value of reporting units on a blended analysis of the present value of future discounted cash flows and market valuation approach. The discounted cash flows model indicates the fair value of the reporting units based on the present value of the cash flows that we expect the reporting units to generate in the future. Our significant estimates in the discounted cash flows model include: our weighted average cost of capital; long-term rate of growth and profitability of our business; and working capital effects. The market valuation approach indicates the fair value of the business based on a comparison of the Company to comparable publicly traded firms in similar lines of business. Our significant estimates in the market approach model include identifying similar companies with comparable business factors such as size, growth, profitability, risk and return on investment and assessing comparable revenue and operating income multiples in estimating the fair value of the reporting units.

If Aptevo is not required to do a quantitative analysis, it will evaluate goodwill using the qualitative assessment method, which permits companies to qualitatively assess whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount. Aptevo considers developments in its operations, the industry in which it operates and overall macroeconomic factors that could have affected the fair value of the reporting unit since the date of the most recent quantitative analysis of the reporting unit's fair value.

The determination of the fair value of a reporting unit is judgmental in nature and involves the use of significant estimates and assumptions. The estimates and assumptions used in calculating fair value include identifying future cash flows, which requires that Aptevo make a number of critical legal, economic, market and business assumptions that reflect best estimates as of the testing date. Aptevo's assumptions and estimates may differ significantly from actual results, or circumstances could change that would cause Aptevo to conclude that an impairment now exists or that it previously understated the extent of impairment. See Note 7 — Impairment of Intangible Assets, In Process Research and Development and Goodwill.

Contingent Consideration

Aptevo records contingent consideration associated with sales-based royalties at fair value. The fair value model used to calculate this obligation is based on the income approach (a discounted cash flow model) that has been risk adjusted based on the probability of achievement of net sales and achievement of the milestones. The inputs Aptevo uses for determining the fair value of the contingent consideration associated with sales based royalties are Level 3 fair value measurements. Aptevo re-evaluates the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the discount rates and updates in the assumed timing of or achievement of net sales. Any future increase in the fair value of the contingent consideration associated with sales based royalties are based on an increased likelihood that the underlying net sales will be achieved.

The associated payment or payments which will therefore become due and payable for sales based royalties will result in a charge to cost of product sales in the period in which the increase is determined. Similarly, any future decrease in the fair value of contingent consideration associated with sales based royalties will result in a reduction in cost of product sales.

Research and Development

Research and development costs are expensed as incurred. Research and development costs primarily consist of internal labor costs, fees paid to outside service providers and the costs of materials used in clinical trials and research and development. Other research and development expenses include facility, maintenance and related support expenses.

A substantial portion of Aptevo's pre-clinical studies and all of its clinical studies have been performed by third-party contract research organizations (CRO). The Company reviews the activities performed by the CROs each period. For pre-clinical studies, the significant factors used in estimating accruals include the percentage of work completed to date and contract milestones achieved. For clinical study expenses, the significant factors used in estimating accruals include the number of patients enrolled and percentage of work completed to date. The Company's estimates are highly dependent upon the timeliness and accuracy of the data provided by its CRO's regarding the status of each program and total program spending and adjustments are made when deemed necessary.

Segment Reporting

The Company has determined that it operates in a single segment and has one reporting unit: the discovery, development, commercialization and sale of novel oncology and hematology therapeutics

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers (Topic 606)." ASU 2014-09 completes the joint effort by the FASB and International Accounting Standards Board (IASB) to improve financial reporting by creating common revenue recognition guidance for GAAP and International Financial Reporting Standards (IFRS). Subsequently, the FASB has issued several additional ASUs to clarify the implementation guidance on principal versus agent considerations, identifying performance obligations, assessing collectability, presentation of sales taxes and other similar taxes collected from customers, non-cash consideration, contract modifications and completed contracts at transition. These ASUs apply to all companies that enter into contracts with customers to transfer goods or services. These ASUs are effective for public entities for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, but not before interim and annual reporting periods beginning after December 15, 2016. Entities have the choice to apply these ASUs either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. Aptevo is currently evaluating the requirements of these standards and have not yet determined the impact on its condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)." ASU 2016-02 requires lessees to recognize a lease liability and a right-of-use asset on the balance sheet and aligns many of the underlying principles of the new lessor model with those in Accounting Standards Codification Topic 606, Revenue from Contracts with Customers. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. Aptevo is currently evaluating the requirements of ASU 2016-02 and have not yet determined the impact on its condensed consolidated financial statements.

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. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted. Aptevo is currently evaluating the requirements of ASU 2016-09 and have not yet determined the impact on its condensed consolidated financial statements.

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. We are currently evaluating the impact of the new standard on our 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 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys decided to adjust the dosing regimen and administration of MOR209/ES414. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; this is called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, 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. Aptevo plans to continue the current clinical trial under an amended protocol with recruitment expected to start in the second half of 2016. As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. In December 2015, Aptevo and MorphoSys amended the collaboration agreement to: (1) decrease the additional contingent payments due to Aptevo upon the achievement of specified development and regulatory milestones of up to \$32.5 million and up to \$41.5 million, respectively, (2) change the total funding requirement cap for Aptevo to up to approximately \$250.0 million and (3) change the jointly funded development cost allocation to the following:

- 2016: Aptevo is responsible for 75%; MorphoSys responsible for 25%
- 2017-2018: Aptevo is responsible for 49%; MorphoSys responsible for 51%
- 2019 and beyond: Aptevo is responsible for 36%; MorphoSys responsible for 64%

In addition, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial.

Aptevo evaluated the MorphoSys Agreement and determined that it was a revenue arrangement with multiple deliverables or performance obligations. Aptevo determined there were two units of accounting under the MorphoSys Agreement: (1) the delivered license to further develop and commercialize MOR209/ES414, and (2) undelivered items related to development services. Aptevo determined that the license had standalone value as the drug candidate has been: (1) developed and is currently Phase 1 clinical trial ready, (2) MorphoSys possesses the knowledge, technology, skills, experience and infrastructure necessary to complete all further development of the drug through commercialization, and (3) MorphoSys has the right to further sublicense the product. 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 nine months ended September 30, 2016 and 2015. The current estimated service period for the undelivered development services under the MorphoSys Agreement is through 2023.

Further, Aptevo determined that contingent payments for the achievement of the development and regulatory milestones are substantive milestones and will be accounted for as revenue in the period in which the milestones are achieved. Aptevo received a \$5.0 million milestone payment from MorphoSys reflecting the initiation of a Phase I clinical study to evaluate the safety, tolerability, and clinical activity of MOR209/ES414 in patients with metastatic castration-resistant prostate cancer. Aptevo recognized this substantive milestone achievement payment as research and development revenue during the 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 and nine months ended September 30, 2016 Aptevo recorded a reduction to research and development expense of \$0.0 million and \$0.1 million, respectively. For the three and nine months ended September 30, 2015 Aptevo recorded a reduction to research and development expense of \$1.0 million and \$3.7 million, respectively.

As of September 30, 2016, 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—Observable inputs for identical assets or liabilities such as quoted prices in active markets;

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

Level 3—Unobservable inputs in which little or no market data exists, which are therefore developed by the Company's management using estimates and assumptions that reflect those that a market participant would use.

The Company held no financial assets measured at fair value as of December 31, 2015. The Company's financial assets measured at fair value consisted of the following as of September 30, 2016:

(in thousands)	September 30, 2016			Total
	Level 1	Level 2	Level 3	
Financial Assets:				
Money market funds	\$ 5,210	\$ —	\$ —	\$ 5,210
Corporate bonds	—	37,864	—	37,864
US government and agency debt securities	—	11,921	—	11,921
Total assets	\$ 5,210	\$ 49,785	\$ —	\$ 54,995

If quoted market prices in active markets for identical assets are not available to determine fair value, then the Company uses quoted prices of similar instruments and other significant inputs derived from observable market data obtained from third-party data providers. These investments are included in Level 2 and consist of debt securities of U.S government agencies and corporate bonds. There were no transfers between Levels 1 and 2 during the three and six-month period ended June 30, 2016.

The following table is a reconciliation of the beginning and ending balance of the liabilities (contingent consideration) measured at fair value using significant unobservable inputs (Level 3) during the nine months ended September 30, 2016. The royalty agreement associated with HepaGam expired on June 30, 2016, and no future royalty payments are expected on sales after that date. The remaining liability is due to accrued but unpaid royalties.

(in thousands)	
Balance at December 31, 2015	\$ 444
Expense included in earnings	19
Settlements	(280)
Balance at September 30, 2016	<u>\$ 183</u>

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 September 30, 2016 were temporary in nature, and the Company currently does not intend to 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.

(in thousands)	September 30, 2016			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Cash equivalents:				
Money market fund	\$ 5,210	\$ —	\$ —	\$ 5,210
Total cash equivalents	<u>\$ 5,210</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,210</u>
Short-term investments:				
Corporate bonds	\$ 37,871	\$ 1	\$ (6)	\$ 37,864
US government and agency debt securities	11,937	2	(14)	11,921
Total short-term investments	<u>\$ 49,808</u>	<u>\$ 3</u>	<u>\$ (20)</u>	<u>\$ 49,785</u>

Note 5. Inventories

Inventories consist of the following:

(in thousands)	September 30, 2016	December 31, 2015
Raw materials and supplies	\$ 4,644	\$ 6,520
Work-in-process	1,652	4,730
Finished goods	5,278	9,072
Total inventories	<u>\$ 11,574</u>	<u>\$ 20,322</u>

CMC ICOS Biologics, Inc., (CMC), is the exclusive manufacturer of bulk drug substance for the IXINITY product. During 2015, Aptevo ordered nine manufacturing lots of bulk drug substance from CMC. CMC has successfully manufactured and released only one of the nine lots of bulk drug substance ordered by Aptevo. On October 4, 2016 we provided a Notice of Interruption in Manufacturing (Notice) to the United States Food and Drug Administration (FDA) notifying the FDA of a potential interruption in the supply of IXINITY® coagulation factor IX (recombinant). The supply interruption relates to an ongoing challenge with the manufacture of bulk drug substance for IXINITY that meets release specifications for the final drug product. As part of the Notice, Aptevo submitted a proposal to the FDA seeking approval for a proposed mitigation plan aimed at ensuring the continued supply of IXINITY to patients. FDA has denied our proposal and therefore we anticipate that there will be a supply interruption of the 1500IU assay in December and the remaining dosage forms of IXINITY in January 2017. Such a supply shortage of IXINITY will adversely affect its sales, and could adversely affect its market position and commercial viability.

Due to the ongoing challenges with the manufacture of our IXINITY product that meets release specifications for the final drug product, in the third quarter of 2016, we wrote off approximately \$2.9 million in unsaleable IXINITY inventory that was in the process of being manufactured. This cost is included in cost of product sales.

Note 6. Debt

Credit Facility

On August 4, 2016, we entered into a \$35.0 million Credit and Security Agreement (the Credit Agreement), by and among Aptevo and certain subsidiaries of Aptevo as borrowers, MidCap Financial Trust, as agent, and the lenders from time to time party thereto. 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 will be 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's promise to pay this \$20.0 million in cash is evidenced by a non-negotiable, unsecured promissory note issued to Aptevo from Emergent.

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, in each case applicable to us and our subsidiaries. The negative covenants include restrictions on, 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. 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. The Credit Agreement also includes provision related to events of default and occurrence of material adverse effect. The occurrence of an event of default could result in the acceleration of the Credit Agreement. There was no event of default under the Credit Agreement as of September 30, 2016.

The Credit Agreement also includes customary events of default, including, among other things, failure to pay principal or interest due under the Credit Agreement, default of covenants, a cross-default on our or our subsidiary's material indebtedness, breach of material contracts by us or our subsidiaries, or commencement of liquidation, reorganization or similar relief. This and further obligations under the Credit Agreement are secured by all of our assets other than: (1) certain voting shares of excluded subsidiaries, (2) any lease, license or other contract where the grant of a security interest would constitute a default, be prohibited by applicable law, or will require certain third-party consents, and (3) intellectual property (except to the extent necessary to have a lien on such intellectual property in order to have a lien on cash and other proceeds arising out of or derived from such intellectual property).

The related financing documents contain: (1) a customary agency fee, (2) an exit fee of up to 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 and (3) a prepayment fee of up to 4% of the amount prepaid for the first year, decreasing over time, for any amounts prepaid prior to the maturity date, whether voluntary or by reason of the occurrence of an event of default or acceleration of the loan, other than certain mandatory prepayments.

The obligations of Aptevo and the other borrowers under the Credit Agreement are secured by all of their assets other than (1) certain voting shares of excluded subsidiaries of Aptevo, (2) any lease, license or other contract where the grant of a security interest would constitute a default, be prohibited by applicable law, or will require certain third-party consents and (3) intellectual property of Aptevo (except to the extent necessary to have a lien on such intellectual property in order to have a lien on cash and other proceeds arising out of or derived from such intellectual property).

Note 7. Impairment of Intangible Assets, In-Process Research and Development and Goodwill

During the period between the spin off date and September 30, 2016, we experienced a significant decline in our stock price. Based on this, we concluded that a sufficient indicator existed to require us to perform an interim assessment of goodwill and indefinite-lived intangible assets as of September 30, 2016. We performed an interim first step of our impairment assessment and determined there was a potential impairment of goodwill. Therefore, we performed the second step of the assessment in which we compared the implied fair value of goodwill to the book value of that goodwill. The implied fair value of goodwill is determined in the same manner as the amount of goodwill recognized in a business combination. That is, the estimated fair value of the business is allocated to all of the assets and liabilities as if the business had been acquired in a business combination and the estimated fair value of the business was the purchase price paid. If the carrying amount goodwill exceeds the implied fair value, an impairment loss is recognized in an amount equal to that excess.

We measured the fair value of both our indefinite-lived and definite lived intangible assets using accepted valuation techniques. The significant estimates used included our weighted average cost of capital, long-term rate of growth and profitability of our business, and working capital effects. Our assumptions are based on actual historical performance, expected results after commercial launch of our otlertuzumab product, and implied risk premiums based on market prices of our equity and debt as of the assessment date. To validate the reasonableness of the fair values, we reconciled the aggregate fair values of the business determined in step one to the enterprise market capitalization. Enterprise market capitalization includes, among other factors, the market capitalization of our stock and an acquisition premium based on historical data from acquisitions within the same or similar industries. In performing the reconciliation, we used the market value of our stock price, the stock price on the valuation date and considered such other quantitative and qualitative factors we considered relevant. This assessment resulted in the recognition in the third quarter of 2016 of a loss on impairment of in process research and development costs related to our otlertuzumab candidate of approximately \$41.8 million and \$13.9 million of goodwill.

As evidenced by a significant decline in our stock price, we determined that the adverse change in the business climate discussed above was an indicator requiring the testing of our long-lived assets for recoverability and performed this test as of September 30, 2016, prior to completing the tests above. We tested the long-lived assets for recoverability based on a comparison of the respective aggregate values of their undiscounted cash flows to the respective carrying values. The results of the evaluation indicated that the carrying values of the related assets were recoverable.

Note 8. 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 September 30, 2016, 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 and nine month periods ended September 30, 2016 and 2015, since the effect is anti-dilutive due to the Company's net losses. Common stock equivalents include stock options and unvested RSUs.

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

<u>(in thousands, except for per share amounts)</u>	<u>As of September 30,</u> <u>2016</u>
Outstanding options to purchase common stock	2,053
Unvested RSUs	3,324

At December 31, 2015, no options or RSU's were outstanding.

Note 9. 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 shareholders and recorded a contribution from Emergent of \$46.4 million, which included a one-time payment of \$45.0 million, and a working capital reimbursement for outstanding payments of \$1.4 million, which we expect to receive by December 31, 2016. In addition, we recorded a promissory note to receive \$20.0 million within six to twelve months, as well as recording a net transfer from Emergent of \$24.2 million, which represents cash and non-cash activity between Emergent and the Company prior to the spin-off.

Converted Equity Awards Incentive Plan

The Company had no stock-based compensation plans prior to 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 Combined Condensed Statements of Operations for the associated periods prior to the spin off.

In connection with the spin off and the employee matters agreement, 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.

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 7 to 10 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 stock market on the date of grant, while options issued as Conversion Awards were priced according to the Converted Plan.

RSUs issued under the 2016 SIP or as part of the Converted Plan 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 period, although certain employees may be awarded RSUs with different time-based vesting criteria. Prior to vesting, RSUs granted under the Stock Plan 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.

Issuance of Shares

When options are exercised or RSU's are converted, it is the Company's policy to issue new shares.

Stock-Based Compensation Expense

Stock-based compensation expense includes amortization of stock options and restricted stock units granted to employees and non-employees and has been reported in our Condensed Consolidated Statements of Operation and Comprehensive Loss as follows:

(in thousands)	September 30, 2016		September 30, 2015	
	Three Months	Nine Months	Three Months	Nine Months
Research and development	\$ 1,027	\$ 1,761	\$ 281	\$ 822
General and administrative	306	306	—	—
Total stock-based compensation expense	<u>\$ 1,333</u>	<u>\$ 2,067</u>	<u>\$ 281</u>	<u>\$ 822</u>

The Company accounts for stock-based compensation by measuring the cost of employee services received in exchange for all equity awards granted based on the fair value of the award as of the grant date. The Company recognizes the compensation expense over the requisite service period, which is generally 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:

	September 30, 2016	
	Three Months	Nine Months
Expected dividend yield	0%	0%
Expected volatility	75%	75%
Risk-free interest rate	1.00%	1.00%
Expected average life of options	3 years	3 years

Management applied an estimated forfeiture rate for the three and nine month periods of 10%.

The following is a summary of option activity for the nine months ended September 30, 2016:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding Aptevo Options at December 31, 2015	—	\$ —	\$ —
Aggregate impact of conversion related to spin-off	1,661,563	2.49	203,644
Granted	387,975	2.94	36,858
Exercised	(6,675)	2.18	(7,062)
Outstanding at September 30, 2016	<u>2,042,863</u>	<u>\$ 2.58</u>	<u>\$ 233,440</u>
Exercisable at September 30, 2016	<u>461,096</u>	<u>\$ 2.29</u>	<u>\$ 126,319</u>

As of September 30, 2016, we had \$0.9 million of unrecognized compensation expense related to options expected to vest over a weighted average period of 2.14 years. The weighted average remaining contractual life of exercisable options is 6.4 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 the third quarter of 2016 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 September 30, 2016. 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 restricted stock activity for the nine months ended September 30, 2016:

	Number of Units	Weighted Average Fair Value per Unit	Aggregate Fair Value
Outstanding Aptevo RSU's at December 31, 2015	—	\$ —	\$ —
Aggregate impact of conversion related to spin-off	1,122,179	2.76	
Granted	2,115,772	2.94	
Converted	(15,051)	2.65	
Outstanding at September 30, 2016	<u>3,222,900</u>	<u>\$ 2.88</u>	<u>\$ 8,250,624</u>
Expected to Vest	<u>2,888,726</u>	<u>\$ 2.88</u>	<u>\$ 7,395,139</u>

As of September 30, 2016, we had \$6.7 million of unrecognized compensation expense related to RSU's expected to vest over a period of 1.5 years. The weighted average remaining contractual life of exercisable RSU's 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.

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.

Overview

On August 6, 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 (cancer) and hematology (blood disease) therapeutics to meaningfully improve patients’ lives and the other a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats. To accomplish this separation, Emergent created a new company, Aptevo Therapeutics Inc., or Aptevo, to be the parent company for the development-based pharmaceuticals business focused on novel oncology and hematology therapeutics. Aptevo was incorporated in Delaware in February 2016 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, Aptevo 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.

Aptevo’s historical consolidated financial statements have been prepared on a standalone basis and are derived from Emergent’s consolidated financial statements and accounting records. The consolidated financial statements reflect Aptevo’s financial position, results of operations, and cash flows as its business was operated as part of Emergent prior to the 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 Aptevo. Cash and cash equivalents held by Emergent were not allocated to Aptevo unless the cash was held by an entity that was transferred to Aptevo in the distribution. All Aptevo intracompany transactions and accounts have been eliminated. All intercompany transactions between Aptevo and Emergent are considered to be effectively settled in the 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 net investment from former parent.

The historical financial statements do not necessarily include all of the expenses that would have been incurred had Aptevo been a separate, standalone entity and may not necessarily reflect Aptevo’s results of operations, financial position and cash flows had Aptevo been a standalone company during the periods presented. Aptevo’s consolidated financial statements include an allocation of expenses related to certain Emergent corporate functions, including senior management, legal, human resources, finance, information technology, and quality assurance. These expenses have been allocated to Aptevo based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, square footage, or other measures. Aptevo considers the expense allocation methodology and results to be reasonable for all periods presented. However, the allocations may not be indicative of the actual expense that would have been incurred had Aptevo operated as an independent, publicly-traded company for the periods presented.

Program Highlights

Aptevo's investigational stage products MOR209/ES414, ES210, and otlertuzumab are built on our novel ADAPTIR™ (modular protein technology) platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. The technology can produce monospecific and multispecific, for example, bispecific therapeutic molecules, which may have structural advantages over monoclonal antibodies (identical antibodies from clones or copies of a unique parent cell that bind to the same target in the same way). The mechanisms of action for MOR209/ES414, ES210, and otlertuzumab include redirected T-cell cytotoxicity, or RTCC, and targeted cytokine delivery. The structural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of other ADAPTIR immunotherapeutics that engage disease targets in a unique manner and produce a unique signaling response. We are skilled at product candidate generation, validation and subsequent clinical development using the ADAPTIR platform. We believe we have the ability to progress ADAPTIR molecules from concept to marketed product by way of our protein engineering, pre-clinical development and process development capabilities and cGMP manufacturing oversight. We also believe we have the ability to launch market and commercialize these product candidates upon approval.

Aptevo's marketed products are:

- 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;
- HepaGamB® Hepatitis B Immune Globulin Intravenous (Human), for prevention of hepatitis-B recurrence following liver transplantation in HBsAg-positive liver transplant patients, and for treatment following exposure to hepatitis-B;
- VARIZIG® Varicella Zoster Immune Globulin (Human), for treatment following exposure to varicella zoster virus, which causes chickenpox, in high-risk individuals; and
- IXINITY® coagulation factor IX (recombinant), indicated in adults and children 12 years of age and older with hemophilia B for control and prevention of bleeding episodes, and management of bleeding during operations.

Aptevo's investigational stage product candidates include:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells. It is being developed under our collaboration with MorphoSys AG for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies;
- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease and other autoimmune and inflammatory diseases;
- otlertuzumab, a monospecific ADAPTIR protein therapeutic that is currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL;
- 5E3 mAb, a monoclonal antibody therapeutic that is currently in pre-clinical development for Alzheimer's disease;
- a bispecific immunotherapeutic ADAPTIR protein that targets ROR1 (receptor tyrosine kinase- like orphan receptor 1, a protein expressed on solid tumors, leukemia's, and lymphomas), which are currently in pre-clinical development for a variety of hematologic malignancies and solid tumors; and
- Other protein therapeutic product candidates primarily targeting immunooncology.

Collaboration with MorphoSys AG

In August 2014, Aptevo entered into a collaboration agreement, or MorphoSys Agreement, with MorphoSys AG for the joint worldwide development and commercialization of MOR209/ES414, a targeted immunotherapeutic protein, which activates host T-cell immunity specifically against cancer cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells. MOR209/ES414 was constructed using Aptevo's proprietary ADAPTIR platform technology.

In accordance with the initial terms of the MorphoSys Agreement, Aptevo received a nonrefundable \$20.0 million upfront payment and could have received up to \$163.0 million in additional contingent payments, comprised of up to \$80.0 million and up to \$83.0 million, respectively, due upon the achievement of specified development and regulatory milestones. MorphoSys and Aptevo agreed to jointly fund further development of MOR209/ES414, with Aptevo responsible for 36% of the total development costs and MorphoSys responsible for the remainder, with Aptevo's funding requirement capped at \$186.0 million. Aptevo's development effort includes the performance of non-clinical, clinical, manufacturing and regulatory activities. Aptevo retains commercialization rights in

the U.S. and Canada, with a tiered royalty obligation to MorphoSys, ranging from mid-single digit up to 20% of sales. MorphoSys has worldwide commercialization rights excluding the U.S. and Canada, with a low single digit royalty obligation to Aptevo.

In December 2015, after a joint review of data from the ongoing Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys decided to adjust the dosing regimen and administration of MOR209/ES414. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; this is called anti-drug antibodies, or ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. We are continuing with the current clinical trial under an amended protocol. Recruitment began in October 2016.

As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. In December 2015, Aptevo and MorphoSys amended the collaboration agreement to (1) decrease the additional contingent payments due Aptevo upon the achievement of specified development and regulatory milestones of up to \$32.5 million and up to \$41.5 million, respectively, (2) change the total funding requirement cap for Aptevo to up to approximately \$250.0 million and (3) change the jointly funded development cost allocation. In addition, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial.

Aptevo evaluated the MorphoSys Agreement and determined that it was a revenue arrangement with multiple deliverables or performance obligations. Aptevo determined there were two units of accounting under the MorphoSys Agreement: (1) the delivered license to further develop and commercialize MOR209/ES414 and (2) undelivered items related to development services. Aptevo determined that the license had standalone value as the drug candidate has been (1) developed and is currently Phase 1 clinical trial ready, (2) MorphoSys possesses the knowledge, technology, skills, experience and infrastructure necessary to complete all further development of the drug through commercialization, and (3) MorphoSys has the right to further sublicense the product. Aptevo allocated the \$20.0 million upfront payment to the two units of accounting using the relative selling price method. Aptevo determined the estimated selling price for the license using the income approach and an appropriate discount rate. The estimated selling price includes unobservable inputs (Level 3), such as estimates of revenues and operating margins; the time and resources needed to complete the development and approval of the product candidate; and the risk related to the viability of and potential for alternative treatments. Aptevo determined the estimated selling price of the development services unit of accounting based on the estimated number of full-time equivalent personnel at the contractual rate as defined in the MorphoSys Agreement, whose rates and terms approximate those of other Emergent or Aptevo service related contracts and those observed generally through other collaboration negotiations. The allocation resulted in \$15.3 million of the \$20.0 million upfront payment being allocated to the license and \$4.7 million being allocated to the development services. Aptevo determined the license fee unit of accounting was delivered and completed on the date the MorphoSys Agreement was executed and thus recognized \$15.3 million of license revenue in August 2014. Revenue related to the development services is recognized as the services are performed with \$0.7 million and \$0.2 million, respectively, recognized in the years ended December 31, 2015 and 2014. The current estimated service period for the undelivered development services under the MorphoSys Agreement is through 2023.

Further, Aptevo determined that contingent payments for the achievement of the development and regulatory milestones are substantive milestones and will be accounted for as revenue in the period in which the milestones are achieved. Aptevo received a \$5.0 million milestone payment from MorphoSys reflecting the initiation of a Phase I clinical study to evaluate the safety, tolerability, and clinical activity of MOR209/ES414 in patients with metastatic castration-resistant prostate cancer. Aptevo recognized this substantive milestone achievement payment as collaborations revenue during the year ended December 31, 2015.

IXINITY

In the acquisition of Cangene Corporation, or Cangene, in February 2014, Aptevo acquired the IXINITY product candidate, an IPR&D intangible asset. As part of the purchase price allocation, Aptevo's management determined that the estimated acquisition date fair value related to the IXINITY IPR&D asset was \$8.3 million. The estimated fair value was determined using the income approach, which discounts probability-adjusted future net cash flows to present value. The projected cash flows used in determining the fair value of IXINITY were based on key assumptions, including: estimates of revenues and operating profits considering its stage of development on the acquisition date, the time and resources needed to complete the development and approval of the product candidate, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, Aptevo made a separate determination as to the then useful life of the asset and begin amortization. In

April 2015, the Food and Drug Administration, or FDA, approved IXINITY for the treatment of Hemophilia B in adults and children. As a result, the \$8.3 million IXINITY IPR&D asset was reclassified as a definite-life intangible asset and is being amortized over 10 years. Since April 2015, we have incurred approximately \$9 million in research and development expense related to IXINITY, primarily for clinical trial activities (approximately \$4 million) and development and qualification activities (approximately \$5 million). 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. 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 (Notice) to the United States Food and Drug Administration (FDA) notifying FDA of a potential interruption in the supply of IXINITY® coagulation factor IX (recombinant.) The supply interruption relates to an ongoing challenge with the manufacture of bulk drug substance for IXINITY that meets release specifications for final drug product. As part of the Notice, Aptevo submitted a proposal to FDA seeking approval for a proposed mitigation plan aimed at ensuring the continued supply of IXINITY to patients. FDA has denied our proposal and therefore we anticipate that there will be a supply interruption of the 1500IU assay in December and the remaining dosage forms of IXINITY in January 2017. Such a supply shortage of IXINITY will adversely affect its sales, and could adversely affect its market position and commercial viability.

Due to the ongoing challenges with the manufacture of our IXINITY product that meets release specifications for the final drug product, in the third quarter of 2016, we wrote off approximately \$2.9 million in unsaleable IXINITY inventory that was in process of being manufactured. This cost is included in cost of product sales.

Results of Operations

Revenue

Product Sales

Revenues consist primarily of product sales of our marketed products and collaboration revenues from our collaborative partners, generally in the form of upfront or milestone payments.

Sales by product are shown in the following table:

(in thousands)	Three Months Ended		Change
	September 30,		
	2016	2015	
WinRho	\$ 2,916	\$ 3,177	\$ (261)
IXINITY	2,816	218	2,598
HepaGam	2,511	2,502	9
VARIZIG	1,161	530	631
Other	1	14	(13)
Total	\$ 9,405	\$ 6,441	\$ 2,964

Product sales revenue increased by \$3.0 million, or 46% to \$9.4 million for the three months ended September 30, 2016 from \$6.4 million for the three months ended September 30, 2015. This increase was primarily related to revenue associated with IXINITY which included \$2.6 million for the three months ended September 30, 2016. Although IXINITY was approved by the FDA in the second quarter of 2015, we did not have meaningful product sales of IXINITY during the three months ended September 30, 2015 as we built out our sales team and began marketing. In addition, the change was impacted by an increase in unit sales of our VARIZIG product.

Sales by product are shown in the following table:

(in thousands)	Nine Months Ended September 30,		Change
	2016	2015	
WinRho	\$ 10,614	\$ 10,580	\$ 34
HepaGam	7,050	7,208	(158)
IXINITY	7,037	218	6,819
VARIZIG	2,797	1,633	1,164
Other	14	65	(51)
Total	\$ 27,512	\$ 19,704	\$ 7,808

Product sales revenue increased by \$7.8 million, or 38%, to \$27.5 million for the nine months ended September 30, 2016 from \$19.7 million for the nine months ended September 30, 2015. This increase was primarily related to revenue associated with IXINITY which included \$6.8 million for the nine months ended September 30, 2016 following IXINITY's FDA approval in the second quarter of 2015 and an increase in unit sales of our VARIZIG product.

Collaborations

Collaborations revenue decreased by \$5.5 million, or 97%, to \$0.1 million for the nine months ended September 30, 2016 from \$5.6 million for the nine months ended September 30, 2015. The decrease in collaboration revenue was primarily due recognition of a \$5.0 million development milestone achievement and payment for the nine months ended September 30, 2015.

Cost of Product Sales

The primary expense that we incur to deliver our marketed products to our customers is manufacturing costs consisting of fixed and variable costs. Variable manufacturing costs consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing and filling operations, and sales-based royalties. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. We determine the cost of product sales for products sold during a reporting period based on the average cost per unit.

Cost of product sales increased by \$2.7 million, or 75%, to \$6.2 million for the three months ended September 30, 2016 from \$3.5 million for the three months ended September 30, 2015 and increased by \$4.5 million, or 39%, to \$16.2 million for the nine months ended September 30, 2016 from \$11.7 million for the nine months ended September 30, 2015. Due to the ongoing challenges with the manufacture of our IXINITY product that meets release specifications for the final drug product, in the third quarter of 2016, we wrote off approximately \$2.9 million in unsaleable IXINITY inventory that was in process of being manufactured. This cost is included in cost of product sales. In the nine months ended September 30, 2016, we wrote off a total of \$4.1 million in unsaleable inventory which includes the \$2.9 million written off in the third quarter of 2016 and \$1.2 million on the second quarter of 2016. The remaining increase in cost of product sales for the nine-month period was primarily due to costs related to increased IXINITY product sales.

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 September 30, 2016 and 2015 are shown in the following table:

(in thousands)	Three Months Ended September 30,		Change
	2016	2015	
ADAPTIR related programs (1)	\$ 3,894	\$ 3,268	\$ 626
ROR-1	1,139	290	849
IXINITY	1,134	2,754	(1,620)
Other/5E3/ES210	369	151	218
MOR209/ES414	562	264	298
otlertuzumab	16	985	(969)
Total	\$ 7,114	\$ 7,712	\$ (598)

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

Research and development expenses decreased by \$0.6 million, or 8%, to \$7.1 million for the three months ended September 30, 2016 from \$7.7 million for the three months ended September 30, 2015. The increase in expense for our MOR209/ES414 product candidate was primarily due to the timing of manufacturing activities. The decrease in expense for our IXINITY product candidate (which was approved by the FDA in April 2015) was primarily due to decreased manufacturing process development activities in 2016 and the timing of clinical trial activities. The increase in ROR-1 was primarily due to lead construct selection and characterization studies. The decrease in expense for our otlertuzumab product candidate was primarily related to the timing of clinical trial activities. The increase in expense for ADAPTIR related programs was primarily due to an increase in characterization studies and non-clinical activities. The expenses for our other activities were primarily related to centralized research and development activities not otherwise attributable to specific product candidates or programs.

Our principal research and development expenses by program for the nine months ended September 30, 2016 and 2015 are shown in the following table:

(in thousands)	Nine Months Ended September 30,		Change
	2016	2015	
ADAPTIR related programs (1)	\$ 5,886	\$ 4,726	\$ 1,160
ROR-1	5,793	1,644	4,149
IXINITY	4,081	13,222	(9,141)
MOR209/ES414	4,029	2,561	1,468
otlertuzumab	1,465	2,936	(1,471)
Other/5E3/ES210	1,597	2,230	(633)
Total	\$ 22,851	\$ 27,319	\$ (4,468)

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

Research and development expenses decreased by \$4.5 million, or 16%, to \$22.9 million for the nine months ended September 30, 2016 from \$27.3 million for the nine months ended September 30, 2015. The increase in expense for our MOR209/ES414 product candidate was primarily due to the timing of manufacturing activities along with decreased reimbursement from MorphoSys for development activities under our collaboration agreement. The decrease in expense for our IXINITY product candidate (which was approved by the FDA in April 2015) was primarily due to a decrease in manufacturing process development activities in 2016 and the timing of clinical trial activities.

The increase in ROR-1 was primarily due to a increase in lead construct selection and characterization studies. The decrease in expense for our otlertuzumab product candidate was primarily related to the timing of clinical trial activities. The increase in expense for ADAPTIR related programs was primarily due to an increase in characterization studies and non-clinical activities. The expenses for our other activities were primarily related to centralized research and development activities not otherwise attributable to specific product candidates or programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses 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 September 30, selling, general and administrative expenses increased by \$3.2 million, or 37%, to \$11.7 million for 2016 from \$8.5 million for 2015. This increase was primarily due to the costs associated with IXINITY selling and marketing in the current year, as well as increased costs associated with our spin-off activities in 2016.

For the nine months ended September 30, selling, general and administrative expenses increased by \$1.1 million, or 4%, to \$30.0 million for 2016 from \$28.9 million for 2015. This increase was primarily due to higher costs associated with IXINITY sales and marketing in 2016 versus lower prelaunch costs in 2015. In addition, there were increased costs associated with our spin-off activities in 2016.

Impairment of Goodwill and Intangible Asset

On September 30, 2016, we recorded impairments of approximately \$55.7 million of long-term assets, which consisted of \$41.8 million of intangible assets and \$13.9 million of goodwill. Impaired intangible assets consisted of certain of our indefinite-lived in process research and development. For additional information about our impairments, see Note 7— Impairment of Intangible Assets, In-Process Research and Development and Goodwill in the notes to consolidated financial statements.

Other Income (Expense), net

Other income (expense), net, consists primarily of interest on debt financing. This increase in 2016 compared to 2015 due to the interest on the loan entered into with Midcap Financial Trust in the third quarter of 2016.

Income Taxes

Benefit from income taxes decreased by \$0.4 million, to \$0.0 million for the three months ended September 30, 2016 from \$0.4 million for the three months September 30, 2015. The decrease in the benefit was primarily due to the timing of Canadian scientific research and experimental development tax credits.

Benefit from income taxes decreased by \$1.4 million, or 100%, to \$0.0 million for the nine months ended September 30, 2016 from \$1.4 million for the nine months September 30, 2015. The decrease in the benefit was primarily due to the timing of Canadian scientific research and experimental development tax credits.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2016.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2016, we had cash, cash equivalents and marketable securities in the amount of \$61.1 million.

At the closing of the spin-off of Aptevo from Emergent, Emergent provided Aptevo cash in the amount of \$45.0 million, along with a commitment in the form of a promissory note to provide another \$20.0 million by August 1, 2017.

In addition, on August 4, 2016, we entered into a \$35.0 million Credit and Security Agreement, or the Credit Agreement, by and among us and certain our subsidiaries as borrowers, MidCap Financial Trust, as agent, and the lenders from time to time party thereto. The Credit Agreement provides us with up to \$35.0 million of available borrowing capacity, which will be available (subject to certain conditions) to us in two tranches of \$20.0 million and \$15.0 million, respectively, through August 31, 2017 and which, once drawn, will amortize on a monthly basis commencing in August 2018 and will mature on February 1, 2021. 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 made available to us 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 and our 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's promise to pay such \$20.0 million in cash is evidenced by a non-negotiable, unsecured promissory note issued to us from Emergent.

We expect our cash, cash equivalents and marketable securities along with the proceeds from our Credit Agreement, will support Aptevo's operations for at least 12 months, based on current operating plans and financial forecasts. Prior to the spin-off, the development-based biosciences business of Emergent was funded entirely by Emergent.

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. Our 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 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 costs associated with the separation from Emergent and costs associated with performance under agreements entered into with Emergent in connection with such separation; and
- the costs associated with replicating or outsourcing from other providers' certain facilities, systems, operational and administrative infrastructure, including information technology infrastructure and personnel, to which we will no longer have access after our separation from Emergent.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2016 and 2015.

<u>(in thousands)</u>	<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Net cash provided by (used in):		
Operating activities	(30,197)	(41,076)
Investing activities	(51,735)	(1,012)
Financing activities	88,189	41,972
Increase (decrease) in cash and cash equivalents	\$ 6,257	\$ (116)

Net cash used in operating activities of \$30.2 million for the nine months ended September 30, 2016 was primarily due to our net loss of \$97.5 million, offset by the noncash impairment of goodwill and intangible assets of \$55.7 million and the write-down of nonsaleable IXINITY inventory of \$4.1 million. Net cash used in operating activities of \$41.1 million for the nine months ended September 30, 2015 was primarily due to our net loss of \$41.4 million.

Net cash used in investing activities for the periods presented was primarily due to the purchase of investment of \$51.7 million in the third quarter of 2016 and the purchases of property and equipment.

Net cash provided by financing activities for the periods presented includes the net proceeds received from entering into the credit facility in August of 2016, cash received from the former parent company upon the spin off and the net investment from the former parent company to support the operations of Aptevo.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There were no material changes during the nine months ended September 30, 2016 regarding the Company market risk.

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 September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We may from time to time be named as a party to legal claims, actions and complaints, including matters involving employment claims, our intellectual property or other third party claims. At this time, the Company is not party to any active legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the following risks and other information in this quarterly report on Form 10-Q in evaluating Aptevo and Aptevo's common stock. Any of the following risks could materially and adversely affect Aptevo's results of operations, financial condition or financial prospects. The risk factors generally have been separated into three groups: risks related to Aptevo's business, risks related to the separation and risks related to Aptevo's common stock.

RISKS RELATED TO OUR BUSINESS

Operating Risks

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

Our historical consolidated financial data was carved out from the financial information of Emergent and shows that had we been a standalone company, we would have had a history of losses, and we may be unable to achieve or sustain profitability going forward.

For the nine months ended September 30, 2016, we incurred a net loss of \$97.5 million and had an accumulated deficit of \$65.7. For that same period, net cash used in our operating activities was \$30.2 million. If we cannot achieve or sustain profitability or generate positive cash from operating activities, our business operations may be adversely impacted and the trading value of our common stock may decline.

We will require significant additional funding and may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, results of operations and financial condition.

In accordance with the separation agreement, Emergent has committed to provide us with a total of approximately \$65.0 million in cash funding. Emergent provided us with a cash contribution of \$45.0 million on August 1, 2016 to be used to fund our operations. Within 12 months following the distribution, it is expected that Emergent will transfer to us an additional \$20.0 million in cash pursuant to a non-negotiable, unsecured promissory note. Emergent's ability to satisfy its obligations under the promissory note will be subject to, among other things, Emergent's capital availability and cash flow following the distribution. As a result, there can be no assurance that we will receive all or any portion of the \$20.0 million contemplated by the promissory note. In addition to the anticipated cash transfers from Emergent in connection with the separation, in the future we will require significant additional funding to grow our business including to develop additional products, support commercial marketing activities or otherwise provide additional financial flexibility. To enhance long-term financial flexibility, Aptevo entered into a credit facility for up to \$35.0 million, \$20.0 million of which was received on August 4, 2016.

As of September 30, 2016, we had cash, cash equivalents and marketable securities in the amount of \$61.1 million. Our future capital requirements will depend on many factors, including, among others:

- the level, timing and cost of product sales;
- the collection of accounts receivable from customers;
- the extent to which we invest in products or technologies;
- the ability to secure partnerships and/or collaborations;
- capital improvements to new or existing facilities;
- the payment obligations under 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 costs associated with the separation from Emergent and costs associated with performance under agreements with Emergent; and
- the costs associated with replicating or outsourcing from other providers' certain facilities, systems, operational and administrative infrastructure, including information technology infrastructure, and personnel, to which we no longer have access after our separation from Emergent.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through bank loans, public or private equity or debt offerings or collaboration and licensing arrangements. Public or bank debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds by issuing equity securities, our stockholders may experience dilution. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Furthermore, to preserve the tax-free treatment to Emergent and its stockholders of the distribution, together with certain related transactions, we are restricted, under the tax matters agreement we entered into with Emergent, from taking any action that prevents the separation from being tax-free for U.S. federal income tax purposes, including restrictions on equity capital market transactions, as discussed in greater detail in the risk factor below entitled

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, consisting of WinRho SDF, HepaGam B, VARIZIG and IXINITY.

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 maintain or increase revenue from sales of our products could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We may choose to increase the price of our products, and these price adjustments may negatively affect our sales volumes. In addition, our product sales may fluctuate significantly from quarter to quarter, depending on the number of patients receiving treatment, the availability of supply to meet the demand for the product, the dosing requirements of treated patients and other factors. If sales of our commercial products were to decline, we could be required to make an allowance for excess or obsolete inventory, increase our provision for product returns, or we could incur other costs related to operating our business, each of which could negatively impact our results of operations and our financial condition.

Commercialization Risks

Our ability to grow revenues and execute on our long-term strategy depends heavily on our ability to discover, develop, and obtain marketing approval for additional products or product candidates.

In order for us to achieve our long-term business objectives, we will need to successfully discover and/or develop and commercialize additional products or product candidates. Although we have made, and expect to continue to make, significant investments in research and development, we have had only a limited number of our internally-discovered product candidates reach the clinical development stage. Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure. The failure by us to successfully discover and/or develop, obtain marketing approval for and commercialize additional products and product candidates would likely have a material adverse effect on our ability to grow revenues and improve our financial condition.

We may not be successful in our efforts to use and further develop our ADAPTIR platform to expand our pipeline of product candidates.

A key element of our strategy is to expand our product pipeline of immuno-therapeutics based on our ADAPTIR platform technology. We plan to select and create redirected T-cell cytotoxicity, or RTCC, candidates for early development, potentially with other collaborative partners. We expect to continue to develop the platform to address unmet medical needs through directed cytokine delivery via bispecifics in areas including oncology, and multispecific molecules in oncology, autoimmune disease and other therapeutic areas. Our goal is to leverage this technology to seek targeted investment in bispecific ADAPTIR therapeutics. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based on our ADAPTIR platform technology, our ability to obtain product revenues in future periods may be adversely affected, which likely would result in harm to our financial position and our financial prospects and adversely affect our stock price.

We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

The development and commercialization of new biotechnology products is highly competitive and subject to rapid technological advances. We may face future competition with respect to our products, our current product candidates and any product candidates we may seek to develop or commercialize in the future obtained from other companies and governments, universities and other non-profit research organizations. Our competitors may develop products that are safer, more effective, more convenient or less costly than any products that we may develop or market, or may obtain marketing approval for their products from the U.S. Food and Drug Administration, or the FDA, or equivalent foreign regulatory bodies more rapidly than we may obtain approval for our products. Our competitors may devote greater resources to market or sell their products, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully than we can, or more effectively negotiate third-party licensing and collaborative arrangements. Many of our competitors are substantially larger than we are and have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

We believe that our most significant competitors in the hematology/oncology, inflammation and transplantation markets include: AbbVie Inc., Affirmed N.V., Amgen Inc., Baxter International Inc., Bayer AG, Biogen Idec Inc., Boehringer Ingelheim GmbH, CSL Behring, a subsidiary of CSL Limited, Genentech Inc. (a subsidiary of F. Hoffmann-La Roche Ltd.), Gilead Sciences, Inc., GlaxoSmithKline plc, Grifols USA LLC, Johnson & Johnson, Macrogenics, Inc., Novartis International AG, Pfizer Inc., Takeda Pharmaceuticals U.S.A., Inc., Xencor, Inc. and Zymeworks Biopharmaceuticals, Inc. We compete, in the case of our approved and marketed products, and expect to compete, in the cases of our products in development, on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed. If we are not successful in demonstrating these attributes, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition and results of operations.

Any reduction in demand for our products as a result of a competing product could adversely affect our results of operations and lead to loss of market share for our products. These competitive pressures could adversely affect our business and operating results.

In addition, many of our competitors are able to deploy more personnel to market and sell their products than we do. We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other biotechnology companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization internationally, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization. We may not be able to achieve any necessary growth in a timely or cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all. We also have to compete with other biotechnology and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect sales of our products. If our specialty sales force and sales organization are not appropriately-sized to adequately promote any current or potential future products, the commercial potential of our current products and any future products may be diminished. We compete with a significant number of pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in the hematology/oncology markets, and our failure to compete effectively in this area could negatively affect our sales of our commercial products.

Our products and product candidates may also compete in the future with new products currently under development by others. Any products that we develop are likely to be in a highly competitive market, and many of our competitors may succeed in developing products before we do or in developing products that may render our products obsolete or noncompetitive.

Our Biologic Products may face risks of competition from biosimilar manufacturers.

Competition for WinRho SDF, HepaGam B, VARIZIG and IXINITY, or our Biologic Products, may be affected by follow-on biologics, or biosimilars, in the United States and other jurisdictions. Biologics are medical products made from a variety of natural sources (human, animal or microorganism) intended to prevent, diagnose or treat diseases and medical conditions.

In the U.S., biosimilars are biologics that are highly similar to licensed reference biological products, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety, purity and potency. Regulatory and legislative activity in the United States and other countries may make it easier for our competitors to manufacture and sell biosimilars of our Biologic Products, which might affect our results of operations or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve an application for a biosimilar until the 12-year exclusivity period for the reference product has expired. Thus, if a competitor were to seek regulatory approval for a biosimilar product citing IXINITY as the reference product, such approval could not be granted until April 2027.

Regulators in the European Union review biosimilar products using a similar regulatory process, although the European Medicines Agency, or EMA, has expressly excluded blood or plasma-derived products from the biosimilar process for a period of time. WinRho SDF, HepaGam B, VARIZIG and IXINITY have not received marketing authorization by the EMA. HepaGam B, VARIZIG and IXINITY are not sold in Europe. WinRho SDF is sold in Portugal, with insignificant revenues to date, but the approval is a country-specific approval. Even if WinRho SDF, HepaGam B or VARIZIG receive EMA marketing authorization, it will not be possible for a follow-on product to seek approval using the EMA biosimilar process due to the exclusion of blood or plasma-derived products from the process.

Similarly, if a competitor were to seek regulatory approval for a biosimilar product citing HepaGam B or VARIZIG as the reference product, such approval could not be granted until January 2018 and December 2024, respectively. A biosimilar application citing WinRho SDF as the reference product could be approved at any time. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business and operating results.

The commercial success of our products will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

The success of our products, including our hyperimmune specialty products, will depend upon, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If any of our products do not achieve and maintain an adequate level of acceptance, we may not generate material revenues from sales of these products. The degree of market acceptance of our products will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the ability to offer our products for sale at competitive prices;
- our ability to continuously supply the market without interruption;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try new products and of physicians to prescribe these products;
- the strength of marketing and distribution support;
- publicity concerning our products or competing products and treatments; and
- the sufficiency of coverage or reimbursement by third parties.

If our products and product candidates do not gain or maintain market acceptance, or do not become widely accepted, by physicians, patients, third-party payors and other members of the medical community, our business, financial condition and operating results could be materially and adversely affected.

Changes in health care systems and payor reimbursement policies could result in a decline in our potential sales and a reduction in our expected revenue from our products.

The revenues and profitability of biotechnology companies like ours may be affected by the continuing efforts of government payors, including Medicare and Medicaid, and other third-party payors to contain or reduce the costs of health care through various means. For example, in certain foreign markets, the pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. Recent U.S. legislation, rules and regulations instituted significant changes to the U.S. healthcare system that could have a material adverse effect on our business, financial condition and results of operations. The trend toward managed health care in the United States, as well as the implementation of the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act), collectively referred to as the Affordable Care Act, and the concurrent growth of organizations such as managed care organizations, accountable care organizations and integrated delivery networks, may result in increased pricing pressures for pharmaceutical products, including any products that may be offered by us in the future. Cost-cutting measures that health care providers are instituting, and the implementation of health care reform, could adversely affect our ability to sell any drug products that are successfully developed by us. We cannot predict what effects, if any, this legislation might have on our company and our products as this legislation continues to be further implemented over the next few years, nor can we predict whether additional legislative or regulatory proposals may be adopted.

In the United States and internationally, sales of our products and our ability to generate revenues on such sales are dependent, in significant part, on the availability and level of reimbursement from third-party payors, including state and federal governments and private insurance plans. Insurers have implemented cost-cutting measures and other initiatives to enforce more stringent reimbursement standards and likely will continue to do so in the future. These measures include the establishment of more restrictive formularies and increases in the out-of-pocket obligations of patients for such products. Third-party payors are also increasingly challenging the prices charged for medical products and services. Third-party payors may limit access to biotechnology products through the use of prior authorizations and step therapy. Any reimbursement granted may not be maintained, or limits on reimbursement available from third parties, may reduce the demand for or negatively affect the price and potential profitability of those products. If these payors do not provide sufficient coverage and reimbursement for our marketed products or any future drug product we may market, these products may be too costly for general use, and physicians may prescribe them less frequently. Our ability to successfully commercialize our products and product candidates and the demand for our products depends, in part, on the extent to which reimbursement and access is available from such third-party payors.

In addition, particularly in the United States and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. Various provisions of the Affordable Care Act increased the levels of rebates and discounts that we have to provide in connection with sales of such products that are paid for, or reimbursed by, certain state and federal government agencies and programs. It is possible that future legislation in the United States and other jurisdictions could be enacted, which could potentially impact the reimbursement rates for our products and also could further impact the levels of discounts and rebates we are required to pay to state and federal government entities.

Certain government pricing programs, including Medicare Part B, the Medicaid rebate program, the 340B/PHS drug pricing program and Federal Supply Schedule, affect the revenues that we derive from WinRho SDF, HepaGam B, VARIZIG and IXINITY. Any future legislation or regulatory actions altering these programs or imposing new ones could have an adverse impact on our business. There have been, and we expect there will continue to be, a number of legislative and regulatory actions and proposals to control and reduce health care costs. These measures may, among other things: negatively impact the level of reimbursement for pharmaceutical products; require higher levels of cost-sharing by beneficiaries; change the discounts required to be provided to government payors and/or providers; extend government discounts to additional government programs and/or providers; or reduce the level of reimbursement for health care services and other non-drug items. Any such measures could indirectly affect demand for pharmaceutical products because they can cause payors and providers to apply heightened scrutiny and/or austerity actions to their entire operations, including pharmacy budgets.

Our revenues also depend on the availability outside the United States of adequate pricing and reimbursement from third-party payors for our current and future drug products, if any.

Outside the United States, certain countries, including a number of EU Member States, set prices and reimbursement for pharmaceutical products, or medicinal products as they are commonly referred to in the European Union, with limited participation from the marketing authorization holders. We cannot be sure that these prices and reimbursement will be acceptable to us or our collaborative partners. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement that are not commercially attractive for us or our collaborative partners, our revenues from sales by us or our collaborative partners, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union.

If we are not able to convince hospitals and managed care organizations to include our products on their approved formulary lists, our revenues may not meet expectations and our business, results of operations and financial condition may be adversely affected.

Hospitals and managed care organizations establish formularies, which are lists of drugs approved for use in the hospital or under a managed care plan. If a drug is not included on the formulary, the ability of our engagement partners and engagement managers to promote and sell the drug may be limited or denied. If we fail to secure and maintain formulary inclusion for our products on favorable terms or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our products and our business, results of operations and financial condition could be materially adversely affected.

If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations with respect to the purchase of our products, our sales, results of operations and financial condition could be adversely affected.

Our ability to sell our products, including WinRho SDF, HepaGam B and IXINITY, to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors. These negotiated prices are then made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts on the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

We rely on third parties to distribute some of our products and those third parties may not perform.

A portion of our revenues from product sales is derived from sales through exclusive distributors in Canada and international markets. For example, in Canada, only two distributors have rights to our WinRho SDF, HepaGam B and VARIZIG products. As a result, we rely on the sales and marketing strength of these distributors and the distribution channels through which they operate for a portion of our revenues. We may not be able to retain these distribution relationships indefinitely and these distributors may not adequately support the sales, marketing and distribution efforts of our products in these markets. If third parties do not successfully carry out their contractual duties in maximizing the commercial potential of our products, or if there is a delay or interruption in the distribution of our products, it could negatively impact our revenues from product sales.

The loss of any of our sole source manufacturers, or delays or problems in the manufacture of our products or product candidates, could result in product shortages, leading to lost revenue, and otherwise materially and adversely affect our business, financial condition, results of operations and growth prospects.

We do not have manufacturing capabilities following the separation 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. We rely on our third-party manufacturers to maintain the facilities at which they manufacture our products or product candidates in compliance with all FDA and other applicable regulatory requirements. If these manufacturers fail to maintain compliance with FDA or other applicable regulatory requirements, they could be ordered to cease manufacturing, which could have a material adverse effect on our revenues and operating results.

If, for any reason, Emergent or our other manufacturers do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our manufacturing arrangements, we may not have adequate remedies for any breach of contract, and their failure to supply us could result in a shortage of our products or product candidates, which could lead to lost revenue and otherwise adversely affect our business, financial condition, results of operations and growth prospects. In addition, if any of our manufacturers fails or refuses to supply us for any reason, we may be forced to consider entering into additional manufacturing arrangements with other third-party manufacturers. In each case, we will incur significant costs and time in obtaining the regulatory approvals for these third-party facilities and in taking the necessary steps to prepare these third parties for the manufacture of our products. Because of contractual restraints and the lead-time necessary to obtain FDA approval of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of these products to our customers, and we may be unable to obtain alternative manufacturing or supply on commercially reasonable terms on a timely basis or at all.

For example, CMC ICOS Biologics, Inc., or CMC, is the exclusive manufacturer of bulk drug substance for our IXINITY product. During 2015, we ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. We continue to work with CMC to resolve the manufacturing issues, although to date in 2016 no lots of bulk drug substance have been successfully manufactured and released. On October 4, 2016 we provided a Notice of Interruption in Manufacturing (“Notice”) to the United States Food and Drug Administration (FDA) notifying FDA of a potential interruption in the supply of IXINITY® coagulation factor IX (recombinant.) The supply interruption relates to an ongoing challenge with the manufacture of bulk drug substance for IXINITY that meets release specifications for final drug product. As part of the Notice, Aptevo submitted a proposal to FDA seeking approval for a proposed mitigation plan aimed at ensuring the continued supply of IXINITY to patients. FDA has denied our proposal and therefore we anticipate that there will be a supply interruption of the 1500IU assay in December and the remaining dosage forms of IXINITY in January 2017. Such a supply shortage of IXINITY will adversely affect its sales and could adversely affect its market position and commercial viability.

Emergent owns the manufacturing know-how necessary for the manufacture of WinRho SDF, HepaGam B and VARIZIG. If our rights to use this manufacturing know-how are terminated, we will not be able to manufacture these products, which would lead to lost revenue and otherwise materially and adversely affect our business, financial condition, results of operations and growth prospects.

Emergent 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. Delays or problems in the manufacture of our products or product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects.

WinRho SDF, HepaGam B, VARIZIG and IXINITY and all of our current product candidates are biologics. The products must be made consistently and in compliance with a clearly defined manufacturing process. Problems may arise during manufacturing for a variety of reasons, including problems with raw materials, equipment malfunction or replacement and failure to follow specific protocols and procedures. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation and contamination including from, among other things, particulates, filtration, filling, labeling, packaging, storage and shipping, and quality control testing, may result in lot failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action.

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.

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, 5E3 and a product candidate 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, for each candidate that will:

- be approved by the FDA and/or other regulatory authorities in the countries where such candidates are to be manufactured or sold;
- provide sufficient quantities of such candidate to meet our clinical trial needs and ultimate market demand; and
- provide such amounts at a cost that will allow us to potentially make an adequate profit.

We and our third-party manufacturers may not be able to meet these manufacturing process requirements for any of our current product candidates, including MOR209/ES414, ES210, otlertuzumab, 5E3 and a product candidate 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.

If Emergent or other third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations or we are unable to establish or maintain such arrangements, the development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase.

Our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage or conduct our clinical trials, manufacture our products and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct all of these activities for all products and product candidates on our own and, as a result, are particularly dependent on third parties in many areas.

We may not be able to maintain our existing arrangements with respect to the commercialization or manufacture of our products or establish and maintain arrangements to develop, manufacture and commercialize our products in development on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to our products or our products in development, our results of operations would be materially and adversely affected.

Third parties may not perform their contractual obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Our collaborative partners may develop, manufacture or commercialize, either independently or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Our collaborative partners may reevaluate their priorities from time to time, including following mergers and consolidations, and change the focus of their development, manufacturing or commercialization efforts. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third-party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to commit sufficient resources to our collaboration or conduct its activities in a timely manner, or fails to comply with regulatory requirements, such breach, termination or failure could:

- delay or otherwise adversely impact the manufacturing, development or commercialization of our products, our products in development or any additional products or product candidates that we may develop;
- require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or
- result in the termination of the development or commercialization of our products.

If we are unable to successfully develop our business infrastructure and operations, our ability to generate future product revenue will be adversely affected.

Our ability to support the sales and marketing of our products in the United States and globally will depend on our ability to properly scale our internal organization and infrastructure to accommodate the development and, upon approval, commercialization of our products and products in development. To manage our existing and planned future growth and the increasing breadth and complexity of our activities, we need to properly invest in personnel, infrastructure, information management systems and other operational resources. Developing our business infrastructure and operations may be more difficult, more expensive or take longer than we anticipate. We may also need to revise our strategy for developing the proper infrastructure and operations periodically.

Future development of our business infrastructure and operations could strain our operational, human and financial resources. In order to manage the development of our business infrastructure and global operations, we must:

- continue to improve operating, administrative, and information systems;
- accurately predict future personnel and resource needs to meet contract commitments;
- track the progress of ongoing projects; and
- attract and retain qualified management, sales, professional, scientific and technical operating personnel.

If we do not take these actions and are not able to manage our business, then our operations may be less successful than anticipated.

We are subject to a number of risks and uncertainties associated with our international activities and operations and may not be successful in our efforts to expand internationally.

We currently have limited operations outside of the United States and Canada. However, we have manufacturing, collaboration, clinical trial and other relationships outside the United States, and our products are marketed internationally through collaborations. We may seek to grow our international operations significantly over the next several years. Our future results of operations will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Europe. Our foreign operations subject us to additional risks and uncertainties, particularly because we have limited experience in marketing, servicing and distributing our products or otherwise operating our business outside of the United States and Canada. These risks and uncertainties include:

- the fact that we have limited experience operating our business internationally;
- unexpected adverse events related to our products or product candidates that occur in foreign markets that we have not experienced in the United States;
- political and economic determinations that adversely impact pricing or reimbursement policies;
- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- compliance with complex and changing foreign legal, tax, accounting and regulatory requirements;
- cross border restrictions on the movement of cash funds and repatriation of earnings;
- language barriers and other difficulties in providing long-range customer support and service;
- longer accounts receivable collection times;
- trade restrictions and restrictions on direct investment by foreign entities;
- reduced protection of intellectual property rights in some foreign countries;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- significant foreign currency fluctuations, which could result in increased or unpredictable operating expenses and reduced revenues;
- local, economic and political conditions, including geopolitical events, such as war and terrorism; and
- compliance with foreign or U.S. laws, rules and regulations, including data privacy requirements, labor relations laws, tax laws, anti-competition regulations, anti-bribery/anti-corruption laws, including but not limited to the FCPA and the Bribery Act in the UK, which could subject us to investigation or prosecution under such foreign or U.S. laws.

Our foreign operations could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, and changes in tariffs and difficulties in staffing and managing foreign operations. These and other risks associated with our international operations may materially adversely affect our business and results of operations.

Regulatory and Compliance Risks

Our long term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize our product candidates and, if we are not successful, our business and operating results may suffer.

Our product candidates and the activities associated with their development, including testing, manufacture, recordkeeping, storage and approval, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Generally, failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have limited resources for use in preparing, filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

The FDA, the European Commission, the EMA, the competent authorities of the EU Member States and other comparable regulatory agencies in foreign countries impose substantial and rigorous requirements for the development, production, marketing authorization and commercial introduction of drug products. These requirements include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory authorities, including the FDA, the European Commission, the EMA and the competent authorities of the EU Member States, evolve in their staff interpretations and practices and may impose more stringent or different requirements than currently in effect, which may adversely affect our planned and ongoing drug development and/or our sales and marketing efforts.

In the United States, to obtain approval from the FDA to market any of our future biologic products, we will be required to submit a biologics license application, or BLA, to the FDA. Ordinarily, the FDA requires a sponsor to support a BLA with substantial evidence of the product's safety, purity and potency in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted.

The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Moreover, recent events, including complications experienced by patients taking FDA-approved drugs, have raised questions about the safety of marketed drugs and may result in new legislation by the U.S. Congress or foreign legislatures and increased caution by the FDA and comparable foreign regulatory authorities in reviewing applications for marketing approval.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient to support approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We have a pipeline of clinical and pre-clinical stage product candidates, including:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells. It is being developed under our collaboration with MorphoSys AG for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies;
- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease and other autoimmune and inflammatory diseases;
- otlertuzumab, a monospecific ADAPTIR protein therapeutic that is currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL;
- 5E3 mAb, a monoclonal antibody therapeutic that is currently in pre-clinical development for Alzheimer's disease;
- A bispecific immunotherapeutic ADAPTIR protein that targets ROR1 (receptor tyrosine kinase-like orphan receptor 1, a protein expressed on solid tumors, leukemias and lymphomas), which are currently in pre-clinical development for a variety of hematologic malignancies and solid tumors; and
- other protein therapeutic product candidates primarily targeting immuno-oncology.

Developing and obtaining regulatory approval for product candidates is a lengthy process, often taking a number of years, is uncertain and is expensive. All of the product candidates that we are developing, or may develop in the future, require research and development, pre-clinical studies, nonclinical testing and clinical trials prior to seeking regulatory approval and commencing commercial sales. In addition, we may need to address a number of technological challenges in order to complete development of our product candidates. As a result, the development of product candidates may take longer than anticipated or not be successful at all.

Generally, no product can receive FDA approval, marketing authorization from the European Commission or the competent authorities of the EU Member States, or approval from comparable regulatory agencies in foreign countries unless data generated in human clinical trials demonstrates both safety and efficacy for each target indication in accordance with such authority's standards.

The large majority of product candidates that begin human clinical trials fail to demonstrate the required safety and efficacy characteristics necessary for marketing approval. Failure to demonstrate the safety and efficacy of any of our product candidates for each target indication in clinical trials would prevent us from obtaining required approvals from regulatory authorities, which would prevent us from commercializing those product candidates. Negative or inconclusive results from the clinical trials or adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that additional trials be conducted, any of which may not be clinically feasible or financially practicable, that the conduct of trials be suspended, or that a program be terminated.

Any regulatory approval we ultimately obtain may limit the indicated uses for the product or subject the product to restrictions or post-approval commitments that render the product commercially non-viable. Securing regulatory approval requires the submission of extensive non-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the regulatory authorities for each therapeutic indication to establish the product's safety and efficacy. If we are unable to submit the necessary data and information, for example, because the results of clinical trials are not favorable, or if the applicable regulatory authority delays reviewing or does not approve our applications, we will be unable to obtain regulatory approval.

Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of the products or product candidates in the jurisdiction for which approval is sought;
- diminish our competitive advantage; and
- defer or decrease our receipt of revenue.

Certain of our products in development have experienced regulatory and/or clinical setbacks in the past. For example, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; this is called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA. We have continued the current clinical trial under an amended protocol. Recruitment started during the second half of 2016. As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. Under the terms of the restructured agreement, MorphoSys' cost sharing in the years 2016 to 2018 was reduced and future milestone payments payable by MorphoSys to us were reduced to a total of up to US \$74.0 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.

The procedures to obtain marketing approvals vary among countries and can involve additional clinical trials or other pre-filing requirements. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all the risks associated with obtaining FDA approval, or different or additional risks. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. Accordingly, approval by the FDA does not ensure approval by the regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by the FDA or regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products and products in development in any market on a timely basis, if at all.

Biotechnology company stock prices have declined significantly in certain instances where companies have failed to obtain FDA or foreign regulatory authority approval of a product candidate or if the timing of FDA or foreign regulatory authority approval is delayed. If the FDA's or any foreign regulatory authority's response to any application for approval is delayed or not favorable for any of our product candidates, our stock price could decline significantly.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the "off-label" use of any of our products.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for IXINITY is not approved for use in patients younger than 12 years old. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines, which could result in the disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or another regulatory or enforcement authority determines that our communications regarding our marketed products are not in compliance with the relevant regulatory requirements and that we have improperly promoted off-label uses, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Even after regulatory approval is received, if we, or third parties on whom we rely to manufacture or distribute our products or product candidates, fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market.

Any drug 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 “black box warnings” in their approved package inserts, such as WinRho SDF.

Failure by Emergent or our other third-party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products or ingredients to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with the FDA’s current cGMP requirements. The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. If, in connection with any future inspection, the FDA finds that any of our third-party manufacturers is not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions such manufacturer may take, the FDA may undertake certain enforcement actions, including product seizure or withdrawal of the product from the market, imposition of restrictions on the marketing or manufacturing of a product and suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements.

Similar actions may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

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.

The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid rebate program will continue to increase our costs and the complexity of compliance and will be time-consuming. Changes to the definition of “average manufacturer price”, or AMP, and the Medicaid rebate amount under the Affordable Care Act and Centers for Medicare & Medicaid Services’, or CMS’s, issuance of final regulations implementing those changes also has affected and could further affect our 340B “ceiling price” calculations. Because we participate in the Medicaid rebate program, we are required to report “average sales price,” or ASP, information to CMS for certain categories of drugs that are paid for under Part B of the Medicare program, including WinRho SDF, HepaGam B, VARIZIG and IXINITY. Future statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pricing and rebate calculations vary among products and programs, involve complex calculations and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate 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 European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review. We and our collaborative partners may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to commercialize our products internationally. The failure to obtain these approvals could harm our business.

Our international operations increase our risk of exposure to potential claims of bribery and corruption.

As we expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the FCPA, the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, or other similar foreign laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices outside the United States are found to be in violation of the FCPA or similar foreign laws, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials.

The U.S. federal budget sequestration process may have a significant impact on our business.

On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering mandatory reductions in federal spending by as much as \$1.1 trillion from 2013 through 2021, referred to as sequestration. The Bipartisan Budget Act of 2013 and subsequent legislation provide billions in sequester relief, but also extends the 2% reduction in Medicare payments, discussed below through fiscal year 2025. Sequestration-related spending reductions may have a significant adverse impact on our business.

Sequestration spending reductions may adversely affect the FDA. While user fees can be used in the review of certain regulatory filings, including NDAs, it is possible that sequestration spending reductions will result in additional backlogs in the approval process that could adversely affect the timing of FDA review of our regulatory filings for our products and product candidates. Sequestration also includes a 2% reduction in Medicare payments, which could also have a significant negative impact on our business. These reductions impact payments to hospitals, physicians, and Medicare managed care and prescription drug plans, under Medicare Parts A, B and D, and the Medicare Advantage program. The significant magnitude of the sequestration payment reductions places additional financial pressures on Medicare providers, including hospitals with high inpatient Medicare volume, which could force these providers to take new measures to address the shortfall in previously-expected reimbursements. It is possible that these measures could result in heightened scrutiny and/or reduced purchasing of branded pharmaceuticals and any future drug product we may market.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

EU Member States, Switzerland and other countries have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the European Union, and guidance on implementation and compliance practices are often updated or otherwise revised. Our failure to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. 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.

Public concern regarding the safety of drug products could result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug approved products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products and revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. The FDAAA also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional pre-clinical studies or clinical trials. If the FDA requires us to provide additional clinical or pre-clinical data for any of our product candidates, the indications for which this product candidate was approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize our product candidates may be otherwise adversely impacted.

Product Development Risks

Our business depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business would be materially and adversely affected.

We have invested significant effort and financial resources in the development of our therapeutics and product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the interest of commercial entities and non-governmental organizations and others in funding the development of certain of our product candidates, the ability to attract and establish external development partnerships and the commercial viability of our developed product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

- successful development and formulation that meets FDA requirements;
- successful completion of clinical or non-clinical development, including toxicology studies;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing and product supply arrangements;
- training of a commercial sales force for the product, whether alone or in collaboration with others;
- successful registration and maintenance of relevant patent and/or other proprietary protection; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

If we are delayed or prevented from developing or commercializing a product candidate in a profitable manner, or if doing so requires us to incur significant unanticipated costs, our growth could be materially and adversely affected.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products.

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners, where applicable, must conduct extensive pre-clinical studies and clinical trials to establish proof of concept and demonstrate the safety and efficacy of our product candidates. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

We may experience unforeseen events or issues during, or as a result of, pre-clinical testing or clinical trials. These issues and events, which could delay or prevent our ability to receive regulatory approval for a product candidate, include, among others:

- lack of efficacy of product candidates during the trials;
- safety issues or inconclusive or incomplete testing, trial or study results;
- our inability or the inability of Emergent and our other third-party manufacturers to manufacture sufficient quantities of materials for use in trials;
- the unavailability or variability in the number and types of subjects for each study;
- government or regulatory restrictions or delays; and
- greater than anticipated costs of trials.

For example, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment.

As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, the co-development agreement with MorphoSys was restructured. As a result of the required change in dosing regimen for MOR209/ES414, the lead RTCC candidate, the termination provisions under the MorphoSys collaboration agreement were similarly amended in MorphoSys' favor. Specifically, MorphoSys, at its sole discretion, has a one-time, no notice termination right exercisable at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the current, re-started Phase 1 trial. Patients receiving weekly doses of MOR209/ES414 developed ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA. Further adverse or inconclusive clinical results could require additional adjustments to the dosing regimen or other parts of the program and could delay or prevent our ability to receive regulatory approval for MOR209/ES414.

In addition, product candidates that experience success in pre-clinical testing and early-stage clinical trials will not necessarily experience the same success in late-stage clinical trials, which are required for marketing approval. The FDA and other countries' regulatory authorities will allow us to begin clinical trials under an IND, or similar document in other countries only if we demonstrate in our submission that the potential product candidate will not expose humans to unreasonable risks and that the compound has pharmacological activity that justifies clinical development. It takes significant time and expense to generate the requisite data to support an IND or similar document. In many cases, companies spend the time and resources only to discover that the data are not sufficient to support an IND or similar document and therefore are unable to enter human clinical trials.

Even if we are successful in advancing a product candidate into the clinical development stage, before obtaining regulatory and marketing approvals, we must demonstrate through extensive human clinical trials that the product candidate is safe and effective for its intended use. Human clinical trials must be carried out under protocols that are acceptable to regulatory authorities and to the independent committees responsible for the ethical review of clinical studies. There may be delays in preparing protocols or receiving approval for them that may delay the start or completion of the clinical trials. In addition, clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global trials increasingly complex. In addition, any deficiency in the design, implementation or oversight of our development programs could cause us to incur significant additional costs, experience significant delays, prevent us from obtaining marketing approval for any product candidate or abandon development of certain product candidates, any of which could harm our business and cause our stock price to decline.

The FDA may designate a product as a fast track drug if it is intended for the treatment of a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for this disease or condition. Sponsors granted a fast track designation for a drug are granted more opportunities to interact with the FDA during the approval process and are eligible for FDA review of the application on a rolling basis, before the application has been completed. Receipt of Fast Track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures, and Fast Track designation may be withdrawn by the FDA at any time. In addition, Fast Track designation does not guarantee the ability to take advantage of the expedited review procedures and does not increase the likelihood of receiving any regulatory approvals.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt our manufacturing and distribution operations and could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If any of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

For example, as noted above, MOR209/ES414 is currently being tested in its first clinical trial in humans. Twelve patients have received the drug. One of the significant serious adverse events associated with the drug is infusion reactions. Infusion reactions are often associated with the infusion of a protein and are expected with this drug that activates T-cells. The events that have been reported with infusion of the drug include: fever, fatigue, hypertension, bronchospasm, chills and rigors. The severity of these reactions varied by patient and were managed medically and resolved. In addition we recently discovered that patients receiving weekly doses of our product candidate MOR209/ES414 developed ADA during use. This ADA, which was not associated with safety issues, developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. Undesirable side effects, such as this, or other unexpected adverse events or properties of any of our candidates, could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our other product candidates. If such an event occurs, a number of potentially significant negative consequences may result, including:

- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- regulatory authorities may require one or more post-market studies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

We depend on third parties to conduct our clinical and non-clinical trials. If these third parties do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and, as a result, our business may suffer.

We do not have the ability to independently conduct the clinical and non-clinical trials required to obtain regulatory approval for our product candidates. We depend on third parties, such as independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but we do not exercise day-to-day control over their activities. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with the FDA-approved good clinical practices, or GCPs, and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable 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 our competitors are able to obtain orphan drug exclusivity for a product that is competitive with one or more of our product candidates and we cannot show that our product candidate is clinically superior, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including Europe and the United States, may designate drugs that target relatively small patient populations as orphan drugs. A disease or condition is considered orphan if it affects fewer than 200,000 people in the United States. Orphan drug exclusivity (afforded to the first applicant to receive approval for an orphan designated drug) prevents FDA approval of applications by others for the same drug for the designated orphan disease or condition. The FDA may approve a subsequent application from another applicant if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need.

We have received an orphan drug designation from the FDA for VARIZIG for treatment following exposure to varicella (chickenpox) in high-risk patient groups, including children with compromised immune systems, newborns and pregnant women. We have also received orphan drug designation for oltertuzumab and we may seek such status with additional product candidates.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity. VARIZIG has orphan drug exclusivity in the United States through December 2019. Our product candidate oltertuzumab was granted orphan drug designation by the FDA in November 2011 and received orphan medicinal product designation from the European Commission in December 2012 for the treatment of chronic lymphocytic leukemia. The exclusivity applies only to the indication for which each drug has been designated and approved. The applicable exclusivity period is seven years in the United States, but this period may be interrupted if a sponsor of a competitive product that is otherwise the same drug for the same use can show that its drug is clinically superior to our orphan drug candidate. The European exclusivity period is ten years, but may be reduced to six years if a drug no longer meets the criteria for orphan drug designation, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified.

A grant of an orphan designation is not a guarantee that a product will be approved by the FDA.

If we do not obtain orphan drug exclusivity for our drug products, which do not have patent protection, our competitors may then sell the same drug to treat the same condition.

We do not have patent protection for WinRho SDF, HepaGam B or VARIZIG. Because not all of our drugs have patent protection, orphan drug designation is particularly important for our products that are eligible for orphan drug designation. As previously noted, VARIZIG has orphan drug exclusivity in the United States for treatment following exposure to varicella (chickenpox) in high-risk patient groups through December 2019. We plan to rely on this exclusivity period under the orphan drug designation for VARIZIG to maintain a competitive position. Our product candidate oltertuzumab was granted orphan drug designation by the FDA in November 2011 and received orphan medicinal product designation from the European Commission in December 2012 for the treatment of chronic lymphocytic leukemia. Orphan designation in Europe qualifies a drug for certain development and commercial incentives, including protocol assistance, access to centralized authorization procedures, reduced fees for regulatory activities, and 10 years of market exclusivity after approval.

Intellectual Property Risks

If we are unable to protect our intellectual proprietary rights, our business could be harmed.

Our commercial success will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology, products and product candidates. Obtaining and maintaining this protection is very costly. The patentability of technology in the biotechnology field generally is highly uncertain and involves complex legal and scientific questions. We cannot be certain that our patents and patent applications, including our own and those that we have rights through licenses from third parties, will adequately protect our intellectual property. Our success protecting our intellectual property depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents, including defending those patents against adverse claims;
- secure patent term extension for the patents covering our approved products;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and
- prevent others from infringing our proprietary rights.

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.

We are currently involved in five opposition proceedings in Europe relating to factor IX proteins such as IXINITY. Baxter International Inc. is the sole counter-party in all five proceedings and our IXINITY product currently undergoes fill-finish in Europe. Of the five European Patent Office Proceedings, three have gone before the European Patent Office Opposition Division. Of these three, two were decided in our favor (in the name of UNC, our licensor) and one was decided in favor of Baxter. Two of these oppositions have been appealed, and we expect Baxter to appeal the third. It may be several years before these oppositions go before the Boards of Appeal for a final decision. The remaining two oppositions have not gone before the European Patent Office Opposition Division. Depending on the final outcome of these proceedings, we may be unable to continue to conduct our current IXINITY fill/finish manufacturing activities.

Patheon UK Limited, through an affiliate, is currently the sole source third-party manufacturer that provides fill and finish services for our IXINITY product, which conducts such activities in Europe. If, as a result of an adverse outcome in these proceedings, we are required to identify an additional fill/finish manufacturer in another location, we would not be able to do so without significant delay and likely significant additional cost.

International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries we may have to expend substantial sums and management resources.

Patent and other intellectual property laws outside the United States are even more uncertain than in the United States and are continually undergoing review and revisions in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, certain countries do not grant patent claims that are directed to business methods and processes. In addition, we may have to participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts. A European Patent Opposition, for instance, is a European Patent Office proceeding that allows for an opponent to challenge the validity of an issued patent. A European Patent Opposition is a proceeding that determines only the validity of a patent and does not determine whether a party infringes a patent. To initiate an Opposition at the European Patent Office, an opponent files a notice that it wishes to oppose the patent within a nine-month period following the publication of the patent grant. After the opponent files the notice, it may be a few years before the merits of the opposition are heard and decided by the European Patent Office Opposition Division and several more years before the Boards of Appeal hears and decides on any appeals.

As previously noted, we are currently involved in five opposition proceedings related to IXINITY and recombinant vitamin K dependent proteins. Depending on the final outcome of these proceedings, we may be unable to sell factor IX products in Europe relating to the subject matter claimed in the European patents we are opposing.

Although we do not have current marketing authorization for IXINITY (our only product based on recombinant vitamin K dependent proteins) in Europe, nor do we sell IXINITY in Europe, if these opposition proceedings are successful, we may never be able to obtain marketing authorization to sell IXINITY in Europe or any other recombinant vitamin K dependent products we may develop in the future. In addition, if any of the patents we own or exclusively license are invalidated during the opposition process, we may be unable to block competitors from performing certain activities in Europe currently covered by the patents.

Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations would be costly, time-consuming, distracting to management and could materially affect our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold sufficient licenses or other rights. Additionally, third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. These third parties may have substantially greater financial resources than us and could bring claims against us that could cause us to incur substantial expenses to defend against these claims and, if successful against us, could cause us to pay substantial damages. Furthermore, if a patent infringement or other similar suit were brought against us, we could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the biotechnology industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, if at all, or if an injunction is granted against us, which could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other adversarial proceedings such as proceedings before the PTAB and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology.

Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Our Aptevo trademarks may be opposed which could have a material and adverse effect on our business.

We have applications pending that cover the APTEVO, APTEVO THERAPEUTICS, APTEVO BIOTHERAPEUTICS and APTEVO RESEARCH AND DEVELOPMENT trademarks. If a third party opposes any of these Aptevo trademarks, we may incur significant expense in the course of participating in the opposition process, which can be expensive and lengthy, and any settlement of which may result in our agreeing to be subject to restrictions on our use of the relevant Aptevo trademark. In addition, if we are unsuccessful in an opposition against an Aptevo trademark, we would lose the ability to obtain trademark registration for one or more uses of the relevant Aptevo mark.

For example, Bristol-Myers Squibb Company has filed with the U.S. Patent and Trademark Office a notice of opposition to several Aptevo trademark applications. At this time, we are in discussions with Bristol-Myers Squibb Company regarding the continued use of the Aptevo trademark. In the event these discussions are not concluded to Bristol-Myers Squibb's satisfaction, Aptevo could lose its ability to obtain trademark registration for one or more of the relevant Aptevo marks, which could have a material and adverse effect on our business.

If a third party files a trademark infringement claim against us, defending ourselves against such claim could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction and damages, all of which could have a material and adverse effect on our business.

If a third party files a trademark infringement claim against us, defending ourselves against such claim could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction and damages.

At this time, we received no indication from Bristol-Myers Squibb Company 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. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license in whole or in part, terminate the exclusive nature of the license and/or sue us for breach, which could cause us to not be able to market any product that is covered by the licensed patents and may be subject to damages.

Any such termination or claim, particularly relating to our agreements with respect to WinRho SDF, HepaGam B, VARIZIG or IXINITY could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, information processes and know-how. These types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants and third parties as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known, including through a potential cyber security breach, or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

Our WinRho SDF, HepaGam B and VARIZIG products are protected by Emergent's manufacturing trade secrets. There are no patents or patent applications pending that support these hyperimmune products. If Emergent fails to adequately protect the trade secrets supporting these products, competitors may be able to copy our products by reproducing the manufacturing processes.

Risks Related to Collaborations

We may not be successful in establishing and maintaining collaborations that leverage our capabilities in pursuit of developing and commercializing our product candidates.

For each of our product candidates, including oltertuzumab, we plan to evaluate the merits of entering into collaboration arrangements with third parties, including leading biotechnology companies or non-governmental organizations.

We currently are party to a collaboration arrangement with MorphoSys AG for the joint worldwide development and commercialization of MOR209/ES414, a targeted immuno-therapeutic protein being developed for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies. In December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of MOR209/ES414 developed ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug, reduced the concentration of MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA.

We have continued the current clinical trial under an amended protocol and recruitment began during the second half of 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. In addition, the amended collaboration agreement changed the total expected funding requirement for us to up to approximately \$250 million. As a result of the required change in dosing regimen for MOR209/ES414, the lead RTCC candidate, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial. Further adverse or inconclusive clinical results could lead to further renegotiation of the terms or cancellation of our collaboration agreement with MorphoSys AG.

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

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

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

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

For example, in 2011, Abbott Laboratories, or Abbott, terminated its collaboration with Emergent for the development of otlertuzumab following a portfolio reprioritization process by Abbott.

The failure of any of our future collaboration partners to perform as expected could place us at a competitive disadvantage and adversely affect us financially, including delay and increased costs of development, loss of market opportunities, lower than expected revenues and impairment of the value of the related product candidate. Collaborations are a critical part of our business strategy, and any inability on our part to establish and successfully maintain such arrangements on terms favorable to us or to work successfully with our collaborative partners could have an adverse effect on our operations and financial performance.

Financial Risks

We may 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 or sustain 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 and from our products in development in order to achieve profitability in light of our planned expenditures. If we are unable to generate greater revenue, we may not achieve profitability in future periods, and may not be able to maintain any profitability we do achieve. If we are unable to generate sufficient revenues, we will not become profitable and may be unable to continue operations without additional funding.

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

On August 4, 2016, we entered into a \$35.0 million Credit and Security Agreement, or the Credit Agreement, by and among us and certain our subsidiaries as borrowers, MidCap Financial Trust, as agent, and the lenders from time to time party thereto. The terms of the Credit Agreement, and borrowings we may make under the Credit Agreement in the future, could have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on borrowings under the Credit Agreement if market rates of interest increase;
- 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; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under any future borrowings under the Credit Agreement. In addition, failure to comply with the 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 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.

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 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, and Chief Financial Officer, Jeffrey G. Lamothe, and Chief Medical Officer, Scott C. Stromatt, or other key employees, our ability to implement our business strategy could be materially harmed. Our industry has experienced a high rate of turnover of management personnel in recent years. We face intense competition for qualified employees from biotechnology companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package or otherwise attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

We are subject to periodic litigation, which could result in losses or unexpected expenditure of time and resources.

From time to time, we may be called upon to defend ourselves against lawsuits relating to our business. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of any such proceedings. An unfavorable outcome in any such proceedings could have an adverse impact on our business, financial condition and results of operations. If our stock price is volatile, we may become involved in securities class action lawsuits in the future. Any litigation in the future, regardless of its merits, could result in substantial costs and a diversion of management's attention and resources that are needed to successfully run our business.

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 present 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. There may also be dis-synergies from separating the businesses that could negatively impact the financial condition and results of operations of either or both businesses. There also can be no assurance that the separation will not adversely affect our business.

We have no history operating as an independent company, and our historical financial information is not necessarily representative of the results that we would have achieved as a separate, publicly-traded company and may not be a reliable indicator of our future results.

The financial information about us in this quarterly report on Form 10-Q refers to our business as operated by and integrated with Emergent, prior to August 1, 2016. Our historical financial information included in this quarterly report is derived from the consolidated financial statements and accounting records of Emergent. Accordingly, the historical financial information included in this quarterly report does not necessarily reflect the financial condition, results of operations or cash flows that we would have achieved as a separate, publicly-traded company during the periods presented or those that we will achieve in the future. Significant changes may occur in our cost structure, management, financing and business operations as a result of operating as an independent company.

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 have entered into a separation and distribution agreement and various other agreements with Emergent, including a non-negotiable promissory note, a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian 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 are in the process of creating our own, or engaging third parties to provide, systems and services to replace many of the systems and services Emergent currently provides to us. We may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Emergent's systems to ours. These systems and services may also be more expensive or less efficient than the systems and services Emergent is expected to provide during the transition period.

As we continue to build our information technology infrastructure and transition our data to our own systems, we could incur substantial additional costs and experience temporary business interruptions.

We are continuing to install and implement our own information technology infrastructure to support our critical business functions, including accounting and reporting, customer service, inventory control and distribution. We may incur temporary interruptions in business operations if we cannot transition effectively from Emergent's existing transactional and operational systems, data centers and the transition services that support these functions as we transition these systems. We may not be successful in implementing our new systems and transitioning our data, and we may incur substantially higher costs for implementation than currently anticipated. Our failure to avoid operational interruptions as we transition systems and replace Emergent's IT services, or our failure to transition systems to replace Emergent's services successfully, could disrupt our business and have a material adverse effect on our results of operations. In addition, if we are unable to replicate or transition certain systems, our ability to comply with regulatory requirements could be impaired.

Our accounting and other management systems and resources may not be adequately prepared to meet the financial reporting and other requirements to which we will be subject as a standalone publicly-traded company following the distribution.

Our financial results previously were included within the consolidated results of Emergent, and we believe that our reporting and control systems were appropriate for those of divisions of a public company. However, we were not directly subject to the reporting and other requirements of the Exchange Act. We are now directly subject to substantial reporting and other obligations under the Exchange Act. These reporting and other obligations will place significant demands on our management and administrative and operational resources, including accounting resources. We may not have sufficient time 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 and potentially need to hire additional accounting and finance staff. We expect to incur additional annual expenses related to these steps, and those expenses may be significant. If we are unable to upgrade our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies under the Exchange Act could be impaired. Any failure to achieve and maintain effective internal controls could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In connection with our separation from Emergent, Emergent has agreed to indemnify us for certain liabilities and we have agreed to indemnify Emergent for certain liabilities. If we are required to pay under these indemnities to Emergent, our financial results could be negatively impacted. The Emergent indemnity may not be sufficient to hold us harmless from the full amount of liabilities for which Emergent will be allocated responsibility, and Emergent may not be able to satisfy its indemnification obligations in the future.

Pursuant to the separation agreement and certain other agreements with Emergent, Emergent has agreed to indemnify us for certain liabilities, and we have 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, Aptevo 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 (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 Aptevo common stock and (ii) each Emergent stockholder would be treated as receiving a taxable distribution in an amount equal to the fair market value of the Aptevo common stock received by such stockholder.

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.

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

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.

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 will continue to have a financial interest in Emergent common stock, which may create, or may create the appearance of, conflicts of interest when these individuals are faced with decisions that could have different implications for Emergent than the decisions have for Aptevo.

Risks Related to Our Common Stock

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

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

The stock market in general, and the market for biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a number of factors, some of which may be beyond our control or unrelated to our operations, including, among others:

- changes in earnings estimated by securities analysts or our ability to meet those estimates;
- investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance;
- the success of competitive products or technologies;
- the timing, expenses and results of clinical and non-clinical trials of our product candidates;
- announcements regarding clinical trial results and product introductions by us or our competitors;
- announcements of acquisitions, collaborations, financings or other transactions by us;
- public concern as to the safety of our products;
- termination or delay of a development program;
- the recruitment or departure of key personnel;
- actual or anticipated variations in our product revenue and results of operations;
- the operating and stock price performance of comparable companies;
- general industry conditions and domestic and worldwide financial, economic and political instability; and
- the other factors described in this “Risk Factors” section.

In addition, when the market price of a company’s common stock drops significantly, stockholders often institute securities class action lawsuits against the company. A lawsuit against us could cause us to incur substantial costs and could divert the time and attention of our management and other resources.

The public announcement of data from clinical studies or news of any developments related to our product pipeline may cause significant volatility in our stock price. If the development of any of our key pipeline products is delayed or discontinued, our stock price could decline significantly.

We expect that investors may place heightened scrutiny on some of our products in development when making investment decisions in Aptevo compared to historic Emergent. The announcement of data from clinical studies by us or our collaborative partners or news of any developments related to our key pipeline products may cause significant volatility in our stock price. Furthermore, the announcement of any negative or unexpected data or the discontinuation of development of any of our key pipeline products, or any delay in our anticipated timelines for filing for regulatory approval, could cause our stock price to decline significantly. There can be no assurance that data from clinical studies will support a filing for regulatory approval or even if approved, that any of our key pipeline products will become commercially successful.

Your percentage of ownership in Aptevo may be diluted in the future.

In the future, your percentage ownership in Aptevo may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we will be granting to our directors, officers and employees. Our employees have options to purchase shares of our common stock after the distribution as a result of conversion of their Emergent stock options to Aptevo stock options. 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 [October 31, 2016], 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, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for: (1) any derivative action or proceeding brought on behalf of Aptevo; (2) any action asserting a claim for breach of a fiduciary duty owed by any director, officer or other employee or stockholder of Aptevo to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of General Corporation Law of the State of Delaware, which we refer to as the DGCL; (4) any action asserting a claim arising pursuant to any provision of our Certificate of Incorporation or by-laws (as they may be amended from time to time); or (5) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage lawsuits against us or our directors or officers. Alternatively, if a court outside of Delaware were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings described above, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

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. Therefore, we currently do not expect to pay dividends. 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. This could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, in connection with the distribution or otherwise, could reduce the market price of our common stock. We are unable to predict whether large amounts of our common stock will be sold in the open market following the distribution. We are also unable to predict whether a sufficient number of buyers would be in the market at that time. The shares issued in the distribution related to the separation are freely tradeable without restriction or further registration under the U.S. Securities Act of 1933, as amended, or the Securities Act, unless the shares are owned by one of our "affiliates," as that term is defined in Rule 405 under the Securities Act. Moreover, holders of an aggregate of approximately 3 million shares of our common stock immediately following the distribution have the right to require us to register these shares of common stock under the Securities Act 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.

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

APTEVO THERAPEUTICS INC.

Date: November 14, 2016

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

Date: November 14, 2016

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

Exhibit Index

Exhibit Number	Description
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.

**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 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: November 14, 2016

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 Inc. on Form 10-Q for the period ending September 30, 2016 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: November 14, 2016

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 Inc. on Form 10-Q for the period ending September 30, 2016 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: November 14, 2016

By: _____ /s/ Jeff Lamothe

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