UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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	**81-1567056**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2401 4th Avenue, Suite 1050 Seattle, Washington	**98121**
(Address of principal executive offices)	**(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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act). ☒

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

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

Title of Each Class	**Trading Symbols(s)**	**Name of Exchange on Which Registered**
Common Stock, $0.001 par value per share	**APVO**	**The Nasdaq Stock Market LLC (The Nasdaq Global Market)**

As of May 7, 2019, the number of shares of the registrant's common stock outstanding was 45,090,219.

Table of Contents

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.

Item 1. Financial Statements.

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

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,011	$ 30,635
Accounts receivable	5,801	5,220
Inventories	4,346	1,785
Prepaid expenses	6,923	6,907
Other current assets	3,561	4,142
Total current assets	57,642	48,689
Restricted cash	7,448	7,448
Property and equipment, net	4,978	5,202
Intangible assets, net	5,043	5,250
Operating lease right-of-use asset	4,481	—
Other assets	1,249	905
Total assets	$ 80,841	$ 67,494
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,043	$ 11,671
Accrued compensation	5,042	3,898
Sales rebates and discounts payable	857	1,245
Other short-term liabilities	1,348	796
Total current liabilities	18,290	17,610
Long-term debt, net	19,415	19,278
Operating lease liability, net of current portion	3,995	—
Other liabilities	11	200
Total liabilities	41,711	37,088
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; 45,090,219 and 22,808,416 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	45	23
Additional paid-in capital	178,511	157,791
Accumulated deficit	(139,426)	(127,408)
Total stockholders' equity	39,130	30,406
Total liabilities and stockholders' equity	$ 80,841	$ 67,494

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

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

	For the Three Months Ended March 31,	
	2019	2018
Revenues:		
Product sales	$ 7,022	$ 4,071
Costs and expenses:		
Cost of product sales	3,847	1,781
Research and development	7,285	8,199
Selling, general and administrative	7,330	7,592
Loss from operations	(11,440)	(13,501)
Other expense, net	(578)	(353)
Net loss	$ (12,018)	$ (13,854)
Basic and diluted net loss per basic share	$ (0.44)	$ (0.63)
Weighted-average shares used to compute per share calculations	27,567,584	22,025,268

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

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

	For the Three Months Ended March 31,	
	2019	2018
Net loss	$ (12,018)	$ (13,854)
Other comprehensive loss:		
Unrealized loss on available-for-sale investments, net	—	22
Total comprehensive loss	$ (12,018)	$ (13,832)

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

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

	For the Three Months Ended March 31,	
	2019	2018
Operating Activities		
Net loss	$ (12,018)	$ (13,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	594	717
Depreciation and amortization	583	587
Non-cash interest expense and other	198	60
Changes in operating assets and liabilities:		
Accounts receivable	(581)	(957)
Inventories	(2,561)	(257)
Prepaid expenses and other current assets	121	97
Operating lease right of use asset	211	—
Accounts payable, accrued compensation and other liabilities	368	(3,371)
Long-term operating lease liability	(371)	—
Sales rebates and discounts	(388)	—
Net cash used in operating activities	(13,844)	(16,978)
Investing Activities		
Proceeds from the maturity of investments	—	25,929
Cash received from sale of Hyperimmune Business	—	54
Purchases of property and equipment	(153)	(473)
Purchases of investments	—	(1,998)
Net cash (used in) provided by investing activities	(153)	23,512
Financing Activities		
Proceeds from issuance of common stock, warrants, and pre-funded warrants, net	20,410	—
Proceeds from exercise of common stock options	—	186
Proceeds from the exercise of pre-funded warrants	21	—
Payment of tax liability for vested equity awards	(58)	(742)
Net cash provided by (used in) financing activities	20,373	(556)
Increase in cash, cash equivalents, and restricted cash	6,376	5,978
Cash, cash equivalents, and restricted cash at beginning of period	38,083	17,495
Cash, cash equivalents, and restricted cash at end of period	$ 44,459	$ 23,473

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	22,808,416	$ 23	$ 157,791	$ (127,408)	$ —	$ 30,406
Issuance of common stock, pre-funded warrants and warrants, net	22,000,000	22	20,184	—	—	20,206
Issuance of commitment shares of common stock, non-cash transaction	195,867	—	—	—	—	—
Common stock issued upon vesting of restricted stock units	85,936	—	(58)	—	—	(58)
Stock-based compensation	—	—	594	—	—	594
Net loss for the period	—	—	—	(12,018)	—	(12,018)
Balance at March 31, 2019	45,090,219	$ 45	$ 178,511	$ (139,426)	$ —	$ 39,130

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	21,605,716	$ 22	$ 155,837	$ (73,719)	$ (105)	$ 82,035
Unrealized losses on available-for-sale investments	—	—	—	—	22	22
Common stock issued upon exercise of stock options	75,425	—	186	—	—	186
Common stock issued upon vesting of restricted stock units	760,833		(742)			(742)
Stock-based compensation	—	—	717	—	—	717
Net loss for the period	—	—	—	(13,854)	—	(13,854)
Balance at March 31, 2018	22,441,974	$ 22	$ 155,998	$ (87,573)	$ (83)	$ 68,364

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

Note 1. Nature of Business and Significant Accounting Policies

Organization and Liquidity

Aptevo Therapeutics Inc. (Aptevo, we, us, or the Company) is a biotechnology company focused on novel oncology (cancer) and hematology (blood disease) therapeutics to meaningfully improve patients' lives. Our core technology is the ADAPTIR (modular protein technology) platform. We currently have one revenue-generating product in the area of hematology, IXINITY, as well as various investigational stage product candidates in the areas of immuno-oncology and autoimmune and inflammatory diseases.

We are currently trading on the Nasdaq Global Market under the symbol "APVO."

In accordance with Financial Accounting Standards Board, or the FASB, Accounting Standards Update No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40), our management evaluates whether there are conditions or events, considered in aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. As of May 9, 2019, there are not such conditions or events, as we expect our existing cash and cash equivalents will be sufficient to fund our operations through May 9, 2020.

In March 2019, we completed a public offering relating to the issuance and sale of 19,850,000 shares of our common stock and warrants to purchase up to 19,850,000 shares of common stock at an exercise price of $1.30 per share, as well as pre-funded warrants to purchase up to 2,150,000 shares of common stock at an exercise price of $0.01 per share and 2,150,000 of related warrants to purchase shares of common stock at $1.30 per share. We received net proceeds of $20.2 million, after underwriting fees, legal fees, and other expenses. If the remaining warrants are fully exercised in the future, additional proceeds to be received upon exercise of these warrants totals up to $28.6 million over the ten-year term of the warrants.

Our results of operations will be highly dependent on IXINITY sales unless or until we develop or partner any of our development stage product candidates, which we expect may take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for one of our development stage product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution, to the extent that such costs are not paid by collaborators. We do not have sufficient cash to complete the clinical development of any of our development stage product candidates and will require additional funding in order to complete the development activities required for regulatory approval of such product candidates. While we may be able to access capital under our existing equity sales agreement with Lincoln Park Financial LLC or our Equity Distribution Agreement with Piper Jaffray, if we are unable to obtain additional financing when needed, or if IXINITY revenue growth does not continue or continue at the rates we expect, we may have to delay, reduce the scope of, suspend or eliminate one or more of our research and development programs.

Basis of Presentation

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

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.

The condensed consolidated financial statements include the accounts of the company and its wholly owned subsidiaries: Aptevo Research and Development LLC; Aptevo BioTherapeutics LLC; and Aptevo Europe Limited. All intercompany balances and transactions have been eliminated.

Significant Accounting Policies

Leases

On January 1, 2019 we adopted ASU No. 2016-02, Leases (ASC 842), which amends the existing standards for lease accounting, requiring lessees to recognize most leases on their balance sheets and disclose key information about leasing arrangements. We adopted the new standard using a modified retrospective transition approach for the leases at the beginning of the current fiscal year, January 1, 2019. We did not adjust comparative periods in our financial statements prior to that period. See note 6 – Leases, of our condensed consolidated financial statements for additional information.

The new standard establishes a right-of-use model that requires a lessee to recognize an operating lease right-of-use asset and lease liability on the balance sheet for all leases with a term longer than twelve months. Leases are to be classified as finance or operating at the lease commencement, which affects the classification of expense recognition in the income statement. Right-of-use assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments, as agreed to in the lease. Operating lease liabilities are recognized at the date of lease commencement based on the present value of lease payments over the lease term. As leases may include options to extend the lease period, or options for early termination, when it is reasonably certain that an entity is going to exercise the renewal option, the additional payments are to be included in the lease's terms. When it is reasonably certain that an early termination option will not be exercised, the lease's terms are to be extended beyond the possible early termination date or dates.

The standard requires that we use our incremental borrowing rate (IBR) as the discount rate in our lease evaluation if a rate implicit in the lease cannot be identified. Due to the significant judgment involved and the complex analysis needed to determine this discount rate, we engaged a third-party valuation specialist to advise us in our determination of our IBR.

An operating right-of-use asset is measured as the amount of the initial measurement of the lease liability, adjusted for prepaid or accrued lease payments, the remaining balance of any lease incentive received, unamortized initial direct costs, and any impairment of the right-of-use asset. The initial measurement of the lease liabilities and right-to-use assets of finance leases is the same as for operating leases.

Lease expense for operating leases is recognized on a straight-line basis over the lease term as part of our selling, general and administrative expenses and our research and development expenses on our consolidated statement of operations. Lease expense for financing leases consists of amortization of the right-of-use asset and interest on the lease liability as part of our research and development expenses on our consolidated statement of operations.

For transition leases, entities are permitted to make an election to apply a package of practical expedients that allows entities not to reassess (i) whether any expired or existing contracts are or contain leases, (ii) lease classification for any expired or existing leases, and (iii) whether initial direct costs for any expired or existing leases qualify for capitalization under ASC 842. These practical expedients must be elected as a package and must be consistently applied to all leases. In addition, entities are also permitted to make an election to use hindsight when determining lease terms and when assessing the impairment of right-of-use assets. We have chosen to elect the package of practical expedients but did not elect the hindsight practical expedient for our transition leases.

Adoption of the new standard resulted in the recognition of a right-to-use asset of $1.5 million, an operating lease liability of $2.2 million dollars, and a related decrease in deferred rent liability of $0.7 million at January 1, 2019.

Other Significant Accounting Policies

Our other significant accounting policies were reported in our Annual Report on Form 10-K for the year ended December 31, 2018 that was filed with the SEC on March 18, 2019. Our other significant accounting policies have not changed materially from the policies previously reported.

Recently Adopted Standards

In February 2016, the FASB issued ASU No. 2016-02, Leases (ASC 842). Under the new guidance, lessees are required to recognize a lease liability and a right-of-use asset for all leases (with the exception of short-term leases) at the commencement date. We adopted this standard on January 1, 2019 and applied the practical expedients thereby continuing to account for leases that commenced before the effective date in accordance with previous GAAP. See note 1 – Significant Accounting Policies, and note 6 – Lease of our condensed consolidated financial statements, for further information.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (ASC 718) – Improvements to Non-employee Share-Based Payment Accounting, which aligns the accounting for share-based payment awards issued to employees and nonemployees. Under ASU 2018-07, the existing employee guidance will apply to nonemployee share-based transactions (as long as the transaction is not effectively a form of financing), with the exception of specific guidance related to the attribution of compensation cost. The cost of nonemployee awards will continue to be recorded as if the grantor had paid cash for the goods or services. In addition, the contractual term will be used in lieu of an expected term in the option-pricing model for nonemployee awards. We adopted this on January 1, 2019, and there was no impact on our consolidated results of operations, financial position, and cash flows.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. Among the amendments is the requirement to present any changes in shareholders' equity in the interim financial statements, either in a separate statement or footnote in the quarterly reports on Form 10-Q. The amendments became effective on November 5, 2018. We have included a separate statement, the Condensed Consolidated Statements of Changes in Stockholders' Equity in this Quarterly Report on Form 10Q.

Note 2. Collaboration Agreements

Alligator

On July 20, 2017, our wholly owned subsidiary Aptevo Research and Development LLC (Aptevo R&D), entered into a collaboration and option agreement (Collaboration Agreement) with Alligator Bioscience AB (Alligator), pursuant to which Aptevo and Alligator will collaboratively develop ALG.APV-527, a lead bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a costimulatory receptor found on activated T-cells, and 5T4, a tumor antigen widely overexpressed in a number of different types of cancer. This product candidate is built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. Under this Collaboration Agreement, Alligator also granted to Aptevo a time-limited option to enter into a second agreement with Alligator for the joint development of a separate bispecific antibody.

In accordance with the terms of the Collaboration Agreement, the parties intend to develop the lead bispecific antibody candidate targeting 4-1BB (CD137) and 5T4 through the completion of Phase II clinical trials in accordance with an agreed upon development plan and budget. Subject to certain exceptions for Aptevo's manufacturing and platform technologies, the parties will jointly own intellectual property generated in the performance of the development activities under the Collaboration Agreement.

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

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

The Collaboration Agreement contains industry standard termination rights, including for material breach following a specified cure period, and in the case of a party's insolvency.

We assessed the arrangement in accordance with ASC 606 and concluded that the contract counterparty, Alligator, is not a customer. As such the arrangement is not in the scope of ASC 606 and is instead treated as a collaborative agreement under ASC 808. For the three months ended March 31, 2019, we recorded a reduction in our research and development expense of $0.4 million and for the three months ended March 31, 2018, we recorded an increase in our research and development expense of less than $0.1 million related to the collaboration arrangement.

Note 3. Fair Value Measurements

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

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

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

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

At March 31, 2019 and December 31, 2018, we had $34.1 million and $29.0 million in money market funds, respectively.

The carrying amounts of our money market funds approximate their fair value. At March 31, 2019, we did not have any level two or level three assets.

Note 4. Cash, Cash Equivalents, and Restricted Cash

The Company's 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. Restricted cash, long-term includes $5.0 million related to the minimum cash covenant included in the Company's Credit and Security Agreement (the Credit Agreement) with MidCap Financial Trust, and $2.4 million securing letters of credit.

The following table shows our cash, cash equivalents and long-term restricted cash as of March 31, 2019 and December 31, 2018:

(in thousands)	March 31, 2019	December 31, 2018
Cash	$ 7,864	$ 6,588
Cash equivalents	29,147	24,047
Restricted cash	7,448	7,448
Total cash, cash equivalents, and restricted cash	$ 44,459	$ 38,083

Note 5. Inventories

Inventories consist of the following:

(in thousands)	March 31, 2019	December 31, 2018
Raw materials and supplies	$ 162	$ 194
Work-in-process	4,023	916
Finished goods	161	675
Total inventories	$ 4,346	$ 1,785

Note 6. Leases

Office Space Lease - Operating

In 2003, we entered into a lease for our corporate headquarters located in Seattle, Washington. This lease has been amended multiple times to add additional space and extend the lease term. Amendment number seven, became effective on September 1, 2014 and expires on April 30, 2020, covering 50,466 square feet of office, laboratory, and meeting space. We are required to pay a proportionate share of certain operating expenses as defined in the agreement with the lessor and a proportionate share of the real estate taxes as assessed. We received a tenant improvement allowance that was settled in June 2017 and which we elected to amortize

as a reduction in rent over the remaining term of the lease. The lease has a two-year renewal option at fair market value on the date of renewal and a termination option by giving nine months' notice and a penalty equal to the unamortized tenant improvement allowance, the unamortized real estate fee, and the market value of free parking. For the three months ended March 31, 2019, we recorded $0.4 million in lease expense, including $0.1 million for variable payments.

We recorded a right-of-use asset for this lease on January 1, 2019, of $1.2 million which reflects the amount of the remaining lease liability, less the balance of accrued and deferred rent, and net of the unamortized balance of tenant incentives. We also recorded a lease liability of $1.9 million which reflects the present value of the remaining lease payments, discounted using our incremental borrowing rate of 16.95% for the remaining term of the lease. The future expense for this lease will be recorded as a straight-line expense, less the unamortized tenant incentive portion, plus any variable expenses due to true-ups of operating costs or real estate taxes.

On March 19, 2019, we entered into a new lease amendment, number eight, for our current headquarters in Seattle, Washington. This amendment extended the terms of the lease for ten years, until April 30, 2030, and reduced the total square footage of our office space to 47,692 after May 1, 2020. We determined we should not include any periods after the termination option when evaluating this amendment as we are not reasonably certain to not exercise the option, therefore we are recording our liability through April 30, 2023. In March 2019, we recorded an increase to our right-of-use asset for this lease amendment of $3.2 million which reflects the amount of the remaining lease liability through April 30, 2023, less the balance of accrued and deferred rent, and net of the unamortized balance of tenant incentives. In March 2019, we also recorded an increase to our lease liability for this lease amendment of $3.2 million which reflects the present value of the remaining lease payments through April 30, 2023, discounted using our incremental borrowing rate of 14.45% for the remaining term of the lease on the date of amendment.

This new amendment has a renewal option of two five-year renewals at fair market value as determined at the time of renewal, and a termination option after month thirty-six with nine months written notice. The termination option also requires a penalty equal to the unamortized tenant improvement allowance at 8% interest, the unamortized real estate taxes at 8% interest, and the equivalent of four-months' rent at the base rent price at the time of termination. The estimated termination penalty has been recorded in our lease payments.

Equipment Leases - Operating

As of January 1, 2019, we have operating leases for one piece of lab equipment and four copiers in our Seattle, Washington headquarters. We recorded a right-of-use asset of $0.3 million on January 1, 2019 which reflects the remaining liability of the leases, less the balance of accrued and deferred rent. We also recorded a lease liability of $0.3 million which reflects the present value of the remaining payment for the leases, discounted using our incremental borrowing rate for the lab equipment lease is 16.53% and for the copier leases it is 16.19%, for the remaining term of the leases. The future expense for these leases will be straight-line and will include any variable expenses that arise.

Equipment Lease – Financing

As of January 1, 2019, we had one equipment lease classified as a financing lease as the lease transfers ownership of the underlying asset to us at the end of the lease term. At the adoption of the standard at January 1, 2019, we did not make any additional reclassification for this lease as the entire carrying amount had already been recorded as a capital lease obligation under ASC 840 – Leases. The remaining term of this lease is seventeen months and has a remaining expense obligation of less than $0.1 million. There were no financing lease payments in the three months ended March 31, 2019.

Components of lease expense:

(in thousands)	For the Three Months Ended March 31, 2019
Operating lease cost	$ 335
Finance lease cost:	
Amortization of right-of-use assets	1
Interest on lease liabilities	1
Total lease cost	$ 337

Supplemental cash flows information related to leases is as follows:

Right of use assets acquired under operating leases:

(in thousands)	For the Three Months Ended March 31, 2019
Operating leases, excluding Seattle office lease	$ 345
Seattle office lease, including amendment	4,347
Total operating leases	$ 4,692

Lease payments:

(in thousands)	For the Three Months Ended March 31, 2019
For operating leases	$ 434

Future minimum payments as of March 31, 2019 are as follows:

(in thousands)	
9 months ended December 31, 2019	$ 1,310
12 months ended December 31, 2020	1,510
12 months ended December 31, 2021	1,387
12 months ended December 31, 2022	1,294
12 months ended December 31, 2023	1,399
Total Future minimum lease payments	6,900
Less: imputed interest	(1,824)
Total	$ 5,076

The long-term portion of the lease liabilities included in the amounts above is $4.0 million and the remainder of our lease liabilities are included in other current liabilities on our condensed consolidated balance sheets.

As of March 31, 2019, the weighted average remaining lease term and weighted discount rate for operating leases was 4.0 years and 14.56%.

Note 7. Debt

Credit Facility

On August 4, 2016, we entered into a Credit and Security Agreement (Credit Agreement), with MidCap Financial Trust. The original Credit Agreement provided us with up to $35.0 million of available borrowing capacity composed of two tranches of $20.0 million and $15.0 million. The first tranche of $20.0 million was made available to us, and drawn, on the closing date of the Credit Agreement. On September 28, 2017, we and MidCap Financial Trust entered into a second amendment to the Credit Agreement in order to accommodate the sale of the Hyperimmune Business under the LLC purchase agreement, and to reflect changes in the remaining business as a result of such sale.

Pursuant to the second Amendment, the agent and the lenders consented to the LLC purchase agreement and the consummation of the sale transaction, released the agent's liens on the assets transferred to one of our subsidiaries prior to the sale, and agreed that no prepayment of the term loans under the credit agreement would be required as a result the sale. As part of the second amendment, the agent and the lenders agreed that: (i) the commitments of the lenders to make the remaining $15.0 million tranche of loans under the credit agreement were terminated, (ii) the covenant levels set forth in the minimum net commercial product revenue covenant were revised, (iii) a new covenant requiring us to maintain a minimum $10.0 million unrestricted cash balance, and (iv) the date on which the term loans begin to amortize would be extended to February 1, 2019 if we achieved net commercial product revenues of $16.0 million for the twelve month period ending June 30, 2018 and maintain such level of net commercial product revenues for each quarter prior to February 1, 2019 thereafter. As we achieved net commercial product revenues of $16.2 million for the twelve month period ending June 30, 2018, our principal repayments have been deferred to February 1, 2020.

On February 23, 2018, we entered into a third Amendment with the agent and lenders to amend certain provisions of the Credit Agreement in order to permit us to maintain a cash collateral account as security for our reimbursement obligations, in respect of certain letters of credit to be issued for our account.

On August 6, 2018, we entered into an Amended and Restated Credit and Security Agreement (Amended Credit Agreement) amending the terms of our original $20 million term loan agreement with MidCap. Under the Amended Credit Agreement, the timeline for us to begin making principal repayments has been extended to February 1, 2020, with an opportunity for further deferral through August 1, 2020. The amount of restricted cash that we are required to maintain on our balance sheet has been reduced from $10 million to $5 million.

In January 2019, our unrestricted cash level fell below $25.0 million which triggered the effectiveness of a security agreement in favor of MidCap with respect to our registered intellectual property to secure our obligations under the Amended Credit Agreement. MidCap now holds a security interest in our registered intellectual property and may take ownership of such intellectual property if we do not satisfy our obligations under the Amended Credit Agreement.

Additionally, this amendment is subject to a subjective acceleration clause, although we believe the likelihood of an acceleration of the due date for this obligation is remote.

The obligations under the Amended Credit Agreement will mature on February 1, 2023. Amounts drawn under the Amended Credit Agreement continue to accrue interest at a rate of LIBOR plus 7.60% per annum.

Note 8. Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period using the as-if converted method. For the purpose of this calculation, warrants, stock options and restricted stock units (RSUs) are only included in the calculation of diluted net income per share when their effect is dilutive.

Common stock equivalents include warrants, 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:

	For the Three Months Ended March 31,	
(in thousands)	**2019**	**2018**
Warrants	22,000	—
Outstanding options to purchase common stock	4,100	3,472
Unvested RSUs	10	196

Note 9. Equity

Common Stock

On March 11, 2019, we completed a public offering of common stock and warrants, as follows:

- for a combined public offering price of $1.00 per share of common stock and related warrants, 19,850,000 shares of common stock and related warrants with a 5-year life to purchase up to 19,850,000 shares of common stock at an exercise price of $1.30 per share,
- for a combined public offering price of $0.99 per pre-funded warrant and related warrant, pre-funded warrants with a 10-year life to purchase up to 2,150,000 shares of common stock at an exercise price of $0.01 per share and related warrants with a 5-year life to purchase up to 2,150,000 shares of common stock at an exercise price of $1.30 per share. These pre-funded warrants were exercised on March 21, 2019.

We received net proceeds of $20.2 million, net of transaction costs, as a result of this offering.

For the three months ended March 31, 2019, we issued 85,936 shares of common stock due to the vesting of RSUs. In addition, pursuant to our purchase agreement with Lincoln Park, we issued 195,867 of commitment shares in a non-cash transaction.

During the three months ended March 31, 2018, we received proceeds of $0.2 million upon the exercise of stock options which resulted in the issuance of 75,425 shares of common stock and issued 760,833 shares of common stock due to the vesting of restricted stock units.

Equity Distribution Agreement

On November 9, 2017, we entered into an Equity Distribution Agreement (the Equity Distribution Agreement) with Piper Jaffray & Co. (Piper Jaffray). The Equity Distribution Agreement provides that, upon the terms and subject to the conditions set forth therein, we may issue and sell through Piper Jaffray, acting as sales agent, shares of our common stock, $0.001 par value per share (the Common Stock) having an aggregate offering price of up to $17.5 million. We have no obligation to sell any such shares under the Equity Distribution Agreement. The sale of such shares of common stock by Piper Jaffray will be effected pursuant to a Registration Statement on Form S-3 which we filed on November 9, 2017. We issued 13,265 shares under the Equity Distribution Agreement in the fourth quarter of 2018, and no shares in the first quarter of 2019.

Converted Equity Awards Incentive Plan

In connection with the spin-off from Emergent BioSolutions, Inc. (Emergent) in August 2016, we adopted the Converted Equity Awards Incentive Plan (Converted Plan) and outstanding equity awards of Emergent held by Aptevo employees were converted into or replaced with equity awards of Aptevo (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. A total of 1.3 million shares of Aptevo common stock have been authorized for issuance under the Converted Plan. Options issued as Conversion Awards were priced according to the Converted Plan. RSUs issued as part of the Converted Plan provide for the issuance of a share of Aptevo's stock at no cost to the holder.

2016 Stock Incentive Plan

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

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

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

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

On May 31, 2017, at the 2017 Annual Meeting of Stockholders (Annual Meeting), the Company's stockholders approved the amendment and restatement of the Company's 2016 SIP (Restated 2016 Plan) to, among other things, increase the number of authorized shares issuable by 1.3 million shares of Aptevo common stock. The Restated 2016 Plan was previously approved, subject to stockholder approval, by the Board of Directors of the Company.

2018 Stock Incentive Plan

On June 1, 2018, at the 2018 Annual Meeting, the Company's stockholders approved a new 2018 Stock Incentive Plan (2018 SIP), which replaces the Restated 2016 Plan on a go-forward basis. All stock options, RSUs or other equity awards granted subsequent to June 1, 2018 will be issued out of the 2018 SIP, which has 2.9 million shares of Aptevo common stock authorized for issuance. The 2018 Plan became effective immediately upon stockholder approval at the Annual Meeting. Any shares subject to outstanding stock

awards granted under the 2016 SIP that (a) expire or terminate for any reason prior to exercise or settlement; (b) are forfeited because of the failure to meet a contingency or condition required to vest such shares or otherwise return to the Company; or (c) otherwise would have returned to the 2016 SIP for future grant pursuant to the terms of the 2016 Plan (such shares, the "Returning Shares") will immediately be added to the share reserve under the 2018 SIP as and when such shares become Returning Shares, up to a maximum of 3,711,620 shares. The 2018 SIP was previously approved, subject to stockholder approval, by the Board of Directors of the Company. As of March 31, 2019, there are 2.0 million shares available to be granted under the 2018 SIP.

Stock options under the 2018 SIP generally vest pro rata over a three-year period and terminate ten years from the grant date, though the specific terms of each grant are determined individually. The Company's executive officers and certain other employees may be awarded options with different vesting criteria, and options granted to non-employee directors also vest over a three-year period. Option exercise prices for new options granted by the Company equal the closing price of the Company's common stock on the Nasdaq Global Market on the date of grant.

Stock-Based Compensation Expense

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

	For the Three Months Ended March 31,	
(in thousands)	**2019**	**2018**
Research and development	$ 251	$ 327
Selling, general and administrative	343	390
Total stock-based compensation expense	$ 594	$ 717

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 vesting period.

Stock Options

Aptevo utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. Set forth below are the assumptions used in valuing the stock options granted:

	For the Three Months Ended March 31,	
	2019	**2018**
Expected dividend yield	0.00%	0.00%
Expected volatility	75.00%	75.00%
Risk-free interest rate	2.52%	2.72%
Expected average life of options	7 years	6 years

Management has applied an estimated forfeiture rate of 10% for the periods presented.

The following is a summary of option activity for the three months ended March 31, 2019:

	Number of Shares	**Weighted-Average Exercise Price**	**Weighted-Average Remaining Term**	**Aggregate Intrinsic Value**
Balance at December 31, 2018	3,329,618	$ 2.74	—	$ —
Granted	821,523	1.60	—	—
Exercised	—	—	—	—
Forfeited	(50,670)	2.42	—	—
Outstanding at March 31, 2019	4,100,471	$ 2.51	7.31	$ —
Exercisable at March 31, 2019	2,062,402	$ 2.56	5.59	$ —

As of March 31, 2019, we had $2.6 million of unrecognized compensation expense related to options expected to vest over a weighted average period of 2.0 years. The weighted average remaining contractual life of outstanding and exercisable options is 5.6 years.

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the closing stock price of Aptevo's common stock on the last trading day of March 2019 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 the last trading day of the quarter. As of December 31, 2018, and March 31, 2019, we had no outstanding options with an exercise price below the trading price of our common stock.

Restricted Stock Units

The following is a summary of RSU activity for the three months ended March 31, 2019:

	Number of Units	Weighted Average Fair Value per Unit	Aggregate Fair Value
Balance at December 31, 2018	133,040	$ 2.97	$ 168,961
Vested	123,442	2.94	—
Forfeited	—	—	—
Outstanding at March 31, 2019	9,618	$ 3.38	$ 8,991
Expected to Vest	9,618	$ 3.38	$ 8,991

As of March 31, 2019, we had less than $0.1 million of unrecognized compensation expense related to RSU's, which will all be fully vested by May 10, 2019.

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

Warrants

In March 2019, as part of a public offering, we issued warrants to purchase up to 24,150,000 shares of our common stock, 22,000,000 of which have an exercise price of $1.30 per share and have a five-year life, and 2,150,000 of pre-funded warrants with an exercise price of $0.01 per share. The pre-funded warrants have a ten-year life and expire on March 11, 2029. The warrants with a $0.01 per share exercise price were exercised in March 2019. We determined the warrants do not meet liability classification pursuant to ASC 480 – Distinguishing Liabilities from Equity. There are therefore included within equity on our consolidated balance sheet. As of March 31, 2019, there were 22,000,000 outstanding.

Note 10. Revenue Reserves

The following table summarizes activity in each of our product revenue allowance and reserve categories for the three months ending March 31, 2019:

(in thousands)	Chargebacks and Cash Discounts	Distribution Fees, Rebates and Patient Assistance
Balance at December 31, 2018	$ (1,323)	$ (865)
Provision related to current period sales	(704)	(923)
Credit or payments made during the period	922	931
Balance at March 31, 2019	$ (1,105)	$ (857)

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

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

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

Overview

We are a biotechnology company focused on novel oncology (cancer) and hematology (blood disease) therapeutics to meaningfully improve patients' lives. Our core technology is the ADAPTIR™ (modular protein technology) platform. We currently have one revenue-generating product in the area of hematology, as well as various investigational stage product candidates in immuno-oncology and autoimmune and inflammatory diseases.

For the three months ended March 31, 2019, we had a net loss of $12.0 million, compared to the three months ended March 31, 2018, when we had a net loss $13.9 million. We had an accumulated deficit of $139.4 million as of March 31, 2019. For the three months ended March 31, 2019, net cash used in our operating activities was $13.8 million. On March 7, 2019, we completed a public offering relating to the issuance and sale of 19,850,000 shares of our common stock and warrants to purchase up to 19,850,000 shares of common stock at $1.30 per share, as well as pre-funded warrants to purchase up to 2,150,000 shares of common stock at an exercise prices of $0.01 per share and 2,150,000 of related warrants to purchase shares of common stock at $1.30 per share. We received net proceeds of $20.2 million, after underwriting fees, legal fees, and other expenses. If the remaining warrants are fully exercised in the future, additional proceeds to be received upon exercise of these warrants totals up to $28.6 million over the ten-year term of the warrants.

Although we expect our existing cash and cash equivalents will be sufficient to fund our operations for at least twelve months from the date of this filing, if we are unable to obtain additional financing when needed, we may have to delay, reduce the scope of, suspend or eliminate one or more of our research and development programs. Our results of operations will be highly dependent on IXINITY sales unless or until we develop or partner any of our development stage product candidates. We will not generate commercial revenues from our development stage product candidates unless and until we or our collaborators successfully complete development and obtain regulatory approval for such product candidates, which we expect will take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for one of our development stage product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution, to the extent that such costs are not paid by collaborators. We do not have sufficient cash to complete the clinical development of any of our development stage product candidates and will require additional funding in order to complete the development activities required for regulatory approval of such product candidates.

Pipeline Highlights

We have one marketed product, 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.

We also have numerous investigational stage product candidates based on our ADAPTIR platform. The ADAPTIR platform technology can produce monospecific and multispecific immunotherapeutic proteins that specifically bind to one or more targets, for example, bispecific therapeutic molecules, which may have structural and functional advantages over monoclonal antibodies. The structural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of ADAPTIR immunotherapeutics that engage immune effector cells and disease targets in a novel manner to produce unique signaling responses and ultimately kill tumors or modulate the immune system to kill tumors. We are skilled at product candidate generation, validation and subsequent preclinical and clinical development using the ADAPTIR platform. We have the ability to progress ADAPTIR molecules from concept to commercialization by way of our protein engineering, preclinical development and process development capabilities, cGMP manufacturing oversight and clinical development capabilities. We also have the ability to launch, market and commercialize these product candidates upon approval.

Our investigational stage product candidates are:

- APVO436, a bispecific ADAPTIR candidate targeting CD123, a cell surface receptor highly expressed on several hematological malignancies and CD3. APVO436 engages T cells to initiate killing of tumor cells. We commenced a Phase 1/1b clinical trial in the United States in December 2018 in patients with AML and MDS. The objective of the trial is to evaluate safety, pharmacokinetics, and pharmacodynamics of APVO436 in patients. We anticipate that we will have anti-drug antibody (ADA) date in the third quarter of 2019, and preliminary Phase 1 safety data in the fourth quarter of 2019.
- APVO210, a bispecific ADAPTIR preclinical candidate with a novel mechanism of action based on targeted cytokine delivery. APVO210 is composed of a humanized anti-CD86 antibody fused with a modified form of IL-10 that specifically induces IL-10 signaling on antigen presenting cells, but not on lymphoid populations. APVO210 functions by suppressing immune responses and inducing certain tolerogenic responses and therefore may have potential benefit for the treatment of autoimmune and inflammatory diseases. We initiated a Phase 1 clinical trial in Australia in March 2019. The Phase 1 clinical trial will evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of APVO210 in healthy volunteers. The trial will consist of two stages. Stage 1 will consist of up to 64 healthy volunteers receiving a single ascending dose. Stage 2 will consist of up to 40 healthy volunteers receiving multiple ascending doses. For both stages of the Phase 1 clinical trial, healthy volunteers will receive APVO210 or placebo administered by intravenous infusion. We anticipate that initial results of APVO210 single dose cohorts will be available in the third quarter of 2019, and that preliminary Phase 1 data will be available in the fourth quarter of 2019 for cohorts enrolled by the beginning of fourth quarter of 2019.
- ALG.APV-527, a bispecific antibody candidate, partnered with Alligator Bioscience, featuring a novel mechanism of action designed to simultaneously target 4-1BB (CD137) and 5T4, a tumor antigen widely overexpressed in a number of different types of cancer. 4-1BB, a costimulatory receptor on T cells, is known to enhance the immune response to cancer through activation of tumor-specific T cells and is believed to be a promising target for new immunotherapeutic approaches. ALG.APV-527 could potentially have utility in the treatment of a broad spectrum of cancers over-expressing the tumor antigen, including breast, cervical, non-small-cell-lung, prostate, renal, gastric, colorectal and bladder cancers. Aptevo intends to file a clinical trial authorization (CTA) in the second half of 2019.
- RORI Bispecific, is a proof-of-concept bispecific candidate in pre-clinical development featuring an immunotherapeutic protein targeting ROR1, an antigen found on several solid tumors and hematologic, or blood-related malignancies and CD3, a component of the T-cell receptor complex expressed on all T-cells. Initial pre-clinical data demonstrate redirected T-cell killing of tumors expressing ROR1 *in vitro* and *in vivo* in animal studies.

Collaboration with Alligator Bioscience AB

On July 20, 2017, our wholly owned subsidiary Aptevo Research and Development LLC (Aptevo R&D), entered into a collaboration and option agreement (Collaboration Agreement) with Alligator Bioscience AB, (Alligator), pursuant to which Aptevo R&D and Alligator are collaboratively developing ALG.APV-527, a lead bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a costimulatory receptor found on activated T-cells, and 5T4 a tumor antigen widely overexpressed in a number of different types of cancer. This product candidate is built on our novel ADAPTIR platform. Under this Collaboration Agreement, Alligator also granted to Aptevo R&D a time-limited option to enter into a second agreement with Alligator for the joint development of a separate bispecific antibody.

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

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

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

The Collaboration Agreement contains industry standard termination rights, including for material breach following a specified cure period, and in the case of a party's insolvency.

IXINITY

IXINITY is a third-generation recombinant human coagulation factor IX approved by the FDA in April 2015 in the United States for the control and prevention of bleeding episodes and for perioperative management in adults and children 12 years of age or older with hemophilia B. Hemophilia B, also known as Christmas disease, is a rare, inherited bleeding disorder. The blood of hemophilia B patients has an impaired clotting ability, which results from substantially reduced or missing factor IX activity. Patients with hemophilia B commonly experience joint bleeding with pain and swelling, which can result in irreversible joint damage. They may also experience more serious or life-threatening hemorrhages. People with hemophilia B require factor IX injections to restore normal blood coagulation temporarily. Many patients use regular, prophylactic treatment to try to prevent bleeding episodes, while others use on-demand treatment to control bleeding episodes after they occur. Treatment selection and approach is individualized based on factors including the patient's condition and age, factor level severity, bleeding pattern, activity level and individual pharmacokinetic parameters.

In 2019, we intend to introduce a new 3,000 IU assay size and anticipate that this new assay will be available mid-2019. The 3,000 IU assay size will provide enhanced convenience for patients who use IXINITY. The 3,000 IU assay size is designed to allow some patients to use fewer vials when infusing. We believe that the 3,000 IU assay size will also be a more attractive option for some patients on IXINITY when traveling.

We anticipate commencing a Phase 4 post-marketing study in the third quarter of 2019 that has the potential to support a pediatric label expansion. We performed a pilot study in patients under 12 years of age that showed that IXINITY was well tolerated. The pilot study also showed comparable results to that of the overall patient population studied in the Phase 3 pivotal clinical trial of IXINITY.

We are exploring distribution and partnership opportunities for IXINITY outside of the U.S. We believe that we may be able to leverage existing relationships to grow the IXINITY market outside of the United States. Currently all IXINITY sales are in the U.S.

Results of Operations

Comparison of the three months ended March 31, 2019 and March 31, 2018

Financial Summary

We recognized a net loss of $12.0 million and $13.9 million for the three months ended March 31, 2019, and March 31, 2018 respectively. For the three months ended March 31, 2019 compared to the three months ended March 31, 2018, product sales were higher by $3.0 million, which was offset by an increase in cost of products sold of $2.1 million. Research and development costs decreased by $0.9 million for the quarter and selling, general and administrative costs decreased for the same period by $0.3 million.

Product Revenue

Product sales of IXINITY increased by $3.0 million, or 73%, to $7.0 million for the three months ended March 31, 2019 from $4.1 million for the three months ended March 31, 2018. This increase was primarily related to the continuing expansion of our Hemophilia B patient base and a price increase which went into effect on January 1, 2019.

Cost of Product Sales

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

The following table provides information regarding our cost of products sales, including gross profit and gross margin percent for the three months ended March 31, 2019 and 2018:

	For the Three Months Ended March 31,			
	2019	2018	Change	Percent
Product sales	$ 7,022	$ 4,071	$ 2,951	73%
Cost of product sales	3,847	1,781	2,066	116%
Gross profit	$ 3,175	$ 2,290	$ 885	39%
Gross margin percent	45%	56%		

Cost of product sales increased by $2.1 million, or 116% for the three months ended March 31, 2019 to $3.8 million from $1.8 million for the three months ended March 31, 2018. This increase in cost of product sales is primarily due to the increase in sales, as well as the first quarter of 2018 having reduced costs of goods sold due to lower cost inventory being sold in the quarter.

Research and Development Expenses

We expense research and development costs as incurred. These expenses consist primarily of the costs associated with our research and development activities, including conducting preclinical studies and clinical trials, fees to professional service providers for analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies, as well as costs of contract manufacturing services for clinical trial material, and costs of materials used in clinical trials and research and development.

Our research and development expenses include:

- employee salaries and related expenses, including stock-based compensation and benefits for our employees involved in our drug discovery and development activities;
- external research and development expense incurred under agreements with third-party contract research organizations (CROs) and investigative sites;
- manufacturing material expense for third-party manufacturing; and
- overhead costs such as rent, utilities and depreciation.

We expect our future research and development spending will also 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. While programs are still in the preclinical trial phase, we do not provide a breakdown of the initial associated expenses as we are often evaluating multiple product candidates simultaneously. Costs are reported in preclinical research and discovery until the program enters the clinic.

Our research and development expenses by program for the three months ended March 31, 2019 and 2018 are shown in the following table:

(in thousands)	For the Three Months Ended March 31, 2019	2018	Change
Clinical programs:			
APVO436	$ 1,154	$ 2,132	$ (978)
APVO210	1,214	1,701	(487)
Other	143	1,008	(865)
Total clinical programs	2,511	4,841	(2,330)
Preclinical program, general research and discovery	4,116	3,120	996
IXINITY	658	238	420
Total	$ 7,285	$ 8,199	$ (914)

Research and development expenses decreased by $0.9 million, to $7.3 million for the three months ended March 31, 2019 from $8.2 million for the three months ended March 31, 2018. These changes were primarily comprised of:

- a decrease in expenses for APVO436 is primarily due to the timing of manufacturing and clinical trial activities;
- a decrease in expense for APVO210 is primarily due to the timing of manufacturing and clinical trial activities;
- a decrease in expenses for other clinical programs is due to discontinuing two of our clinical trials in the third quarter of 2018; offset by
- an increase in the expenses for our preclinical program, general research and discovery programs, which is primarily related to research and development activities around new pipeline product candidates or programs as they are being evaluated; and
- an increase in expense for IXINITY associated with start-up costs relating to the pediatric clinical study which will be commencing in 2019.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executive, IXINITY sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expenses.

For the three months ended March 31, 2019, selling, general and administrative expenses decreased by $0.3 million, or 3%, to $7.3 million from $7.6 million for March 31, 2018. This decrease was primarily due to reduced personnel and professional services costs.

Critical Accounting Policies and Significant Judgements and Estimates

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

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

- Revenue recognition and
- Stock-based compensation

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of March 31, 2019.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2019, we had cash, and cash equivalents in the amount of $37.0 million, and accounts receivable of $5.8 million that we expect to collect in a timely fashion. In addition, we have an Equity Distribution Agreement (the Equity Distribution Agreement) with Piper Jaffray & Co. (Piper Jaffray) and a Purchase Agreement (the Purchase Agreement) with Lincoln Park Capital Fund, LLC (Lincoln Park) as discussed in the paragraphs below. In March 2019, we received net proceeds of $20.2 million, after underwriting fees, legal fees, and other expenses, from an underwritten public offering of common stock and related warrants. See Note 1 – Organization and Liquidity of our condensed consolidated financial statements, for additional information.

For the three months ended March 31, 2019, we reported a net loss of $12.0 million and we had an accumulated deficit of $139.4 million as of March 31, 2019. For the three months ended March 31, 2019, net cash used in our operating activities was $13.8 million. In March 2019, we completed a public offering relating to the issuance and sale of 19,850,000 shares of our common stock and warrants to purchase up to 19,850,000 shares of common stock at $1.30 per share, as well as pre-funded warrants to purchase up to 2,150,000 shares of common stock at an exercise prices of $0.01 per share and 2,150,000 of related warrants to purchase shares of common stock at $1.30 per share. We received net proceeds of $20.2 million, after underwriting fees, legal fees, and other expenses. If the remaining warrants are fully exercised in the future, additional proceeds to be received upon exercise of these warrants totals up to $28.6 million over the ten-year term of the warrants.

Although we expect our existing cash and cash equivalents will be sufficient to fund our operations for at least twelve months from the date of this filing, if we are unable to obtain additional financing when needed, we may have to delay, reduce the scope of, suspend or eliminate one or more of our research and development programs. Our sole marketed product is IXINITY, and therefore IXINITY will be our only source of product revenue. As such, our results of operations will be highly dependent on IXINITY sales unless or until we develop or partner any of our development stage product candidates. We will not generate revenues from our development stage product candidates unless and until we or our collaborators successfully complete development and obtain regulatory approval for such product candidates, which we expect will take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for one of our development stage product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution, to the extent that such costs are not paid by collaborators. We do not have sufficient cash to complete the clinical development of any of our development stage product candidates and will require additional funding in order to complete the development activities required for regulatory approval of such product candidates. While we may be able to access capital under our existing equity sales agreement with Lincoln Park Financial LLC or our Equity Distribution Agreement with Piper Jaffray, if we are unable to obtain additional financing when needed, or if IXINITY revenue growth does not continue or continue at the rates we expect, we may have to delay, reduce the scope of, suspend or eliminate one or more of our research and development programs.

Credit Agreement

On August 4, 2016, we entered into a Credit and Security Agreement or the Credit Agreement, with MidCap Financial Trust or MidCap. The original Credit Agreement provided us with up to $35.0 million of available borrowing capacity composed of two tranches of $20.0 million and $15.0 million. The first tranche of $20.0 million was made available to us, and drawn, on the closing date of the Credit Agreement. On September 28, 2017, we and MidCap Financial Trust entered into a second amendment to the Credit Agreement in order to accommodate the sale of the Hyperimmune Business under the LLC purchase agreement, and to reflect changes in the remaining business as a result of such sale.

Pursuant to the second amendment, the agent and the lenders consented to the LLC purchase agreement and the consummation of the sale transaction, released the agent's liens on the assets transferred to one of our subsidiaries prior to the sale, and agreed that no prepayment of the term loans under the credit agreement would be required as a result the sale. As part of the second amendment, the agent and the lenders agreed that: (i) the commitments of the lenders to make the remaining $15.0 million tranche of loans under the credit agreement were terminated, (ii) the covenant levels set forth in the minimum net commercial product revenue covenant were revised, (iii) a new covenant requiring us to maintain a minimum $10.0 million unrestricted cash balance, and (iv) the date on which the term loans begin to amortize would be extended to February 1, 2019 if we achieved net commercial product revenues of $16.0 million for the twelve month period ending June 30, 2018 and maintain such level of net commercial product revenues for each quarter prior to February 1, 2019 thereafter. As we achieved net commercial product revenues of $16.2 million for the twelve month period ending June 30, 2018, our principal repayments were deferred to February 1, 2019.

On February 23, 2018, we entered into a third amendment with the agent and lenders to amend certain provisions of the Credit Agreement in order to permit us to maintain a cash collateral account as security for our reimbursement obligations, in respect of certain letters of credit to be issued for our account.

On August 6, 2018, we entered into an Amended and Restated Credit and Security Agreement, or the Amended Credit Agreement, amending the terms of our original $20 million term loan agreement with MidCap. Under the Amended Credit Agreement, the timeline for us to begin making principal repayments has been extended to February 1, 2020, with an opportunity for further deferral through August 1, 2020. The amount of restricted cash that we are required to maintain on our balance sheet has been reduced from $10.0 million to $5.0 million. On December 14, 2018, we entered into an amendment to the Amended Credit Agreement to amend certain provisions as related to our Equity Distribution Agreement.

In January 2019, our unrestricted cash level fell below $25.0 million which triggered the effectiveness of a security agreement in favor of MidCap with respect to our registered intellectual property to secure our obligations under the Amended Credit Agreement.

This amendment is subject to a subjective acceleration clause, although we believe the likelihood of an acceleration of the due date for this obligation is remote.

The obligations under the Amended Credit Agreement will mature on February 1, 2023. Amounts drawn under the Amended Credit Agreement continue to accrue interest at a rate of LIBOR plus 7.60% per annum

Equity Distribution Agreement

On November 9, 2017, we entered into an Equity Distribution Agreement with Piper Jaffray. The Equity Distribution Agreement provides that, upon the terms and subject to the conditions set forth therein, we may issue and sell through Piper Jaffray, acting as sales agent, shares of our common stock having an aggregate offering price of up to $17.5 million. We have no obligation to sell any such shares under the Equity Distribution Agreement. The sale of the shares of our common stock by Piper Jaffray will be effected pursuant to a Registration Statement on Form S-3 which we filed on November 9, 2017. We have issued 13,265 shares under the Equity Distribution Agreement as of March 31, 2019.

The Equity Distribution Agreement will terminate upon the issuance and sale of all shares under the Equity Distribution Agreement or upon the earlier termination thereof at any time by us or Piper Jaffray upon notice to the other party.

Purchase Agreement

On December 20, 2018 we entered into the Purchase Agreement, and a registration rights agreement, with Lincoln Park, pursuant to this agreement Lincoln Park has committed to purchase up to $35.0 million worth of our common stock over a 36-month period commencing on February 13, 2019, the date the registration statement covering the resale of the shares was deemed effective by the SEC. Pursuant to this purchase agreement we issued 105,467 commitment shares of common stock in December 2018, and 195,867 commitment shares of common stock in the first quarter of 2019.

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase shares of our common stock provided that Lincoln Park's maximum commitment on any single day not exceed $2.0 million. The purchase price per share will be based off of prevailing market prices of our common stock immediately preceding the time of sale. In addition, we may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of our common stock exceeds certain threshold prices as set forth in the Purchase Agreement.

Actual sales of shares of our common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors as determined by us from time to time, including, among others, market conditions, the trading price of our common stock and additional determinations as to the appropriate sources of funding for our operations. Lincoln Park has no right to require any sales but is obligated to make purchases as we direct in accordance with the Purchase Agreement.

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 IXINITY product sales;
- the collection of accounts receivable from customers;
- the extent to which we invest in products or technologies;
- capital improvements to new or existing facilities;
- the payment obligations under any future indebtedness;
- the scope, progress, results and costs of our development activities; and
- the costs of commercialization activities, including product marketing, sales and distribution.

We expect our cash and cash equivalents will support our operations for the next twelve months, at least, based on current operating plans and financial forecasts. If we are unable to obtain additional financing when needed, we may have to delay, reduce the scope of, suspend or eliminate one or more of our research and development programs. If we obtain regulatory approval for one of our development stage product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution, to the extent that such costs are not paid by collaborators. We do not have sufficient cash to complete the clinical development of any of our development stage product candidates and will require additional funding in order to complete the development activities required for regulatory approval of such product candidates. We expect to continue to incur negative cash flows until other sources of revenue such as corporate partnering generates sufficient cash inflows to finance our operations and debt service requirements, or IXINITY revenue and profitability grows significantly. Until we are cash flow positive, we anticipate we will need to continue to raise operating funds through the issuance of public or private equity securities, incurring additional debt or pursuing additional partnerships.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2019 and 2018:

	For the March 31,	
(in thousands)	**2019**	**2018**
Net cash (used in) provided by:		
Operating activities	$ (13,844)	$ (16,978)
Investing activities	(153)	23,512
Financing activities	20,373	(556)
Increase in cash, cash equivalents, and restricted cash	$ 6,376	$ 5,978

Net cash used in operating activities of $13.8 million for the three months ended March 31, 2019 was primarily due to our net loss of $12.0 million and changes in working capital accounts. Net cash used in operating activities of $17.0 million for the three months ended March 31, 2018 was primarily due to our net loss of $13.9 million, and changes in working capital accounts.

Net cash used in investing activities for the three months ended March 31, 2019, was due to the purchase of property and equipment. For the three months ended March 31, 2018, the largest components of the cash provided by investing activities were $25.9 million in maturity and redemption of investments, offset by $2.0 million in purchases of corporate bonds and U.S. government debt securities.

Net cash provided by financing activities for the three months ended March 31, 2019 is primarily due to $20.2 million received from the issuance of common stock and purchase of warrants exercised. Net cash used in financing activities for the three months ended March 31, 2018 was primarily due to the payment of tax liability associated with restricted stock units that vested in the quarter.

Contractual Obligations

Since our Annual Report on Form 10-K for the year ended December 31, 2018 that was filed with the SEC on March 18, 2019, we have entered into an amendment to our building lease. See note 6 – Leases for our future contractual obligations as of March 31, 2019.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of March 31, 2019, there was no material changes to the information provided under Item 7A, Quantitative and Qualitative Disclosures About Market Risk in our Annual Report filed on Form 10-K for the year ended December 31, 2018 and filed on March 18, 2019.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of March 31, 2019, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a- 15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2019, the design and operation of our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

You should carefully consider the following risks and other information in this quarterly report on Form 10-Q in evaluating us and our common stock. Any of the following risks could materially and adversely affect our results of operations, financial condition or financial prospects.

RISKS RELATED TO OUR BUSINESS

Financial Risks

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

For the three months ended March 31, 2019, we had a net loss of $12.0 million. Except for the third quarter of 2017 and year ended December 31, 2017, we have experienced net losses in all other periods since our spin-off from Emergent. The net income for the third quarter of 2017 and year ended December 31, 2017 were the result of our receipt of proceeds from the sale of our Hyperimmune Business in September 2017. As of March 31, 2019, we had an accumulated deficit of $139.4 million. Although we expect our existing cash and cash equivalents will be sufficient to fund our operations for at least twelve months from the date of this filing, if we cannot achieve profitability or generate positive cash from operating activities, our business operations may be adversely impacted and the trading value of our common stock may decline.

We will require additional capital and may be unable to raise capital when needed or on acceptable terms.

As of March 31, 2019, we had cash, cash equivalents, and restricted cash in the amount of $44.5 million. If we are not able to secure adequate additional funding, we plan to make reductions in spending. This may include extending payment terms with suppliers, liquidating assets, and suspending or curtailing planned programs. We may also have to delay, reduce the scope of, suspend or eliminate one or more research and development programs. A failure to raise the additional funding or to effectively implement cost reductions could harm our business, results of operations and future prospects. We will require additional funding to grow our business including to develop additional products, support commercial marketing activities or otherwise provide additional financial flexibility. Our future capital requirements will depend on many factors, including:

- the level, timing and cost of IXINITY sales;
- the collection of accounts receivable from customers;
- the ability to comply with the continued listing requirements of the Nasdaq Capital Market and the risk that our common shares will be delisted if we cannot do so;
- the extent to which we invest in products or technologies;
- the ability to satisfy the payment obligations and covenants under our credit facility or any future indebtedness;
- the ability to secure partnerships and/or collaborations that generate additional cash;
- capital improvements to our facilities;
- the scope, progress, results and costs of our development activities;
- the costs of commercialization activities, including product marketing, sales and distribution; and
- the ability to collect the milestone payments totaling up to $7.5 million related to the achievement of certain gross profit milestones and up to $2.0 million related to collection of certain accounts receivable from Saol.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through bank loans, public or private equity or debt offerings, a sale of commercial assets, collaboration and licensing arrangements or other strategic transactions. Future issuances of common stock may include (i) any sale of up to $17.5 million worth of shares of our common stock pursuant to our Equity Distribution Agreement with Piper Jaffray & Co entered into in November 2017 and (ii) any sale of up to $35.0 million worth of shares of our common stock in a private placement pursuant to our Purchase Agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park, entered into in December 2018. Public or bank debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds by issuing equity securities, our stockholders will experience dilution. If we raise funds through collaboration and licensing arrangements with third parties or enter into other strategic transactions, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Current economic conditions may make it difficult to obtain additional financing on attractive terms, or at all. If financing is unavailable or lost, our business, results of operations, financial condition and financial prospects would be adversely affected and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

We currently rely on only one revenue-generating product, IXINITY.

We currently have only one revenue-generating product, IXINITY. The commercial success of IXINITY depends upon:

- the acceptance by regulators, physicians, patients and other key decision-makers of IXINITY as a safe, therapeutic and cost-effective option;
- our ability to further develop IXINITY and obtain marketing approval for its use in additional patient populations and the clinical data we generate to support expansion of the product label;
- the ability of AGC Biologics and our third-party service providers to provide us with sufficient saleable quantities of IXINITY;
- 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 IXINITY;
- to what extent and in what amount government and third-party payors cover or reimburse for the costs of IXINITY; and
- our success and the success of our third-party distributors in selling and marketing IXINITY.

The failure to maximize the financial contribution of IXINITY 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 IXINITY, 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 IXINITY, the dosing requirements of treated patients and other factors. If sales of IXINITY were to decline, we could be required to make an allowance for excess or obsolete inventory, increase our provision for product returns, or we could incur other costs related to operating our business, each of which could negatively impact our results of operations and our financial condition. We are constantly evaluating commercial and strategic transactions to generate revenue that include any current collaborations and collaborations or a sale of assets in the future.

Our operating results are unpredictable and may fluctuate.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year, and IXINITY revenue figures will likely fluctuate from month to month. IXINITY sales are difficult to predict from period to period and as a result, you should not rely on IXINITY sales results in any period as being indicative of future performance, and sales of IXINITY may be below the expectations of management, securities analysts or investors in the future. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the level and timing of commercial sales of IXINITY as well as our product candidates, if and when such candidates are approved or commercialized;
- the extent of coverage and reimbursement for IXINITY and the amount of IXINITY chargebacks, rebates and product returns;
- the extent of any payments received from collaboration arrangements and development funding as well as the achievement of development and clinical milestones under collaboration and license agreements that we may enter into from time to time and that may vary significantly from quarter to quarter; and
- the timing, cost and level of investment in our research and development activities as well as expenditures we will or may incur to acquire or develop additional technologies, products and product candidates.

In addition, the number of indications in which IXINITY or any of our product candidates, if commercialized, would be used may be significantly less than the total number of such indications or total possible market size. These and other factors, including our limited history of product sales, may make it difficult for us to forecast and provide accurate guidance (including updates to prior guidance) related to our expected financial performance. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

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

In August 2016, we entered into a 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 was amended and restated in August 2018. The terms of the Credit Agreement and borrowings we may make under the Credit Agreement in the future, could have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on borrowings under the Credit Agreement if market rates of interest increase;
- not complying with restrictive covenants restricting, among other things, indebtedness, liens, dividends and other distributions, repayment of subordinated indebtedness, mergers, dispositions, investments (including licensing), acquisitions, transactions with affiliates and modification of organizational documents or certain other agreements;
- not complying with affirmative covenants including payment, reporting and revenue covenants; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

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

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 IXINITY or any other product candidates 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 IXINITY or our 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 IXINITY or any product candidates we successfully develop, 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 IXINITY could materially adversely affect our business by rendering us unable to sell IXINITY 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 IXINITY, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, the European Medicines Agency, or EMA, or the competent authorities of the EU Member States. Such investigations could also potentially lead to a recall of IXINITY 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.

Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. If we are unable to retain the services of one or more of the principal members of senior management, including our Chief Executive Officer, Marvin L. White, our Chief Financial Officer, Jeffrey G. Lamothe, and our Chief Medical Officer, Scott C. Stromatt, or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biotechnology and pharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package or otherwise attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

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

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

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the President of the United States signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2018, we had approximately $20.3 million and $2.3 million of federal and state net operating loss carryforwards, respectively, available to reduce future taxable income that will begin to expire in 2028 for federal purposes and 2018 for state tax purposes. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provision of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not assessed whether such an ownership change has previously occurred, including as a result of our recent public offering of common stock and warrants. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change has occurred or occurs in the future and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Product Development Risks

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.

Undesirable side effects, 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;
- regulatory authorities may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, Field Safety Corrective Actions or equivalent, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under GCPs and similar regulations outside of the United States. Our failure, or the failure of our product manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would increase our development costs and delay or impact the likelihood of regulatory approval.

If third parties do not carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

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.

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 our 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. For example, in 2018, we announced the discontinuation of development of APVO414 and otlertuzumab as a result of clinical trial results. Failure to successfully discover and/or develop, obtain marketing approval for and commercialize additional products and product candidates would likely have a material adverse effect on our ability to grow revenues and improve our financial condition.

We may not be successful in our efforts to use and further develop our ADAPTIR platform.

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

We face substantial competition.

The development and commercialization of new biotechnology products is highly competitive and subject to rapid technological advances. We may face future competition with respect to IXINITY, 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 FDA, or equivalent foreign regulatory bodies more rapidly than we may obtain approval for our product candidates. Our competitors may devote greater resources to market or sell their products, research and development capabilities, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully, or more effectively negotiate third-party licensing and collaborative arrangements.

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

In addition, many of our competitors are able to deploy more personnel to market and sell their products than we do. We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other biotechnology companies with marketed products similar to IXINITY. Each of our sales representatives is responsible for a territory of significant size. The continued growth of IXINITY 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 IXINITY. IXINITY and our product candidates may also compete in the future with new products currently under development by others or biosimilar products. 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.

IXINITY or any of our product candidates, if approved, may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The success of IXINITY and our product candidates, if approved, 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 IXINITY or any of our product candidates 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.

In the United States and internationally, sales of IXINITY and our ability to generate revenues on such sales are dependent, in significant part, on the availability of coverage and level of reimbursement from third-party payors, including government payors, such as Medicare and Medicaid, 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 adequate reimbursement for IXINITY 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 IXINITY 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 IXINITY that are reimbursed by such entities. Various provisions of the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act), or ACA, increased the levels of rebates and discounts that we have to provide in connection with sales of IXINITY that are paid for, or reimbursed by, certain state and federal government agencies and programs. It is possible that future legislation and regulatory changes in the United States and other jurisdictions could be enacted, which could potentially impact the reimbursement rates for IXINITY and also could further impact the levels of discounts and rebates we are required to pay to state and federal government entities.

Our future revenues will depend on the availability outside the United States of adequate coverage, pricing and reimbursement from third-party payors for IXINITY, if we pursue registration and sale of IXINITY outside of the United States, and future drug products, if any.

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

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

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

Healthcare legislature reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to legal and political challenges, as well as efforts by the Trump Administration to repeal or replace certain aspects of the ACA. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties as of January 1, 2019 for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts & Jobs Act. While the Texas U.S. District Court Judge, as well as the current U.S. Presidential administration and the Centers for Medicare and Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. We continue to evaluate how the ACA and recent efforts to repeal and replace or limit the implementation of the ACA will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2 percent per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken.

Additionally, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers and accordingly, our financial operations.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for IXINITY or any product candidates we successfully develop or additional pricing pressures.

If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations and our distributors our financial condition could be adversely affected.

Our ability to sell IXINITY to hospitals and clinics in the United States depends in part on our relationships with group purchasing organizations, or GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors. These negotiated prices are then made available to a GPOs affiliated hospitals and clinics and other members. If we are not one of the providers selected by a GPO, affiliated hospitals, clinics and other members may be less likely to purchase IXINITY, 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.

Additionally, we rely on the sales and marketing strength of these distributors and the distribution channels through which they operate for a portion of our revenues. If third parties do not successfully carry out their contractual duties, or if there is a delay or interruption in the distribution of our products, it could negatively impact our revenues from product sales.

The loss of any of our sole source manufacturers, or delays or problems in the manufacture of IXINITY ***or our product candidates, could result in product shortages and loss in revenue or delays in clinical development.***

We do not have manufacturing capabilities and do not plan to develop such capacity in the foreseeable future. We depend on a limited number of sole source third-party suppliers, including AGC Biologics, for our products and product candidates. Accordingly, our ability to develop and deliver products in a timely and competitive manner depends on our third-party manufacturers being able to continue to meet our ongoing commercial and clinical trial needs and perform their contractual obligations. Increases in the prices we pay our suppliers, interruptions in the supply of raw materials or IXINITY or lapses in quality could adversely impact our margins, profitability, cash flows and prospects.

If, for any reason, AGC, sole manufacturer of bulk drug substance for our IXINITY product, does not continue to supply us with IXINITY in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fails or refuses to comply with its obligations to us under our manufacturing arrangement, we may not have adequate remedies for any breach of contract, and its failure to supply us could result in a shortage of IXINITY, which could lead to lost revenue and otherwise adversely affect our business, financial condition, results of operations and growth prospects. In addition, if AGC 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 IXINITY. Because of contractual restraints and the lead-time necessary to obtain FDA approval of a new manufacturer, replacement of any of AGC may be expensive and time consuming and may cause interruptions in our supply of IXINITY to our customers or an inability to manufacture.

For example, during 2015, we ordered nine manufacturing lots of bulk drug substance from AGC and only one of those lots was successfully manufactured and released in 2015. During 2016, we ordered five manufacturing lots of bulk drug substance from AGC and none of these lots satisfied product release specifications.

Manufacturer of our products and product candidates, especially in large quantities, is complex and time consuming.

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

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

We rely on third parties to manufacture all clinical trial materials for our product candidates, and we will rely on third parties to manufacture commercial supplies, if any such product candidates are ultimately approved for commercial sale. Our product candidates, including APVO210, APVO436, and ALG.APV-527 will not be approved for marketing by the FDA or other foreign regulatory authorities unless the FDA or their foreign equivalents also approve the facilities used by our third-party manufacturers to produce them for commercialization. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, the FDA or their foreign counterparts will not approve their manufacturing facilities, which would result in significant delays in obtaining FDA or foreign marketing approvals for our product candidates. In order to successfully develop and commercialize our product candidates in a timely manner, we and our third-party manufacturers must be able to develop and execute on manufacturing processes and reach agreement on contract terms.

We and our third-party manufacturers may not be able to meet these manufacturing process requirements for any of our current product candidates, all of which have complex manufacturing processes, which make meeting these requirements even more challenging. If we are unable to develop manufacturing processes for our clinical product candidates that satisfy these requirements, we will not be able to supply sufficient quantities of test material to conduct our clinical trials in a timely or cost effective manner, and as a result, our development programs will be delayed, our financial performance will be adversely impacted and we will be unable to meet our long-term goals.

Development and commercialization of IXINITY and our product candidates may be terminated or delayed.

Our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage or conduct our clinical trials, manufacture IXINITY and our product candidates and market and sell our products outside of the United States and maintaining our existing arrangements with respect to the commercialization or manufacture of our products. We may not have the expertise or the resources to conduct all of these activities for all products and product candidates on our own and, as a result, are particularly dependent on third parties in many areas. Any current or future arrangements for development and commercialization may not be successful, as the amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products candidates are not within our control. If we are not able to establish or maintain agreements relating to IXINITY and our product candidates in development, our results of operations would be materially and adversely affected.

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

We currently have limited operations outside of the United States. However, we have manufacturing, collaboration, clinical trial and other relationships outside the United States, and 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 our product sales in foreign markets, particularly in Europe. Our foreign operations subject us to additional risks and uncertainties, particularly because we have limited experience in marketing, servicing and distributing our products or otherwise operating our business outside of the United States and Canada. These risks and uncertainties include: political and economic determinations that adversely impact pricing or reimbursement policies; our customers' ability to obtain reimbursement for procedures using our products in foreign markets; export licensing requirements, political and economic instability, trade restrictions, and changes in tariffs and difficulties in staffing and managing foreign operations; cross border restrictions on the movement of cash funds and repatriation of earnings; foreign currency fluctuations; longer accounts receivable collection times; reduced protection of intellectual property rights in some foreign countries; the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute; and compliance with foreign or U.S. laws, rules and regulations, including data privacy requirements, labor relations laws, tax laws, anti-competition regulations, anti-bribery/anti-corruption laws, including but not limited to the U.S. Foreign Corrupt Practices Act, or FCPA, and the U.K. Bribery Act of 2010, which could subject us to investigation or prosecution under such U.S. or foreign laws.

Regulatory and Compliance Risks

Our long-term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize our product candidates.

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

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

In the United States, to obtain approval from the FDA to market any of our future biologic products, we will be required to submit a biologics license application, or BLA, to the FDA. Ordinarily, the FDA requires a sponsor to support a BLA with substantial evidence of the product's safety, purity and potency in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase 3 safety and efficacy trials conducted in patients with the disease or condition being targeted.

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. For example, in December 2015, after a review of data from the Phase 1 dose escalation study of APVO414 in prostate cancer patients, we concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of APVO414 developed ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug that could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active APVO414 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. The protocol was amended to continuous intravenous infusion which delayed the development of ADA compared to the weekly IV infusion. However, with longer dosing, ADA developed that cleared the drug from the blood in some patients. We elected to discontinue the development of APVO414 and are no longer enrolling patients into the Phase 1 clinical study, although we will continue to monitor the patients remaining on the therapy.

In addition, in 2018 we commenced a pilot Phase 2 clinical trial of otlertuzumab in combination with bendamustine in peripheral T cell lymphoma (PTCL). Otlertuzumab is a first-generation monospecific antibody targeting CD37. Reports in the literature showed that CD37 appeared to be overexpressed in various T-cell lymphomas, suggesting a potential role for otlertuzumab in the treatment of T-cell malignancies. One patient showed a complete response, there was some evidence of tumor regression (43% in primary tumor) in a second patient, and there has been no evidence of an early response in the remaining patients. Preliminary immunohistochemistry analysis has revealed that the number of patients with tumors expressing CD37, and the degree of CD37 expression within the tumors, is much lower than that found on panels of PTCL patient samples that were tested prior to the initiation of the pilot study. At this time, we have elected to discontinue the otlertuzumab development program and to close the study to further enrollment, although we will continue to monitor patients remaining on therapy and to explore options to partner or sell this asset.

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 FDAs 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 IXINITY or any of our future product candidates if approved.

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

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote the products is limited to those indications and patient populations 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 FDAs regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines, which could result in the disgorgement of money, operating restrictions, injunctions or civil or criminal enforcement, any of which could harm our business.

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

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

Any drug or biologic for which we receive FDA approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, 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 REMS after a product has been approved. Facilities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other laws. The FDA also closely monitors advertising and promotional materials we may disseminate for our products for compliance with restrictions on off-label promotion and other laws. We may not promote our products for conditions of use that are not included in the approved package inserts for our products. Certain additional restrictions on advertising and promotion exist for products that have so-called boxed warnings in their approved package inserts.

Failure by AGC 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.

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 foreign, federal, state and local 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, state, local and foreign healthcare laws and regulations pertaining to fraud and abuse and patients' rights are 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 makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, to induce, or in return for, either the referral of an individual, or the purchase, lease, prescribing or recommendation of an item, good, facility or service reimbursable by a federally funded healthcare program, such as the Medicare or Medicaid program. The term "remuneration" has been interpreted broadly and may constrain our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities, among other activities;
- federal civil and criminal false claims, including the federal False Claims Act, and false statement laws and civil monetary penalty laws, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, on individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent or knowingly making any materially false statement in connection with the delivery or payment for healthcare benefits, items or services;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, and their respective implementing regulations mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy, security and transmission of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates", or independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, biologics, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the CMS, certain payments and transfers of value made to physicians and teaching hospitals, and ownership or investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; 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; state and foreign 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; state, local and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, obtain pharmaceutical agent licensure, and/or otherwise restrict payments that may be made to healthcare providers and entities; and state, local and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or entities, or marketing expenditures.

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 ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal health care fraud statutes, so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA 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 Act.

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, interactions with specialty pharmacies, and patient assistance programs may also violate fraud and abuse 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.

In addition, certain state and local laws mandate that we comply with a state code of conduct, adopt a company code of conduct under state criteria, disclose marketing payments made to health care professionals and entities, disclose drug pricing information 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, state, local and foreign privacy, security, fraud and transparency 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 sanctions, including civil and administrative penalties, criminal fines, damages, disgorgement, exclusion from participation in U.S. federal or state health care programs, individual imprisonment, integrity obligations, 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 ACA and CMS, issuance of final regulations implementing those changes also has affected and could further affect our 340B "ceiling price" calculations. Because we participate in the Medicaid rebate program, we are required to report "average sales price," or ASP, information to CMS for certain categories of drugs that are paid for under Part B of the Medicare program, including IXINITY. 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 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 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 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 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 wholesale 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 $184,767 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.

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.

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, European Union, or EU, member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the EU is now governed under the EU General Data Protection Regulation, or the GDPR, effective in May 2018. The GDPR, which is wide-ranging in scope, imposed several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. The GDPR increases our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. However, despite our ongoing efforts to bring our practices into compliance with the GDPR, we may not be successful either due to various factors within our control, such as limited financial or human resources, or other factors outside our control. It is also possible that local data protection authorities may have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures, or measures relating to privacy, data security, marketing, or communications) by us to comply with laws, regulations, policies, legal or contractual obligations, industry standards, or regulatory guidance relating to privacy or data security, may result in governmental investigations and enforcement actions, litigation, fines and penalties or adverse publicity. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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, that are meaningful to our products, 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 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. Further, patents may lapse prior to the regulatory approval of the underlying product in one or more territories. 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 (PTAB) of the US Patent and Trademark Office (USPTO), or the Opposition Division of the European Patent Office (EPO). 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 and Opposition Division of the EPO, 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 USPTO, 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. Patent and intellectual property laws outside of the United States may also change and be uncertain.

Patent and other intellectual property laws outside the United States are even more uncertain than in the United States and are continually undergoing review and revisions in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, certain countries do not grant patent claims that are directed to business methods and processes. In addition, we may have to participate in additional opposition proceedings, like the proceedings described above, to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts.

Additionally, in January 2019, our unrestricted cash level fell below $25.0 million which triggered the effectiveness of a security agreement in favor of MidCap with respect to our registered intellectual property to secure our obligations under the Amended Credit Agreement. MidCap now holds a security interest in our registered intellectual property and may take ownership of such intellectual property if we do not satisfy our obligations under the Amended Credit Agreement.

Our collaborative partners and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend intellectual property rights in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties.

Our patents, once obtained, also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to market and sell our products, and therefore our business, financial condition and operating results, could be materially and adversely affected.

If the outcome of a patent opposition proceeding currently pending in Europe relating to IXINITY is unsuccessful, we may need to identify an additional fill/finish manufacturer, which could result in significant production delays and additional costs associated with moving our fill/finish manufacturing activities and identifying another fill/finish manufacturer.

A European Patent Opposition is a European Patent Office proceeding that allows for an opponent to challenge the validity of an issued patent. A European Patent Opposition is a proceeding that determines only the validity of a patent and does not determine whether a party infringes a patent. To initiate an Opposition at the European Patent Office, an opponent files a notice that it wishes to oppose the patent within a nine-month period following the publication of the patent grant. After the opponent files the notice, it may be a few years before the merits of the opposition are heard and decided by the European Patent Office Opposition Division and

several more years before the Boards of Appeal hears and decides on any appeals. We are currently opposing a European patent owned by Baxalta Incorporated, which relates to factor IX proteins such as IXINITY. Depending on the final outcome of the currently pending opposition proceeding, we may be unable to continue to conduct our current IXINITY fill/finish manufacturing activities. We were previously involved in five similar opposition proceedings in Europe relating to factor IX proteins in which Baxter International Inc., former parent of Baxalta, or Baxalta was the patentee or opposing party. None of the previous five oppositions are still pending, and all came to a conclusion in a manner favorable to Aptevo.

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 this proceeding, we are required to identify an additional fill/finish manufacturer in another location, we would not be able to do so without significant delay and likely significant additional cost.

In addition, depending on the final outcome of this proceeding, we may be unable to sell factor IX products in Europe relating to the subject matter claimed in the European patent we are opposing.

Although we do not have current marketing authorization for IXINITY in Europe, nor do we sell IXINITY in Europe, if we are unsuccessful in opposing Baxalta's European patent, 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.

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

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

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

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other adversarial proceedings such as proceedings before the PTAB and opposition proceedings in the European Patent Office, regarding intellectual property rights that could impact 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 THERAPEUTICS, APTEVO BIOTHERAPEUTICS and APTEVO RESEARCH AND DEVELOPMENT trademarks. We refer to these trademarks as our house marks. If a third party opposes any of these house marks and we are unable to reach settlement prior to the commencement of an opposition proceeding, we may incur significant expense in the course of participating in the opposition process, which can be expensive and lengthy. Any settlement with a third party may result in our agreeing to be subject to restrictions on our use of the relevant house mark. In addition, if we are unsuccessful in an opposition against a house mark, we would lose the ability to obtain trademark registration for one or more uses of the relevant mark both in the United States and in other territories which could have a material and adverse effect on our business.

The Bristol Myers Squibb Company, or BMS, previously opposed several of our house marks in and outside the United States. We entered into a settlement and co-existence agreement with BMS and its licensee, Ono Pharmaceutical Co., Ltd on July 5, 2017. BMS subsequently withdrew oppositions of our house marks. The settlement and co-existence agreement places restrictions on how we can use our house marks and how we can seek trademark protection for our house marks.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

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

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.

If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records, capture laboratory data, maintain clinical trial data and corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events including but not limited to natural disaster. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could delay or negatively impact our sales of IXINITY or the development and commercialization of our product candidates, which could adversely impact our business. If operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe. In addition, our information technology systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive or personal 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, patients in our clinical trials, customers and others, any of which could have a material adverse effect on our business, financial condition and results of operations. Moreover, a security breach or privacy violation that leads to destruction, loss, alteration, unauthorized use or access, disclosure or modification of, personally identifiable information or personal data, could harm our reputation, compel us to comply with federal, state and/or international breach notification laws, subject us to mandatory corrective or regulatory action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, including the GDPR, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, a data security breach could result in loss of clinical trial data or damage to the integrity of that data. If we are unable to implement and maintain adequate organizational and technical measures to prevent such security breaches or privacy violations, or to respond adequately in the event of a breach, our operations could be disrupted, and we may suffer loss of reputation, problems with regulatory authorities, financial loss and other negative consequences. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Risk 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 we plan to evaluate the merits of entering into collaboration arrangements with third parties, including leading biotechnology companies or non-governmental organizations. In July 2017, we entered into a collaboration agreement with Alligator Bioscience AB, or Alligator, pursuant to which Aptevo R&D and Alligator will collaboratively develop ALG.APV-527, a lead bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a costimulatory receptor found on activated T-cells, and 5T4, a tumor antigen widely overexpressed in a number of different types of cancer. We expect to selectively pursue collaboration arrangements with third parties that have particular technology, expertise or resources for the development or commercialization of our product candidates or for accessing particular markets. We face, and will continue to face, significant competition in seeking appropriate partners for our product candidates. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on a timely basis, on acceptable terms or at all, or if the arrangements we establish are unproductive for us, we may fail to meet our business objectives for the particular product candidate. Our ability to enter into such arrangements with respect to products in development that are subject to licenses may be limited by the terms of those licenses.

Our collaboration agreement with Alligator, or any collaboration agreement we may consider entering into, may not be successful and the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborative partners. It is likely that our collaborative partners will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

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

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

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

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

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

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

In connection with our separation from Emergent, we and Emergent agreed to indemnify the other party for certain liabilities. The Emergent indemnity may not be sufficient to hold us harmless from the full amount of liabilities for which Emergent will be allocated responsibility, and Emergent may not be able to satisfy its indemnification obligations in the future.

Pursuant to the separation agreement and certain other agreements with Emergent, Emergent has agreed to indemnify us for certain liabilities, and we agreed to indemnify Emergent for certain liabilities. Indemnities that we may be required to provide Emergent are not subject to any cap, may be significant and could negatively impact our business, particularly indemnities relating to our actions that could impact the tax-free nature of the distribution. Third parties could also seek to hold us responsible for any of the liabilities that Emergent has agreed to retain. Any amounts we are required to pay pursuant to these indemnification obligations and other liabilities could require us to divert cash that would otherwise have been used in furtherance of our operating business. Further, the indemnity from Emergent may not be sufficient to protect us against the full amount of such liabilities, and Emergent may not be able to fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from Emergent any amounts for which we are held liable, we may be temporarily required to bear these losses ourselves. Each of these risks could negatively affect our business, results of operations and financial condition.

Risks Related to Our Common Stock

Our stock price may be volatile.

Our stock price has fluctuated in the past and is likely to be volatile in the future. Since August 1, 2016, the reported closing price of our common stock has fluctuated between $0.82 and $5.94 per share. The stock market in general, and the market for biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a number of factors, some of which may be beyond our control or unrelated to our operations, including, among others:

- changes in earnings estimated by securities analysts or management, or our ability to meet those estimates;
- investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance;
- the success of competitive products or technologies;
- the timing, expenses and results of clinical and non-clinical trials of our product candidates;
- announcements regarding clinical trial results and product introductions by us or our competitors;
- announcements of acquisitions, collaborations, financings or other transactions by us or our competitors;
- 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 trials or news of any developments related to our product pipeline may cause significant volatility in our stock price.

The announcement of data from clinical trials by us or our collaborative partners or news of any developments related to our key pipeline product candidates 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 product candidates, 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 trials will support a filing for regulatory approval or even if approved, that any of our key pipeline products will become commercially successful.

Our common stock may be at risk for delisting from the Nasdaq Global Market in the future. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is currently listed on the Nasdaq Global Market. The Nasdaq Stock Market LLC has minimum requirements that a company must meet in order to remain listed on Nasdaq, including a requirement that we maintain a minimum closing bid price of $1.00 per share. On April 18, 2019, we received a letter from the listing qualifications department staff of Nasdaq notifying us that for the last 30 consecutive business days the bid price of our common stock had closed below $1.00 per share.

In accordance with Nasdaq listing rules, we have 180 calendar days, or until October 15, 2019, to regain compliance with the minimum bid price rule. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of ten consecutive business days before October 15, 2019.

If our common stock does not achieve compliance by October 15, 2019, we may be eligible for an additional 180-day period to regain compliance if we submit, prior to October 15, 2019, a transfer application to transfer our listing of shares to the Nasdaq Capital Market. We will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards of the Nasdaq Capital Market, with the exception of the bid price requirement, and must provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, Nasdaq could provide notice that our common stock will become subject to delisting. In the event we receive notice that our common stock is being delisted, Nasdaq rules permit us to appeal any delisting determination by the Nasdaq staff to a hearings panel.

We intend to actively monitor the closing bid price of our common stock between now and October 15, 2019 and will evaluate available options to resolve the deficiency and regain compliance with the minimum bid price rule. However, if our common stock were to be delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease.

In addition, if delisted, we would no longer be subject to Nasdaq rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards. Our failure to be listed on Nasdaq or another established securities market would have a material adverse effect on the value of your investment in us.

If our common stock is not listed on Nasdaq or another national exchange, the trading price of our common stock is below $5.00 per share and we have net tangible assets of $6,000,000 or less, the open-market trading of our common stock will be subject to the “penny stock” rules promulgated under the Securities Exchange Act of 1934, as amended. If our shares become subject to the “penny stock” rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser’s written agreement to the transaction prior to sale;
- provide the purchaser with risk disclosure documents which identify certain risks associated with investing in “penny stocks” and which describe the market for these “penny stocks” as well as a purchaser’s legal remedies; and
- Obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a “penny stock” can be completed.

As a result of these requirements, the market price of our securities may be adversely impacted, and current stockholders may find it more difficult to sell our securities.

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

In the future, your percentage ownership in Aptevo may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards to our directors, officers and employees. Our employees have options to purchase shares of our common stock and from time to time, we expect to issue additional options, restricted stock units, or other stock-based awards to our employees under our employee benefits plans.

Future issuances of common stock may include (i) any sale of up to $17.5 million worth of shares of our common stock pursuant to our Equity Distribution Agreement with Piper Jaffray & Co entered into in November 2017, (ii) any sale of up to $35.0 million worth of shares of our common stock in a private placement pursuant to our Purchase Agreement with Lincoln Park, entered into in December 2018 and (iii) the issuance of up to 22,000,000 share of common stock upon the exercise of warrants issued in connection with our March 2019 public offering of common stock and warrants.

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.

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.

Our by-laws include an exclusive forum provision that could limit our stockholders' ability to obtain a judicial forum viewed by stockholders as more favorable for disputes with us or our directors, officers or other employees or certain stockholders.

Our by-laws provide that the Chancery Court of the State of Delaware will be the sole and exclusive forum for certain legal proceedings, unless we consent in writing to the selection of an alternative forum. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage lawsuits against us or our directors or officers. Alternatively, if a court outside of Delaware were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings described above, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

A significant portion of our shares may be sold into the market at any time which could depress our stock price

If our stockholders sell a substantial number of shares of our common stock in the public market, our market price could decline. In connection with the transaction with Lincoln Park, we have agreed to register under the Securities Act of 1933, as amended, the resale of shares of common stock that have been and may be issued under the Purchase Agreement with Lincoln Park. Any such sales by Lincoln Park, or the perception that such sales may occur, could decrease the market price of our common stock. In addition, holders of an aggregate of approximately three million shares of our common stock have the right to require us to register these shares of common stock under 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.

Item 6. Exhibits

Exhibit Index

Exhibit Number	Description
4.1	Form of Warrant (incorporated by reference from exhibit 4.1 to Current Report on Form 8-K (File No. 001-37746) filed by Aptevo Therapeutics Inc. with the SEC on March 11, 2019).
4.2	Form of Pre-Funded Warrant (incorporated by reference from exhibit 4.2 to Current Report on Form 8-K (File No. 001-37746) filed by Aptevo Therapeutics Inc. with the SEC on March 11, 2019.
10.1	Intellectual Property Security Agreement dated February 7, 2019, by and among, Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC., Aptevo Research and Development, LLC and MidCap Financial Trust (incorporated by reference from exhibit 10.44 to Annual Report on Form 10-K (File No. 001-37746) filed by Aptevo Therapeutics Inc. with the SEC on March 18, 2019).
10.2	Eighth Amendment to Office Lease, dated as of March 19, 2019, by and between Aptevo Therapeutics Inc. and Selig Real Estate Holdings Eight L.L.C. (incorporated by reference from exhibit 10.1 to Current Report on Form 8-K (File No. 001-37746) filed by Aptevo Therapeutics Inc. with the SEC on March 22, 2019.
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 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.
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 Executive 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.

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: May 9, 2019

By: /s/ Marvin White

Marvin White
President and Chief Executive Officer

Date: May 9, 2019

By: /s/ Jeffrey G. Lamothe

Jeffrey G. Lamothe
Senior Vice President, Chief Financial Officer, and Treasurer

Exhibit 31.1

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

I, Marvin White, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aptevo Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant'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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: May 9, 2019

By: /s/ Marvin White

Marvin White
President and Chief Executive Officer

Exhibit 31.2

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

I, Jeff Lamothe, certify that:

1. I have reviewed this Quarterly Report on form 10-Q of Aptevo Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant'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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: May 9, 2019

By: /s/ Jeff Lamothe

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AND
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Aptevo Therapeutics Inc. on Form 10-Q for the period ending March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 9, 2018

By: /s/ Marvin White

Marvin White
President and Chief Executive Officer

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aptevo Therapeutics Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form-K), irrespective of any general incorporation language contained in such filing."

Exhibit 32.2

CERTIFICATION PURSUANT TO
RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AND
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Aptevo Inc. on Form 10-Q for the period ending March 31, 2019 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, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 9, 2019

By: /s/ Jeff Lamothe

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

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aptevo Therapeutics Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form-K), irrespective of any general incorporation language contained in such filing."