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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

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**

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value	**The Nasdaq Stock Market LLC**

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

None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definition 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. ☒

The aggregate market value of common stock held by non-affiliates of the Registrant as of June 30, 2018, the last business day of the Registrant's most recently completed second fiscal quarter, was $90.1 million, based upon the closing price of the Registrant's common stock on the Nasdaq Stock Market LLC on June 29, 2018, the last trading day of the fiscal quarter.

Excludes an aggregate of 4,606,417 shares of the Registrant's common stock held as of such date by officers, directors, and stockholders that the registrant has concluded are or were affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

As of March 14, 2019, the number of shares of Registrant's common stock outstanding was 42,940,219

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, relating to the Registrant's 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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In this Annual Report on Form 10-K, "we," "our," "us," "Aptevo," and the "Company" refer to Aptevo Therapeutics Inc. and, where appropriate, its consolidated subsidiaries.

PART I

Cautionary Note Regarding Forward-Looking Information

This Annual Report on Form 10-K 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 annual 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 annual report. Our forward-looking statements in this annual 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 annual report.

Item 1. Business.

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.

In August 2015, Emergent BioSolutions Inc., or Emergent, announced a plan to separate into two independent publicly traded companies, one a biotechnology company and the other a global specialty life sciences company. To accomplish this separation, Emergent created a new company, Aptevo Therapeutics Inc., or Aptevo, to be the parent company for the development-based biotechnology business focused on novel oncology, hematology, and autoimmune and inflammatory therapeutics. We were incorporated in Delaware in February 2016 as a wholly owned subsidiary of Emergent. To effect the separation, Emergent made a pro rata distribution of Aptevo's common stock to Emergent's stockholders on August 1, 2016.

We 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 designed to produce unique signaling responses that may kill tumors or modulate the immune system to kill tumors. ADAPTIR redirected T-cell cytotoxicity (RTCC) molecules have shown more potent tumor killing in *in vitro* studies compared to heterodimer formats targeting the same tumor antigen. In addition, in *in vitro* studies, ADAPTIR bispecific candidates have generated lower levels of cytokines when tumor antigen presented compared to other formats targeting the same tumor antigen, and have induced comparable T-cell cytotoxicity.

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.

STRATEGY

We seek to grow our business by, among other things:

Advancing our ADAPTIR platform, initially focusing on immunotherapy and the development of novel bispecific and multi-specific proteins for the treatment of cancer and autoimmune disease. We focus on product development using our ADAPTIR platform. We plan to generate additional bispecific protein immunotherapies for early development, potentially with other collaborative partners, to further validate the potential of the ADAPTIR platform. We intend to favor the development of bispecific candidates that have the potential to demonstrate proof of concept early in development and are differentiated in key oncology indications. We expect to continue to expand the ADAPTIR product pipeline to address areas of unmet medical need. Bispecifics and multispecific ADAPTIR proteins will be generated to target tumors using the immune system or direct cytokine delivery to selective cell populations or modulate immune cells to treat diseases. We believe these product candidates may have utility in oncology, autoimmune disease and other therapeutic areas.

Continuing to develop new products. We are committed to new product development. We have expertise in molecular biology, antibody engineering and the development of protein therapeutics, including cell line development, protein purification, process development and analytical characterization. We believe that these core areas of expertise enable the development of therapeutics based on the ADAPTIR platform technology from design, pre-clinical testing, and clinical development to preparation of a biologics license application, or BLA.

Establishing collaborative partnerships to broaden our pipeline and provide funding for research and development. We intend to continue to develop and grow our product portfolio through internal research and development as well as through collaborations with other biotechnology and pharmaceutical companies, academia and non-governmental organizations.

Supporting the future growth of our pipeline by maximizing the financial contribution of IXINITY. We intend to continue to maximize the financial contribution of IXINITY for the purpose of funding our research and development efforts. This may require further investments.

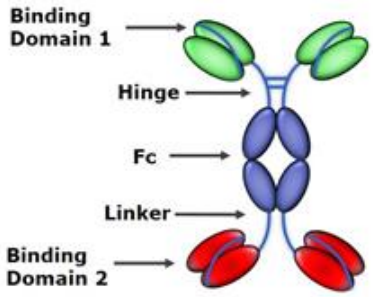
PLATFORM TECHNOLOGY AND PRODUCT CANDIDATES

Platform Technology

ADAPTIR Platform. The platform can be used to produce monospecific, bispecific and multispecific immunotherapeutic proteins that specifically bind to one or more targets and receptors found on immune cells to mediate tumor killing and improve disease response by modulating the immune cells directly or immune environment. We believe we are well positioned for the development of bispecific therapeutics, which are antibody-based molecules that are able to bind two targets of therapeutic interest, utilizing our innovative ADAPTIR (modular protein technology) platform. This allows us to take a novel approach to cancer immunotherapy.

Structurally, ADAPTIR molecules are similar to antibodies; they can exhibit the same biological functions of an antibody, but can be easily modified to either eliminate or incorporate new activities, all the while maintaining a similar size, stability and manufacturing advantages of a monoclonal antibody. The ADAPTIR molecules are single-chain polypeptides comprising customized elements including a protein domain that binds to one or more target binding domains to a hinged domain and a set of antibody constant domains known as the fragment crystallizable region, or Fc region of a human antibody. The antibody Fc region can elicit an immune response by binding to the corresponding Fc receptors found on various immune cells such as natural killer, or NK, cells, and other cells, including cancer cells to mediate antibody-dependent cell cytotoxicity resulting in killing of the cancer cell. With the ADAPTIR platform, the Fc region can be modified to enhance or eliminate these functions. Incorporation of the Fc region into the ADAPTIR platform also provides for an extended serum half-life by engaging recycling via the neonatal Fc receptor or FcRn. A long serum half-life could potentially reduce dosing frequency and dose quantity.

Multispecific ADAPTIR molecules are similar in structure to monospecific ADAPTIR molecules with the exception that they have two or more customized target binding domains on the ends of the Fc region. Multiple targeting domains allow ADAPTIR molecules to bind to two or more targets. We have created several bispecific molecules that are able to redirect T-cell cytotoxicity (RTCC). T-cells are white blood cells that fight infections and tumor cells. RTCC ADAPTIR molecules are designed to cause T-cells to specifically kill a tumor by binding to a common component (CD3) found on the T-cell and then binding to a specific tumor antigen on a specific tumor, thereby activating the T-cell to kill the tumor.



Components	Functions
Binding Domain 1 (scFv, ECD or ligand)	Binds to or engages Target 1
Hinge (typically from IgG1)	Modulates binding and biological activity
IgG Fc (eg. IgG1, IgG2, IgG4)	Isotype independent Extends serum half-life Confers ADCC, CDC activity if desired
Linker	Length and composition can be varied to modulate binding and activity
Binding Domain 2 (scFv, ECD or ligand)	Binds to or engages target 2

scFv = Single Chain Fragment Variable
ECD = ExtraCellular Domain of a receptor

We believe the ADAPTIR platform is a promising platform technology within the rapidly growing field of immuno-oncology therapeutics. The structural differences between ADAPTIR molecules and monoclonal antibodies, allow for the development of new immunotherapeutics that engage disease targets in a novel manner and produce a unique signaling response. By customizing the binding domains of our ADAPTIR molecules, we are able to select for desired potency, half-life, toxicity and stability/manufacturability. We have the potential to develop products with mechanisms of action including but not limited to RTCC and targeted cytokine delivery. We are able to expand our ADAPTIR platform to generate bispecifics that target tumor antigens in combination with costimulatory molecules including TNF-Receptor family members. We believe the ADAPTIR platform may prove to have advantages over other immunotherapeutics and other bispecific T-cell engaging technologies. In pre-clinical studies, we have gathered data indicating that APVO436, a RTCC ADAPTIR bispecific that binds CD123, may have high potency and activity at low doses, a long half-life, and reduced cytokine release. This molecule is able to be produced using standard manufacturing practices. Further clinical and pre-clinical studies may not confirm or establish the anticipated benefits of this platform.

Our ADAPTIR platform intellectual property (IP) portfolio consists of IP that we solely own and control with the exception of non-exclusive licenses to Chinese hamster ovary (CHO) cell lines and related expression systems. See section entitled “Intellectual Property” for additional information about the ownership rights to ADAPTIR platform intellectual property. We have a non-exclusive research license with Lonza Sales AG, or Lonza, for certain CHO cell lines, which are cells derived from the ovary of a Chinese hamster. The Lonza CHO cell line is often used in the production of therapeutic proteins, in protein expression and the GS (glutamine synthetase) Gene Expression System™, or GS System (GS Gene Expression System is a registered trademark of Lonza).

Product Portfolio

Product Candidates

Our pipeline includes investigational stage product candidates in immuno-oncology, autoimmune, and inflammatory diseases.

APVO436. We have developed APVO436, an ADAPTIR bispecific immunotherapeutic protein targeting CD123, a cell surface receptor highly expressed on several hematological malignancies and CD3, a component of the T-cell receptor. APVO436 utilizes RTCC to initiate killing of CD123 expressing tumor cells. Pre-clinical data on this anti-CD123 ADAPTIR bispecific was presented at the 2017 annual meeting of the American Association for Cancer Research and 2017 American Society of Hematology (ASH). These data demonstrate *in vitro* RTCC activity and *in vivo* tumor cell killing in animal models of disease and demonstrate that APVO436 can kill acute myeloid leukemia (AML) blasts using patient derived peripheral blood cells in the presence of APVO436. Potential indications for APV0436 include AML, myelodysplastic syndrome, or MDS, acute lymphocytic leukemia, or ALL, and hairy cell leukemia, for each of which we believe there is a strong unmet need for safe and effective therapies. APVO436 is expressed from a single gene construct from CHO production cell line and manufactured using traditional antibody-like processes. APVO436 has a half-life of up to 12.5 days in rodents and 3.5 days in non-human primates. In a cytokine release assay *in vitro*, administration of APVO436 resulted in lower levels of cytokine release as compared to an anti-CD123 x anti-CD3 in the dual-affinity retargeting, or D.A.R.T. format. In an *in vitro* assay using AML patient samples, APVO436 induced rapid activation and proliferation of endogenous T cells and showed a progressive reduction of CD123+ cells over the 96-hour culture period. In a murine therapeutic delivery model, treatment with APVO436 resulted in a rapid reduction in skeletal tumor burden in mice which were previously established with MOLM-13 tumors.

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. Phase 1 will consist of up to 60 patients and is designed to determine the maximum tolerated dose and recommended dose for Phase 1b. The primary endpoint for Phase 1 will be the incidence of dose-limiting toxicities occurring during Cycle 1 of each dose cohort. Phase 1b will consist of up to 48 patients and is designed to assess clinical activity at the recommended dose. The primary endpoint for Phase 1b is to assess clinical activity, including overall response rate. In both Phase 1 and Phase 1b, patients will receive APVO436 by intravenous dosing once weekly for six 28-day cycles. We anticipate that we will have anti-drug antibody (ADA) data in the third quarter of 2019, and preliminary Phase 1 safety data in the fourth quarter of 2019.

APVO210. APVO210 is an anti-inflammatory molecule engineered using our ADAPTIR platform technology currently in pre-clinical development. It is under development for the treatment of psoriasis and inflammatory bowel disease, including ulcerative colitis and other autoimmune and inflammatory diseases. APVO210 is a targeted cytokine therapeutic, specifically, it is designed to deliver a modified form of the anti-inflammatory cytokine, IL-10, to antigen presenting cells, or APCs, via targeting CD86. APCs are a therapeutic target of interest for an anti-inflammatory therapeutic such as APVO210 because, as described further below, APCs play a critical role in the immune response. APVO210 is unique in that it can deliver a modified form of IL-10 to APC without stimulation of resting and activated lymphocytes. Additionally, APVO210 has the potential to modulate long-term antigen specific immune responses through generation of antigen-specific tolerogenic dendritic cells.

Structurally, APVO210 contains monomeric IL-10, a modified form of IL-10, coupled to a humanized binding domain specific for CD86, linked by an antibody Fc region. Humanized refers to chemically altering animal proteins to resemble natural human amino acid sequences (or the order in which they bond). By targeting monomeric IL-10 to desired cell populations, APVO210 is designed to increase the exposure of target cells (APCs) to the drug and to reduce toxicity and increase efficacy (i.e., therapeutic window) as compared to IL-10 therapies. The mechanism of action results in suppression of T-cell responses through inhibition of antigen presentation. Antigen presenting cells play a central role in the generation and regulation of immune response and inflammation; therefore, inhibiting their function represents a therapeutic opportunity to suppress immunopathological processes in autoimmune and inflammatory disease. APVO210 pre-clinical data demonstrate potent *in vitro* and *in vivo* antagonism of T-cell proliferation in human mixed lymphocyte reactions and in a humanized graft-versus-host disease model. The APVO210 ADAPTIR molecule has potential to suppress immune responses and serve in anti-inflammation

applications that occurs, for instance, in inflammatory bowel disease, psoriasis, rheumatoid arthritis, graft versus host disease (GVHD) and in the treatment of transplant rejection. As a molecule designed using our ADAPTIR platform technology, the half-life of APVO210 is extended as compared to wildtype IL-10 as demonstrated in pre-clinical rodent studies and non-human primate studies. In non-human primate studies, APVO210 exhibited a half-life of 30 to 40 hours which is significantly longer than that of IL-10 which is in single-digit hours. Also, manufacturing benefits are realized because the platform enables use of a manufacturing process that is typically used for making antibodies.

We have received authorization to initiate dosing in Australia and intend to initiate a Phase 1 clinical trial 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. ALG.APV-527 is a bispecific antibody candidate, partnered with Alligator Bioscience AB, or Alligator, 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 is designed to target T cells previously activated by tumor antigen, exert tumor-localized T cell activation upon 5T4 binding, and to not stimulate resting or naïve T cells. ALG.APV-527 has the potential advantage of improved efficacy and safety as the result of being a targeted therapy. In *in vivo* studies, ALG-APV-527 localized specifically to 5T4 positive tumors but not 5T4 negative tumors. Additionally, in *in vitro* studies, ALG-APVO-527 bound to human and cynomologous 5T4 and 4-1BB expressing cells and activated T cells. *In vitro* studies induced 4-1BB activation in a reporter-based activity assay only when 5T4 targets were present. In *in vitro* assays, ALG.APV-527 induced CD8+ T cell proliferation and IFN-γ production in the presence of 5T4 antigen, and induced NK cell activation only in the presence of 5T4 targets. In *in vivo* studies, ALG-APV-527 localized to 5T4-expressing tumors and reduced colon carcinoma tumor growth in an HCT116 tumor model. 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, pancreatic, renal, gastric, colorectal, ovarian, and bladder cancers. ALG.APV-527 has the potential advantage of having utility in multiple solid tumor cancers that express the 5T4 antigen. Aptevo and Alligator intend to file a clinical trial authorization, or CTA, in the fourth quarter of 2019.

ROR1 Bispecific. ROR1 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 models.

ADAPTIR Therapeutic Candidates. We have multiple additional candidates that are focused on immuno-oncology and based on the ADAPTIR platform technology that are in different stages of pre-clinical development.

In 2018, we elected to discontinue the APVO414 development program, a first generation bispecific ADAPTIR candidate, including the Phase 1 clinical program, targeting prostate specific membrane antigen (PSMA), an antigen that is expressed on the surface of prostate cancer cells, and CD3. APVO414 redirected T cells to specifically kill PSMA-expressing tumors and was being developed for metastatic castration-resistant prostate cancer (mCRPC), which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies. To date, no dose limiting toxicities have been reported with continuous infusion in the Phase 1 mCRPC clinical trial. In that study, continuous infusion delayed the development of anti-drug antibodies (ADA) compared to weekly IV infusions, but with longer dosing, ADA developed that cleared the drug from the blood in some patients. While we are no longer enrolling patients into the Phase 1 APVO414 clinical trial, we will continue to monitor the patients remaining on the therapy.

In 2018, we also elected to discontinue the otlertuzumab development program, a first generation monospecific ADAPTIR candidate including the Phase 2 clinical program for the treatment of peripheral T-cell lymphoma (PTCL). A previous Phase 2 clinical trial evaluating otlertuzumab for the treatment of chronic lymphocytic leukemia (CLL) showed that otlertuzumab in combination with bendamustine, compared to bendamustine alone, demonstrated a significant increase in median progression free survival for the combination, from approximately 10 to 16 months. One patient showed a complete response and there was some evidence of tumor regression (43% primary tumor) in a second patient in the PTCL pilot Phase 2 clinical trial. 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. Due to these reasons, we elected to close the study to further enrollment. However, we will continue to monitor the patients remaining on therapy.

Potential adverse events related to our product candidates

Experimental drugs may have a variety of adverse events related to their target, mechanism of action or off target toxicities. Clinical trials are conducted to define the efficacy and safety of a new molecule and this data is reviewed by the FDA prior to FDA approval. The majority of the drugs that we are developing are intended for the treatment of cancer. Because cancer is a serious and life threatening disease, these patients experience a number of serious adverse events as part of their disease. The risk-benefit ratio for new treatments of cancer is different from other less serious diseases. For example, for the treatment of hypertension, it is not acceptable for a drug to lower the number of white blood cells that fight infections. However, chemotherapy for the treatment of cancer frequently lowers the number of white blood cells and infections do occur, which physicians manage in the course of a patient's cancer treatment. In order to distinguish whether a new drug causes adverse events, a controlled trial is frequently conducted comparing a new drug to another therapy.

Competition

Our product candidates face significant competition. Any product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, as well as other novel product candidates that are in development for the same indications. Specifically, the competition with respect to our clinical product candidates includes the following:

- ***APVO436***. If approved for AML, we anticipate that APVO436 would compete with other agents targeting CD123 that are in development if they are also approved. Bispecifics in development targeting CD123 include: MGD006 (Macrogenics), JNJ-63709178 (Janssen) and XmAb14045 (Xencor), and Sanofi. There are at least two CAR-T therapies in development: CART123 (University of Penn.) and CARTCD123 (NCI/City of Hope). Other competitive products targeting CD123 are: SL-401 (antibody immunotoxin, Stemline), KHK2833 (monoclonal antibody, Kyowa Hakko Kirin Pharma), and CSL362 (monoclonal antibody, CSL/Janssen).
- ***APVO210.*** If approved, we anticipate that APVO210 would compete with products indicated for inflammatory bowel diseases such as ulcerative colitis, including: HUMIRA® (AbbVie Inc.), Remicade® (Janssen Pharmaceuticals, Inc. of Johnson and Johnson) and Entyvio® (Takeda Pharmaceuticals U.S.A., Inc., a subsidiary of Takeda Pharmaceutical Company Limited). Depending on what APVO210 is approved for, we anticipate that it could also compete with products indicated for moderate to severe Crohn's Disease, including: Stelara (Janssen Pharmaceuticals, Inc. of Johnson and Johnson) and Xeljanz (Pfizer Inc.). If approved, APVO210 would compete against a number of other drugs for additional autoimmune diseases. For example, in psoriasis alone there are four anti-TNF inhibitors and four anti-interleukins approved by the FDA.

COLLABORATIONS AND LICENSES

Collaboration with Alligator Bioscience AB

On July 20, 2017, our wholly owned subsidiary Aptevo Research and Development LLC or Aptevo R&D, entered into a collaboration and option agreement or the Collaboration Agreement with Alligator Bioscience AB, (Alligator), pursuant to which Aptevo R&D and Alligator are collaborating to develop ALG.APV-527, a lead bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a co-stimulatory 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 2 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.

Collaboration with MorphoSys AG

In August 2014, we entered into a collaboration agreement with MorphoSys AG (MorphoSys Agreement) for the joint development of MOR209/ES414, a targeted immunotherapeutics protein, which activates host T-cell immunity specifically against cancer cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells. Effective August 31, 2017, MorphoSys terminated the MorphoSys Agreement. As a result of the termination, we have no ongoing obligation related to this agreement and therefore recognized the total remaining deferred revenue balance of $3.7 million as collaborations revenue in the third quarter of 2017.

MARKETED PRODUCT

IXINITY (coagulation factor IX (recombinant)). 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. We 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 from the hyperimmune business sold in September 2017 to grow the IXINITY market outside of the United States.

Manufacturing

We rely primarily on AGC Biologics, formally known as CMC Biologics, Inc. (AGC) for drug substance manufacture of IXINITY, on Patheon UK Limited, or Patheon, for fill-finish services of IXINITY and on Rovi Contract Manufacturing, S.L. or Rovi for supply of the syringe pre-filled with water for injection packaged with IXINITY.

Sources and Availability of Raw Materials

Agreement with AGC Biologics. We rely on AGC, for the manufacture of the substance that becomes the active ingredient (the bulk drug substance) in the production of our IXINITY product. On June 17, 2017, we entered into a non-exclusive Commercial Supply (Manufacturing Services) Agreement with AGC, pursuant to which, subject to specified exceptions, we are obligated to purchase at least four batches and AGC is obligated to maintain a maximum capacity for ten batches of IXINITY bulk drug substance per full year. The agreement has a five-year term renewable with twenty-four months' prior notice before the expiry of the term for successive two-year terms. AGC is obligated to use commercially reasonable efforts to perform services in accordance with our forecast and projected delivery dates. In the event there is a supply failure as defined under the agreement, the agreement becomes non-exclusive with respect to 50% of our forecasted demand (or up to the unsupplied quantities until supply reinstatement).

The agreement provides for fees for services. Each party may terminate the agreement if the other party fails to pay any amount properly due and payable with ten business days of notice demanding payment after the expiration of the original payment term or if the other party materially breaches the agreement and fails to remedy any such breach capable of remedy during a twenty business day notice period. Each party may terminate the agreement if the other party experiences certain bankruptcy events. This agreement may be terminated by either party in the event of a material breach by the other party; however, termination shall not affect the accrued rights of either party. We may also terminate our obligations under the agreement with a specified amount of prior notice, if AGC has any material permit or regulatory license permanently revoked preventing the performance of services by AGC, if AGC is subject to certain competitor change of control events, or where there is a supply failure prior to a supply reinstatement where AGC does not reinstate supply within twelve months of the supply failure.

Agreement with Patheon. Patheon, through an affiliate, is currently the sole source third-party manufacturer that performs the services of filling the bulk drug substance into vials for our IXINITY product. We have a non-exclusive Manufacturing Services Agreement with Patheon pursuant to which we are obligated to order, and Patheon agrees to perform, a specified amount of such services on an annual basis. Under the agreement, Patheon also agrees to use commercially reasonable efforts to perform services in excess of such minimum purchase commitments subject to its available capacity. The agreement had an initial three-year term that expired on May 26, 2018, and pursuant to its terms, automatically renewed for an additional two-year term that expires on May 26, 2020. The agreement will continue to automatically renew for successive terms of two years each, unless either party gives the other party at least eighteen months' notice. We may terminate the agreement on a specified amount of notice if a regulatory authority prevents us from importing, exporting, purchasing or selling the product or if we no longer order services for a product due to the product's discontinuance in the market; however, we must still perform any surviving obligations as specified in the agreement. Patheon may terminate the agreement upon six months' notice if we assign our rights under the agreement to an assignee that, in Patheon's opinion acting reasonably, is not a credit-worthy substitute, a Patheon competitor, or an entity with whom Patheon has had prior unsatisfactory business relations. Each party may terminate the agreement if the other party breaches the agreement and the breach is not cured within a specified period of time, if the other party experiences certain bankruptcy events, or upon a period of notice if the parties do not agree upon certain pricing adjustments. Except in respect of liability for certain third party claims, breach of confidentiality obligations, or replacement of defective product, Patheon's liability is limited under the agreement to 10% of the revenues for such year to Patheon under the agreement. Patheon's liability in respect of replacement of defective product is limited to the amount paid by us to Patheon for such product. Except in respect of a breach of confidentiality obligations, neither party is liable to the other under the agreement for any loss of profits or other damages of an indirect or consequential nature.

Agreement with Rovi. Rovi is currently the sole source third-party manufacturer that supplies the syringe pre-filled with water for injection, that is packaged with and required for reconstitution of our IXINITY product. We have a non-exclusive supply agreement with Rovi pursuant to which Rovi is obligated to use its best efforts to supply the quantity of syringes ordered by us. The agreement has a five-year term expiring on April 28, 2019, and will automatically renew for successive five-year terms, unless Rovi provides us with written notice of its intent not to renew at least twenty-four months prior to the expiration of the term or any renewal term. We may terminate the agreement for any reason on at least twelve months' prior notice. Each party may terminate the agreement if the other party breaches the agreement and the breach is not cured within a specified period of time.

License with the University of North Carolina to IXINITY intellectual property rights

In connection with our separation from Emergent, we assumed an exclusive license from the University of North Carolina, or UNC, to make, have made, use, offer for sale, sell and import factor IX and factor VII(a) therapeutics, including IXINITY, under certain UNC's patents. We are required to pay a low single digit royalty obligation to UNC under the license. The license agreement expires when the last of the licensed patents expire, on a country-by-country basis. Most of the licensed patents expire in or around September 2024. A licensed United States patent received patent term extension and will now expire in or around November 2028. UNC may terminate the license if a material breach is not cured forty-five days after notice, we become bankrupt or insolvent, or we do not pay a yearly minimum earned royalty (in the mid-five digits). We can terminate the license with sixty days' notice to UNC.

Trademark License Agreement with Emergent

We entered into a trademark license agreement with Emergent pursuant to which Emergent granted us a non-exclusive, royalty-free, worldwide, non-sublicensable license under certain trademarks of Emergent to distribute the physical inventory of packaging and marketing materials assigned to us as part of the distribution, solely to sell, offer to sell and otherwise commercialize the commercial products until such inventory of packaging and marketing materials is depleted or, if earlier, the third anniversary of the distribution. We may terminate our rights under the agreement at any time by providing written notice to Emergent. Emergent may terminate the agreement if we breach the agreement and the breach is not cured within a specified period of time or is uncurable.

Distribution

Our IXINITY product is sold in the United States by our commercial sales force and distributed to end-users through major U.S. distributors and wholesalers, and other specialty distributors. All third-party logistics (including, for instance, warehousing, inventory management, and shipping) of final drug product are provided by a third-party logistics company.

Marketing & Sales

We have biotechnology commercial operations and medical affairs teams with experience in sales, marketing, distribution, reimbursement and medical support.

The commercial operations team includes a U.S.-based field sales force. This hemophilia sales team focuses its selling efforts primarily on hemophilia treatment centers and hematology clinics. Orders are filled upon receipt, and we generally have no orders on backlog. Reimbursement support, patient assistance/compassionate use and non-medical customer inquiries are handled by customer service personnel within our commercial operations team.

Our medical affairs team includes field-based medical science liaisons, who respond to customer requests for information, establish and maintain company relationships with researchers and clinicians, train our product specialists and sales personnel and interface with clinical trial investigators. Our medical affairs team also supports customers by providing medical information, drug safety and pharmacovigilance services.

Competition

Currently, IXINITY competes with five recombinant factor IX products that are marketed in North America. Two are standard half-life products: BeneFIX® (Pfizer Inc.) and RIXUBIS® (Shire US Inc.), and three are enhanced half-life products: IDELVION® (CSL Behring LLC), ALPROLIX® (Bioverativ Therapeutics Inc.), and Rebinyn® (Novo Nordisk Inc.).

SALE OF HYPERIMMUNE BUSINESS

On August 31, 2017, we entered into an LLC purchase agreement with Saol International Limited, or Saol, whereby we agreed to sell our Hyperimmune Business, which consisted of the following products: WinRho® SDF for autoimmune platelet disorder and hemolytic disease of the newborn; HepaGam B® for the prevention of Hepatitis B following liver transplantation and for treatment following hepatitis B exposure; and VARIZIG® for treatment following exposure to varicella zoster virus for individuals with compromised immune systems.

On September 28, 2017, we announced that we completed the sale of our Hyperimmune Business to Saol for total consideration of up to $74.5 million. At the closing of the acquisition, Saol paid us an upfront payment totaling $65.0 million, including $3.3 million that was deposited in an escrow account for the purposes of satisfying any indemnification claims brought by Saol pursuant to the LLC purchase agreement. This $3.3 million escrow amount was collected in full in December 2018. In addition, we may receive (1) an additional potential milestone payment totaling up to $7.5 million related to the achievement of certain gross profit milestones and (2) up to $2.0 million related to collection of certain accounts receivable after the closing. The up to $7.5 million potential milestone payment, if earned, will be collectable in the fourth quarter of 2020.

INTELLECTUAL PROPERTY

We actively seek intellectual property protection for our products and product candidates. We own or exclusively license the patents and patent applications in our patent portfolio that support IXINITY, the ADAPTIR platform and pipeline products, including APVO210 and APVO436, with the exception of certain cell line rights which we license on a non-exclusive basis. We practice patent life cycle management by filing patent applications to protect new inventions relating to meaningful improvements to our products and related methods. We primarily seek patent protection for inventions that support our products and product candidates, but from time to time, we seek patent protection for inventions that could, for instance, support a potential business opportunity or block a competitor from designing around our existing patents.

In general, and where possible, we pursue patent protection in countries where we believe there will be a significant market for the corresponding product or product candidate. We generally do not seek patent protection in countries where we have reason to believe we would not be able to enforce patents. For instance, we tend to not file in countries that are frequently listed on the Priority Watch List of the Special 301 Report prepared by the Office of the United States Trade Representative, with the exception that we typically file patent applications in China, Russia and India. We may also decide to take a narrower filing approach for secondary and improvement type inventions as compared to inventions that are more foundational to our products. We do not seek patent protection in countries that are on the United Nations, or U.N., list of Least Developed Countries.

The term of protection for various patents associated with and expected to be associated with our marketed product and product candidates is typically twenty years from the filing date but may vary depending on a variety of factors including the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. The protection afforded by a patent varies on a product-by-product basis and country-to-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the necessity for terminal disclaimers, the availability of legal remedies in a particular country, and the validity and enforceability of the patents.

In some cases, we may decide that the best way to protect our intellectual property is to retain proprietary information as trade secrets and confidential information rather than to apply for patents, which would involve disclosure of proprietary information to the public. When determining whether to protect intellectual property as a trade secret, we consider many factors including, for instance, our ability to maintain the trade secret, the likelihood that a competitor will independently develop the information, our ability to patent protect the intellectual property and the likelihood we would be able to enforce a resulting patent.

We are a party to a number of license agreements under which we license patents, patent applications and other intellectual property. These agreements impose various commercial diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future.

ADAPTIR Platform. We protect the ADAPTIR platform technology through a combination of patents and trade secrets. We own all ADAPTIR platform intellectual property, with the exception that we have non-exclusive commercial licenses and a research license with Lonza to certain intellectual property related to Lonza's CHO cell lines and vectors. Under our Lonza research license, we have an option to take a license to use the GS System to develop and manufacture therapeutic proteins for our commercial purposes.

The intellectual property we own that supports our ADAPTIR platform was generated internally at Emergent or at Trubion Pharmaceuticals, Inc., or Trubion, prior to its acquisition by Emergent in 2010, or at Aptevo following the separation. One patent family which supports use of unique linkers in the homodimer (a molecule consisting of two identical halves) version of the platform was invented jointly by Trubion and Wyeth Pharmaceuticals, Inc., or Wyeth, as part of a collaboration between the two companies. Upon termination of a product license agreement between Wyeth and Trubion, Wyeth assigned the rights it had in that platform patent family to Trubion. These rights have since transferred to us.

In order to differentiate our platform inventions from antibodies and other antibody-like constructs that have been publicly disclosed, many of our patents and patent applications are directed to unique aspects or components of our platform such as linkers or binding domains. Our ADAPTIR platform can be homodimeric or heterodimeric. Although most of our patent families protect both homodimeric and heterodimeric forms of the platform, we also have a patent family that is focused on the heterodimeric form of the platform.

We have filed patent applications for the ADAPTIR platform in the United States and in countries and territories, including Australia, Brazil, Canada, China, Egypt, Europe, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Singapore, South Africa, South Korea, United Arab Emirates and Vietnam. We plan to continue to improve our ADAPTIR platform and to file patent applications on those improvements. Our decision as to where to file any new ADAPTIR improvement inventions will be based in part on the significance of the improvement. If patents issue on the pending ADAPTIR patent applications, the patent term for those patents are estimated to expire between June 2027 and September 2036.

IXINITY (coagulation factor IX (recombinant)). We license patents and patent applications from UNC, which support the manufacture of factor IX and other Vitamin K Dependent Proteins. In addition to the patent assets licensed from UNC, we own a patent portfolio with claims generally directed to factor IX pharmaceutical compositions, methods of making recombinant factor IX protein, and cell lines producing recombinant factor IX protein. This patent portfolio includes issued patents in Australia, Europe and Japan and pending patent applications in other territories including the United States. If patents issue on our pending patent applications, the patent term for those patents is estimated to expire between December 2026 and October 2030. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

APVO436. We have a pending patent cooperation treaty, or PCT, patent application which supports our APVO436 product candidate. We plan to file national stage applications when due in March and April 2019. In addition to the PCT application, we have a pending United States continuation-in-part or CIP, patent application.

APVO210. We have patents and pending patent applications supporting our APVO210 product candidate. We have foundational patents and patent applications in countries and territories, including the United States, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Japan, Mexico, New Zealand, Singapore, South Africa and South Korea. The foundational patents granted in this patent family are estimated to expire in October 2029 outside of the United States and October 2030 inside the United States. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

Trademarks owned by Aptevo Therapeutics Inc. and its subsidiaries. Where possible, we pursue registered trademarks for our marketed products in significant markets. We own trademark registrations and pending applications for the marks: APTEVO THERAPEUTICS, APTEVO BIOTHERAPEUTICS, APTEVO RESEARCH AND DEVELOPMENT, the Aptevo logo, IXINITY, IXINITY with logo, IXPERIENCE, and ADAPTIR in relevant jurisdictions. We own registrations or pending trademark applications for the mark APTEVO per se in Iraq, Nicaragua, Pakistan, and Ukraine.

REGULATION

Regulations in the United States and other countries have a significant impact on our product development, manufacturing and marketing activities.

Product Development for Therapeutics

Pre-clinical Testing. Before beginning testing of any compounds with potential therapeutic value in human subjects in the United States, stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing includes both in vitro, or in an artificial environment outside of a living organism, and in vivo, or within a living organism, laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. We perform pre-clinical testing on all of our product candidates before we initiate any human trials.

Investigational New Drug Application. Before clinical testing may begin, the results of pre-clinical testing, together with manufacturing information, analytical data and any other available clinical data or literature, must be submitted to the United States Food and Drug Administration, or FDA, as part of an Investigational New Drug Application, or IND. The sponsor must also include an initial protocol detailing the first phase of the proposed clinical investigation, together with information regarding the qualifications of the clinical investigators. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical studies in human volunteers. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA imposes a clinical hold within that 30-day time period.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients with the target disease or disorder under the supervision of a qualified physician (also called an investigator) pursuant to an FDA-reviewed protocol. Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another. Clinical trials must be conducted under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria, if any, to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

- Phase 1 clinical trials test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, for early evidence regarding efficacy.
- Phase 2 clinical trials involve a small sample of individuals with the target disease or disorder and seek to assess the efficacy of the drug for specific targeted indications to determine dose response and the optimal dose range and dose regimen and to gather additional information relating to safety and potential adverse effects.
- Phase 3 clinical trials consist of expanded, large-scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product and dosing regimen. The safety and efficacy data generated from Phase 3 clinical trials typically form the basis for FDA approval of the product candidate.
- Phase 4 clinical trials, if conducted, are conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific population. As part of a product approval, the FDA may require that certain Phase 4 studies, which are called post-marketing commitment studies, be conducted post-approval.

Good Clinical Practice. All of the phases of clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations and Good Clinical Practices, or GCP, which are ethical and scientific quality standards for conducting, recording and reporting clinical trials to assure that the data and reported results are credible and accurate and that the rights, safety and well-being of trial participants are protected. Additionally, an Institutional Review Board at each site participating in a trial must obtain ongoing approval for conduct of the trial at that site.

Marketing Approval—Biologics

Biologics License Application. All data obtained from a comprehensive development program, including research and product development, manufacturing, pre-clinical and clinical trials, labeling and related information are submitted in a biologics license application, or BLA, to the FDA and in similar regulatory filings with the corresponding agencies in other countries for review and approval. The submission of an application is not a guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application and request additional information rather than accept the application for filing, in which case the application must be resubmitted with the supplemental information. The FDA has two months to review an application for its acceptability for filing. Once an application is accepted for filing, the Prescription Drug User Fee Act, or PDUFA, establishes a two-tiered review system: Standard Review and Priority Review. When conducting Priority Review, the FDA has a goal to review and act on BLA submissions within six months from the date of the FDA's acceptance for filing of the application, rather than the ten-month goal under a Standard Review. The FDA gives Priority Review status to product candidates that provide safe and effective therapies where no satisfactory alternative exists or to a product candidate that constitutes a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, BLAs and certain supplements must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug or biologic for an indication for which orphan designation has been granted.

In reviewing a BLA, the FDA may grant approval or deny the application through a complete response letter if it determines the application does not provide an adequate basis for approval requesting additional information. Even if such additional information and data are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The receipt of regulatory approval often takes many years, involving the expenditure of substantial financial resources. The speed with which approval is granted often depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may also impose conditions upon approval. For example, it may require a Risk Evaluation and Mitigation Strategy, or REMS, for a product. This can include various required elements, such as publication of a medication guide, patient package insert, a communication plan to educate health care providers of the drug's risks and/or restrictions on distribution and use, such as limitations on who may prescribe or dispense the drug. The FDA may also significantly limit the indications approved for a given product and/or require, as a condition of approval, enhanced labeling, special packaging or labeling, post-approval clinical trials, expedited reporting of certain adverse events, pre-approval of promotional materials or restrictions on direct-to-consumer advertising, any of which could negatively impact the commercial success of a drug.

Fast Track Designation. The FDA may designate a product as a fast track drug if it is intended for the treatment of a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for this disease or condition. Sponsors granted a fast track designation for a drug are granted more opportunities to interact with the FDA during the approval process and are eligible for FDA review of the application on a rolling basis, before the application has been completed.

Breakthrough Therapy. Under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA may designate a product as a breakthrough therapy if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Orphan Drugs. Under the Orphan Drug Act, an applicant can request the FDA to designate a product as an "orphan drug" in the United States if the drug is intended to treat an orphan, or rare, disease or condition. A disease or condition is considered orphan if it affects fewer than 200,000 people in the United States. Orphan drug designation must be requested before submitting a BLA. Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, waived filing fees for marketing applications and a seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity (afforded to the first applicant to receive approval for an orphan designated drug) prevents FDA approval of applications by others for the same drug for the designated orphan disease or condition. The FDA may approve a subsequent application from another applicant if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. A grant of an orphan designation is not a guarantee that a product will be approved. Our product candidate otlertuzumab was granted orphan drug designation for the treatment of CLL by the FDA in November 2011 and received orphan medicinal product designation from the European Commission in December 2012 for the treatment of CLL. Orphan designation in Europe qualifies a drug for certain development and commercial incentives, including protocol assistance, access to centralized authorization procedures, reduced fees for regulatory activities, and ten years of market exclusivity after approval.

Post-Approval Requirements. Any biologic for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, current good manufacturing practices, or cGMP, and restrictions on advertising and promotion. Adverse events that are reported after marketing approval can result in additional limitations being placed on the product's distribution or use and, potentially, withdrawal or suspension of the product from the market. In addition, the FDA authority to require post-approval clinical trials and/or safety labeling changes if warranted. 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 boxed warnings in their approved package inserts.

Pricing, Coverage and Reimbursement

In the United States and internationally, sales of our products and our ability to generate revenues on such sales are dependent, in significant part, on the availability and level of reimbursement from third-party payors, including state and federal governments and private insurance plans. Insurers have implemented cost-cutting measures and other initiatives to enforce more stringent reimbursement standards and likely will continue to do so in the future. These measures include the establishment of more restrictive formularies and increases in the out-of-pocket obligations of patients for such products. In addition, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. Various provisions of the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act), collectively referred to as the Affordable Care Act, increased the levels of rebates and discounts that we have to provide in connection with sales of such products that are paid for, or reimbursed by, certain state and federal government agencies and programs. It is possible that future legislation in the United States and other jurisdictions could be enacted, which could potentially impact the reimbursement rates for our products and also could further impact the levels of discounts and rebates we are required to pay to state and federal government entities. The most significant governmental reimbursement programs in the United States relevant to our products are described below:

Medicare Part B. Medicare Part B covers certain drug products provided in a physician's office or hospital outpatient setting under a payment methodology using "average sales price," or ASP, information. We are required to provide ASP information to the Centers for Medicare & Medicaid Services, or CMS, on a quarterly basis. Medicare payment rates using an ASP methodology are currently set at ASP plus six percent, although this rate could change in future years. If we fail to timely or accurately submit ASP, we could be subject to civil monetary penalties and other sanctions.

Medicaid Rebate Program. For products to be covered by Medicaid, drug manufacturers must enter into a rebate agreement with the Secretary of HHS on behalf of the states and must regularly submit certain pricing information to CMS. The pricing information submitted, including information about the "average manufacturer price," or AMP, and "best price" for each of our covered drugs, determines the amount of the rebate we must pay. The total rebate also includes an "additional" rebate, which functions as an "inflation penalty." The Affordable Care Act increased the amount of the basic rebate and, for some "line extensions," increased the additional rebate. It also requires manufacturers to pay rebates on utilization by enrollees in managed care organizations. If we fail to timely or accurately submit required pricing information, we could be subject to civil, monetary and other penalties. In addition, the Affordable Care Act changed the definition of AMP to address which manufacturer sales are to be considered, which affected the rebate liability for our products.

340B/PHS Drug Pricing Program. The availability of federal funds to pay for IXINITY under the Medicaid and Medicare Part B programs requires that we extend discounts under the 340B/Public Health Service, or PHS, drug pricing program. The 340B/PHS drug pricing program requires participating manufacturers to charge no more than a statutorily-defined "ceiling" price to a variety of community health clinics and other covered entities that receive health services grants from the PHS, as well as the outpatient departments of hospitals that serve a disproportionate share of Medicaid and Medicare beneficiaries. A product's ceiling price for a quarter reflects its Medicaid AMP from two quarters earlier less its Medicaid rebate amount from two quarters earlier. Therefore, the above-mentioned revisions to the Medicaid rebate formula and AMP definition enacted by the Affordable Care Act could cause the discount produced by the ceiling price to increase. Under the Affordable Care Act, several additional classes of entities were made eligible for these discounts, increasing the volume of sales for which we must now offer the 340B/PHS discounts.

Federal Supply Schedule. We make IXINITY available for purchase by authorized users of the Federal Supply Schedule, or FSS, administered by the Department of Veterans Affairs, or DVA, pursuant to our FSS contract with the DVA. Under the Veterans Health Care Act of 1992, we are required to offer deeply discounted FSS contract pricing to four federal agencies—the DVA, the Department of Defense, or DoD, the Coast Guard and the PHS (including the Indian Health Service)—for federal funding to be made available for reimbursement of any of our products under the Medicaid program, Medicare Part B and for our products to be eligible to be purchased by those four federal agencies and certain federal grantees. FSS pricing to those four federal agencies must be equal to or less than the "Federal Ceiling Price," which is, at a minimum, 24% less than the Non-Federal Average Manufacturer Price for the prior fiscal year.

Foreign Regulation

Currently, we maintain a commercial presence in the United States. In the future, we may further expand our commercial presence to additional foreign countries and territories. In the European Union, or EU, medicinal products are authorized following a process similarly demanding as the process required in the United States. Medicinal products must be authorized in one of two ways, either through the decentralized procedure, which provides for the mutual recognition procedure of national approval decisions by the competent authorities of the EU Member States or through the centralized procedure by the European Commission, which provides for the grant of a single marketing authorization that is valid for all EU member states. The authorization process is essentially the same irrespective of which route is used. We are also subject to many of the same continuing post-approval requirements in the EU as we are in the United States (*e.g.,* good manufacturing practices). We will be subject to varying preapproval, approval and post-approval regulatory requirements similar to those imposed by the FDA in each foreign country in which we conduct regulated activities.

Healthcare Fraud and Abuse and Anti-Corruption Laws

We are subject to various federal and state laws pertaining to health care "fraud and abuse," including state and federal anti-kickback laws false claims laws, and patent privacy and security laws. Anti-kickback laws make it illegal for a drug manufacturer to knowingly and willfully solicit, offer, receive or pay any remuneration in exchange for, to induce, or in return for, the referral of business that may be reimbursed by a third party payor (including Medicare and Medicaid), including the purchase, prescribing or recommendation of a particular drug. Due to the breadth of the statutory provisions, it is possible that our practices might be challenged under anti-kickback or similar laws. Civil and criminal false claims laws, false statement laws and civil monetary penalty laws prohibit, among other things, anyone from knowingly presenting, or causing to be presented for payment, to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Privacy and security laws, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, create federal criminal and civil liability for executing a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, and their respective implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information.

If we violate the healthcare fraud and abuse laws, we could be subject to sanctions, including civil and administrative penalties, criminal, fines, damages, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, 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. Similar restrictions are imposed on the promotion and marketing of medicinal products in other countries. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct are often strictly enforced.

In addition, as part of the Affordable Care Act, the federal government enacted the Physician Payment Sunshine Act. Manufacturers of drugs biologics and devices that are reimbursed by Medicare, Medicaid or the Children's Health Insurance Program are required to annually report to CMS payments and transfers of value made to physicians and teaching hospitals, and ownership or investment interest held by physicians and their family members. This information is posted on a public website. Failure to timely and accurately submit required information could subject us to civil penalties. Some local, state and foreign governments have similar compliance, marketing, licensure and/or transparency laws. Many of these transparency requirements are new and uncertain and the extent to which the laws will be enforced is not always clear.

Our operations are also subject to compliance with the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits corporations and individuals from directly or indirectly paying, offering to pay, or authorizing the payment of anything of value to any foreign government official or employee, or any foreign political party or political candidate in an attempt to obtain or retain business or to otherwise influence such official, employee, party or candidate in his or her or its official capacity. We also may be implicated under the FCPA by activities taken on our behalf by our partners, collaborative partners, consultants, distributors, contract research organizations, vendors or other agents and representatives. As a public company, the FCPA also requires us to make and keep books and records that accurately and fairly reflect all of our transactions and to devise and maintain an adequate system of internal accounting controls. Our operations are also subject to compliance with the U.K. Bribery Act of 2010, which applies to activities both in the public and private sector, Canada's Corruption of Foreign Public Officials Act and similar laws in other countries where we do business.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the Affordable Care Act, or the ACA, was enacted which, among other things, includes changes to the coverage and payment for products under government health care programs. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to judicial and Congressional 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. Additionally, President Trump signed the Tax Cuts and Jobs Act of 2017 on December 22, 2017, which includes a provision repealing the individual mandate under the ACA, effective January 1, 2019.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 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 2012 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 up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Furthermore, 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 bills 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.

Additionally, on December 13, 2016, the 21st Century Cures Act, or Cures Act, was signed into law, which is designed to modernize and personalize healthcare, spur innovation and research, and streamline the discovery and development of new therapies through increased federal funding of particular programs. Among other provisions, the Cures Act reauthorizes the existing priority review voucher program for certain drugs intended to treat rare pediatric diseases until 2020; creates a new priority review voucher program for drug applications determined to be material national security threat medical countermeasure applications; revises the Food, Drug, and Cosmetic Act to streamline review of combination product applications; requires FDA to evaluate the potential use of "real world evidence" to help support approval of new indications for approved drugs; provides a new "limited population" approval pathway for antibiotic and antifungal drugs intended to treat serious or life-threatening infections; and authorizes FDA to designate a drug as a "regenerative advanced therapy," thereby making it eligible for certain expedited review and approval designations.

Other Regulation

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, export, use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents used in connection with our product development, are or may be applicable to our activities.

EMPLOYEES AND OFFICE LOCATION

Aptevo employed 118 full-time persons as of December 31, 2018. The team is comprised of a dedicated group of accomplished professionals who bring a broad range of academic achievements combined with significant industry experience. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees are represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

Our principal executive offices are located at 2401 4th Ave., Suite 1050, Seattle, Washington 98121. Our telephone number is (206) 838-0500.

AVAILABLE INFORMATION

The Aptevo investor website is located at *www.AptevoTherapeutics.com*. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or the Exchange Act, are available on our website free of charge as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission, or SEC.

Also available free of charge on our website, the reports filed with the SEC by our executive officers, directors and ten percent stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, all disclosures that are required to be posted by applicable law, the rules of the SEC or the Nasdaq listing standards regarding any amendment to, or waiver of, our code of business conduct and ethics are available free of charge on our website. We have included our website address as an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of, or incorporated by reference into, this annual report.

Item 1A. Risk Factors.

You should carefully consider the following risks and other information in this annual report on Form 10-K 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 year ended December 31, 2018, we had a net loss of $53.7 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 December 31, 2018, we had an accumulated deficit of $127.4 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 December 31, 2018, we had cash, cash equivalents, and restricted cash in the amount of $38.1 million. Subsequently, on March 11, 2019, we received gross proceeds of $22.0 million, before underwriting fees, legal fees, and other expenses, in a public offering of common stock and related warrants. 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 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 $1.19 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. Our closing trading price has been as low as $0.84, which is below the minimum. If the trading price of our common stock does not increase, we expect that The Nasdaq Stock Market LLC will notify us that we have failed to meet the minimum listing requirements. If we are unable to timely cure such failure, Nasdaq may initiate the delisting process. 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 24,150,000 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 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease our headquarters office and laboratory space in Seattle, Washington. The Seattle facility is approximately 51,000 square feet and the lease for the Seattle facility expires in April 2020.

Item 3. 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been listed on The Nasdaq Global Market under the symbol "APVO" since August 1, 2016.

Holders of Common Stock

As of March 14, 2019, there were 254 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, future debt instruments may materially restrict our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of the board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of current or then-existing debt instruments and other factors the board of directors deems relevant.

Recent Sales of Unregistered Securities

Except as previously disclosed in a Current Report on Form 8-K filed on December 24, 2018, we did not sell any unregistered securities during the year ended December 31, 2018.

Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the year ended December 31, 2018.

Item 6. Selected Financial Data.

Not required.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis together with the financial statements and the related notes to those statements included elsewhere in this report. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of this report captioned "Risk Factors" and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements.

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.

In August 2015, Emergent BioSolutions Inc., or Emergent, announced a plan to separate into two independent publicly traded companies, one a biotechnology and the other a global specialty life sciences company. To accomplish this separation, Emergent created a new company, Aptevo Therapeutics Inc., or Aptevo, to be the parent company for the development-based biotechnology business focused on novel oncology, hematology, and autoimmune and inflammatory therapeutics. We were incorporated in Delaware in February 2016 as a wholly owned subsidiary of Emergent. To effect the separation, Emergent made a pro rata distribution of Aptevo's common stock to Emergent's stockholders on August 1, 2016.

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

For the year ended December 31, 2018, we had a net loss of $53.7 million, and for the year ended December 31, 2017, we recognized net income of $7.0 million, due to the sale of our Hyperimmune Business, which consisted of the following products: WinRho® SDF; HepaGam B®; and VARIZIG®, or the Hyperimmune Business. We had an accumulated deficit of $127.4 million as of December 31, 2018. For the year ended December 31, 2018, net cash used in our operating activities was $51.7 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 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. Following the sale of the Hyperimmune Business, our sole marked 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 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.

Corporate and Financial Highlights

Commercial Portfolio:

- Achieved record year-over-year annual IXINITY net revenue of $23.1 million in 2018, representing a 111% increase compared to revenue of $10.9 million in 2017.
- Continued to expand the patient base for IXINITY bringing additional new Hemophilia B patients onto therapy throughout the year.
- Improved supply chain logistics and cost efficiencies for IXINITY by contracting with new third-party logistics providers.
- Presented new data from a small retrospective study of IXINITY at the *Thrombosis and Hemostasis 2018 Summit of North America* annual meeting describing patient-reported outcomes data for IXINITY for various clinical and quality of life measures; overall, respondents in this study reported a high level of satisfaction with IXINITY with low annualized bleed rates and a positive impact on quality of life scores.
- Introduced new growth initiatives for IXINITY (launch of new 3,000 IU assay; pediatric clinical trial, and pursuit of ex-U.S. distribution and partnership opportunities) commencing in 2019; the initiation of the pediatric trail is required for the pursuit of business in markets such as Europe.

Pipeline:

- Commenced patient dosing in a Phase 1/1b open-label, dose-escalation study of APVO436 in patients with Acute Myeloid Leukemia (AML) and High-Grade Myelodysplastic Syndrome (MDS); anticipate reporting preliminary anti-drug antibody (ADA) read-out in the third quarter of 2019 and reporting preliminary Phase 1 safety data in data in the fourth quarter of 2019.
- Presented comprehensive new pre-clinical data for APVO436 at the American Association for Cancer Research (AACR) Annual Meeting demonstrating potent T cell-directed tumor killing with reduced cytokine release in pre-clinical studies compared to an Aptevo-generated competitor bispecific construct.
- Completed preparations to begin a Phase 1 clinical study of APVO210 evaluating single and multiple ascending doses in healthy volunteers; APVO210 is being developed for the treatment of autoimmune and inflammatory diseases.
- Received authorization in Australia to commence dosing in APVO210; Phase 1 clinical trial scheduled to begin March 2019 with initial results for the single dose group cohort anticipated in the third quarter of 2019, and preliminary Phase I safety data in the fourth quarter of 2019.
- Published comprehensive pre-clinical data in the journal, *Frontiers in Immunology*, showing that APVO210 has a unique mechanism of action for delivering the cytokine, IL-10, which can generate antigen specific T-regulatory cells, and suppress inflammation and immune activation without stimulating pro-inflammatory cytokines.
- Advanced ALG.APV-527 (partnered with Alligator Bioscience) which targets 4-1BB, a co-stimulatory receptor found on activated T cells and 5T4 (a solid tumor antigen), illustrating the capability of the ADAPTIR platform to generate immunotherapeutic antibodies with different mechanisms of immune system engagement. A bispecific candidate targeting 4-1BB and the tumor antigen, 5T4 is a novel approach with potential to improve clinical outcomes in several solid tumors; anticipate filing a clinical trial authorization (CTA) in the fourth quarter of 2019.
- Presented new pre-clinical data for ALG.APV-527 at several industry conferences showing that it has the potential to selectively activate and enhance tumor-specific T-cell responses at the tumor site without triggering systemic immune activation, supporting the advantages of this novel pathway for tumor immunotherapy.
- Focused our ADAPTIR portfolio on next-generation ADAPTIR candidates that have the potential to provide increased stability, improved potency, and an improved cytokine release profile.

Corporate:

- Increased our available cash by approximately $18 million through the execution of a new term loan agreement with MidCap Financial extending the interest only repayment period to February 1, 2020 with an opportunity for further deferral through August 1, 2020.
- Executed a share purchase agreement with Lincoln Park Capital (LPC) establishing a three-year, $35 million equity line with LPC.
- Completed a public equity offering of common stock and related warrants in March 2019 raising gross proceeds of $22 million, before underwriting fees, legal fees, and other expenses.

Results of Operations

Except as otherwise stated below, the following discussions of our results of operations reflect the results of our continuing operations, excluding the results related to the Hyperimmune Business. The Hyperimmune Business has been separated from continuing operations and reflected as a discontinued operation. See Note 2 – Sale of Hyperimmune Business, to the accompanying financial statements for additional information.

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Revenue

Product sales of IXINITY increased by $12.1 million, or 111%, to $23.1 million for the year ended December 31, 2018 from $10.9 million for the year ended December 31, 2017. This increase was primarily related to continuing expansion of our Hemophilia B patient base and expansion of our distribution channel for IXINITY.

Collaborations revenue for 2017 was due to a one-time recognition of the remaining deferred revenue related to our collaboration with MorphoSys, which was terminated in the third quarter of 2017.

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 margin for the years ended December 31, 2018 and 2017:

	For the Year Ended December 31,			
	2018	2017	Change	Percent
Product sales	$ 23,067	$ 10,949	$ 12,118	111%
Cost of product sales	11,214	5,010	6,204	124%
Gross profit	$ 11,853	$ 5,939	$ 5,914	
Gross margin percent	51%	54%		

Cost of product sales increased by $6.2 million, or 124%, to $11.2 million for the year ended December 31, 2018 from $5.0 million for the year ended December 31, 2017. The increase in cost of product sales is mainly due to the increase in product sales, as well as lower cost inventory in 2017 due to inventory being received in settlement against an outstanding inventory credit.

Research and Development Expenses

We expense research and development costs as incurred. These expenses consist primarily of the costs associated with our research and discovery activities, including conducting pre-clinical 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 primarily consist of:

- 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 (CRO's) and investigative sites;
- manufacturing material expense for third-party manufacturing; and
- overhead costs such as rent, utilities and depreciation.

We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, and the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials. While programs are still in the pre-clinical 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 pre-clinical research and discovery until the program enters the clinic.

Our principal research and development expenses by program for the year ended December 31, 2018 and 2017 are shown in the following table:

	For the Year Ended December 31,		
(in thousands)	2018	2017	Change
Clinical programs:			
APVO414	$ 3,699	$ 3,465	$ 234
otlertuzumab	1,361	1,245	116
Total clinical programs	5,060	4,710	350
Pre-clinical program, general research and discovery	29,070	22,330	6,740
IXINITY	1,255	1,981	(726)
Total	$ 35,385	$ 29,021	$ 6,364

Research and development expenses increased by $6.4 million, to $35.4 million for the year ended December 31, 2018 from $29.0 million for the year ended December 31, 2017. This change was primarily comprised of:

- an increase in manufacturing costs for clinical drug product associated with APVO210 and APVO436, and our general research and discovery programs, which are primarily related to research and development activities around new pipeline product candidates or programs as they are being evaluated; offset by
- a decrease in expense for IXINITY which resulted from less costs in 2018 relating to manufacturing process development activities compared to 2017.

Selling, General and Administrative Expenses

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

For the year ended December 31, 2018 selling, general and administrative expenses decreased by $6.4 million, or 19%, to $28.1 million from $34.5 million for December 31, 2017. This decrease was primarily due to reduced personnel and professional services costs.

Other Expense, net

Other expense, net consists primarily of interest on debt financing and income from the collection of certain accounts receivable transferred to Saol during the sale of our Hyperimmune Business. This increase in expense of $0.1 million in 2018 compared to 2017 was due to $0.2 million for interest on the loan entered into with MidCap Financial Trust, as a result of an increase in the LIBOR rate in 2018 compared to 2017, offset by $0.1 million in income due to the collection of certain accounts receivable related to our Hyperimmune Business that were transferred to Saol at the time of the sale of our discontinued operations.

Discontinued Operations

On September 28, 2017, we sold our Hyperimmune Business to Saol International Limited (Saol). As a result of this sale, our Hyperimmune Business activity has been excluded from continuing operations for all periods herein and reported as discontinued operations. In the year ended December 31, 2017, we recorded income from discontinued operations, net of tax, of $39.6 million. See Note 2 – Sale of Hyperimmune Business in the accompanying consolidated financial statements for further information on the divestiture.

Income Taxes

During the periods prior to spin-off, the Company did not file separate tax returns as it was included in the tax returns of Emergent entities within the respective tax jurisdictions. The income tax provision included in these financial statements was calculated using a separate return basis, as if the Company was a separate taxpayer. Under this approach, the Company determines its current taxes, deferred tax assets and liabilities and related tax expense as if it were filing separate tax returns in each tax jurisdiction.

The following table provides information regarding our income tax for both continuing and discontinued operations for the periods ended December 31, 2018 and 2017:

	For the Year Ended December 31,	
	2018	2017
Loss from continuing operations before income taxes	(53,689)	(55,893)
Benefit from income taxes on continuing operations	—	23,301
Net loss from continuing operations	(53,689)	(32,592)
Discontinued operations		
Income from discontinued operations, before income taxes	—	62,864
Income tax expense	—	(23,299)
Income from discontinued operations	—	39,565
Net income (loss)	$ (53,689)	$ 6,973

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements at December 31, 2018.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2018, we had cash, and cash equivalents in the amount of $30.6 million, and accounts receivable of $5.2 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) and a registration right agreement with Lincoln Park Capital Fund, LLC (Lincoln Park) as discussed in the paragraphs below. In March 2019, we received gross proceeds of $22.0 million, before underwriting fees, legal fees, and other expenses, from an underwritten public offering of common stock and related warrants. See Note 1 – Organization and Liquidity, for additional information.

For the year ended December 31, 2018, we reported a net loss of $53.7 million and we had an accumulated deficit of $127.4 million as of December 31, 2018. For the twelve months ended December 31, 2018, net cash used in our operating activities was $51.4 million. Although we expect our existing cash and cash equivalents will be sufficient to fund our operations for at least fifteen 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. Following the sale of the Hyperimmune Business, 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.

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 December 31, 2018.

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 a purchase agreement, or 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 the Company's 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.

Under the Purchase Agreement, on any business day selected by the Company, the Company 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 fifteen 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 years ended December 31, 2018 and December 31, 2017:

	For the Year Ended December 31,	
(in thousands)	**2018**	**2017**
Net cash provided by (used in):		
Operating activities	(51,401)	(41,573)
Investing activities	72,776	29,458
Financing activities	(787)	9,534
Increase (Decrease) in cash and cash equivalents	$ 20,588	$ (2,581)

Net cash used in operating activities of $51.4 million for the year ended December 31, 2018 was primarily due to our net loss of $53.7 million and changes in working capital accounts. Net cash used in operating activities of $41.6 million for the year ended December 31, 2017 was primarily due to our net income of $7.0 million, offset by the recognition of $52.7 million for the gain on the sale of our Hyperimmune Business, and changes in working capital accounts.

Net cash provided by investing activities for the year ended December 31, 2018, was primarily due to the maturity and redemption of investments of $90.2 million, offset by investment purchases of $16.5 million. For the year ended December 31, 2017, the largest components of the cash provided in investing activities were $70.7 million redemption of investments and by $59.8 million for the cash received from the sale of our Hyperimmune Business, offset by $99.6 million in purchases of corporate bonds and U.S. government debt securities.

Net cash used in financing activities for the year ended December 31, 2018 is primarily due to changes in equity for the tax liability of RSUs, which vested in the period, the payment of $0.6 million in debt issuance costs associated with the Amended Credit Agreement entered into with MidCap in August of 2018, offset by cash received due to the exercise of stock options. Net cash provided by financing activities for the year ended December 31, 2017 includes $20.0 million from our former parent, offset by $10.0 million in restricted cash related to our MidCap loan agreement.

Contractual Obligations

Our contractual obligations as of December 31, 2018 were as follows:

	Payments due by period			
(in thousands)	Total	Less than 1 year	1 to 3 Years	More than 4 years
Operating lease obligations	$ 2,507	$ 1,732	$ 775	$ —

Critical Accounting Policies and Significant Judgements and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

On January 1, 2018, we adopted Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers using the modified retrospective transition method. Upon adoption, we evaluated our existing contracts with customers and determined the adoption of the standard did not change the timing or the amounts of our previously recognized revenues.

To determine revenue recognition for arrangements that an we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customers. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and identify, as a performance obligation, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Research and Development Costs

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

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

Stock-Based Compensation

Under the Financial Accounting Standards Board's (FASB) ASC 718, *Compensation—Stock Compensation*, we measure and recognize compensation expense for restricted stock units (RSUs), and stock options granted to our employees and directors based on the fair value of the awards on the date of grant. The fair value of stock options is estimated at the date of grant using the Black-Scholes option pricing model that requires management to apply judgment and make estimates, including:

- the expected term of the stock option award, which we calculate using the simplified method, as permitted by the SEC Staff Accounting Bulletin No. 110, *Share-Based Payment*, as we have insufficient historical information regarding our stock options to provide a basis for an estimate;
- the expected volatility of our underlying common stock, which we estimate based on the historical volatility of a representative group of publicly traded biopharmaceutical companies with similar characteristics to us, and our own historical and implied future volatility;
- the risk-free interest rate, which we based on the yield curve of U.S. Treasury securities with periods commensurate with the expected term of the options being valued;
- the expected dividend yield, which we estimate to be zero based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends; and
- the fair value of our common stock on the date of grant.

Stock-based compensation expense for RSUs, and stock options is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. We are required to estimate a forfeiture rate to calculate the stock-based compensation expense for our awards. Our forfeiture rate is based on an analysis of our actual forfeitures since the adoption of our equity award plan. We routinely evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover, and expectations of future option exercise behavior.

Income Taxes

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

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

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

New Accounting Standards

For a discussion of new accounting standards please see Note 1 of the Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Our exposure to market risk is primarily confined to our investment securities. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities.

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Item 8. Financial Statements and Supplementary Data

APTEVO THERAPEUTICS INC.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Aptevo Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aptevo Therapeutics Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

Seattle, Washington
March 18, 2019

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

	As of December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,635	$ 7,095
Short-term investments	—	73,688
Accounts receivable	5,220	2,141
Inventories	1,785	1,028
Prepaid expenses	6,907	4,022
Other current assets	4,142	6,710
Restricted cash	—	400
Total current assets	48,689	95,084
Restricted cash, net of current portion	7,448	10,000
Property and equipment, net	5,202	5,843
Intangible assets, net	5,250	6,080
Other assets	905	—
Total assets	$ 67,494	$ 117,007
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 11,671	$ 7,350
Accrued compensation	3,898	4,626
Sales rebates and discounts payable	1,245	623
Current portion of long-term debt	—	3,333
Other current liabilities	796	2,578
Total current liabilities	17,610	18,510
Long-term debt, net	19,278	15,728
Other liabilities	200	734
Total liabilities	37,088	34,972
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; 22,808,416 and 21,605,716 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	23	22
Additional paid-in capital	157,791	155,837
Accumulated other comprehensive loss	—	(105)
Accumulated deficit	(127,408)	(73,719)
Total stockholders' equity	30,406	82,035
Total liabilities and stockholders' equity	$ 67,494	$ 117,007

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

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

	For the Year Ended December 31,	
	2018	2017
Revenues:		
Product sales	$ 23,067	$ 10,949
Collaborations	—	3,709
Total revenues	23,067	14,658
Costs and expenses:		
Cost of product sales	11,214	5,010
Research and development	35,385	29,021
Selling, general and administrative	28,133	34,576
Loss from operations	(51,665)	(53,949)
Other expense:		
Other expense, net	(2,024)	(1,944)
Loss before income taxes	(53,689)	(55,893)
Benefit from income taxes	—	23,301
Net loss from continuing operations	(53,689)	(32,592)
Discontinued operations (Note 2):		
Income from discontinued operations, before income taxes	—	62,864
Income tax expense	—	(23,299)
Income from discontinued operations	—	39,565
Net income (loss)	$ (53,689)	$ 6,973
Basic and diluted net income (loss) per share:		
Net loss from continuing operations	$ (2.39)	$ (1.53)
Net income from discontinued operations	$ —	$ 1.86
Net income (loss)	$ (2.39)	$ 0.33
Weighted-average shares used to compute per share calculation	22,500,053	21,335,157

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

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

	For the Year Ended December 31,	
	2018	2017
Net (loss) income	$ (53,689)	$ 6,973
Other comprehensive loss:		
Unrealized gain (losses) on available-for-sale investments, net	105	(72)
Total comprehensive (loss) income	$ (53,584)	$ 6,901

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

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

	For the Year Ended December 31,	
	2018	2017
Operating Activities		
Net income (loss)	$ (53,689)	$ 6,973
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	2,140	4,884
Depreciation and amortization	2,390	3,127
Non-cash interest expense and other	988	636
Gain on sale of Hyperimmune Business	—	(52,697)
Changes in operating assets and liabilities:		
Accounts receivable	(3,079)	(1,834)
Inventories	(757)	(567)
Prepaid expenses and other current assets	(1,315)	(1,628)
Accounts payable, accrued compensation and other liabilities	1,279	195
Sales rebates and discounts	621	345
Assets and liabilities held for sale and amount due to Saol	—	2,700
Deferred revenue	—	(3,707)
Net cash used in operating activities	(51,422)	(41,573)
Investing Activities		
Proceeds from the maturity of investments	90,243	70,730
Cash proceeds from sale of Hyperimmune Business	65	59,763
Purchases of property and equipment	(976)	(1,402)
Purchases of investments	(16,535)	(99,633)
Net cash provided by investing activities	72,797	29,458
Financing Activities		
Common stock issued upon exercise of stock options, and under the ATM arrangement, net	623	442
Payment of tax liability for vested equity awards	(808)	(758)
Fees paid to lender in connection with amendment of debt agreement	(602)	(150)
Settlement of contribution receivable from former parent	—	20,000
Net cash (used in) provided by financing activities	(787)	19,534
Increase in cash, cash equivalents, and restricted cash	20,588	7,419
Cash, cash equivalents, and restricted cash at beginning of period	17,495	10,076
Cash, cash equivalents, and restricted cash at end of period	$ 38,083	$ 17,495
Supplemental disclosures:		
Cash paid for interest	$ 1,930	$ 1,778

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Contribution Receivable from Former Parent	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2016	$ 20,271,737	$ 20	$ 151,271	$ (80,692)	$ (20,000)	$ (33)	$ 50,566
Unrealized losses on available-for-sale investments	—	—	—	—	—	(72)	(72)
Transfers from former parent	—	—	—	—	20,000	—	20,000
Common stock issued upon exercise of stock options	174,763	—	440	—	—	—	440
Common stock issued upon vesting of restricted stock units	1,159,216	2	(758)	—	—	—	(756)
Stock-based compensation	—	—	4,884	—	—	—	4,884
Net income for the period	—	—	—	6,973	—	—	6,973
Balance at December 31, 2017	$ 21,605,716	$ 22	$ 155,837	$ (73,719)	$ —	$ (105)	$ 82,035
Unrealized gain on available-for-sale investments	—	—	—	—	—	105	105
Common stock issued upon exercise of stock options, sales under ATM arrangement, and issuance of commitment shares	386,866	1	622	—	—	—	623
Common stock issued upon vesting of restricted stock units	815,834	—	(808)	—	—	—	(808)
Stock-based compensation	—	—	2,140	—	—	—	2,140
Net loss for the period	—	—	—	(53,689)	—	—	(53,689)
Balance at December 31, 2018	$ 22,808,416	$ 23	$ 157,791	$ (127,408)	$ —	$ —	$ 30,406

The accompanying notes are an integral part of these 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."

On September 28, 2017, Aptevo completed the sale of its hyperimmune business which consisted of the following products: WinRho® SDF for autoimmune platelet disorder and hemolytic disease of the newborn; HepaGam B® for the prevention of Hepatitis B following liver transplantation and for treatment following hepatitis B exposure; and VARIZIG® for treatment following exposure to varicella zoster virus for individuals with compromised immune systems (Hyperimmune Business). The Hyperimmune Business met all the conditions to be classified as a discontinued operation since the sale of Hyperimmune Business represented a strategic shift that will have a major effect on the Company's operations and financial results. Aptevo will not have further significant involvement in the operations of the discontinued Hyperimmune Business. The operating results of the Hyperimmune Business are reported as income from discontinued operations, both pre-tax and net of tax, in the consolidated statements of operations for the nine months ended September 30, 2017 reporting period. See Note 2 - Sale of Hyperimmune Business for additional information.

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 March 18, 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 March 18, 2020.

In March 2019, we completed a public offering of common stock and warrants. We received gross proceeds of $22.0 million, before underwriting fees, legal fees, and other expenses, on March 13, 2019 upon the issuance of 19,850,000 shares of common stock, warrants to purchase 19,850,000 shares of common stock at an exercise price of $1.30 per share, pre-funded warrants to purchase 2,150,000 shares of our common stock with an exercise price of $0.01 per share, and warrants to purchase up to 2,150,000 shares of our common stock with an exercise price of $1.30 per share. If fully exercised in the future, additional proceeds to be received upon exercise of the 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 consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). These 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 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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

Principles of Consolidation

The 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.

Cash Equivalents

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

Restricted Cash

We have restricted cash, long-term, which 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.

Short-Term Investments

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

Concentrations of Credit Risk

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

Major Customers

We sell IXINITY through a limited number of customers and specialty pharmacies. Each of these wholesalers, together with entities under their common control, accounted for greater than 10% of total revenues for the years ended December 31, 2018 and 2017 and greater than 10% of accounts receivable as of December 31, 2018 and 2017 as noted below.

	2018		2017	
	Percentage of Total Revenue	Percentage of Accounts Receivable	Percentage of Total Revenue	Percentage of Accounts Receivable
Customer A	72%	70%	83%	73%
Customer B	17%	19%	—	—
Customer C	—	—	13%	27%

Accounts Receivable

Aptevo records accounts receivable net of an allowance for doubtful accounts based upon its assessment of collectability, and of applicable discounts. Aptevo performs ongoing credit evaluations of its customers and generally does not require collateral. As a result of its sale of its Hyperimmune Business in September 2017, accounts receivable net of an allowance for doubtful accounts has been revised to reflect the removal of its allowance for doubtful accounts, as the prior balance solely related to the Hyperimmune Business. See Note 2, Sale of Hyperimmune Business for additional information on the divestiture.

Inventories

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

Property and Equipment

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

Furniture and equipment	7-10 years
Software and hardware	3-5 years or product life
Leasehold improvements	Lesser of the asset life or the remaining lease term

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

Fair Value of Financial Instruments

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

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

Product Sales, Rebates and other Discounts

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

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

Debt Issuance Costs

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

Revenue Recognition

Effective January 1, 2018, we adopted Financial Accounting Standards Board (FASB) Accounting Standard Update (ASU) No. 2014-09, Revenue from Contracts with Customers (ASC 606) on a modified retrospective basis, which required the cumulative effect of the adoption to be recognized as an adjustment to opening retained earnings in the first period of 2018. For Aptevo, there was no financial impact for the cumulative effect of this change, and therefore there was no adjustment to opening retained earnings. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaborative arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customers. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and identify, as a performance obligation, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

Aptevo has one marketed commercial product, IXINITY, a coagulation factor IX (recombinant) therapeutic 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 sell IXINITY to a limited number of specialty distributors in the United States, collectively, our customers. These customers subsequently resell IXINITY to health care providers and patients. Revenue from product sales are recognized when the customer obtains control of the IXINITY product. Our customers provide us with a new order for every purchase of goods. This incorporates the terms and conditions of the contract, including pricing. Acceptance of the order is the point at which we are obligated to provide the product, and we have determined that each order represents a unique performance obligation. Product revenue is recorded at the amount we expect to receive, which is net of any rebates or chargebacks.

Reserves for Variable Consideration

We have identified the following fees, discounts and rebates that result in consideration being variable: chargebacks, distributor and Group Purchasing Organizations (GPO) fees, government rebates, return rights, and patient assistance. As part of determining variable consideration we noted that although the distributors are our customers, there are additional indirect customers in the distribution chain to whom we make payments. These indirect customers are not customers; however, unless a distinct good or service is provided to us, payments to these indirect customers need to be accounted for as a reduction in the transaction price, and therefore constitute an element of variable consideration, under ASC 606. Further, if material, we would also account for returns as variable consideration.

These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

We have established provisions for the following types of variable consideration:

Chargebacks: We make payments to customers (in the form of credit memos) which are based on the difference between the price paid by the distributor and contracted prices paid by the authorized customers of the distributor. Specialty pharmacies and other smaller specialty distributors buy the product from the distributors at prices agreed to in contracts with us, or if they are eligible, at government established prices (PHS/Medicaid/Medicare/VA prices). When the distributor sells the product at contracted prices lower than their acquisition price, the distributor is allowed to charge the difference between their price and the contract price paid by their customer to Aptevo. We refer to this as a “Chargeback”.

These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and we generally issue credits for such amounts within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consist of credits we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to qualified healthcare providers, and chargebacks that Customers have claimed but for which we have not yet issued a credit.

Distribution, Dispensing, and Data Fees: We pay fees (in the form of direct payments) to the distributors and some indirect customers for distribution and dispensing of the products and for transmission of data. Fees owed to our distributors is based on their purchases and is calculated as a direct percent of quarterly purchases. Although fees can vary from distributor to distributor, the fees associated with a specific sale is known at the time of the sale. Fees owed to GPOs are determined based on volume of indirect sales to GPS members.

Government Rebates: Certain sales by the specialty pharmacies are to qualified PHS/Medicaid/Medicare/VA and other publicly insured patients. We have contracts with these agencies, some of which require rebates for sales made under these programs. We estimate our Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses on the consolidated balance sheet. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at period end.

Commercial Rebates: We currently offer the option to receive a rebate based on volume thresholds. This rebate is estimated at the time of the sale and is based on the terms of the Customer agreements. There are minimum volume requirements in order to receive this rebate, which varies per Customer.

Cash Discounts: Most customers have the option to receive a cash discount for early payment. Typically, cash discounts are two-percent of the invoice amount if the payment is made within thirty days.

Patient Assistance: Certain patients may be eligible for the IXINITY Savings Program, which provides for up to $12,000 annual benefit to assist with co-payments. Historically, this has been insignificant to our revenue as the total benefit provided since sales of IXINITY commenced in 2015 has been less than $0.1 million.

The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at period end.

Returns: If product is damaged in shipment (either observable or hidden), or the incorrect number of units was shipped (for example, if the customer ordered 1 unit and 10 were shipped) these are allowable returns under our Return Policy (a component of the distributor agreements). However, as product is generally received by the distributors within 1 business day, and product damage is usually noted upon inspection, we would not recognize revenue on those shipments as part of our normal revenue recognition process. To date there has not been any such damaged product and we expect any such issues to be rare; however, if returns were to become significant a reserve estimate would be developed and accounted for as a reduction of revenue. See Note 15 – Revenue Reserves for additional information.

Collaborations

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

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

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

Research and Development Costs

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

A substantial portion of Aptevo's pre-clinical studies and all of its clinical studies have been performed by third-party CROs. The Company reviews the activities performed by the CROs each period. For pre-clinical studies, the significant factors used in estimating accruals include the percentage of work completed to date and contract milestones achieved. For clinical study expenses, the significant factors used in estimating accruals include the number of patients enrolled and services provided but not yet invoiced. The Company's estimates are highly dependent upon the timeliness and accuracy of the data provided by its CROs regarding the status of each program and total program spending and adjustments are made when deemed necessary.

Selling, General and Administrative Expenses

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

Stock-Based Compensation

Under the Financial Accounting Standards Board's (FASB) ASC 718, Compensation—Stock Compensation, we measure and recognize compensation expense for restricted stock units (RSUs), and stock options granted to our employees and directors based on the fair value of the awards on the date of grant. The fair value of stock options is estimated at the date of grant using the Black-Scholes option pricing model that requires management to apply judgment and make estimates, including:

- the expected term of the stock option award, which we calculate using the simplified method, as permitted by the SEC Staff Accounting Bulletin No. 110, Share-Based Payment, as we have insufficient historical information regarding our stock options to provide a basis for an estimate;
- the expected volatility of our underlying common stock, which we estimate based on the historical volatility of a representative group of publicly traded biopharmaceutical companies with similar characteristics to us, and our own historical and implied future volatility;
- the risk-free interest rate, which we based on the yield curve of U.S. Treasury securities with periods commensurate with the expected term of the options being valued;
- the expected dividend yield, which we estimate to be zero based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends; and
- the fair value of our common stock on the date of grant.

Stock-based compensation expense for RSUs is recognized on a straight-line basis over the vesting period of the respective award. Stock-based compensation expense for our stock options, both converted and Aptevo granted, is recognized on a straight-line basis over the vesting period of the respective award.

We have elected to estimate a forfeiture rate to calculate the stock-based compensation expense for our awards. Our forfeiture rate for the converted RSUs and options is based on an analysis of the actual forfeitures experienced by Emergent. For the RSUs and options issued by Aptevo, we have estimated a forfeiture rate of ten-percent. Since inception our actual forfeiture rate has been de minimis. We routinely evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover, and expectations of future option exercise behavior.

Income Taxes

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

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

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

Segment Reporting

We have determined that we operate in a single segment and have one reporting unit: the discovery, development, commercialization and sale of novel oncology and hematology therapeutics.

New Accounting Pronouncements

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

In December 2017, the SEC issued Staff Accounting Bulletin (SAB) 118 to address the application of U.S. GAAP in situations in which a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act (the Tax Reform Act) which was signed into law on December 22, 2017. In March 2018, the FASB issued ASU 2018-05, which amended ASC 740 to incorporate the requirements of SAB 118. We recognized the provisional tax impacts of the Tax Reform Act in the fourth quarter of 2017. During the third quarter of 2018, we filed our U.S. federal tax return for 2017. While we do not anticipate any remaining adjustments related to the Tax Reform Act, the measurement period under SAB 118 remains open as there is still anticipated guidance clarifying certain aspects of the Tax Reform Act. We did not have any subsequent adjustments in the fourth quarter of 2018 when the full analysis was completed.

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; however, the SEC has stated it will not object if filers first include the additional disclosure for the first quarter that begins after the effective date of the amendments. As a result, Aptevo will first provide the additional disclosure in its quarterly report on Form 10-Q for the first quarter of 2019. We will be adding an additional disclosure to our filing, but currently do not anticipate there to be any financial impact.

Recently Adopted Standards

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (ASC 606), and has subsequently issued a number of amendments to ASU 2014-09. We adopted this standard effective January 1, 2018 on a modified retrospective basis. The new standard as amended, provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, included industry-specific guidance.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows: Restricted cash. This standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, restricted cash, and restricted cash equivalents when reconciling the beginning-of and ending-of period total amounts shown on the statement of cash flows. This guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We adopted this standard effective January 1, 2018. Upon adoption of this standard, we applied the retrospective transition method for each period presented. As a result of this adoption we adjusted our consolidated statement of cash flows to include $10.4 million of restricted cash at December 31, 2017 and $7.8 million in restricted cash at December 31, 2018. See Note 5 – Cash, cash equivalents, and restricted cash for additional information.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (ASC 230): Classification of Certain Cash Receipts and Cash Payments, which clarifies the classification and presentation of eight specific cash flow issues in the statement of cash flows. We adopted this standard effective January 1, 2018. Adoption of this standard had no impact on our consolidated statements of cash flows or related disclosures.

Note 2. Sale of Hyperimmune Business

On August 31, 2017, Aptevo entered into a sale agreement with Saol International Limited (Saol) whereby Aptevo agreed to sell its Hyperimmune Business. The sale was completed on September 28, 2017.

At the closing of the sale, Saol paid an amount equal to $65.0 million, including $3.3 million that was deposited in an escrow account for the purposes of satisfying any indemnification claims brought by Saol pursuant to the LLC purchase agreement, which was released in December 2018. In addition, Aptevo may receive (1) an additional potential milestone payment totaling up to $7.5 million related to the achievement of certain gross profit milestones, which if earned, will be collectable in the fourth quarter of 2020, and (2) up to $2.0 million related to collection of certain accounts receivable after the closing.

The following table represents the components attributable to the Hyperimmune Business presented as income from discontinued operations (in thousands):

	2017
Cash payment received	$ 61,750
Escrow receivable	3,250
Collection of accounts receivable	37
Total consideration	65,037
Less:	
Net carrying value of assets transferred to Saol	10,315
Transaction costs	1,273
Working capital adjustment	752
Net gain on sale of business	$ 52,697

As a result of Aptevo's decision to sell the Hyperimmune Business, the consolidated balance sheet for the year ended December 31, 2017, has been revised to reflect the results from the sale of the Hyperimmune Business, and related assets and liabilities, as discontinued operations. The amounts calculated for the discontinued operations include certain allocations that management believes fairly reflect the Hyperimmune Business operations.

The following table presents a reconciliation of the carrying amounts of assets and liabilities of the hyperimmune assets held for sale, net in the consolidated balance sheet (in thousands):

	December 31, 2017
ASSETS	
Accounts receivable	$ 3,977
Inventories	6,178
Total current assets, held for sale	10,155
Intangible assets, net	7,624
Total assets held for sale	$ 17,779
LIABILITIES	
Accounts payable and other accrued liabilities	$ 3,928
Total current liabilities	$ 3,928

The following table represents the components attributable to the Hyperimmune Business presented as income from discontinued operations in the consolidated statements of operations (in thousands):

	2017
Revenues:	
Product sales	$ 18,886
Total revenues	18,886
Costs and expenses:	
Cost of product sales	7,730
Research and development	44
Selling, general and administrative	945
Income from operations	10,167
Gain on sale of Hyperimmune Business	52,697
Other income	—
Income from discontinued operations, before income taxes	62,864
Income tax expense	(23,299)
Income from discontinued operations	$ 39,565

Amortization for the Hyperimmune Business was $0.8 million for the year ended December 31, 2017. The net gain on sale of the Hyperimmune Business totaling, $52.7 million, was calculated as the difference between the fair value of the consideration received for the Hyperimmune Business, the carrying value of the net assets transferred to Saol, less the transaction costs incurred and a working capital adjustment. The net gain on sale of the business may be adjusted in future periods by the contingent consideration based upon the achievement of certain gross profit milestones and collection of certain outstanding accounts receivable.

In the year ended December 31, 2018, we recorded $0.1 million due to the collection of certain accounts receivable transferred to Saol during the sale and $3.3 million due to the collection of the amount placed in escrow in September 2017. As of December 31, 2018, there were no claims against these escrow funds and they were released. There was no depreciation, capital expenditures or other significant operating or investing non-cash items for the year ended December 31, 2018.

Note 3. 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 2 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 year ended December 31, 2018, Alligator incurred a higher share of the research and development costs than those of Aptevo which netted to $0.6 million and is reflected as a reduction in our research and development expenses.

MorphoSys

In August 2014, Aptevo entered into a collaboration agreement with MorphoSys AG (MorphoSys Agreement) for the joint development of MOR209/ES414, a targeted immunotherapeutics protein, which activates host T-cell immunity specifically against cancer cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells. Effective August 31, 2017, MorphoSys terminated the MorphoSys Agreement. As a result of the termination, Aptevo has no ongoing obligation related to this agreement.

As a result of the termination, we recognized the total remaining deferred revenue balance of $3.7 million in the third quarter of 2017.

Note 4. Fair Value Measurements

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

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

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

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

The Company's financial assets measured at fair value consisted of the following as of December 31, 2018 and December 31, 2017:

	December 31, 2018			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds(1)	$ 29,047	$ —	$ —	$ 29,047
Total assets	$ 29,047	$ —	$ —	$ 29,047

	December 31, 2017			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds(1)	$ 10,997	$ —	$ —	$ 10,997
Corporate bonds	—	16,443	—	16,443
US government and agency debt securities	—	33,300	—	33,300
Foreign government and agency debt securities	—	23,945	—	23,945
Total assets	$ 10,997	$ 73,688	$ —	$ 84,685

(1) As of December 31, 2018, the money market funds included $5.0 million in restricted cash, and as of December 31, 2017, the money market funds included $10.0 in restricted cash.

If quoted market prices in active markets for identical assets are not available to determine fair value, then the Company uses quoted prices of similar instruments and other significant inputs derived from observable market data obtained from third-party data providers. These investments are included in Level 2 and consist of debt securities of U.S government agencies and corporate bonds. There were no transfers between Levels 1 and 2 during the twelve-month period ended December 31, 2018.

Note 5. 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 with commercial banks and financial institutions. 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 restricted cash, both current and long-term portion as of December 31, 2018 and December 31, 2017:

	For the Year Ended December 31,	
(in thousands)	**2018**	**2017**
Cash	$ 29,047	$ 6,098
Cash equivalents	1,588	997
Restricted cash, current portion	—	400
Restricted cash, net of current portion	7,448	10,000
Total cash, cash equivalents, and restricted cash	$ 38,083	$ 17,495

Note 6. Investments

Investments are classified as available-for-sale debt securities and are carried at fair value with unrealized temporary holding gains and losses included in other comprehensive income or loss and as a net amount in accumulated other comprehensive income or loss until such gains and losses are realized. We did not recognize any realized gains or losses in net income during 2018. Available-for-sale securities are written down to fair value through income whenever it is necessary to reflect other than temporary impairments. We have determined that the unrealized gains on our marketable securities as of December 31, 2018 were temporary in nature, and currently does not intend to sell these securities before recovery of their amortized cost basis. All short-term investments are limited to a final maturity of less than one year from the reporting date.

	December 31, 2018			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding (Losses)	Fair Value
Cash equivalents:				
Money market funds[1]	$ 29,047	$ —	$ —	$ 29,047
Total cash equivalents	$ 29,047	$ —	$ —	$ 29,047
Short-term investments:				
Corporate bonds	$ —	$ —	$ 12	$ 12
US government and agency debt securities	—	—	31	31
Foreign government and ageny debt securities	—	—	62	62
Total short-term investments	$ —	$ —	$ 105	$ 105

	December 31, 2017			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding (Losses)	Fair Value
Cash equivalents:				
Money market funds[1]	$ 10,997	$ —	$ —	$ 10,997
Total cash equivalents	$ 10,997	$ —	$ —	$ 10,997
Short-term investments:				
Corporate bonds	$ 16,455	$ —	$ (12)	$ 16,443
US government and agency debt securities	33,331	—	(31)	33,300
Foreign government and ageny debt securities	24,007	—	(62)	23,945
Total short-term investments	$ 73,793	$ —	$ (105)	$ 73,688

[1] As of December 31, 2018, the money market funds included $5.0 million in restricted cash, and as of December 31, 2017, the money market funds included $10.0 in restricted cash.

Note 7. Inventories

Inventories consist of the following:

	Ended December 31,	
(in thousands)	2018	2017
Raw materials and supplies	$ 194	$ 56
Work-in-process	916	482
Finished goods	675	490
Total inventories	$ 1,785	$ 1,028

Note 8. Property and equipment, net

Property, plant and equipment consist of the following:

(in thousands)	For the Year Ended December 31, 2018	2017
Leasehold improvements	$ 2,278	$ 2,228
Furniture and equipment	11,622	11,139
Property and equipment, gross	13,900	13,367
Less: Accumulated depreciation	(8,698)	(7,524)
Total property and equipment, net	$ 5,202	$ 5,843

Depreciation expense for the year ended December 31, 2018 and December 31, 2017 was $1.6 million and $1.5 million, respectively.

Note 9. IXINITY Intangible Assets, Net

Intangible assets, net, is solely related to our IXINITY product. For the years ended December 31, 2018 and 2017, the Company recorded $0.8 million, respectively, of intangible asset amortization expense. As of December 31, 2018, the weighted average amortization period remaining for intangible assets was 75 months.

Future amortization expense as of December 31, 2018 is as follows:

(in thousands)	
2019	$ 830
2020	830
2021	830
2022 and beyond	2,760
Total remaining amortization	$ 5,250

Note 10. 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.

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.

Future principal and interest payments in connection with the Credit Agreement as of December 31, 2018 are as follows:

(in thousands)		
2019	$	1,936
2020		5,215
2021		9,257
2022		8,482
2023		2,022
Total principal and interest payments	$	26,912

Note 11. Net Income (Loss) per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (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, stock options and restricted stock units are only included in the calculation of diluted net income per share when their effect is dilutive.

We utilize the control number concept in the computation of diluted earnings per share to determine whether potential common stock instruments are dilutive. The control number used is loss from continuing operations. The control number concept requires that the same number of potentially dilutive securities applied in computing diluted earnings per share from continuing operations be applied to all other categories of income or loss, regardless of their anti-dilutive effect on such categories. Therefore, no dilutive effect has been recognized in the calculation of income from discontinued operations per share.

Prior to the spin-off, Aptevo did not operate as a separate entity and as a result did not have any common stock outstanding other than 1,000 shares held by Emergent. The calculation of basic and diluted net loss per share assumes that the 20,229,849 ordinary shares issued to Aptevo stockholders in connection with the spin-off were outstanding from the beginning of the periods presented. In March 2019, pursuant to our public offering, we issued 19,850,000 shares of common stock, warrants to purchase 19,850,000 shares of common stock, pre-funded warrants to purchase 2,150,000 shares of common stock, and warrants to purchase 2,150,000 shares of common stock.

Common stock equivalents include stock options and unvested RSUs.

The following table presents the computation of basic and diluted net income (loss) per share (in thousands, except share and per share amounts):

	For the Year Ended December 31,	
	2018	2017
Net income (loss)	$ (53,689)	$ 6,973
Basic and diluted net income (loss) per share:		
Net loss from continuing operations	$ (2.39)	$ (1.53)
Net income from discontinued operations	$ —	$ 1.86
Net income (loss)	$ (2.39)	$ 0.33
Weighted-average shares used to compute per share calculation	22,500,053	21,335,157

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 Year Ended December 31,	
(in thousands, except for per share amounts)	2018	2017
Outstanding options to purchase common stock	3,330	2,819
Unvested RSUs	133	1,211

Note 12. Equity

Common Stock

For the year ended December 31, 2018, we received proceeds of $0.6 million upon the exercise of stock options which resulted in the issuance of 373,601 shares of common stock. For the year ended December 31, 2017 there was no proceeds from the exercise of stock options and no issuance of shares of common stock. We also issued 815,834 and 1,159,216 shares of common stock in the years ended December 31, 2018 and December 31, 2017, respectively, upon the vesting of RSUs.

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 the Shares by Piper Jaffray will be effected pursuant to a Registration Statement on Form S-3 which we filed on November 9, 2017 (the Registration Statement). We have issued 13,265 shares under the Equity Distribution Agreement as of December 31, 2018.

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 December 31, 2018, there are 2.8 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 restricted stock units granted to employees and non-employees and has been reported in our Consolidated Statements of Operation and Comprehensive Loss as follows:

(in thousands)	For the Year Ended December 31, 2018	2017
Research and development	$ 884	$ 2,256
Selling, general and administrative	1,256	2,628
Total stock-based compensation expense	$ 2,140	$ 4,884

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 Year Ended December 31, 2018	2017
Expected dividend yield	0.00%	0.00%
Expected volatility	75.00%	75.00%
Risk-free interest rate	2.74%	1.90%
Expected average life of options	6 years	6 years

Management applied an estimated forfeiture rate for the 2018 plan period of 10%.

The following is a summary of option activity for the year ended December 31, 2018:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Term	Aggregate Intrinsic Value
Balance at December 31, 2017	2,819,344	$ 2.41	—	$ 5,156,881
Granted	907,388	3.55	—	—
Exercised	(238,808)	2.17	—	539,140
Forfeited	(158,306)	2.46	—	247,227
Outstanding at December 31, 2018	3,329,618	$ 2.74	6.99	$ —
Exercisable at December 31, 2018	1,600,258	$ 2.50	5.17	$ —

As of December 31, 2018, we had $2.1 million of unrecognized compensation expense related to options expected to vest over a weighted average period of 1.9 years. The weighted average remaining contractual life of outstanding and exercisable options is 5.2 years. As of December 31, 2018, none of our outstanding or exercisable stock options are in the money, and as such there is no aggregate intrinsic value for either the outstanding or exercisable stock options in the above table.

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 2018 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 December 31, 2018.

Restricted Stock Units

The following is a summary of restricted stock activity for the year ended December 31, 2018:

	Number of Units	Weighted Average Fair Value per Unit	Aggregate Fair Value
Balance at December 31, 2017	1,211,487	$ 2.91	$ 5,136,705
Granted	—	—	—
Vested	(1,059,836)	2.90	3,514,900
Forfeited	(18,611)	2.96	51,748
Outstanding at December 31, 2018	133,040	$ 2.97	$ 168,961
Expected to Vest	130,357	$ 2.97	$ 165,554

As of December 31, 2017, we had less than $0.1 million of unrecognized compensation expense related to RSU's, which will all be fully vested by March 11, 2019.

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

Note 13. 401(k) savings plan

Aptevo has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers all employees. Under the 401(k) Plan, employees may make elective salary deferrals. Aptevo currently provides for matching of qualified deferrals up to 50% of 401(k) employee deferral contributions, based on a maximum employee deferral rate of 6% of compensation. During the year ended December 31, 2018 and December 31, 2017, Aptevo's related share of matching contributions was approximately $0.5 million and $0.5 million.

Note 14. Leases and Contingencies

The Company leases laboratory and office facilities, and office equipment under operating lease agreements. The Company recognizes rent expense under such arrangements on a straight-line basis over the term of the lease. Our current operating lease for our laboratory and office facilities expires in April 2020. During the year ended December 31, 2018 and December 31, 2017 total lease expense was $1.2 million and $1.7 million, respectively.

As of December 31, 2018, we are committed to future minimum lease payments under operating lease agreements as follows:

(in thousands)	
2019	$ 1,732
2020	664
2021	103
2022	8
Total	$ 2,507

Note 15. Revenue Reserves

The following table summarizes activity in each of our receivable-related allowances and revenue-related liabilities for the year ended December 31, 2018:

(in thousands)	Chargebacks and Rebates	Distribution Fees, Cash Discounts and Patient Assistance
Balance at December 31, 2017	$ (428)	$ (240)
Provision related to current period sales	(2,515)	(1,879)
Credit or payments made during the period	1,620	1,254
Balance at December 31, 2018	$ (1,323)	$ (865)

Note 16. Income Taxes

On December 22, 2017, the President of the United States signed into law Public Law No. 115-97, commonly referred to as the Tax Reform Act, following its passage by the United States Congress. The Tax Act made significant changes to U.S. federal income tax laws, including reduction of the corporate tax rate from 35.0% to 21.0%, limitation of the deduction for net operating losses to 80.0% of current year taxable income and elimination of net operating loss carrybacks, one-time taxation of offshore earning 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.

In December 2017, the SEC issued Staff Accounting Bulletin (SAB) 118 to address the application of U.S. GAAP in situations in which a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act (the Tax Reform Act) which was signed into law on December 22, 2017. In March 2018, the FASB issued ASU 2018-05, which amended ASC 740 to incorporate the requirements of SAB 118. We recognized the provisional tax impacts of the Tax Reform Act in the fourth quarter of 2017. During the fourth quarter of 2018, we filed our US federal tax return and completed our determination of the accounting implications of the Tax Reform Act.

Significant components of the provisions for income taxes attributable to operations consist of the following:

	Year ended December 31,	
(in thousands)	2018	2017
Current		
Federal	$ —	$ 12,051
State	—	710
International	—	2
Total current	—	12,763
Deferred		
Federal	—	9,636
State	—	902
International	—	—
Total deferred	—	10,538
Total income tax benefit from continuing operations	$ —	$ 23,301

The table above excludes income tax expense from discontinued operations of $23.3 million for 2017.

Loss from continuing operations before income taxes is comprised of:

(in thousands)	Year ended December 31, 2018	2017
US	$ (53,692)	$ (55,885)
International	3	(8)
Loss from continuing operations before benefit from income taxes	$ (53,689)	$ (55,893)

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities are presented below:

(in thousands)	For the Year Ended December 31, 2018	2017
Federal losses carryforward	$ 20,251	$ 8,454
Intangible assets	4,210	4,470
State losses carryforward	2,260	1,246
Other	1,543	1,262
Stock compensation	844	1,128
Other tax credits	713	502
Fixed assets	488	309
Deferred tax asset	30,309	17,371
Prepaid expenses	—	(224)
Deferred tax liability	—	(224)
Valuation allowance	(30,309)	(17,147)
Net deferred tax liabilities	$ —	$ —

As of December 31, 2018, and 2017, we have recorded federal net operating losses (NOL) carryforwards of approximately $96.4 and $41.5 million, respectively, state NOL carryforwards of approximately $44.5 million and $20.2, respectively, and tax credit carryforwards of $0.7 million and $0.5 million, respectively. The federal losses and credits will begin to expire in 2037. The state net operating losses will begin to expire in varying periods. Carryforwards of net operating losses and tax credits are subject to possible limitation, should a change in ownership occur, as defined by Internal Revenue Code Section 382.

The Company files income tax returns in the U.S. and several state jurisdictions and are open to review by taxing authorities for the 2016 tax filings and thereafter.

We are subject to the accounting guidance for uncertain income tax positions. We believe that our income tax positions and deductions will be sustained on audit and do not anticipate any adjustments that will result in a material adverse effect on our financial condition, results of operations, or cash flow. Our policy for recording interest and penalties associated with audits and uncertain tax positions is to record such items as a component of income tax expense, and amounts recognized to date are insignificant. No uncertain income tax positions are recorded, and we do not expect our uncertain tax position to change during the next twelve months.

The reconciliation of the federal statutory income tax rate to the Company's effective income tax from continuing operations is as follows:

	Year ended December 31,	
	2018	2017
Federal tax at statutory rates	21.0%	35.0%
State taxes, net of federal benefit	2.5%	2.4%
Change in valuation allowance	-24.5%	22.7%
Tax credits	0.4%	0.6%
Permanent differences	-0.2%	-0.3%
Other	0.8%	-1.3%
Tax Reform	0.0%	-17.4%
Total income tax benefit	0.0%	41.7%

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2018, 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 December 31, 2018, 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.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the 1934 Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. As a result of this assessment, management concluded that, as of December 31, 2018, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Change 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 year ended December 31, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls

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

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executives Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A in connection with our 2019 Annual Meeting of Stockholders (the Proxy Statement), which is expected to be filed not later than 120 days after December 31, 2018, under the headings "Executive Officers," "Proposal 1 -Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," and "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

Item 11. Executive Compensation.

Information required by this item will be contained in the Proxy Statement under the headings "Executive Compensation" and "Director Compensation," and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be contained in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

Item 13. Certain Relationships, Related Transactions and Director Independence.

Information required by this item will be contained in the Proxy Statement under the headings "Transactions with Related Persons" and "Information Regarding the Board of Directors and Corporate Governance," and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

Information required by this item will be contained in the Proxy Statement under the heading "Proposal 2 – Ratification of the Selection of Independent Registered Public Accounting Firm," and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. Consolidated Financial Statements

See Index to Consolidated Financial Statements at Item 8 herein.

2. Consolidated Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

3. Exhibits

Exhibit Index

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
2.1	Contribution Agreement, dated July 29, 2016, by and among Emergent BioSolutions Inc., Aptevo Therapeutics Inc., Aptevo Research and Development LLC and Aptevo BioTherapeutics LLC	8-K	2.1	August 2, 2016	001-37746	
+2.2	Separation and Distribution Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	2.2	August 2, 2016	001-37746	
†+2.3	LLC Purchase Agreement, dated as of August 31, 2017, by and among Aptevo BioTherapeutics LLC, Aptevo Therapeutics Inc., Venus Bio Therapeutics Sub LLC, and Saol International Limited.	10-Q	2.1	November 13, 2017	001-37746	
3.1	Amended and Restated Certificate of Incorporation of Aptevo Therapeutics Inc.	8-K	3.1	August 2, 2016	001-37746	
3.2	Amended and Restated Bylaws of Aptevo Therapeutics Inc.	8-K	3.2	August 2, 2016	001-37746	
4.1	Form of Common Stock Certificate	10	4.1	June 29, 2016	001-37746	
4.2	Registration Rights Agreement, dated as of August 1, 2016, by and among Aptevo Therapeutics Inc. and certain of its stockholders	8-K	4	August 2, 2016	001-37746	
4.3	Registration Rights Agreement, dated December 20, 2018, by and between Aptevo Therapeutics Inc. and Lincoln Park Capital Fund, LLC.	8-K	10.2	December 24, 2018	001-37746	
10.1	Promissory Note, dated July 29, 2016, made by Emergent BioSolutions Inc. in favor of Aptevo Therapeutics Inc.	8-K	10.1	August 2, 2016	001-37746	
10.2	Transition Services Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.2	August 2, 2016	001-37746	
10.3	Tax Matters Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.3	August 2, 2016	001-37746	
10.4	Employee Matters Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.4	August 2, 2016	001-37746	
10.5	Amended and Restated Manufacturing Services Agreement, dated September 28, 2017, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	10-K	10.5	March 13, 2018	001-37746	

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
10.6	Canadian Distributor Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.6	August 2, 2016	001-37746	
10.7	Amended and Restated Trademark License Agreement, dated September 28, 2017, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	10-K	10.7	March 13, 2018	001-37746	
10.8	Product License Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.8	August 2, 2016	001-37746	
C 10.9	Aptevo Therapeutics Inc. Amended and Restated 2016 Stock Incentive Plan.	10-Q	4.1	August 10, 2017	001-37746	
C 10.10	Aptevo Therapeutics Inc. Converted Equity Awards Incentive Plan	8-K	10.10	August 2, 2016	001-37746	
C 10.11	Aptevo Therapeutics Inc. Senior Management Severance Plan	8-K	10.11	August 2, 2016	001-37746	
C 10.12	Form of Indemnity Agreement for directors and senior officers	10	10.9	April 15, 2016	001-37746	
10.13	Fourth and Battery Office Lease, dated as of April 28, 2003, by and between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc. and Genecraft, Inc.) and Selig Real Estate Holdings Eight L.L.C. , or the Seattle Office Lease	10	10.12	April 15, 2016	001-37746	
10.14	Seattle Office Lease Amendment, dated December 8, 2004	10	10.13	April 15, 2016	001-37746	
10.15	Seattle Office Lease Amendment, dated February 1, 2006	10	10.14	April 15, 2016	001-37746	
10.16	Seattle Office Lease Amendment, dated February 2, 2007	10	10.15	April 15, 2016	001-37746	
10.17	Seattle Office Lease Amendment, dated June 7, 2010	10	10.16	April 15, 2016	001-37746	
10.18	Seattle Office Lease Amendment, dated December 21, 2010	10	10.17	April 15, 2016	001-37746	
10.19	Seattle Office Lease Amendment, dated July 17, 2012	10	10.18	April 15, 2016	001-37746	
10.20	Seventh Amendment to Seattle Office Lease, dated December 5, 2014	10	10.19	April 15, 2016	001-37746	
†10.21	License and Co-Development Agreement, dated as of August 19, 2014, by and between Emergent Product Development Seattle, LLC and MorphoSys AG, or the MorphoSys Collaboration Agreement	10	10.20	June 29, 2016	001-37746	

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
†10.22	First Amendment to MorphoSys Collaboration Agreement, dated June 19, 2015	10	10.21	April 15, 2016	001-37746	
†10.23	Second Amendment to MorphoSys Collaboration Agreement, dated December 7, 2015	10	10.22	April 15, 2016	001-37746	
10.24	Third Amendment to MorphoSys Collaboration Agreement, dated December 12, 2016	8-K	10.1	December 15, 2016	001-37746	
10.25	Fourth Amendment MorphoSys Collaboration Agreement, dated June 19, 2017.	10	10.3	August 10, 2017	001-37746	
†10.26	Amended and Restated License Agreement, dated as of November 28, 2008, by and between Cangene Corporation (as successor-in-interest to Inspiration Biopharmaceuticals, Inc.) and The University of North Carolina at Chapel Hill, as amended on June 14, 2012	10	10.23	April 15, 2016	001-37746	
†10.27	CMC Commercial Supply (Manufacturing Services) Agreement, dated June 17, 2011, between CMC ICOS Biologics, Inc. and Aptevo BioTherapeutics LLC (as successor-in-interest to Inspiration Biopharmaceuticals, Inc.)	10	10.24	May 31, 2016	001-37746	
†10.28	Amended and Restated Commercial Supply Agreement, dated as of June 16, 2017, between CMC ICOS Biologics, Inc. and Aptevo BioTherapeutics LLC.	10	10.2	August 10, 2017	001-37746	
†10.29	Supply Agreement, dated April 29, 2014, between Aptevo BioTherapeutics LLC and Rovi Contract Manufacturing, S.L.	10	10.26	May 31, 2016	001-37746	
†10.30	Manufacturing Services Agreement, dated May 27, 2015, Aptevo BioTherapeutics LLC and Patheon UK Limited	10	10.27	May 31, 2016	001-37746	
10.31	Credit and Security Agreement, dated August 4, 2016 by and among Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC, Aptevo Research and Development LLC and MidCap Financial Trust, as agent, and the lenders from time to time party thereto.	8-K	10.1	August 5, 2016	001-37746	
10.32	Fee Letter dated August 4, 2016 by and among Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC, Aptevo Research and Development LLC and MidCap Financial Trust, as agent.	8-K	10.2	August 5, 2016	001-37746	
10.33	Third Amendment to License and Co-Development Agreement, dated as of December 12, 2016 by and between Aptevo Research and Development LLC and MorphoSys AG.	8-K	10.1	December 15, 2016	001-37746	

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
10.34	Amendment No.1 to the Credit and Security Agreement, dated May 11, 2017, by and among Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC and MidCap Financial Trust, as agent and the lenders from time to time thereto	10-Q	10.1	May 12, 2017	001-37746	
10.35	Amendment No. 2 to Credit and Security Agreement, dated as of September 28, 2017, by and among Aptevo Therapeutics Inc. and certain of its subsidiaries and Midcap Financial Trust (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 29, 2017).	8-K	10.1	September 28, 2017	001-37746	
10.36	Equity Distribution Agreement, dated November 9, 2017, between Aptevo Therapeutics, Inc. and Piper Jaffray and Company LLC.	8-K	1.1	November 9, 2017	001-37746	
10.37	Collaboration and Option Agreement, dated as of July 20, 2017, by and between Aptevo Research and Development LLC, and Alligator Bioscience AB.	10-Q	10.2	November 13, 2017	001-37746	
10.38	Amendment No. 3 to Credit and Security Agreement, dated as of February 23, 2018, by and among Aptevo Therapeutics Inc. and certain of its subsidiaries and Midcap Financial Trust.	10-K	10.38	March 13, 2018	001-37746	
10.39	Aptevo Therapeutics Inc. 2018 Stock Incentive Plan.	10-Q	10.1	August 9, 2018	001-37746	
10.40	Aptevo Therapeutics Inc. Non-Statutory Stock Option Agreement.	10-Q	10.2	August 9, 2018	001-37746	
10.41	Amended and Restated Credit and Security Agreement, dated August 16, 2018, by and among, Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC, Aptevo Research and Development LLC and MidCap Financial Trust.	10-Q	10.1	November 14, 2018	001-37746	
10.42	Purchase Agreement, dated December 20, 2018, by and between Aptevo Therapeutics Inc. and Lincoln Park Capital Fund, LLC.	8-K	10.1	December 24, 2018	001-37746	
10.43	Amendment No. 1 to Amended and Restated Credit and Security Agreement, dated December 14, 2018, by and among, Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC, Aptevo Research and Development LLC and MidCap Financial Trust.					X
10.44	Intellectual Property Security Agreement, dated February 7, 2019, by and amoung, Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC., Aptevo Research and Development, LLC and MidCap Financial Trust					X
21.1	Subsidiaries of Aptevo Therapeutics Inc.					X
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm					X

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
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.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
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.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

* Document has been furnished, is not deemed filed and is not to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, irrespective of any general incorporation language contained in any such filing.

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

C Management contract or compensatory plan.

\+ Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Aptevo will furnish copies of any such schedules to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary

We have chosen not to include the summary permitted by this Item 16.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Company Name

Date: March 18, 2019

By: */s/ Marvin L. White*
Marvin L. White
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/Marvin L. White **Marvin L. White**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2019
/s/Jeffrey G. Lamothe **Jeffrey Lamothe**	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 18, 2019
/s/Fuad El-Hibri **Fuad El-Hibri**	Chairman of the Board of Directors	March 18, 2019
/s/Daniel J. Abdun-Nabi **Daniel J. Abdun-Nabi**	Director	March 18, 2019
/s/Grady Grant, III **Grady Grant, III**	Director	March 18, 2019
/s/Zsolt Harsanyi, Ph. D. **Zsolt Harsanyi, Ph. D.**	Director	March 18, 2019
/s/Barbara Lopez Kunz **Barbara Lopez Kunz**	Director	March 18, 2019
/s/John E. Niederhuber, M.D. **John E. Niederhuber, M.D.**	Director	March 18, 2019

AMENDMENT NO. 1 TO AMENDED AND RESTATED CREDIT AND SECURITY AGREEMENT

This AMENDMENT NO. 1 TO AMENDED AND RESTATED CREDIT AND SECURITY AGREEMENT (this "**Agreement**") is made as of December 14, 2018, by and among **APTEVO THERAPEUTICS INC.**, a Delaware corporation ("**Aptevo Therapeutics**"), **APTEVO BIOTHERAPEUTICS LLC**, a Delaware limited liability company ("**Aptevo BioTherapeutics**"), **APTEVO RESEARCH AND DEVELOPMENT LLC**, a Delaware limited liability company ("**Aptevo R&D**", and Aptevo R&D together with Aptevo Therapeutics and Aptevo BioTherapeutics, each individually, a "**Borrower**" and collectively, the "**Borrowers**"), **MIDCAP FINANCIAL TRUST**, a Delaware statutory trust, as Agent (in such capacity, together with its successors and assigns, "**Agent**") and the other financial institutions or other entities from time to time parties to the Credit Agreement referenced below, each as a Lender.

RECITALS

A. Agent, Lenders and Borrowers have entered into that certain Amended and Restated Credit and Security Agreement, dated as of August 6, 2018 (as further amended, modified, supplemented and restated prior to the date hereof, the "**Original Credit Agreement**" and as the same is amended hereby and as it may be further amended, modified, supplemented and restated from time to time, the "**Credit Agreement**"), pursuant to which the Lenders have agreed to make certain advances of money and to extend certain financial accommodations to Borrowers in the amounts and manner set forth in the Credit Agreement.

B. Borrowers have requested, and Agent and Lenders constituting at least the Required Lenders have agreed, to amend certain provisions of the Original Credit Agreement to add a certain Securities Account of Borrower as an "Excluded Account", in accordance with the terms and subject to the conditions set forth herein.

AGREEMENT

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

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

2. **Amendments to Original Credit Agreement**. Subject to the satisfaction of the conditions to effectiveness set forth in Section 4 below, the Original Credit Agreement is hereby amended as follows:

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

> "**Piper Jaffray Securities Account**" means that certain Securities Account of Borrower maintained as a brokerage account at [Piper Jaffray Investment Management, LLC], with an account number of [_____] for purposes of receiving proceeds from the sale of Aptevo Therapeutics' common stock; *provided* that the aggregate amount on deposit in such Securities Account shall not at any time exceed $250,000.

(b) The third sentence of Section 5.14 of the Original Credit Agreement is hereby amended by replacing such sentence in its entirety with the following new sentence:

> ""The provisions of this Section requiring Deposit Account Control Agreements shall not apply to (a) the Wells Fargo Cash Collateral Account, (b) the Wells Fargo LC Cash Collateral Account during the Wells Fargo LC Period, (c) all times from and after November 16, 2018, the Piper Jaffray Securities Account, and (d) Deposit Accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrowers' employees and identified to Agent by Borrowers as such (the Deposit Accounts in clauses (a) through (d), collectively, "**Excluded Accounts**"); *provided, however*, that at all times that any Obligations remain outstanding following the date that is thirty (30) days following the Closing Date (the "**Post-Closing Payroll Account Period**"), Borrower shall maintain one or more separate Deposit Accounts to hold any and all amounts to be used for payroll, payroll taxes and other employee wage and benefit payments, and shall not commingle any monies allocated for such purposes with funds in any other Deposit Account."

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

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

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

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

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

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

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

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

8. **Miscellaneous**.

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

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

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

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

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

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

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

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

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

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

[SIGNATURES APPEAR ON FOLLOWING PAGES]

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

AGENT:

MIDCAP FINANCIAL TRUST,
as Agent

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

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

By: /s/ Maurice Amsellem
Name: Maurice Amsellem
Title: Authorized Signatory

LENDER:

APOLLO INVESTMENT CORPORATION

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

By: ACC Management, LLC, as its General Partner

By: /s/ Tanner Powell
Name: Tanner Powell
Title: Authorized Signatory

LENDER: **FLEXPOINT MCLS SPV LLC**

By: /s/ Daniel Edelman
Name: Daniel Edelman
Title: Vice President

LENDER:

ELM 2016-1 TRUST

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

By: /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

LENDER:

ELM 2018-2 TRUST

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

By: /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

BORROWERS:

APTEVO THERAPEUTICS INC.

By: /s/ Jeffrey Lamothe
Name: Jeffrey Lamothe
Title: Treasurer

APTEVO BIOTHERAPEUTICS LLC

By: /s/ Jeffrey Lamothe
Name: Jeffrey Lamothe
Title: Treasurer

APTEVO RESEARCH AND DEVELOPMENT LLC

By: /s/ Jeffrey Lamothe
Name: Jeffrey Lamothe
Title: Treasurer

INTELLECTUAL PROPERTY SECURITY AGREEMENT

This Intellectual Property Security Agreement is entered into as of the 7th day of February, 2019 by and among **MIDCAP FINANCIAL TRUST**, a Delaware statutory trust ("Agent") and **APTEVO THERAPEUTICS INC.**, a Delaware corporation ("Aptevo Therapeutics"), **APTEVO BIOTHERAPEUTICS LLC**, a Delaware limited liability company ("Aptevo BioTherapeutics"), and **APTEVO RESEARCH AND DEVELOPMENT LLC**, a Delaware limited liability company ("Aptevo R&D, and Aptevo R&D together with Aptevo Therapeutics, Aptevo BioTherapeutics and any other Person that joins this agreement as a Grantor, each a "Grantor" and collectively, the "Grantors").

RECITALS

A. The Lenders made and have agreed to make certain advances of money and to extend certain financial accommodation to the Grantors (the "Credit Extensions") in the amounts and manner set forth in that certain Amended and Restated Credit and Security Agreement by and between Agent, the Lenders and the Grantors dated as of August 4, 2018 (as amended by the First Amendment to Credit and Security Agreement, dated as of May 11, 2017, and as the same may be further amended, modified or supplemented from time to time, the "Credit Agreement"; capitalized terms used herein without definition are used as defined in the Credit Agreement). The Lenders are willing to continue to make the Credit Extensions to the Grantors, but only upon the condition, among others, that the Grantors shall grant to Agent, for the ratable benefit of the Lenders, a security interest in certain Copyrights, Trademarks, Patents, and Mask Works (as each term is described below) to secure the obligations of the Grantors under the Credit Agreement.

B. Pursuant to the terms of the Credit Agreement, each Grantor has granted to Agent, for the ratable benefit of the Lenders, a security interest in all of such Grantor's right, title and interest, whether presently existing or hereafter acquired, in, to and under all of the Collateral.

NOW, THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, and intending to be legally bound, as collateral security for the prompt and complete payment when due of its obligations under the Credit Agreement, each Grantor hereby represents, warrants, covenants and agrees as follows:

AGREEMENT

To secure its obligations under the Credit Agreement, each Grantor grants and pledges to Agent, for the ratable benefit of the Lenders, a security interest in all of such Grantor's right, title and interest in, to and under its Intellectual Property other than any Excluded Property (all of which shall collectively be called the "Intellectual Property Collateral"), including, without limitation, the following (except, in each case, to the extent constituting Excluded Property):

(a) Any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret, now or hereafter existing, created, acquired or held, including without limitation those set forth on Exhibit A attached hereto (collectively, the "Copyrights");

(b) Any and all trade secrets, and any and all intellectual property rights in computer software and computer software products now or hereafter existing, created, acquired or held;

(c) Any and all design rights that may be available to such Grantor now or hereafter existing, created, acquired or held;

(d) All patents, patent applications and like protections including, without limitation, improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same, including without limitation the patents and patent applications set forth on Exhibit B attached hereto (collectively, the "Patents");

(e) Any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of such Grantor connected with and symbolized by such trademarks, including without limitation those set forth on Exhibit C attached hereto (collectively, the "Trademarks");

(f) All mask works or similar rights available for the protection of semiconductor chips, now owned or hereafter acquired, including, without limitation those set forth on Exhibit D attached hereto (collectively, the "Mask Works");

(g) Any and all claims for damages by way of past, present and future infringements of any of the rights included above, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the intellectual property rights identified above;

(h) All licenses or other rights to use any of the Copyrights, Patents, Trademarks, or Mask Works and all license fees and royalties arising from such use to the extent permitted by such license or rights;

(i) All amendments, extensions, renewals and extensions of any of the Copyrights, Trademarks, Patents, or Mask Works; and

(j) All proceeds and products of the foregoing, including without limitation all payments under insurance or any indemnity or warranty payable in respect of any of the foregoing.

The security interest granted under this Intellectual Property Security Agreement is granted in conjunction with the security interest granted to Agent, for the ratable benefit of the Lenders, under the Credit Agreement. The rights and remedies of Agent with respect to the security interest granted hereby are in addition to those set forth in the Credit Agreement and the other Financing Documents, and those which are now or hereafter available to Agent as a matter of law or equity. Each right, power and remedy of Agent provided for herein or in the Credit Agreement or any of the Financing Documents, or now or hereafter existing at law or in equity shall be cumulative and concurrent and shall be in addition to every right, power or remedy provided for herein and the exercise by Agent of any one or more of the rights, powers or remedies provided for in this Intellectual Property Security Agreement, the Credit Agreement or any of the other Financing Documents, or now or hereafter existing at law or in equity, shall not preclude the simultaneous or later exercise by any person, including Agent, of any or all other rights, powers or remedies.

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

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

[Signature page follows.]

IN WITNESS WHEREOF, the parties have caused this Intellectual Property Security Agreement to be duly executed by its officers thereunto duly authorized as of the first date written above.

GRANTORS:

APTEVO THERAPEUTICS INC.

By: */s/ Jeff Lamothe*
Name: Jeff Lamothe
Title: Chief Financial Officer

APTEVO BIOTHERAPEUTICS LLC

By: */s/ Jeff Lamothe*
Name: Jeff Lamothe
Title: Chief Financial Officer

APTEVO RESEARCH AND DEVELOPMENT LLC

By: */s/ Jeff Lamothe*
Name: Jeff Lamothe
Title: Chief Financial Officer

Address:

Aptevo Therapeutics, Inc.
2401 4th Avenue, Suite 1050
Seattle, WA 98121
Attn: Shawnte Mitchell
E-Mail: MitchellS@apvo.com

AGENT:

MIDCAP FINANCIAL TRUST

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

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

By: */s/ Maurice Amsellem*
Name: Maurice Amsellem
Title: Authorized Signatory

EXHIBIT A

Copyrights

Description	Registration/ Application Number	Registration/ Application Date
None.		

EXHIBIT B

Patents

Description	Registration/ Application Number	Registration/ Application Date

[See attached.]

EXHIBIT C

Trademarks

Description	Registration/ Application Number	Registration/ Application Date

[See Attached.]

EXHIBIT D

Mask Works

Description	Registration/ Application Number	Registration/ Application Date
None.		

EXHIBIT 21.1

LIST OF SUBSIDIARIES

Name of Subsidiary	**Jurisdiction of Incorporation or Organization**
Aptevo BioTherapeutics LLC	Delaware
Aptevo Research and Development LLC	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-213108) pertaining to Converted Equity Awards Incentive Plan and 2016 Stock Incentive Plan of Aptevo Therapeutics Inc.,
(2) Registration Statement (Form S-8 No. 333-219875) pertaining to the 2016 Stock Incentive Plan of Aptevo Therapeutics Inc.,
(3) Registration Statement (Form S-8 No. 333-226717) pertaining to the 2018 Stock Incentive Plan of Aptevo Therapeutics Inc.,
(4) Registration Statement (Form S-3 No. 333-221499) of Aptevo Therapeutics Inc., and
(5) Registration Statement (Form S-3 No. 333-229115) of Aptevo Therapeutics Inc.;

of our report dated March 18, 2019, with respect to the consolidated financial statements of Aptevo Therapeutics Inc. included in this Annual Report (Form 10-K) of Aptevo Therapeutics Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Seattle, Washington
March 18, 2019

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 Annual Report on Form 10-K 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;

   (b) 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

   (c) 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: March 18, 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 Annual Report on Form 10-K 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;

   (b) 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

   (c) 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: March 18, 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. (the "Company") on Form 10-K for the period ending December 31, 2018 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 Section 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 results of operations of the Company.

Date: March 18, 2019

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

"This certification accompanies the Form 10-K 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 Therapeutics Inc. (the "Company") on Form 10-K for the period ending December 31, 2018 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 Section 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 results of operations of the Company.

Date: March 18, 2019

By: /s/ Jeff Lamothe

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

"This certification accompanies the Form 10-K 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."