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, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-37746

APTEVO THERAPEUTICS INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**81-1567056**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2401 4th Avenue, Suite 1050 Seattle, Washington	**98121**
(Address of principal executive offices)	(Zip Code)

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

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

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

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 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. ☒

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

The aggregate market value of common stock held by non-affiliates of the Registrant as of June 30, 2019, the last business day of the Registrant's most recently completed second fiscal quarter, was $36.6 million, based upon the closing price of the Registrant's common stock on the Nasdaq Stock Market LLC on June 28, 2019, the last trading day of the fiscal quarter.

Excludes an aggregate of 3,883,301 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 25, 2020, the number of shares of Registrant's common stock outstanding was 45,279,244

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 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

Table of Contents

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 clinical-stage biotechnology company focused on developing novel immunotherapies for the treatment of cancer. Our lead clinical candidate, APVO436, and preclinical candidates, ALG.APV-527 and APVO603 were developed based on the Company's versatile and robust ADAPTIR™ modular protein technology platform. The ADAPTIR platform is capable of generating highly differentiated bispecific antibodies with unique mechanisms of action for the treatment of different types of cancer. At December 31, 2019, we had one revenue-generating product in the area of hematology, IXINITY coagulation factor IX (recombinant), which was acquired by Medexus Pharma, Inc. (Medexus). On February 28, 2020, Aptevo entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioTherapeutics LLC ("Aptevo BioT"), a subsidiary of Aptevo which wholly owns the IXINITY and related Hemophilia B business.

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 to produce unique signaling responses and ultimately kill tumors or modulate the immune system to kill tumors. We are skilled at product candidate generation, validation and subsequent preclinical and clinical development using the ADAPTIR platform. We have the ability to progress ADAPTIR molecules from concept to commercialization by way of our protein engineering, preclinical development and process development capabilities, cGMP manufacturing oversight and clinical development capabilities.

Prior to February 28, 2020, we had one marketed product, IXINITY, 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. On February 28, 2020, Aptevo entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioT, a subsidiary of Aptevo which wholly owns the IXINITY and related Hemophilia B business. As a result of the transaction, Medexus obtained all rights, title and interest to the IXINITY product and intellectual property. In addition, Aptevo BioT personnel responsible for the sale and marketing of IXINITY also transitioned to Medexus as part of the transaction.

As consideration for the sale, at closing Aptevo received an amount equal to $30 million in cash, subject to certain customary adjustments in respect of Aptevo's estimates of cash, indebtedness, working capital and transaction expenses of Aptevo BioT as of the closing. Such consideration will be subject to a final post-closing adjustment pursuant to the terms of the Purchase Agreement. From the $30 million payment at closing, Medexus withheld $0.9 million which was deposited with an escrow agent (i) to fund potential payment obligations of Aptevo with respect to the final post-closing adjustment and (ii) to fund potential post-closing indemnification obligations of Aptevo. In addition to the payment received at closing, Aptevo may also earn milestone and deferred payments from Medexus in the future. We used $22.1 million of the $30 million in proceeds to repay in full our term debt facility with MidCap financial, including $20 million of principal and $2.1 million in an end of facility fee, accrued interest, legal fees and prepayment fees. The parties also agreed that Aptevo would provide transition services for a limited period of time.

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. 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 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.

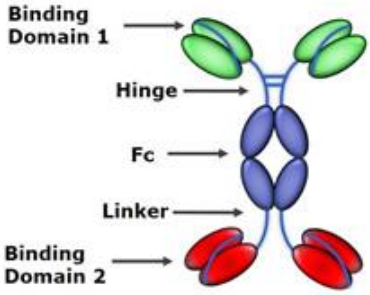
PLATFORM TECHNOLOGY AND PRODUCT CANDIDATES

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 or improve other diseases such as autoimmune or inflammatory diseases 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 or more targets of therapeutic interest, utilizing our innovative ADAPTIR (modular protein technology) platform. This allows us to take a novel approach to cancer immunotherapy or for treatment of other diseases.

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 compared to other bispecifics targeting the same tumor antigens and CD3. The ADAPTIR bispecifics can 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 which we non-exclusively license from various third parties. See section entitled “Intellectual Property” for additional information about the ownership rights to ADAPTIR platform intellectual property.

Product Portfolio

Product Candidates

Our pipeline includes investigational clinical and pre-clinical stage product candidates for use in both hematologic and solid tumor cancers.

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 4.5 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. At present, dosing in cohorts 1 through 5 has been completed with dosing in cohort 6 scheduled to begin shortly. A total of 19 patients have been enrolled and treated with APVO436 to date. A dose-limiting toxicity was observed in 1 of 6 patients in cohort 4. No evidence of dose-limiting toxicities was observed in the latest dose cohort (cohort 5). Also, importantly, no evidence of drug-induced anti-drug antibodies (ADA) has been observed in 17 patient blood samples analyzed to date.

On November 26, 2019, the FDA granted Orphan Drug Designation to APVO436.

ALG.APV-527. a novel investigational bispecific ADAPTIR candidate, partnered with Alligator Bioscience, featuring a novel mechanism of action designed to simultaneously target 4-1BB (CD137) and 5T4, a tumor antigen overexpressed in a number of different types of cancer. 4-1BB, a costimulatory receptor on T cells, is known to enhance the immune response to cancer through activation of tumor-specific T cells and is believed to be a promising target for new immunotherapeutic approaches. ALG.APV-527 could potentially have utility in the treatment of a broad spectrum of cancers over-expressing the 5T4 tumor antigen, including mesothelioma, non-small-cell-lung, head and neck, pancreatic, renal, ovarian and bladder cancers. Aptevo and Alligator have made a joint decision to delay submission of the clinical trial authorization (CTA) for ALG-APV.527 previously planned for the fourth quarter of 2019. Alligator and Aptevo have made a joint decision to focus efforts on partnering ALG.APV-527 prior to phase 1 clinical development. The adjustment to the development plan for ALG.APV -527 will allow both Aptevo and Alligator to align their resources to meet the needs of their respective ongoing clinical programs. The companies are initiating discussions with potential partners for the upcoming clinical development of ALG.APV-527.

APVO603. a preclinical dual agonist bispecific ADAPTIR candidate employing a novel mechanism of action to simultaneously target 4-1BB (CD137) and OX40 (CD134), both members of the TNF-receptor family. Dual targeting of 4-1BB and OX40 provides synergistic co-stimulation of T cells with the potential to amplify the cytotoxic function of activated T cells and NK cells, potentially leading to more robust anti-tumor responses. APVO603's combined activation of both the 4-1BB and OX40 TNF receptors represents an attractive approach in potentially overcoming the suppressive tumor microenvironment. The targeted co-stimulation of 4-1BB and OX40 has the potential to promote an important immunological cascade, enhancing T-cell activation, prolonging T-cell survival, and improving tumor killing. This product candidate is not dependent on any one tumor antigen and has the potential to treat multiple solid tumors.

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 2019, we elected to discontinue the APVO210 development program. The decision followed the review of data from the Phase 1 multiple ascending dose (MAD) clinical study of APVO210 in healthy volunteers that suggests that APVO210 would not meet the desired target product profile for future commercialization. Specifically, the clinical data showed evidence of increasing titers of ADA with repeated doses of APVO210, which had varying impact on APVO210 drug levels in subjects' blood. The cause of the ADA is uncertain; however we believe that appearance of ADA is related to the mechanism of action of APVO210, and not due to the structure, or sequences characteristic of the ADAPTIR platform. The rapidity in which the ADA developed in the APVO210 program is uncharacteristic of a typical immune response, which suggests that it is related to the mechanism of action of the drug. APVO210 binds to CD86 on antigen presenting cells (APC). This may have led to internalization and presentation of APVO210 more efficiently than the anticipated and intended suppression of antigen presentation driven by the IL-10 component of APVO210. The uncharacteristic timing and appearance of the ADA and the robustness of the response suggests that it is specific to the drug mechanism of action and not related to sequences in the candidate. For APVO 436, at present, dosing in cohorts 1 through 5 has been completed with dosing in cohort 6 scheduled to begin shortly. A total of 19 patients have been enrolled and treated with APVO436 to date. A dose-limiting toxicity was observed in 1 of 6 patients in cohort 4. No evidence of dose-limiting toxicities was observed in the latest dose cohort (cohort 5). Also, importantly, no evidence of drug-induced anti-drug antibodies (ADA) has been observed in 17 patient blood samples analyzed to date.

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 candidate 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: flotetuzumab (formerly MGD006, Macrogenics), JNJ-63709178 (Janssen) and XmAb14045 (Xencor), and a bispecific antibody from Sanofi. There are numerous CAR-T therapies in development: CART123 (University of Penn.), CARTCD123 (NCI/City of Hope), UCART123 (Cellectis), MB-102 (Mustang Bio) and several others in development in China. Other competitive products targeting CD123 are: tagraxofusp (formerly SL-401, an antibody immunotoxin, Stemline), KHK2833 (monoclonal antibody, Kyowa Hakko Kirin Pharma), CSL362 (monoclonal antibody, CSL/Janssen) and IMGN632 (ImmunoGen and Jazz Pharmaceuticals).

COLLABORATIONS WITH ALLIGATOR BIOSCIENCE

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

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. Under the terms of the Collaboration Agreement, the parties intend to share revenue received from a third-party commercialization partner equally, or, if the development costs are not equally shared under the Collaboration Agreement, in proportion to the development costs borne by each party.

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

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

IXINITY

IXINITY (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.

On February 28, 2020, we entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioT, a subsidiary of Aptevo wholly owns IXINITY and related Hemophilia B business. As a result of the transaction, Medexus obtained all rights, title and interest to the IXINITY product and intellectual property. In addition, Aptevo BioT personnel responsible for the sale and marketing of IXINITY also transitioned to Medexus as part of the transaction.

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 the ADAPTIR platform and pipeline products, including 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. In addition to the Lonza CHO cell line licenses, we have non-exclusive research licenses to other CHO cell lines and related vectors from other suppliers, and we have the ability to obtain non-exclusive commercial licenses to these cell lines and vectors as needed.

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.

APVO436. We have nationalized our core patent family which covers the APVO436 product candidate in various countries and territories including the U.S., Australia, Brazil, Canada, China, Colombia, Europe, Eurasia, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Philippines, Singapore, South Africa, South Korea, Ukraine, and Vietnam.

ALG.APV-527. We co-own with Alligator Biosciences a patent family corresponding to PCT application PCT/EP2018/069850, which covers the ALG.APV-527 product candidate. In January and February of 2020, this patent family was nationalized in various countries. Aptevo and Alligator also co-own US patent 10,239,949, which was filed through the U.S.P.T.O.'s Cancer Immunotherapy Pilot Program.

In addition to the co-owned assets, Alligator owns a patent family corresponding to PCT application PCT/EP2017/059656, which also covers ALG.APVO-527. Aptevo has a license (co-exclusive with Alligator) to this patent family for the development of the ALG.APV-527 product candidate.

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, 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. On November 26, 2019 FDA granted Orphan Drug Designation to APVO436, a bispecific antibody candidate intended for the treatment of acute myelogenous leukemia (AML). APVO436 is currently being evaluated in a Phase 1/1b clinical trial in patients with AML and myelodysplastic syndrome (MDS).

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. 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 monthly 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 any of our future products 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.

Foreign Regulation

In the future, we may have a 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. Products derived from biotechnology must be authorized via a centralized procedure by the European Commission, which provides for the grant of a single marketing authorization that is valid for all EU member states. 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.

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.

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. 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.

State Transparency Laws

The Washington State Health Care Authority (HCA) is currently in the planning phase of the prescription drug cost transparency effort, as a result of the Engrossed Second Substitute House Bill 1224 in 2019. Drug manufacturers and pharmacy benefit managers are not expected to submit data in 2019. The HCA anticipates being ready to collect data by October 2020.

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 80 full-time persons as of December 31, 2019. 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.

ORGANIZATIONAL HISTORY

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.

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, 2019 and 2018, we had net losses of $40.4 million and $53.7 million, respectively. As of December 31, 2019, we had an accumulated deficit of $167.9 million.

Our management and board of directors have concluded that a substantial doubt is deemed to exist concerning our ability to continue as a going concern.

Accounting Standards Update, or ASU, 2014-15, requires management to assess our ability to continue as a going concern for one year after the date the financial statements are issued. As further discussed in Note 1, Nature of Business and Significant Accounting Policies to our condensed consolidated financial statements in this Form 10-K, substantial doubt is deemed to exist about the company's ability to continue as a going concern through March 2021. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern will require us to generate positive cash flow from operations, obtain additional financing, enter into strategic alliances and/or sell assets. The reaction of investors to the inclusion of a going concern statement in this report on Form 10-K, our current lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital and enter into strategic alliances. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

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

As of December 31, 2019, we had cash, cash equivalents, and restricted cash in the amount of $19.9 million. We will require additional funding to grow our business including to develop additional products, support commercial marketing activities or otherwise provide additional financial flexibility. On October 3, 2019, we announced that we implemented an expense reduction plan that reduced annual expenditures by approximately 30%. Including streamlining research and development programs, through reducing investment in certain programs; cut-backs in legal, professional and consulting expenses; reduction of leased space, cut-backs in non-commercial headcount; and reductions in executive and board cash compensation. If we are not able to secure adequate additional funding, we may need to make additional reductions in spending. This may include extending payment terms with suppliers, liquidating assets, and suspending or curtailing planned programs. We may also have to further 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. Our future capital requirements will depend on many factors, including:

- the collection of accounts receivable from customers;
- the level, timing and receipt of any milestone or deferred payments under our agreement with Medexus with respect to the sale of IXINITY;
- the ability to comply with the continued listing requirements of the Nasdaq Capital Market and the risk that our common shares will be delisted if we cannot do so;
- the extent to which we invest in products or technologies;
- the ability to satisfy the payment obligations and covenants under our credit agreement 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; and
- the costs of commercialization activities, including product marketing, sales and distribution

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 the remaining $17.3 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 Capital Fund, LLC, or Lincoln Park, entered into in December 2018, and (iii) the issuance of up to 22,000,000 shares of common stock upon the exercise of warrants issued in connection with our March 2019 public offering of common stock and warrants. Public or bank debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds by issuing equity securities, our stockholders will experience dilution. If we raise funds through collaboration and licensing arrangements with third parties or enter into other strategic transactions, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

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

Our 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, as a result due to a variety of factors, including:

- the level and timing of any milestone or deferred payments with respect to sales of IXINITY by Medexus;
- 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.

These and other factors 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.

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 any 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 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 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.

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, 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.

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

As of December 31, 2019, we had approximately $28.2 million and $3.0 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 2019 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 March 2019 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.

The COVID-19 coronavirus could adversely impact our business, including our clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States and several European countries. Depending upon the severity of the COVID-19 coronavirus' spread in the United States, we may experience disruptions that could severely impact our business and clinical trials, including:

- limitation of company operations, including work from home policies and office closures;
- delays or difficulties in receiving deliveries of critical experimental materials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; and
- limitations in employee resources that would otherwise be focused on our business, including the conduct of our clinical trials, such as because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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. For example, Dr. Scott Stromatt, former full-time chief medical officer, is now providing clinical trial and medical affairs oversight duties as a third-party consultant. 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 and individuals 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. In addition, on October 3, 2019, we announced our decision to discontinue development of APVO210, a novel investigational bispecific antibody candidate under development for the treatment of autoimmune diseases. The decision followed the review of data from Phase 1 multiple ascending dose (MAD) clinical study of APVO210 in healthy volunteers that suggests that APVO210 would not meet the desired target product profile for future commercialization. Specifically, the clinical data showed evidence of increasing titers of ADA with repeated doses of APVO210, which had varying impact on APVO210 drug levels in subjects' blood. 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 and other therapeutic areas. Our goal is to leverage this technology to make targeted investment in bispecific ADAPTIR therapeutics. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based on our ADAPTIR platform technology, our ability to obtain product revenues in future periods may be adversely affected, which likely would result in harm to our financial position and our financial prospects and adversely affect our stock price.

We face substantial competition.

The development and commercialization of new biotechnology products is highly competitive and subject to rapid technological advances. We may face future competition with respect to our 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 oncology market include: AbbVie Inc., Aduro, Inc., Affirmed, Amgen Inc., AnaptysBio, Inc., Astellas Pharma Inc., Bayer AG, Biogen Idec Inc., Boehringer Ingelheim GmbH, Genentech Inc. (a subsidiary of F. Hoffmann-La Roche Ltd.), Genmab A/S, GlaxoSmithKline plc, Grifols USA LLC, ImmunoGen, Inc., Immunomedics, Inc., Janssen BioTech Inc., Johnson & Johnson, Macrogenics, Inc., Novartis International AG, Pieris Pharmaceuticals, Inc., Sanofi-Aventis US LLC, Takeda Pharmaceuticals U.S.A., Inc., Xencor, Inc. and Zymeworks Biopharmaceuticals, Inc. We expect to compete on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed. If we are not successful in demonstrating these attributes, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition and results of operations.

Any 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 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 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.

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 any product candidates we successfully develop or additional pricing pressures.

The loss of any of our sole source manufacturers, or delays or problems in the manufacture our product candidates, could result in product shortages 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 for our 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 clinical trial needs and perform their contractual obligations.

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

All of our current product candidates are biologics. 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 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 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 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 our product candidates in development, our results of operations and prospects would be materially and adversely affected.

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.

Finally, the development program for APVO210 was terminated due to the development of ADA. The cause of the ADA is uncertain, however, the rapidity in which the ADA developed suggests that it is more related to the mechanism of action of the drug. APVO210 binds to CD86 on antigen presenting cells (APC) and that may have led to internalization of APVO210, before the IL10 component of APVO210 could down regulate the APC.

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.

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.

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, such as the California Consumer Privacy Act of 2018, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States, 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.

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.

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.

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 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 and Other Agreements

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.

Our future revenue will be dependent on the ability of Medexus to successfully further develop, market and commercialize IXINITY, resulting in the payment of milestone and deferred payments.

On February 28, 2020, Aptevo entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioT, a subsidiary of Aptevo wholly owns the IXINITY and related Hemophilia B business. We are entitled to receive future potential payments as the result of the achievement of certain regulatory and commercial milestones and through deferred payments based on net sales of IXINITY. Following such sale, we do not control the development, marketing and commercialization of IXINITY and are dependent on Medexus to successfully do so. Although Medexus has agreed to use commercially reasonable efforts to commercialize IXINITY in the ordinary course of business in good faith, Medexus may not commit adequate resources to the further development, marketing and commercialization of IXINITY, may experience financial difficulties, may face competition, or may prioritize other products or initiatives. The failure of Medexus to perform as expected under the purchase agreement, including because of factors outside of Medexus' control, could result in lower than expected milestone or deferred payments and negatively impact our future financial and operating results.

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

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

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

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

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

Risks Related to Our Common Stock

Our stock price may be volatile.

Our stock price has fluctuated in the past and is likely to be volatile in the future. Since August 1, 2016, the reported closing price of our common stock has fluctuated between $0.25 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 Capital 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 Capital Market. The Nasdaq Stock Market LLC has minimum requirements that a company must meet in order to remain listed on Nasdaq, including a requirement that we maintain a minimum closing bid price of $1.00 per share. On April 18, 2019, we received a letter from the listing qualifications department staff of Nasdaq notifying us that for the last 30 consecutive business days the bid price of our common stock had closed below $1.00 per share. On October 11, 2019, we submitted to the Listing Qualifications Department of Nasdaq an application to transfer the listing of our common stock from The Nasdaq Global Market to The Nasdaq Capital Market, On October 16, 2019, we received notice from Nasdaq that our application to transfer listing of our common stock had been approved. The transfer was effective at the opening of business on October 18, 2019.

We are eligible for an additional 180-day period (through April 13, 2020) to regain compliance with the minimum bid price, which requires that the closing bid price of our common stock be at least $1.00 per share for a minimum of ten consecutive days. In the event that we are not able to regain compliance during this additional compliance period, we intend to cure the deficiency during the second compliance period by effecting a reverse stock split. We note that we have sufficient shareholder votes supporting a reverse split. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, Nasdaq could provide notice that our common stock will become subject to delisting. In the event we receive notice that our common stock is being delisted, Nasdaq rules permit us to appeal any delisting determination by the Nasdaq staff to a hearings panel.

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 the remaining $17.3 million worth of shares of our common stock pursuant to our Equity Distribution Agreement with Piper Jaffray & Co entered into in November 2017, (ii) any sale of up to $35.0 million worth of shares of our common stock in a private placement pursuant to our Purchase Agreement with Lincoln Park, entered into in December 2018 and (iii) the issuance of up to 22,000,000 share of common stock upon the exercise of warrants issued in connection with our March 2019 public offering of common stock and warrants.

In addition, our restated certificate of incorporation authorizes us to issue, without the approval of our stockholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our common stock respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, we could grant the holders of preferred stock the right to elect some number of our directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock.

Provisions under Delaware law and in our restated certificate of incorporation and amended and restated by-laws may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

Certain provisions in our restated certificate of incorporation and amended and restated by-laws, and under Delaware law, may discourage, delay or prevent a merger, acquisition or other changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our incumbent directors and management.

These provisions include:

- the classification of our directors;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- advance notice requirements for stockholder nominations of candidates for election to the Board of Directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

The affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. The affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, Section 203 of the General Corporation Law of Delaware prohibits a corporation from engaging in a business combination with an interested stockholder, generally a person which, together with its affiliates, owns or within the last three years has owned 15% or more of the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

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

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease our headquarters office and laboratory space in Seattle, Washington. The Seattle facility is approximately 48,000 square feet and the lease for the Seattle facility expires in April 2030.

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 Capital Market under the symbol "APVO" since October 18, 2019, and was listed on The Nasdaq Global Market from August 1, 2016 to October 17, 2019.

Holders of Common Stock

As of March 25, 2020, there were 162 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 then-existing debt instruments and other factors the board of directors deems relevant.

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the year ended December 31, 2019.

Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the year ended December 31, 2019.

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 clinical-stage biotechnology company focused on developing novel immunotherapies for the treatment of cancer. Our lead clinical candidate, APVO436, and preclinical candidates, ALG.APV-527 and APVO603 were developed based on the Company's versatile and robust ADAPTIR™ modular protein technology platform. The ADAPTIR platform is capable of generating highly differentiated bispecific antibodies with unique mechanisms of action for the treatment of different types of cancer and autoimmunity. At December 31, 2019, we had one revenue-generating product in the area of hematology, IXINITY, which was acquired by Medexus on February 28, 2020.

For the years ended December 31, 2019 and 2018, we generated product revenue of $32.4 million and $23.1 million, respectively, and had net losses of $40.4 million and $53.7 million, respectively. We had an accumulated deficit of $167.9 million as of December 31, 2019. For the year ended December 31, 2019, net cash used in our operating activities was $42.4 million. As of December 31, 2019, our sole marketed product was IXINITY®, and therefore IXINITY was our only source of product revenue. On February 28, 2020, Aptevo entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioT, a subsidiary of Aptevo which wholly owns the IXINITY and related Hemophilia B business. As a result of the transaction, Medexus obtained all rights, title and interest to the IXINITY product and intellectual property. In addition, Aptevo BioT personnel responsible for the sale and marketing of IXINITY also transitioned to Medexus as part of the transaction.

As consideration for the sale, at closing Aptevo received an amount equal to $30 million in cash, subject to certain customary adjustments in respect of Aptevo's estimates of cash, indebtedness, working capital and transaction expenses of Aptevo BioT as of the closing. Such consideration will be subject to a final post-closing adjustment pursuant to the terms of the Purchase Agreement. From the $30 million payment at closing, Medexus withheld $0.9 million which was deposited with an escrow agent (i) to fund potential payment obligations of Aptevo with respect to the final post-closing adjustment and (ii) to fund potential post-closing indemnification obligations of Aptevo. In addition to the payment received at closing, Aptevo may also earn milestone and deferred payments from Medexus in the future. We used $22.1 million of the $30 million in proceeds to repay in full our term debt facility with MidCap financial, including $20 million of principal and $2.1 million in an end of facility fee, accrued interest, legal fees and prepayment fees. The parties also agreed that Aptevo would provide transition services for a limited period of time. We will not generate commercial revenues from our development stage product candidates unless and until we or potential 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 Highlights:

- Continued enrollment in a dose escalation Phase 1/1b open-label clinical study of APVO436 in patients with Acute Myeloid Leukemia and High-Grade Myelodysplastic Syndrome; completed dosing in cohorts 1-5 (through March 2020); dosing in Cohort 6 to begin shortly
- Presented new preclinical data for APVO436 at the American Association for Cancer Research (AACR) 2019 annual meeting demonstrating T cell differentiation into effector cells with exposure to APVO436 in preclinical studies, in addition to key data demonstrating potent T-cell cytotoxicity of tumors expressing CD123 with reduced cytokine release, suggesting the potential for increased clinical benefit and an improved safety profile

- Announced the selection of APVO436 for inclusion in the Leukemia & Lymphoma Society's Beat AML Master Clinical Trial; APVO436 being evaluated in patients newly diagnosed with AML
- Received orphan drug designation for APVO436
- Presented new preclinical data for ALG.APV-527 at AACR showing that it was well tolerated in a dose-range finding pilot toxicology study demonstrating an extended half-life of 5-7 days with no major changes in liver enzyme levels, cytokine levels or immune cell populations
- Made a joint decision with Aptevo's co-development partner, Alligator Bioscience to focus efforts on out-licensing ALG.APV-527 and delay submission of the clinical trial authorization for ALG-APV.527
- Announced the selection of a new ADAPTIR bispecific candidate, APVO603, a dual agonist bispecific antibody employing a novel mechanism of action to simultaneously target 4-1BB (CD137) and OX40 (CD134), both members of the TNF-receptor family
- Presented preclinical data at the 10th Annual World Bispecific Summit on APVO603 showing that dual targeting of 4-1BB and OX40 provides synergistic co-stimulation of T cells with the potential to amplify the cytotoxic function of activated T cells and NK cells
- Discontinued development of APVO210 in October 2019, the Company's investigational targeted cytokine bispecific antibody candidate; the decision to discontinue development was based on data from a multiple ascending dose study of APVO210 in healthy volunteers suggesting that it would not meet the desired target product profile for future commercialization
- Achieved a 41% increase in year-over-year 2019 IXINITY net revenue through continued expansion of the patient base for IXINITY; achieved record net annual IXINITY revenue of $32.4 million
- Launched a new, more desirable 3,000 IU assay for IXINITY providing advantages for Hemophilia B patients
- Completed preparations to begin dosing in a clinical study of IXINITY in pediatric patients (under 12 years of age) for potential label expansion of IXINITY in the United States in a pediatric setting; commenced patient dosing in January 2020
- Completed the sale of worldwide rights to IXINITY to Medexus Pharmaceuticals for estimated total proceeds in excess of $100 million, including an upfront payment to Aptevo of $30 million; potential milestone payments totaling up to $11 million; and the opportunity to receive deferred payments on future U.S. and Canadian net sales of IXINITY estimated in excess of $60 million based on the most recent Aptevo forecast
- Fully repaid Aptevo's $20 million term debt facility with MidCap Financial in February 2020 establishing a debt-free balance sheet
- Completed a public equity offering in March 2019 raising gross proceeds of approximately $22 million
- Received an accelerated performance-based $4.3 million milestone payment from Saol Therapeutics, part of a purchase agreement between Aptevo and Saol, originally executed in August 2017, under which Saol acquired three hyperimmune products previously marketed by Aptevo: WinRho SDF, HepaGam B, and VARIZIG
- Implemented an expense reduction plan in October 2019 reducing Aptevo's estimated 2019 annual cash burn rate

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Product Sales and Gross Profit

Product sales represents sales of IXINITY.

The primary expense we incurred to deliver IXINITY to our customers was 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, 2019 and 2018:

	For the Year Ended December 31,			
	2019	2018	Change	Percent
Product sales	$ 32,424	$ 23,067	$ 9,357	41%
Cost of product sales	19,927	11,214	8,713	78%
Gross profit	$ 12,497	$ 11,853	$ 644	5%
Gross margin percent	39%	51%		

Product sales of IXINITY increased by $9.4 million, or 41%, to $32.4 million for the year ended December 31, 2019 from $23.1 million for the year ended December 31, 2018. This increase was primarily related to continuing expansion of our Hemophilia B patient base and the launch of the 3000 IU assay size in Q2 2019, which resulted in increased IU's sold during the period, and price increases in 2019.

Gross profit increased by $0.6 million, or 5%, to $12.5 million for the year ended December 31, 2019 from $11.9 million for the year ended December 31, 2018. The increase in gross profit is mainly due to increased IU's sold in the period. This increase was partially offset by a higher cost of product in 2019 due to a $3.0 million credit received from our supplier and used to purchase product in 2018, and costs for stability for the new 3000 IU assay size, which was launched in June 2019 to the market, and the inventory write-offs in the year ended December 31, 2019.

We had a royalty obligation related to net product sales of IXINITY which was triggered if year-to-date net product sales from the U.S. exceeds $25 million. This double-digit royalty was owed on the portion of net product sales in excess of $25 million. The royalty percentage varies by geography, with the highest royalty rates applicable in the United States and Canada and lower rates in other jurisdictions. We recorded expenses related to this royalty obligation, as we have recognized in excess of $25 million in net product sales from IXINITY in the year ended December 31, 2019.

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, 2019 and 2018 are shown in the following table:

(in thousands)	For the Year Ended December 31, 2019	2018	Change
Clinical programs:			
APVO436	$ 4,467	$ 7,039	$ (2,572)
IXINITY Pediatric (APVO101-903)	4,563	1,277	3,286
Other	4,574	14,089	(9,515)
Total clinical programs	13,604	22,405	(8,801)
Pre-clinical program, general research and discovery	16,153	12,979	3,174
Total	$ 29,757	$ 35,385	$ (5,628)

Research and development expenses decreased by $5.6 million, to $29.7 million for the year ended December 31, 2019 from $35.4 million for the year ended December 31, 2018. Research and development expenses decreased primarily due to a decrease in expenses for APVO436 related to the timing of manufacturing and clinical trial activities, a decrease in expenses for other clinical programs, including lower costs for programs discontinued in 2018 and APVO210, which was discontinued in October 2019. This was offset by an increased spending for our IXINITY pediatric clinical program and our preclinical, 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. As IXINITY was sold to Medexus in February 2020, we no longer have an obligation to fund the IXINITY pediatric clinical program.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executive, IXINITY sales and marketing, business development, finance, accounting, information technology, quality assurance, 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, 2019 selling, general and administrative expenses decreased by $2.8 million, or 10%, to $25.3 million from $28.1 million for December 31, 2018. 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 income. Other expense was $2.1 million for the year ended December 31, 2019 and $2.0 million for the year ended December 31, 2018.

Discontinued Operations

In the third quarter of 2019, we received a $4.25 million milestone payment from Saol International Limited, in connection with the sale of our hyperimmune business in September 2017. No additional amounts are outstanding related to the milestones. This was recorded as a gain in discontinued operations of $4.25 million.

On February 28, 2020, Aptevo entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioTherapeutics LLC (“Aptevo BioT”), a subsidiary of Aptevo which wholly owns the IXINITY and related Hemophilia B business. As a result of the transaction, Medexus obtained all rights, title and interest to the IXINITY product and intellectual property. In addition, Aptevo BioT personnel responsible for the sale and marketing of IXINITY also transitioned to Medexus as part of the transaction.

As consideration for the sale, at closing Aptevo received an amount equal to $30 million in cash, subject to certain customary adjustments in respect of Aptevo's estimates of cash, indebtedness, working capital and transaction expenses of Aptevo BioT as of the closing. Such consideration will be subject to a final post-closing adjustment pursuant to the terms of the Purchase Agreement. From the $30 million payment at closing, Medexus withheld $0.9 million which was deposited with an escrow agent (i) to fund potential payment obligations of Aptevo with respect to the final post-closing adjustment and (ii) to fund potential post-closing indemnification obligations of Aptevo. In addition to the payment received at closing, Aptevo may also earn milestone and deferred payments from Medexus in the future. We used $22.1 million of the $30 million in proceeds to repay in full our term debt facility with MidCap financial, including $20 million of principal and $2.1 million in an end of facility fee, accrued interest, legal fees and prepayment fees. The parties also agreed that Aptevo would provide transition services for a limited period of time.

Income Taxes

During the periods prior to the spin-off from Emergent, 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 pre and post-tax for both continuing and discontinued operations for the periods ended December 31, 2019 and 2018:

	For the Year Ended December 31,	
	2019	2018
Net loss from continuing operations	$ (44,698)	$ (53,689)
Discontinued operations		
Income from discontinued operations, before income taxes	4,250	—
Net loss	$ (40,448)	$ (53,689)

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements at December 31, 2019.

Liquidity and Capital Resources

Cash Flows

We have financed our operations to date primarily through revenue generated from our commercial products, the sale of our hyperimmune business, public offerings of our common stock, loan proceeds, license fees, milestone payments and research and development funding from strategic partners, and funds received at the date of our spin-off from Emergent. As of December 31, 2019, we had cash, and cash equivalents in the amount of $12.4 million and restricted cash of $7.5 million. In February 2020, we used $22.1 million of the $30 million in proceeds from the sale of Aptevo BioT to Medexus to repay in full our term debt facility with MidCap financial, including $20 million of principal and $2.1 million in an end of facility fee, accrued interest, legal fees and prepayment fees. Under the terms of our credit facility agreement with MidCap, we were required to maintain a restricted cash account of $5 million. Repayment of the debt relieved us of the obligation to keep $5 million of cash restricted.

The following table provides information regarding our cash flows for year ended December 31, 2019 and 2018:

(in thousands)	For the Year Ended December 31, 2019	2018
Net cash provided by (used in):		
Operating activities	$ (42,383)	$ (51,422)
Investing activities	4,097	72,797
Financing activities	20,149	(787)
Increase (Decrease) in cash and cash equivalents	$ (18,137)	$ 20,588

Net cash used in operating activities for the year ended December 31, 2019 and 2018 was primarily due to our net operating loss and changes in working capital accounts.

Net cash provided by investing activities for the year ended December 31, 2019, was primarily due to the receipt of the $4.25 million milestone payment from Saol International Limited, in conjunction with the sale in September 2017 of our hyperimmune business, net of the purchase of property and equipment. For the year ended December 31, 2018, the largest components of the cash provided by investing activities were primarily due to the maturity and redemption of investments of $90.2 million, offset by investment purchases of $16.5 million.

Net cash provided by financing activities for the year ended December 31, 2019 is primarily due to $20.3 million received from the issuance of common stock and related warrants and the exercise of warrants. Net cash used in financing activities for the year ended December 31, 2018 was primarily due to the payment of tax liability associated with restricted stock units that vested in the quarter.

Sources of Liquidity

Public Offering – March 2019

On March 11, 2019, we completed a public offering relating to the issuance and sale of 19,850,000 shares of our common stock and warrants to purchase up to 19,850,000 shares of common stock at $1.00 per share and warrants at $1.30 per share, as well as pre-funded warrants to purchase up to 2,150,000 shares of common stock at an exercise prices of $0.01 per share and 2,150,000 of related warrants to purchase shares of common stock at $1.30 per share. We received net proceeds of $20.2 million, after underwriting fees, legal fees, and other expenses. If the remaining warrants are fully exercised in the future, additional proceeds to be received upon exercise of these warrants totals up to $28.6 million, which have a five-year life.

Credit Agreement

During 2018 and 2019, we were party to an Amended and Restated Credit and Security Agreement or the Credit Agreement, with MidCap. In February 2020, we used a portion of the $30 million in proceeds from the sale of the IXINITY business to repay in full our obligations to MidCap, inclusive of $2.1 million in an end of facility fee, accrued interest, legal fees and prepayment fees. Under the terms of our credit facility agreement with MidCap Financial Trust, we were required to maintain a restricted cash account of $5 million. Repayment of the debt relieved us of the obligation to keep $5 million of cash restricted.

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 issued 13,265 shares under the Equity Distribution Agreement in the fourth quarter of 2018, and 180,421 shares in the third quarter of 2019 and received net proceeds of $0.2 million from these transactions. Following such prior sales, we have the ability to sell up to an additional $17.3 million of common stock under the Equity Distribution Agreement.

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

Purchase Agreement

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

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase shares of our common stock provided that Lincoln Park's maximum commitment on any single day does 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; provided, however, that we cannot direct any such purchase if the prevailing market price is less than $1.00. 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.

Liquidity

Due to our significant research and development expenditures, we have generated significant operating losses from inception and we expect to incur significant operating losses in the future. We have funded our operations primarily through sales of our equity securities, utilization of our credit agreement, the sale of our former hyperimmune business, product sales, and payments from our former parent. We had a net loss of $40.4 million and $53.7 million for the years ended December 31, 2019 and December 31, 2018, respectively. We had cash and cash equivalents of $12.5 million, restricted cash of $7.5 million and an accumulated deficit of $167.9 million as of December 31, 2019.

For the year ended December 31, 2019, net cash used in our operating activities was $42.4 million.

On February 28, 2020, Aptevo entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioT, a subsidiary of Aptevo which wholly owns the IXINITY and related Hemophilia B business. As a result of the transaction, Medexus obtained all rights, title and interest to the IXINITY product and intellectual property. In addition, Aptevo BioT personnel responsible for the sale and marketing of IXINITY also transitioned to Medexus as part of the transaction.

As consideration for the sale, at closing Aptevo received an amount equal to $30 million in cash, subject to certain customary adjustments in respect of Aptevo's estimates of cash, indebtedness, working capital and transaction expenses of Aptevo BioT as of the closing. Such consideration will be subject to a final post-closing adjustment pursuant to the terms of the Purchase Agreement. From the $30 million payment at closing, Medexus withheld $0.9 million which was deposited with an escrow agent (i) to fund potential payment obligations of Aptevo with respect to the final post-closing adjustment and (ii) to fund potential post-closing indemnification obligations of Aptevo. In addition to the payment received at closing, Aptevo may also earn milestone and deferred payments from Medexus in the future. We used $22.1 million of the $30 million in proceeds to repay in full our term debt facility with MidCap financial, including $20 million of principal and $2.1 million in an end of facility fee, accrued interest, legal fees and prepayment fees. Under the terms of our credit facility agreement with MidCap Financial Trust, we were required to maintain a restricted cash account of $5 million. Repayment of the debt relieved us of the obligation to keep $5 million of cash restricted. As a result of these transactions, our cash position improved by $10.3 million.

While we expect to generate cash inflows from milestones and deferred payments from Medexus' future sales of IXINITY and regulatory approval, our results of operations will be highly dependent on our research and development spending. When considered in aggregate, these factors raise substantial doubt about our ability to continue as a going concern for the one-year period from the date of issuance of these financial statements. Our ability to continue as a going concern will require us to generate positive cash flow from operations, obtain additional financing, enter into strategic alliances and/or sell assets.

Our plans to address this condition include pursuing one or more of the following options to secure additional funding, none of which can be guaranteed or are entirely within our control:

- Raise funding through the possible additional sales of our common stock, through our existing equity sales agreement with Lincoln Park Financial LLC or our Equity Distribution Agreement with Piper Jaffray or other public or private equity financings.
- Partner or sell a portion or all rights to any of our assets to secure potential additional non-dilutive funds.
- Establish additional credit lines or other debt financing sources.

There can be no assurance, however, that we will receive cash proceeds from any of these potential resources or to the extent cash proceeds are received such proceeds would be sufficient to support our current operating plan for at least the next twelve months from the date of filing this Annual Report on Form 10-K.

There are numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products. Accordingly, our future funding requirements may vary from our current expectations and will depend on many factors, including, but not limited to:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and of conducting preclinical and clinical trials;
- the timing of, and the costs involved in, completing our clinical trials and obtaining regulatory approvals for our product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;

- the timing, receipt and amount of milestone payments and any deferred payments from Medexus with respect to IXINITY; and
- our ability to continue as a going concern.

If we are unable to raise substantial additional capital in the next year, whether on terms that are acceptable to us, or at all then we may be required to:

- delay, limit, reduce or terminate our clinical trials or other development activities for one or more of our product candidates; and/or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, if approved.

The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all.

Our future success is dependent on our ability to develop our product candidates and ultimately upon our ability to attain profitable operations. We anticipate that we will continue to incur significant operating losses for the next several years as we incur expenses to continue to execute on our development strategy to advance our preclinical and clinical stage assets. 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. We will require substantial additional funds to continue our development programs and to fulfill our planned operating goals.

Contractual Obligations

Our contractual obligations as of December 31, 2019 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	$ 5,560	$ 1,480	$ 4,080	$ —
Purchase Obligations	$ 8,099	$ 1,657	$ 6,442	$ —

In January 2020, we entered into a contract with The Leukemia & Lymphoma Society (LLS) to be part of an ongoing national AML master clinical trial called the ‘Beat AML Master Clinical Trial.’ The Beat AML Master Clinical Trial provides access to leading academic cancer centers and allows us to study APVO436 in a front-line AML setting. Our purchase obligation for the Beat AML Master Clinical Trial totals $8.1 million over the next three years. We note that the Clinical Trial Participation Agreement contains a termination for convenience clause where we may terminate the agreement with 180 days prior written notice.

Critical Accounting Policies and Significant Judgements and Estimates

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

Revenue Recognition - Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers

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 Expenses

Research and development expenses 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 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 historical and future taxable income, future reversals of existing taxable temporary differences, taxable income in prior carryback years, 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

On January 1, 2019 we adopted ASU No. 2016-02, Leases (ASC 842), which amended the existing standards for lease accounting, requiring lessees to recognize most leases on their balance sheets and disclose key information about leasing arrangements. We adopted the new standard using a modified retrospective transition approach at the beginning of the current fiscal year, January 1, 2019. We did not adjust comparative periods in our financial statements prior to that period. For further discussion of new accounting standards, please see Note 1 of the Consolidated Financial Statements contained in this Annual Report on Form 10-K.

On December 18, 2019 we adopted ASU No. 2019-12, Income Taxes (Topic 740), which amended the existing standards for income tax accounting, eliminating the legacy exception on how to allocate income tax expense or benefit for the year to continuing operations, discontinued operations, other comprehensive income, and other charges or credits recorded directly to shareholder's equity. We did not adjust comparative periods in our financial statements prior to that period. For further 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.

Table of Contents

Index to Consolidated Financial Statements

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company’s ability to continue as a going concern. Management's evaluation of the events and conditions and management’s plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Adoption of FASB Accounting Standard Update Leases (Topic 842)

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU Topic 842, Leases.

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 25, 2020

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

	As of December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,448	$ 30,635
Accounts receivable	7,022	5,220
Inventories	6,139	1,785
Prepaid expenses	4,226	6,907
Other current assets	160	4,142
Total current assets	29,995	48,689
Restricted cash, net of current portion	7,498	7,448
Property and equipment, net	3,946	5,202
Intangible assets, net	4,420	5,250
Operating lease right-of-use asset	3,747	—
Other assets	3,802	905
Total assets	$ 53,408	$ 67,494
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 13,043	$ 11,671
Accrued compensation	3,524	3,898
Sales rebates and discounts payable	726	1,245
Current portion of long-term debt	19,863	—
Other current liabilities	1,083	796
Total current liabilities	38,239	17,610
Long-term debt, net	—	19,278
Other liabilities	—	200
Operating lease liability	3,327	—
Total liabilities	41,566	37,088
Stockholders' equity:		
Preferred stock: $0.001 par value; 15,000,000 shares authorized, zero shares issued or outstanding	—	—
Common stock: $0.001 par value; 500,000,000 shares authorized; 45,279,244 and 22,808,416 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	45	23
Additional paid-in capital	179,653	157,791
Accumulated deficit	(167,856)	(127,408)
Total stockholders' equity	11,842	30,406
Total liabilities and stockholders' equity	$ 53,408	$ 67,494

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,	
	2019	2018
Revenues:		
Product sales	$ 32,424	$ 23,067
Costs and expenses:		
Cost of product sales	19,927	11,214
Research and development	29,757	35,385
Selling, general and administrative	25,336	28,133
Loss from operations	(42,596)	(51,665)
Other expense:		
Other expense, net	(2,102)	(2,024)
Net loss from continuing operations	(44,698)	(53,689)
Discontinued operations (Note 2):		
Income from discontinued operations	4,250	—
Income from discontinued operations	4,250	—
Net loss	$ (40,448)	$ (53,689)
Basic and diluted net income (loss) per share:		
Net loss from continuing operations	$ (1.09)	$ (2.39)
Net income from discontinued operations	$ 0.10	$ —
Net loss	$ (0.99)	$ (2.39)
Weighted-average shares used to compute per share calculation	40,838,491	22,500,053

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,	
	2019	2018
Net loss	$ (40,448)	$ (53,689)
Other comprehensive loss:		
Unrealized gain on available-for-sale investments, net	—	105
Total comprehensive loss	$ (40,448)	$ (53,584)

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,	
	2019	2018
Operating Activities		
Net loss	$ (40,448)	$ (53,689)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	1,598	2,140
Depreciation and amortization	2,235	2,390
Non-cash interest expense and other	699	988
Gain on milestone payment related to sale of Hyperimmune Business	(4,250)	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,802)	(3,079)
Inventories	(4,354)	(757)
Prepaid expenses and other current assets	3,614	(1,315)
Operating lease right of use asset	945	—
Accounts payable, accrued compensation and other liabilities	938	1,279
Long-term operating lease liability	(1,039)	621
Sales rebates and discounts	(519)	—
Net cash used in operating activities	(42,383)	(51,422)
Investing Activities		
Proceeds from the maturity of investments	—	90,243
Milestone payment from sale of Hyperimmune Business	4,250	65
Purchases of property and equipment	(153)	(976)
Purchases of investments	—	(16,535)
Net cash provided by investing activities	4,097	72,797
Financing Activities		
Payments of long-term debt, issuance costs and modification fees	(137)	—
Proceeds from issuance or exercise of common stock, warrants, and pre-funded warrants	20,344	623
Payment of tax liability for vested equity awards	(58)	(808)
Fees paid to lender to amend debt agreement	—	(602)
Net cash provided by (used in) financing activities	20,149	(787)
(Decrease) increase in cash, cash equivalents, and restricted cash	(18,137)	20,588
Cash, cash equivalents, and restricted cash at beginning of period	38,083	17,495
Cash, cash equivalents, and restricted cash at end of period	$ 19,946	$ 38,083

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	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	$ 21,605,716	$ 22	$ 155,837	$ (73,719)	$ (105)	$ 82,035
Unrealized losses on available-for-sale investments	—	—	—	—	105	105
Common stock issued upon exercise of stock options	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
Issuance of common stock, pre-funded warrants and warrants, net	22,180,421	22	20,322	—		20,344
Issuance of commitment shares of common stock, non-cash transaction	195,867	—	—	—	—	—
Common stock issued upon vesting of restricted stock units	94,540	—	(58)	—	—	(58)
Stock-based compensation	—	—	1,598	—	—	1,598
Net loss for the period	—	—	—	(40,448)	—	(40,448)
Balance at December 31, 2019	$ 45,279,244	$ 45	$ 179,653	$ (167,856)	$ —	$ 11,842

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 clinical-stage biotechnology company focused on developing novel immunotherapies for the treatment of cancer. Our lead clinical candidate, APVO436, and preclinical candidates, ALG.APV-527 and APVO603 were developed based on the Company's versatile and robust ADAPTIR™ modular protein technology platform. The ADAPTIR platform is capable of generating highly differentiated bispecific antibodies with unique mechanisms of action for the treatment of different types of cancer. At December 31, 2019, we had one revenue-generating product in the area of hematology, IXINITY®.

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

The accompanying financial statements have been prepared on a basis that assumes we will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. For the year ended December 31, 2019 and 2018, we generated product revenue of $32.4 million and $23.1 million, respectively, and had a net loss of $40.4 million and $53.7 million, respectively. We had an accumulated deficit of $167.9 million as of December 31, 2019. For the year ended December 31, 2019, net cash used in our operating activities was $42.4 million. As of December 31, 2019, our sole marketed product was IXINITY®, and therefore IXINITY was our only source of product revenue. We have suffered recurring losses from operations and negative cash flows from operating activities. When considered in aggregate, these factors raise substantial doubt about our ability to continue as a going concern for the one-year period from the date of issuance of these financial statements. We will need to raise additional funds to support our operating and capital needs in 2020.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to: (a) changes we may make to the business that affect ongoing operating expenses; (b) changes we may make in our business strategy; (c) changes we may make in our research and development spending plans; (d) potential decreases in our expected milestone and deferred payments from Medexus with respect to IXINITY; and (e) other items affecting our forecasted level of expenditures and use of cash resources. We may attempt to obtain additional funding through our existing equity sales agreement with Lincoln Park Financial LLC or our Equity Distribution Agreement with Piper Jaffray, or other public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. However, we may not be able to secure such funding in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals may be adversely affected.

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 and Aptevo BioTherapeutics LLC. 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 and Aptevo BioTherapeutics LLC. 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

As of December 31, 2019, we had restricted cash, long-term, which included $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 $2.5 million securing letters of credit. Under the terms of our credit facility agreement with MidCap Financial Trust, we were required to maintain a restricted cash account of $5 million. Repayment of the debt in February 2020 relieved us of the obligation to keep $5 million of cash restricted.

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 sold 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, 2019 and 2018 and greater than 10% of accounts receivable as of December 31, 2019 and 2018 as noted below.

	2019		2018	
	Percentage of Total Revenue	Percentage of Accounts Receivable	Percentage of Total Revenue	Percentage of Accounts Receivable
Customer A	36%	72%	72%	70%
Customer B	27%	18%	17%	19%
Customer C	20%	0%	—	—

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.

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.

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.

Leases

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

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

We determine if an arrangement is a lease at inception date. Leases are to be classified as finance or operating at the lease commencement date, which affects the classification of expense recognition in the income statement. Right-of-use assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments, as agreed to in the lease. Operating lease liabilities and the corresponding right-of-use assets are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. An operating right-of-use asset is measured as the amount of the initial measurement of the lease liability, adjusted for prepaid or accrued lease payments, the remaining balance of any lease incentive received, unamortized initial direct costs, and any impairment of the right-of-use asset. The initial measurement of the lease liabilities and right-to-use assets of finance leases is the same as for operating leases. We include options to extend the lease and certain termination options in our lease liability and right-of-use asset when it is reasonably certain that we will exercise those options.

As our existing leases do not contain an implicit interest rate, we estimate our incremental borrowing rate (IBR) based on information available at commencement date in determining the present value of future payments. Due to the significant judgment involved and the complex analysis needed to determine this discount rate, we engaged a third-party valuation specialist to advise us in our determination of our IBR for the initial adoption of the standard.

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

Adoption of the new standard resulted in the recognition of a right-of-use asset of $1.5 million, an operating lease liability of $2.2 million dollars, and a related decrease in deferred rent liability of $0.7 million at January 1, 2019. Refer to Note 11 for additional information. We note that there was no cumulative effect due to the deferred rent change.

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 marketed and sold IXINITY through commercial wholesalers (direct customers) who purchased IXINITY 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, continued to purchase Aptevo’s product from the wholesalers, but at their respective contractual prices. Per its wholesaler agreements, Aptevo guaranteed 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

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 had 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.

On February 28, 2020, Aptevo entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioT, a subsidiary of Aptevo which wholly owns the IXINITY and related Hemophilia B business.

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: The Company makes payments to customers (in the form of credit memos) which are based on the difference between the price paid by the distributor (the "WAC") and contracted prices paid by the authorized customers of the distributor. Specialty pharmacies, GPO's and other smaller specialty distributors buy the product from the distributors at prices agreed to in contracts with Aptevo 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 the WAC, the distributor is allowed to charge the Company back the difference between the WAC and the contract price paid by their customer, this is referred to as a "Chargeback".

Distribution and Data fees – The Company pays fees (in the form of direct payments) to the distributors and some GPO's (indirect customers) for distribution of the products and for transmission of data. These services satisfy business needs for Aptevo.

Commercial Rebate Programs – From time to time, the Company enters into rebate programs with customers. These programs vary in time and scope, but in general, the programs involving paying a per IU rebate if a specific customer or purchasing organization dispenses a certain number of IU's over a specific period of time.

Government Rebates: Certain sales by the specialty pharmacies and GPO's are to qualify PHS/Medicaid/Medicare/TRICARE/VA and other government patients. The Company has contracts with these agencies that require rebates for sales made under the programs.

Cash Discounts: All customers have the option to receive a cash discount for early payment.

Patient Assistance: All patients are eligible for the IXINITY Savings Program – This provides for up to to $12,000 annual benefit to assist with co-payments. Historically, this has been insignificant to the Company.

Research and Development Expenses

Research and development expenses 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 the historical and implied future volatility of our common stock;
- 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. We have estimated a forfeiture rate of ten-percent. 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 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 historical and future taxable income, future reversals of existing taxable temporary differences, taxable income in prior carryback years, 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 June 2016, the FASB issued ASU 2016-13, Financial Instruments — Credit Losses, (Topic 326) which changes how entities account for credit losses on most financial assets and certain other instruments and expands disclosures. The standard is effective for annual and interim periods beginning after December 15, 2022, with early adoption permitted, for Aptevo, as we meet the definition of a smaller reporting company (SRC). We expect to adopt the standard on January 1, 2021 and are still in the process of evaluating the effect of adoption on our consolidated financial statements and disclosures.

Recently Adopted Standards

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

Adoption of the new standard resulted in the recognition of a right-to-use asset of $1.5 million, an operating lease liability of $2.2 million dollars, and a related decrease in deferred rent liability of $0.7 million at January 1, 2019. Refer to Note 11 for additional information.

On December 18, 2019 we adopted ASU No. 2019-12, Income Taxes (Topic 740), which amended the existing standards for income tax accounting, eliminating the legacy exception on how to allocate income tax expense or benefit for the year to continuing operations, discontinued operations, other comprehensive income, and other charges or credits recorded directly to shareholder's equity. We did not adjust comparative periods in our financial statements prior to that period.

Adoption of the new standard resulted in determining the tax effect of income or loss from continuing operations using a computation that does not consider the tax effects of items that are not included in continuing operations. As such, we did not record a tax expense or benefit in the income from discontinued operations. Refer to Note 2 for additional information.

Note 2. Discontinued Operations – Milestone Payment

In the third quarter of 2019, we received a $4.25 million milestone payment from Saol International Limited, in connection with the sale of our hyperimmune business in September 2017. No additional amounts are outstanding related to the milestones. This was recorded as a gain in discontinued operations of $4.25 million.

On February 28, 2020, we entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioT, a subsidiary of Aptevo which wholly owns the IXINITY and related Hemophilia B business. We note that the IXINITY asset was not classified as held-for-sale as of December 31, 2019, as the sale of Aptevo BioTherapeutics LLC was approved by the board of directors on February 27, 2020.

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.

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. 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.

Aptevo and Alligator have made a joint decision to delay submission of the clinical trial authorization (CTA) for ALG-APV.527 previously planned for the fourth quarter of 2019. Alligator and Aptevo have made a joint decision to focus efforts on partnering ALG.APV-527 prior to phase 1 clinical development. The adjustment to the development plan for ALG.APV -527 will allow both Aptevo and Alligator to align their resources with their respective ongoing clinical programs. The companies are initiating discussions with potential partners for the upcoming clinical development of ALG.APV-527.

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, 2019, we recorded a reduction in our research and development expense of $1.4 million, and for the year ended December 31, 2018, we recorded a decrease in our research and development expense of $0.6 million, related to the collaboration arrangement.

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, 2019 and December 31, 2018:

	December 31, 2019			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds(1)	$ 12,494	$ —	$ —	$ 12,494

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

(1) As of December 31, 2019, and 2018, the money market funds included $5.0 million 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, 2019.

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 $2.5 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, 2019 and December 31, 2018:

	For the Year Ended December 31,	
(in thousands)	2019	2018
Cash	$ 4,954	$ 6,588
Cash equivalents	7,494	24,047
Restricted cash	7,498	7,448
Total cash, cash equivalents, and restricted cash	$ 19,946	$ 38,083

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 2019. Available-for-sale securities are written down to fair value through income whenever it is necessary to reflect other than temporary impairments.

	December 31, 2019			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding (Losses)	Fair Value
Cash equivalents:				
Money market funds(1)	$ 12,494	$ —	$ —	$ 12,494
Total cash equivalents	$ 12,494	$ —	$ —	$ 12,494

	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

(1) As of December 31, 2019, the money market funds included $5.0 million in restricted cash, and as of December 31, 2018, the money market funds included $5.0 million in restricted cash.

Note 7. Inventories

Inventories consist of the following:

	Ended December 31,	
(in thousands)	2019	2018
Raw materials and supplies	$ 491	$ 194
Work-in-process	1,958	916
Finished goods	3,690	675
Total inventories	$ 6,139	$ 1,785

Note 8. Property and equipment, net

Property and equipment consist of the following:

(in thousands)	For the Year Ended December 31, 2019	2018
Leasehold improvements	$ 2,264	$ 2,278
Furniture and equipment	11,606	11,622
Property and equipment, gross	13,870	13,900
Less: Accumulated depreciation	(9,924)	(8,698)
Total property and equipment, net	$ 3,946	$ 5,202

Depreciation expense for the year ended December 31, 2019 and December 31, 2018 was $1.4 million and $1.6 million, respectively.

Note 9. IXINITY Intangible Assets, Net

Intangible assets, net, is solely related to our IXINITY product. For the year ended December 31, 2019, the Company recorded $0.8 million, respectively, of intangible asset amortization expense. As of December 31, 2019, the weighted average amortization period remaining for intangible assets was 63 months.

Future amortization expense as of December 31, 2019 is as follows:

(in thousands)	
2020	$ 830
2021	830
2022	830
2023	830
2024 and beyond	1,100
Total remaining amortization	$ 4,420

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.

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 was extended to February 1, 2020, with an opportunity for further deferral through August 1, 2020. The amount of restricted cash that we were required to maintain on our balance sheet was reduced from $10 million to $5 million.

We used $22.1 million of the $30 million in proceeds from the sale of the IXINITY business to Medexus on February 28, 2020 to repay in full our term debt facility with MidCap financial, including $20 million of principal and $2.1 million in an end of facility fee, accrued interest, legal fees and prepayment fees. Under the terms of our credit facility agreement with MidCap, we were required to maintain a restricted cash account of $5 million. Repayment of the debt will also relieve us of the obligation to keep $5 million of cash restricted.

Note 11. Leases and Contingencies

Office Space Lease – Operating

We have an operating lease related to our office and laboratory space in Seattle, Washington. This lease was amended and extended in March 2019. The term of the amended lease is through April 2030 and we have two options to extend the lease term, each by five years, as well as a one-time option to terminate the lease in April 2023.

We recorded a right-of-use asset for this lease on January 1, 2019 of $1.2 million which reflects the amount of the remaining lease liability, less the balance of accrued and deferred rent, and net of the unamortized balance of tenant incentives. We also recorded a lease liability of $1.9 million, which reflects the present value of the remaining lease payments, discounted using our incremental borrowing rate of 16.95% for the remaining term of the lease. The future expense for this lease will be recorded as a straight-line expense, less the unamortized tenant incentive portion, plus any variable expenses due to true-ups of operating costs or real estate taxes. In August of 2019, we amended the lease to reduce the space included in the original lease to equal the space in the renewed lease. As a result, we recorded an adjustment of $0.1 million to the right-of-use asset and lease liability.

As a result of the lease amendment in March 2019, we recorded an increase to our right-of-use asset for this lease amendment of $3.2 million which reflects the amount of the remaining lease liability through April 30, 2023, less the balance of accrued and deferred rent, and net of the unamortized balance of tenant incentives. In March 2019, we also recorded an increase to our lease liability for this lease amendment of $3.2 million which reflects the present value of the remaining lease payments through April 30, 2023, discounted using our incremental borrowing rate of 14.45% for the remaining term of the lease on the date of amendment.

The amended lease has a renewal option of two five-year renewals at fair market value as determined at the time of renewal, and a termination option after month thirty-six with nine months written notice. The termination option also requires a penalty equal to the unamortized tenant improvement allowance at 8% interest, the unamortized real estate taxes at 8% interest, and the equivalent of four-months' rent at the base rent price at the time of termination. The estimated termination penalty has been recorded in our lease payments. We determined we should not include any periods after the termination option when evaluating this amendment as we are not reasonably certain to not exercise the option, therefore we are recording our liability through April 30, 2023.

For the year ended December 31, 2019, we recorded $0.5 million related to variable expenses.

Equipment Leases - Operating

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

Equipment Lease – Financing

As of January 1, 2019, we had one equipment lease classified as a financing lease as the lease transfers ownership of the underlying asset to us at the end of the lease term. The remaining term of this lease is eight months and has a remaining expense obligation of less than $0.1 million. There were no financing lease payments in the year ended December 31, 2019.

Components of lease expense:

(in thousands)	For the year ended December 31, 2019
Operating lease cost	$ 1,526
Finance lease cost:	
Amortization of right-of-use assets	6
Interest on lease liabilities	2
Total lease cost	$ 1,534

Right of use assets acquired under operating leases:

(in thousands)	For the year ended December 31, 2019
Operating leases, excluding Seattle office lease	$ 241
Seattle office lease, including amendment	3,506
Total operating leases	$ 3,747

Lease payments:

(in thousands)	For the year ended December 31, 2019
For operating leases	$ 1,714

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

(in thousands)		
2020	$	1,480
2021		1,387
2022		1,294
2023		1,399
Total Future minimum lease payments		5,560
Less: imputed interest		(1,306)
Total	$	4,254

The long-term portion of the lease liabilities included in the amounts above is $3.3 million and the remainder of our lease liabilities are included in other current liabilities on our condensed consolidated balance sheets.

As of December 31, 2019, the weighted average remaining lease term and weighted discount rate for operating leases was 3.3 years and 14.55%.

Note 12. Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period using the as-if converted method. For the purpose of this calculation, 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.

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 warrants, stock options and unvested RSUs.

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

	For the Year Ended December 31,			
	2019		2018	
Net loss	$	(40,448)	$	(53,689)
Basic and diluted net income (loss) per share:				
Net loss from continuing operations	$	(1.09)	$	(2.39)
Net income from discontinued operations	$	0.10	$	—
Net loss	$	(0.99)	$	(2.39)
Weighted-average shares used to compute per share calculation		40,838,491		22,500,053

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

(in thousands, except for per share amounts)	For the Year Ended December 31, 2019	2018
Warrants	22,000	—
Outstanding options to purchase common stock	4,691	3,330
Unvested RSUs	245,001	133

Note 13. Equity

Common Stock

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

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

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

For the year ended December 31, 2019, we issued 94,540 shares of common stock due to the vesting of RSUs.

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 0.4 million shares of common stock. We also issued 815,834 shares of common stock in the year ended December 31, 2018, upon the vesting of RSUs.

Purchase Agreement

On December 20, 2018, we entered into the Purchase Agreement, and a registration rights agreement, with Lincoln Park. Pursuant to the purchase agreement, Lincoln Park has committed to purchase up to $35.0 million worth of our common stock over a 36-month period commencing on February 13, 2019, the date the registration statement covering the resale of the shares was declared effective by the SEC. Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase shares of our common stock provided that Lincoln Park's maximum commitment on any single day does 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; provided, however, that we cannot direct any such purchase if the prevailing market price is less than $1.00. Pursuant to this purchase agreement we issued 105,467 commitment shares of common stock in December 2018, and 195,867 commitment shares of common stock in the first quarter of 2019.

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, and 180,421 shares in the year ended December 31, 2019 and received net proceeds of $0.2 million from these transactions. Following such prior sales, we have the ability to sell up to an additional $17.3 million of common stock under the Equity Distribution Agreement.

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 Capital 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 replaced 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, 2019, there are 1.3 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 Capital 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:

	For the Year Ended December 31,	
(in thousands)	**2019**	**2018**
Research and development	$ 532	$ 884
Selling, general and administrative	1,066	1,256
Total stock-based compensation expense	$ 1,598	$ 2,140

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,	
	2019	**2018**
Expected dividend yield	0.00%	0.00%
Expected volatility	79.78%	75.00%
Risk-free interest rate	2.04%	2.74%
Expected average life of options	5 years	6 years

Management applied an estimated forfeiture rate for all periods of 10%.

The following is a summary of option activity for the year ended December 31, 2019:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Term	Aggregate Intrinsic Value
Balance at December 31, 2018	3,329,618	$ 2.74	6.99	$ —
Granted	1,786,857	1.02	—	—
Exercised	—	—	—	—
Forfeited	(425,118)	2.29	—	—
Outstanding at December 31, 2019	4,691,357	$ 2.14	7.28	$ 63,511
Exercisable at December 31, 2019	2,210,593	$ 2.65	5.35	$ —

As of December 31, 2019, we had $1.8 million of unrecognized compensation expense related to options expected to vest over a weighted average period of 1.4 years. The weighted average remaining contractual life of outstanding and exercisable options is 5.4 years.

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the closing stock price of Aptevo's common stock on the last trading day of 2019 and the exercise price, multiplied by the number of in the money options) that would have been received by the option holders had all the option holders exercised their options on December 31, 2019.

Restricted Stock Units

The following is a summary of restricted stock activity for the year ended December 31, 2019:

	Number of Units	Weighted Average Fair Value per Unit	Aggregate Fair Value
Balance at December 31, 2018	133,040	$ 2.97	$ 168,961
Granted	248,201	0.58	142,964
Vested	133,040	2.97	201,642
Forfeited	3,200	—	—
Outstanding at December 31, 2019	245,001	$ 0.58	$ —
Expected to Vest	245,001	$ 0.58	$ —

As of December 31, 2019, there was no unrecognized stock-based compensation expense related to unvested RSUs.

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 The Nasdaq Capital Market.

Warrants

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

Note 14. 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, 2019 and December 31, 2018, Aptevo's related share of matching contributions was approximately $0.4 million and $0.5 million.

Note 15. Revenue Reserves

The following table summarizes activity in each of our receivable-related allowances and revenue-related liabilities for the years ended December 31, 2019 and December 31, 2018:

(in thousands)	Chargebacks and Rebates	Distribution Fees, Cash Discounts and Patient Assistance
Balance at December 31, 2018	$ (1,323)	$ (865)
Provision related to current period sales	(3,917)	(2,492)
Credit or payments made during the period	3,394	2,631
Balance at December 31, 2019	$ (1,845)	$ (726)

(in thousands)	Chargebacks	Distribution/Data Fees
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

We did not have an income tax benefit or income tax expense from continuing operations in the year ended December 31, 2019 nor December 31, 2018.

Loss from continuing operations before income taxes is comprised of:

	Year ended December 31,	
(in thousands)	2019	2018
US	$ (44,698)	$ (53,692)
International	—	3
Loss from continuing operations before benefit from income taxes	$ (44,698)	$ (53,689)

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, 2019	2018
Federal losses carryforward	$ 28,221	$ 20,251
Intangible assets	3,869	4,210
Stock compensation	1,023	844
State losses carryforward	3,044	2,260
Other deferred tax assets	1,718	1,543
Other tax credits	1,447	713
Lease Liabilities	992	—
Fixed assets	453	488
Deferred tax asset, gross	40,767	30,309
Valuation allowance	(39,895)	(30,309)
Deferred tax assets, net of valuation	872	—
ROU Assets	(874)	—
Deferred tax liability	(874)	—
Net deferred tax liabilities	$ (2)	$ —

As of December 31, 2019, and 2018, we have recorded federal net operating losses (NOL) carryforwards of approximately $134.4 million and $96.4 million, state NOL carryforwards of approximately $59.4 million and $44.5 million, and tax credit carryforwards of $1.4 million and $0.7 million, respectively. $41.0 million of the federal losses and credits would begin to expire in 2037, while $93.4 million of federal losses may be carried forward indefinitely. 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, if any, associated with audits and uncertain tax positions is to record such items as a component of income tax expense. 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, 2019	2018
Federal tax at statutory rates	21.0%	21.0%
State taxes, net of federal benefit	1.8%	2.5%
Change in valuation allowance	-23.7%	-24.5%
Tax credits	1.6%	0.4%
Permanent differences	-0.7%	-0.2%
Other	0.0%	0.8%
Total income tax benefit	0.0%	0.0%

Note 17. Subsequent Events

On February 28, 2020, Aptevo entered into an LLC Purchase Agreement with Medexus, pursuant to which Aptevo sold all of the issued and outstanding limited liability company interests of Aptevo BioTherapeutics LLC ("Aptevo BioT"), a subsidiary of Aptevo which wholly owns the IXINITY and related Hemophilia B business. As a result of the transaction, Medexus obtained all rights, title and interest to the IXINITY product and intellectual property. In addition, Aptevo BioT personnel responsible for the sale and marketing of IXINITY also transitioned to Medexus as part of the transaction.

As consideration for the sale, at closing Aptevo received an amount equal to $30 million in cash, subject to certain customary adjustments in respect of Aptevo's estimates of cash, indebtedness, working capital and transaction expenses of Aptevo BioT as of the closing. Such consideration will be subject to a final post-closing adjustment pursuant to the terms of the Purchase Agreement. From the $30 million payment at closing, Medexus withheld $0.9 million which was deposited with an escrow agent (i) to fund potential payment obligations of Aptevo with respect to the final post-closing adjustment and (ii) to fund potential post-closing indemnification obligations of Aptevo. In addition to the payment received at closing, Aptevo may also earn milestone and deferred payments from Medexus in the future. We used $22.1 million of the $30 million in proceeds to repay in full our term debt facility with MidCap financial, including $20 million of principal and $2.1 million in an end of facility fee, accrued interest, legal fees and prepayment fees. The parties also agreed that Aptevo would provide transition services for a limited period of time.

On March 23, 2020, a reverse stock split was approved by a majority vote of the Company's stockholders. No common stock or per share data included in these financial statements has been restated to give effect to the reverse stock split as it has not been effected by our Board of Directors as of the date of these financial statements.

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

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, 2019 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, 2019, 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.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the year ended December 31, 2019, 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 2020 Annual Meeting of Stockholders (the Proxy Statement), which is expected to be filed not later than 120 days after December 31, 2019, under the headings “Executive Officers,” “Proposal 1 -Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” and “Delinquent Section 16(a) Reports,” 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. Exhibit Index

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	
+2.3	LLC Purchase Agreement by and among Aptevo Therapeutics Inc. and Medexus Pharma, Inc. dated February 28, 2020.	8-K	2.1	March 2, 2020	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	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	
10.2	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	
10.3	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 10.4	Aptevo Therapeutics Inc. Amended and Restated 2016 Stock Incentive Plan.	10-Q	4.1	August 10, 2017	001-37746	
C 10.5	Aptevo Therapeutics Inc. Converted Equity Awards Incentive Plan	8-K	10.10	August 2, 2016	001-37746	
C 10.6	Aptevo Therapeutics Inc. Senior Management Severance Plan	8-K	10.11	August 2, 2016	001-37746	

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
C 10.7	Form of Indemnity Agreement for directors and senior officers	10	10.9	April 15, 2016	001-37746	
10.8	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	
10.9	Seattle Office Lease Amendment, dated December 8, 2004	10	10.13	April 15, 2016	001-37746	
10.10	Seattle Office Lease Amendment, dated February 1, 2006	10	10.14	April 15, 2016	001-37746	
10.11	Seattle Office Lease Amendment, dated February 2, 2007	10	10.15	April 15, 2016	001-37746	
10.12	Seattle Office Lease Amendment, dated June 7, 2010	10	10.16	April 15, 2016	001-37746	
10.13	Seattle Office Lease Amendment, dated December 21, 2010	10	10.17	April 15, 2016	001-37746	
10.14	Seattle Office Lease Amendment, dated July 17, 2012	10	10.18	April 15, 2016	001-37746	
10.15	Seventh Amendment to Seattle Office Lease, dated December 5, 2014	10	10.19	April 15, 2016	001-37746	
†10.16	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	
†10.17	First Amendment to MorphoSys Collaboration Agreement, dated June 19, 2015	10	10.21	April 15, 2016	001-37746	
†10.18	Second Amendment to MorphoSys Collaboration Agreement, dated December 7, 2015	10	10.22	April 15, 2016	001-37746	
10.19	Third Amendment to MorphoSys Collaboration Agreement, dated December 12, 2016	8-K	10.1	December 15, 2016	001-37746	
10.20	Fourth Amendment MorphoSys Collaboration Agreement, dated June 19, 2017.	10	10.3	August 10, 2017	001-37746	
10.21	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	
10.22	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	
10.23	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	

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
10.24	Aptevo Therapeutics Inc. 2018 Stock Incentive Plan.	10-Q	10.1	August 9, 2018	001-37746	
10.25	Aptevo Therapeutics Inc. Non-Statutory Stock Option Agreement.	10-Q	10.2	August 9, 2018	001-37746	
10.26	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	
10.27	Eighth Amendment to Office Lease, dated as of March 19, 2019, by and between Aptevo Therapeutics Inc. and Selig Real Estate Holdings Eight L.L.C.	8-K	10.1	March 22, 2019	001-37746	
10.28	Amendment to 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	10.1	August 9, 2019	001-37746	
10.29	Amendment to Lease Dated April 28, 2003 by and between Selig Real Estate Holdings Eight, LLC and later assigned to SREH 2018 Holdings LLC and Aptevo Research and Development LLC.	10-Q	10.2	November 7, 2019	001-37746	
21.1	Subsidiaries of Aptevo Therapeutics Inc.					X
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm					X
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

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
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 25, 2020

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 25, 2020
/s/Jeffrey G. Lamothe **Jeffrey Lamothe**	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2020
/s/Fuad El-Hibri **Fuad El-Hibri**	Chairman of the Board of Directors	March 25, 2020
/s/Daniel J. Abdun-Nabi **Daniel J. Abdun-Nabi**	Director	March 25, 2020
/s/Grady Grant, III **Grady Grant, III**	Director	March 25, 2020
/s/Zsolt Harsanyi, Ph. D. **Zsolt Harsanyi, Ph. D.**	Director	March 25, 2020
/s/Barbara Lopez Kunz **Barbara Lopez Kunz**	Director	March 25, 2020
/s/John E. Niederhuber, M.D. **John E. Niederhuber, M.D.**	Director	March 25, 2020

EXHIBIT 21.1

LIST OF SUBSIDIARIES

Name of Subsidiary	**Jurisdiction of Incorporation or Organization**
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 the 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 25, 2020, 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, 2019.

/s/ Ernst & Young LLP

Seattle, Washington
March 25, 2020

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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2020

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 25, 2020

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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 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 25, 2020

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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 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 25, 2020

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."