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, 2016

OR

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

Commission File Number 001-37746

APTEVO THERAPEUTICS INC.

(Exact name of Registrant as specified in its Charter)

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

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

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

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

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

None

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

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

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). YES ☒ NO ☐

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a small reporting company)	Small reporting company	☒

As of March 24, 2017 the number of shares of Registrant's common stock outstanding was 20,918,290. Prior to the separation of Registrant from Emergent BioSolutions Inc. on August 1, 2016, the Registrant was a wholly-owned subsidiary of Emergent BioSolutions Inc. Consequently, there were no aggregate market value of common stock held by non-affiliates of the Registrant prior to August 1, 2016. The aggregate market value of common stock held by non-affiliates of the Registrant as of March 24, 2017 was $30.8 million, based upon the closing price of the Registrant's common stock on the NASDAQ Stock Market LLC.

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

EXPLANATORY NOTE

This Annual Report on Form 10-K for the year ended December 31, 2016 includes consolidated financial statements for the years ended December 31, 2015 and December 31, 2016. The audited consolidated financial statements for the year ended December 31, 2015 are restated. Aptevo Therapeutics Inc. and its subsidiaries (the Company) has also restated certain unaudited quarterly financial information related to March 31, 2016, and June 30, 2016, and the three and nine months ended September 30, 2016.

Additionally, in part as a result of these restatements, management has concluded that our deferred income tax account controls and procedures were not effective as of December 31, 2015, and September 30, 2016 following the August 1, 2016 spin-off resulting in a material weakness around these tax controls. Subsequent to the date of the spin-off we enhanced our deferred income tax account-related controls to ensure the proper determination of the effect on deferred income tax accounts from certain purchase accounting transactions prior to Aptevo's spin-off. While these controls are not subject to an audit by our Independent Registered Public Accounting Firm, management has evaluated these controls and concluded that the material weakness has been sufficiently remediated, refer to Item 9A -- Controls and Procedures in this Form 10-K.

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

PART I

Cautionary Note Regarding Forward-Looking Information

This Annual Report on Form 10-K contains 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. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Item 1A—Risk Factors." We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Item 1. Business.

OVERVIEW

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

On August 6, 2015, Emergent BioSolutions Inc., (Emergent or Former Parent), announced a plan to separate into two independent publicly traded companies. To accomplish this separation, Emergent created Aptevo Therapeutics Inc. or Aptevo, to be the parent company for the development-based biotechnology business focused on novel oncology and hematology therapeutics. Aptevo was incorporated in Delaware in February 2016 as a wholly owned subsidiary of Emergent. To effect the separation, Emergent made a pro rata distribution of Aptevo's common stock to Emergent's stockholders on August 1, 2016. We are currently trading on the NASDAQ Global Market under the symbol "APVO."

Our pipeline is composed of marketed products for hematology and infectious disease indications and investigational stage candidates based on our ADAPTIR platform, primarily focused on immuno-oncology indications. Our investigational stage product candidates MOR209/ES414 and otlertuzumab and our preclinical candidates, ES210, APVO436, and a proof of concept bispecific immunotherapeutic protein targeting ROR1 are built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. The platform can be used to produce monospecific, bispecific and multispecific immunotherapeutic proteins that specifically bind to one or more targets, which we believe provide structural and functional advantages over monoclonal antibodies. The mechanisms of action for MOR209/ES414, ES210, APVO436, otlertuzumab and a proof of concept bispecific immunotherapeutic protein targeting ROR1 include direct tumor cytotoxicity, antibody-dependent cell-cytotoxicity, redirected T-cell cytotoxicity, or RTCC, and targeted cytokine delivery. The structural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of other ADAPTIR immunotherapeutics that engage immune effector cells and disease targets in a novel manner to produce unique signaling responses. We are skilled at product candidate generation, validation and subsequent pre-clinical and clinical development using the ADAPTIR platform. We intend to progress ADAPTIR molecules from concept to marketed product by way of our protein engineering, pre-clinical development, process development and CRO management, cGMP manufacturing oversight and clinical development capabilities. We also expect to have the ability to launch, market and commercialize these product candidates upon approval and might also use contracted resources to augment our capabilities.

Our pipeline is composed of marketed products for hematology and infectious disease indications and investigational stage candidates based on our ADAPTIR platform, primarily focused on immuno-oncology indications. Our investigational stage product candidates MOR209/ES414 and otlertuzumab and our preclinical candidates, ES210, APVO436, and a proof of concept bispecific immunotherapeutic protein targeting ROR1 are built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. The platform can be used to produce monospecific, bispecific and multispecific immunotherapeutic proteins that specifically bind to one or more targets, which we believe provide structural and functional advantages over monoclonal antibodies. The mechanisms of action for MOR209/ES414, ES210, APVO436, otlertuzumab and a proof of concept bispecific immunotherapeutic protein targeting ROR1 include direct tumor cytotoxicity, antibody-dependent cell-cytotoxicity, redirected T-cell cytotoxicity, or RTCC, and targeted cytokine delivery. The st ructural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of other ADAPTIR immunotherapeutics that engage immune effector cells and disease targets in a novel manner to produce unique signaling responses. We are skilled at product candidate generation, validation and subsequent pre-clinical and clinical development using the ADAPTIR platform. We intend to progress ADAPTIR molecules from concept to marketed product by way of our protein engineering, pre-clinical development, process development and CRO management, cGMP manufacturing oversight and clinical development capabilities. We also expect to have the ability to launch, market and commercialize these product candidates upon approval and might also use contracted resources to augment our capabilities.

Our marketed products are:

- IXINITY® coagulation factor IX (recombinant), indicated in adults and children 12 years of age and older with hemophilia B for control and prevention of bleeding episodes, and management of bleeding during operations;
- WinRho® SDF Rho(D) Immune Globulin Intravenous (Human), for treatment of autoimmune platelet disorder, also called immune thrombocytopenic purpura, or ITP, and, separately, for the treatment of hemolytic disease of the newborn, or HDN;
- HepaGamB® Hepatitis B Immune Globulin Intravenous (Human), for prevention of Hepatitis-B recurrence following liver transplantation in HBsAg-positive liver transplant patients, and for treatment following exposure to Hepatitis-B; and
- VARIZIG® Varicella Zoster Immune Globulin (Human), for treatment following exposure to varicella zoster virus, which causes chickenpox, in high-risk individuals.

Our investigational stage product candidates include:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1 clinical development, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells, and a component of the T-cell receptor complex, or TCR complex, expressed on all T-cells. The mechanism of action of MOR209/ES414 is redirected T-cell cytotoxicity, or RTCC against tumors expressing PSMA. It is being developed under our collaboration with MorphoSys AG, or MorphoSys, for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies.
- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease, including ulcerative colitis, Crohn's Disease, and other autoimmune and inflammatory diseases.
- otlertuzumab, a monospecific ADAPTIR protein therapeutic that is currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL.
- a proof of concept bispecific immunotherapeutic ADAPTIR protein targeting ROR1, an antigen found on several solid tumors and hematologic, or blood-related, malignancies. One pair of binding domains bind to ROR1 on tumors; the other pair of binding domains bind to CD3 an invariant component of the TCR complex. Initial preclinical data demonstrates RTCC activity in vitro and killing of tumors in animal models demonstrating that ROR1 can be targeted with an ADAPTIR bispecific.

- APVO436, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development targeting CD123, a cell surface receptor highly expressed on several hematological malignancies and CD3, a component of the T-cell receptor. Similar to MOR209/ES414 and the ROR1 preclinical program, APVO436 utilizes RTCC to initiate killing of tumor cells. Preclinical data on this anti-CD123 ADAPTIR bispecific will be presented at the 2017 annual meeting of the American Association for Cancer Research. These data demonstrate in vitro RTCC activity and in vivo tumor cell killing in animal models of disease, demonstrating that CD123 can be targeted with an ADAPTIR bispecific.
- Other therapeutic protein product candidates primarily targeting cancer based on mechanisms of action that modulate the immune system (immuno-oncology based mechanism of action).

Our principal executive offices are located at 2401 4th Ave., Suite 1050, Seattle, Washington 98121. Our telephone number is (206) 838-0500. We maintain a web site at www.AptevoTherapeutics.com. Our website and the information contained on the website or connected to the website shall not be deemed to be incorporated into this Form 10-K filing, and you should not rely on any such information in making an investment decision.

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 proteins for the treatment of cancer. We focus on product development using our ADAPTIR platform. We are developing the MOR209/ES414 ADAPTIR bispecific program in collaboration with MorphoSys, with the goal of commercializing the product in North America. 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 from other strategies 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. We believe these product candidates may have utility in oncology, autoimmune disease and other therapeutic areas.

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

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

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

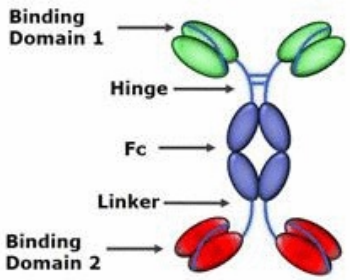
PLATFORM TECHNOLOGY AND PRODUCT PORTFOLIO

Platform Technology

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

Structurally, ADAPTIR molecules are similar to antibodies; they can exhibit the same biological functions of an antibody, but can be easily modified to either eliminate or incorporate new activities, all the while maintaining a similar size, stability and manufacturing advantages of a monoclonal antibody. The ADAPTIR molecules are single-chain polypeptides comprising customized elements including a protein domain that binds to one or more target binding domains to a hinged domain and a set of antibody constant domains known as the fragment crystallizable region, or Fc region of a human antibody. The antibody Fc region can elicit an immune response by binding to the corresponding Fc receptors found on various immune cells such as natural killer (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 (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. T-cells are white blood cells that fight infections and tumor cells. RTCC ADAPTIR molecules 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, activating a 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 believe the ADAPTIR platform may prove to have advantages over other immunotherapeuti cs and other bispecific T-cell engaging technologies. In particular, in pre-clinical studies, we have gathered data indicating that MOR209/ES414 may have high potency and activity at low doses, a long half-life, and reduced cytokine release. This molecule is able to be produced using standard manufacturing practices. Further clinical and preclinical studies may not confirm or establish the anticipated benefits of this platform.

We own all ADAPTIR platform intellectual property except that we have a non-exclusive research license with Lonza Sales AG, or Lonza, for certain Chinese hamster ovary, or CHO, cell lines, which are cells derived from the ovary of a Chinese hamster. The CHO is often used in the production of therapeutic proteins, in protein expression and the GS (glutamine synthetase) Gene Expression System™, or GS System. See section entitled "Intellectual Property" for additional information about the ownership rights to ADAPTIR.

Product Portfolio

Our marketed products are in the areas of hematology and infectious diseases.

Marketed Products

Product	Indication(s)	Regulatory Approvals
IXINITY® [coagulation factor IX (recombinant)]	Control and prevention of bleeding episodes and for perioperative management in adults and children, 12 years of age and older, with hemophilia B.	United States
WinRho® SDF [(Rho(D) Immune Globulin Intravenous (Human)]	ITP—immune thrombocytopenic purpura (described further below) HDN—hemolytic disease of the newborn (described further below) Preventing Rho(D) immunization in Rho(D)(-) women. Treating Rho(D)(-) patients after transfusions with incompatible Rho(D)(+) blood or erythrocyte (red blood cell) products.	Canada—ITP, HDN United States—ITP, HDN Portugal—HDN Hong Kong – ITP, HDN South Korea – ITP, HDN Turkey – ITP, HDN Uruguay – ITP, HDN Iraq- ITP, HDN Kuwait – ITP, HDN
HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)]	Treatment following exposure to hepatitis B Prevention of hepatitis B recurrence following liver transplantation in patients who are positive for hepatitis B surface antigen (a protein found on the surface of hepatitis B virus and in the blood or serum of hepatitis B infected individuals)	United States Canada Israel Kuwait Turkey

Product	Indication(s)	Regulatory Approvals
VARIZIG® [Varicella Zoster Immune Globulin (Human)]	Treatment following exposure to varicella zoster virus (chickenpox) in high-risk patient groups, including [1] adults or children with compromised immune systems, newborns of mothers with varicella shortly before or after delivery, neonates and infants less than one year of age, and pregnant women (United States); and [2] prevention and reduction of severity in maternal infections within four days of exposure to varicella zoster virus (Canada).	United States—[1] Canada—[2]

IXINITY (coagulation factor IX (recombinant)). IXINITY is a third-generation recombinant human coagulation factor IX approved 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.

WinRho SDF Rho(D) Immune Globulin Intravenous (Human). WinRho SDF is made from human plasma and is comprised of purified polyclonal human immune globulins that bind to red blood cells that are positive for Rho(D) (also known as Rho(D)(+) red blood cells). WinRho SDF is approved in the United States and Canada to treat an autoimmune platelet disorder called ITP, a disease characterized by both platelet destruction mediated by autoantibodies and impaired platelet production. ITP can be either short-lived or chronic and symptoms can vary from mild bruising to serious bleeding such as gastrointestinal hemorrhage or intracranial hemorrhage. WinRho SDF is also approved in the United States and Canada to prevent Rh immunization in Rho(D) negative mothers not previously sensitized to Rho(D) factor. This prevents the development of Rh antibodies in the mother thereby preventing hemolytic disease of the newborn, or HDN, in which the mother's immune system attacks a Rh-positive newborn's red blood cells.

HepaGam B Hepatitis B Immune Globulin Intravenous (Human). HepaGam B is comprised of purified polyclonal human immune globulins that are directed to the hepatitis B surface antigen, which is a protein found on the surface of the hepatitis B virus and in the blood or serum of hepatitis B infected individuals. In the United States, Canada, Israel, Kuwait and Turkey, HepaGam B has been approved for two indications: for the prevention of hepatitis B reinfection after liver transplantation and for use following exposure to the hepatitis B virus. Hepatitis B is a chronic infection and a major global health concern; up to 2.2 million individuals in the United States and an estimated 240 million people worldwide are chronically infected. Chronic infection can lead to cirrhosis, hepatocellular carcinoma, and even death, so prevention of hepatitis B infection is an important public health issue. In addition, prior to the availability of hepatitis B immune globulin such as HepaGam B and antivirals, liver transplantation was associated with poor survival, HepaGam B is the first hepatitis B immune globulin product to be licensed in the United States for the liver transplant-related indication.

VARIZIG Varicella Zoster Immune Globulin Human. VARIZIG is comprised of purified polyclonal human immune globulins directed to the varicella zoster virus, the virus that causes chickenpox. While most North American adults have developed immunity to chickenpox, certain at-risk patient populations may be susceptible to infection. VARIZIG is approved in the United States to reduce the severity of varicella (chickenpox) following exposure in high-risk patient groups, including adults and children with compromised immune systems, newborns of mothers with varicella shortly before or after delivery, neonates and infants less than one year of age, and pregnant women. VARIZIG has orphan drug exclusivity in the United States through December 2019. In Canada, VARIZIG is approved for the prevention and reduction of severity in maternal infections within four days of exposure to varicella zoster virus.

Product Candidates

Our pipeline includes investigational stage product candidates in immune-oncology.

MOR209/ES414. MOR209/ES414 is a targeted immunotherapeutic protein under development for metastatic castration-resistant prostate cancer, currently in Phase 1 clinical development. MOR209/ES414, a bispecific protein, was constructed using our ADAPTIR platform technology. It activates host T-cells to specifically kill tumor cells expressing prostate specific membrane antigen, or PSMA, an enzyme that is commonly overexpressed on the surface of prostate cancer cells. MOR209/ES414 contains two pairs of binding domains, one targeting the CD3 of the TCR complex and one targeting PSMA on tumor cells; these binding domains are linked to opposite ends of an antibody Fc region which extends the serum half-life and enables use of a purification process typical of antibodies. In pre-clinical studies, MOR209/ES414 has been shown to redirect T-cell cytotoxicity towards prostate cancer cells expressing PSMA. In December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. See the section entitled “Collaborations and Licenses” for additional information about our collaboration with MorphoSys to develop MOR209/ES414.

ES210. ES210 is an anti-inflammatory molecule engineered using our ADAPTIR platform technology currently in pre-clinical development. It is under development for the treatment of inflammatory bowel disease, including ulcerative colitis and Crohn’s Disease, and other autoimmune and inflammatory diseases. ES210 is a targeted cytokine therapeutic, specifically, it is designed to deliver a modified form of the anti-inflammatory cytokine, IL-10, to antigen presenting cells, or APCs, that express CD86. APCs are a therapeutic target of interest for an anti-inflammatory therapeutic such as ES210 because, as described further below, APCs play a critical role in the immune response. Structurally, ES210 contains a modified form of IL-10, coupled to binding sites specific for CD86, linked by an antibody Fc region. The mechanism of action results in suppression of T-cell responses through inhibition of antigen presentation. Antigen presenting cells play a central role in the generation and regulation of immune response and inflammation; therefore, inhibiting their function represents a therapeutic opportunity to suppress immunopathological processes in autoimmune and inflammatory disease. ES210 preclinical data demonstrate potent *in vitro* and *in vivo* antagonism of T-cell proliferation in human mixed lymphocyte reactions and in a humanized graft-versus-host disease model. Humanized refers to chemically altering animal proteins to resemble natural human amino acid sequences (or the order in which they bond). The ES210 ADAPTIR molecule also has potential anti-inflammation applications in rheumatoid arthritis and in the treatment of transplant rejection. As a molecule designed using our ADAPTIR platform technology, the ES210 half-life is extended as demonstrated in preclinical rodent studies. Also, manufacturing benefits are realized because the platform enables use of a purification process that is typically used for making antibodies.

otlertuzumab. Otlertuzumab is a monospecific protein therapeutic intended for the treatment of CLL. CLL is a type of cancer that affects the blood and bone marrow and is caused by B-cells within the blood and bone marrow that abnormally proliferate and die. Otlertuzumab is a humanized anti-CD37 monospecific protein therapeutic built using the ADAPTIR platform technology. It specifically binds to CD37, a receptor found on malignant B-cells. It functions like an antibody by direct killing of tumor and also engages natural killer cells, which are lymphocytes of the immune system, and other effector cells to kill the tumor cell. We believe that otlertuzumab’s novel properties may provide patients with improved therapeutic options and enhanced efficacy when used in combination with chemotherapy or other targeted therapeutics.

We completed a Phase 2 clinical trial evaluating the combination of otlertuzumab and bendamustine (a chemotherapy agent) versus bendamustine alone in people with relapsed CLL (Study 16201). In that study the combination of otlertuzumab and bendamustine was superior to bendamustine alone. The combination was well tolerated with significantly increased response rate (69% vs. 39%, p=0.003) and prolonged progression free survival rate (15.9 months vs. 10.1 months, p=0.0059) over single agent bendamustine treatment. The overall incidence of serious adverse events was similar between the two treatment cohorts. There was a higher incidence of adverse events of fever, neutropenia (which is a low white blood cell count that could predispose a patient to infection) and thrombocytopenia (which is a low platelet count that if severe could lead to bleeding) with the combination. The addition of otlertuzumab did not appear to increase the number of serious adverse events, as there were fewer discontinuations for adverse events with the combination compared to bendamustine alone.

We are conducting a Phase 1b study to evaluate the safety and efficacy of otlertuzumab in combination with rituximab, an anti-CD20-directed biologic that binds to CD20, a receptor found primarily on the surface of immune system B-cells. We amended our Phase 1b single-arm study to include evaluating otlertuzumab in combination with obinutuzumab in patients with previously untreated CLL (Study 16009). Patients began enrolling in this arm of the study mid-2015. Preliminary data showed that the combination was active and generally tolerated. We continue to evaluate opportunities for otlertuzumab as a product candidate in the treatment of CLL.

ROR1. We have developed a proof of concept bispecific immunotherapeutic protein that targets ROR1, an antigen found on several solid tumors and hematologic, or blood-related, malignancies and CD3. The proof of concept molecules were created using our ADAPTIR platform; each with one pair of binding domains, with one pair binding to ROR1 on tumors and the other pair of binding domains binding to the CD3, a component of the TCR complex. Its mechanism of action is RTCC against tumors expressing ROR1. Initial preclinical data demonstrate significant RTCC against tumors in preclinical models demonstrating that ROR1 can be targeted with an ADAPTIR bispecific. We are currently developing product candidates targeting ROR1 that will be designed for therapeutic uses.

APVO436. We have developed APVO436, a preclinical 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. Similar to MOR209/ES414 and the ROR1 preclinical program, APVO436 utilizes redirected T-cell cytotoxicity (RTCC) to initiate killing of tumor cells. Preclinical data on this anti-CD123 ADAPTIR bispecific will be presented at the 2017 annual meeting of the American Association for Cancer Research. These data demonstrate in vitro RTCC activity and in vivo tumor cell killing in animal models of disease, demonstrating that CD123 can be targeted with an ADAPTIR bispecific.

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

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 than 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.

In clinical trials to date with otlertuzumab, a variety of adverse events have been reported. The events that have been reported with infusion of the drug include: infusion reactions, fever, neutropenia and thrombocytopenia. Severe infusion reactions were infrequent. When these reactions are severe they lead to hypotension (low blood pressure) and bronchospasm (difficulty breathing). Neutropenia is a low white blood cell count that could predispose a patient to infection. The neutropenia observed with otlertuzumab was mild to moderate, not prolonged and did not increase the infection rate in a controlled clinical trial. Thrombocytopenia is a low platelet count that if severe could lead to bleeding. The thrombocytopenia observed with otlertuzumab was infrequent and not associated with bleeding. Any of these events or others that have not yet been experienced, could lead to adverse events, including death and severely limit the drug's use in the market or even its ability to be approved by a regulatory body.

MOR209/ES414 is currently being tested in its first clinical trial in humans. Fifteen patients have received the drug. One of the significant serious adverse events associated with the drug to date is infusion reactions. Infusion reactions are often associated with the infusion of a protein and are expected with this drug that activates T-cells. The other serious adverse events that have been reported with infusion of the drug include: fever, fatigue, hypertension, bronchospasm, chills and rigors. The severity of these reactions varied by patient and were managed medically and resolved.

As previously noted, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. See section entitled "Collaborations and Licenses" for additional information about our collaboration with MorphoSys to develop MOR209/ES414.

Research and Development

We are engaged in research and development of therapeutics including the product candidates listed above and other new candidates. We incur substantial expenses for these activities. These expenses generally include the cost of inventing new technologies and products, as well as development work on new product candidates. We pursue partnerships with various third parties and these partnerships and the sales of our approved products partially offset these expenditures. Research and development expenses for the years ended December 31, 2016 and 2015 totaled approximately $29.5 million and $37.4 million, respectively. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Research and Development Expense" in this Annual Report on Form 10-K for additional information regarding expenditures related to material research and development activities.

Distribution

Our products are sold in the United States by our commercial sales force and distributed to end-users through major U.S. distributors and wholesalers, including Cardinal Health, Inc., McKesson Corporation, AmerisourceBergen Corporation and other specialty distributors. In Canada, our products are sold to Canadian Blood Services and Héma-Québec, with Emergent acting as our exclusive Canadian distributor. Outside of North America, our commercial products are distributed primarily through third-party distributors. All third-party logistics (including, for instance, warehousing, inventory management, and shipping) of final drug product are provided by Emergent out of its facilities in either Winnipeg, Manitoba, Canada or Baltimore, Maryland pursuant to the terms of our Manufacturing Services Agreement.

Marketing & Sales

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

The commercial operations team includes two U.S.-based field sales forces. The hemophilia sales team focuses its selling efforts primarily on hemophilia treatment centers and hematology clinics, while the immunology team concentrates on hematology/oncology and medical oncology clinics, transplant centers and public and private hospitals. Outside of the United States, our products are sold through a network of regional independent distributors. Orders are filled upon receipt, and we generally have no orders on backlog. The commercial operations team also includes a marketing team with experience in building pharmaceutical and biological brands across all stages of the product life cycle. Reimbursement support, patient assistance/compassionate use and non-medical customer inquiries are handled by customer service personnel within our commercial operations team.

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

Competition

Our products and product candidates face significant competition. Any product or 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 products and product candidates includes the following:

- ***IXINITY***. Currently, IXINITY competes with four recombinant factor IX products that are marketed in North America: Rixubis (Baxalta US Inc.), Benefix® (Pfizer Inc.) Idelvion® (CSL Behring) and Alprolix® (Biogen Idec Inc.) recombinant factor IX products. We expect that Novo Nordisk Inc. will also launch a factor IX agent in the future.
- ***WinRho SDF***. In the United States, the use of WinRho SDF is primarily for the ITP indication. In the United States ITP market, WinRho SDF competes with IVIG (several manufacturers), Rhophylac® (CSL Behring, a subsidiary of CSL Limited), Nplate® (Amgen Inc.) and Promacta® (GlaxoSmithKline plc). In Canada, the use of WinRho SDF is primarily for the HDN indication. There are several products in late phase clinical trials for ITP also expected to enter this category.
- ***HepaGam B***. HepaGam B is currently the only intravenous hepatitis B immune globulin licensed for the liver transplantation indication in the United States and Canada. HepaGam B competes with two products that are marketed in North America: Nabi-HB® (Biotest Pharmaceuticals Corporation) and HyperHEP B® S/D (Grifols USA, LLC). Nabi-HB® and HyperHEP B® S/D are both licensed to treat acute exposure to blood containing hepatitis B surface antigen (post-exposure prophylaxis) and administered via intramuscular injection. The use of anti-viral drugs is also a competitive threat to this product.
- ***VARIZIG***. No other currently manufactured competitive product is marketed in the North American markets.
- ***MOR209/ES414.*** If approved for the treatment of metastatic castration-resistant prostate cancer, we anticipate that MOR209/ES414 would compete with Taxotere® (Sanofi-Aventis U.S. LLC), Jevtana (Sanofi-Aventis U.S. LLC), Zytiga® (Janssen Biotech, Inc.), Xtandi® (Astellas Pharma, Inc.), Xofigo® (Bayer HealthCare Pharmaceuticals Inc.), Provenge® (Dendreon Corporation) and potentially other products currently under development. There is a potential that MOR209/ES414 could also be used in combination with these same agents. According to the American Cancer Society, prostate cancer is the most common cancer in men in the United States. Screening, radiation, surgery and hormone ablation therapy have greatly improved the detection and treatment of early stage prostate cancer. New therapies approved recently for patients with metastatic castration-resistant prostate cancer only improve life expectancy by a few months, and a significant medical need still exists for these individuals.

- ***ES210.*** If approved, we anticipate that ES210 would compete with products indicated for inflammatory bowel diseases such as ulcerative colitis, including: HUMIRA® (AbbVie Inc.), Remicade® (Janssen Pharmaceuticals, Inc. of Johnson and Johnson) and Entyvio® (Takeda Pharmaceuticals U.S.A., Inc., a subsidiary of Takeda Pharmaceutical Company Limited). Depending on what ES210 is approved for, we anticipate that it could also compete with products indicated for moderate to severe Crohn's Disease, including: Stelara (Janssen Pharmaceuticals, Inc. of Johnson and Johnson) and Xeljanz (Pfizer Inc.).
- ***otlertuzumab***. If approved for CLL, we anticipate that otlertuzumab would compete with, or be combined with, other B-cell depleting therapies, targeted therapies and chemotherapeutics, including: Rituxan® (Genentech, Inc., a member of the Roche Group), Treanda® (Cephalon, a subsidiary of Teva Pharmaceutical Industries Ltd.), Arzerra® (GlaxoSmithKline plc and Genmab A/S), Imbruvica™ (Pharmacyclics, Inc. and Johnson and Johnson), Gayzva™ (Genentech USA, Inc., a member of the Roche Group), Zydelig® (Gilead Sciences, Inc.) and Venclexta™ (AbbVie). Nordic Nanovector has a product candidate targeting CD37 in Phase 1 development. In addition, Boehringer Ingelheim GmbH and ImmunoGen, Inc. are in early stage development for monoclonal antibodies directed to CD37. In addition, Boehringer Ingelheim GmbH and ImmunoGen, Inc. are in early stage development for monoclonal antibodies directed to CD37.
- ***ROR1.*** If approved, we anticipate that the proof of concept bispecific immunotherapeutic protein targeting ROR1 we develop may compete with other ROR1 directed protein therapeutics, including those that block the growth of cancer cells by binding to specific proteins needed for tumor formation and growth and that are under current clinical and pre-clinical development. We also anticipate that any proof of concept bispecific immunotherapeutic protein targeting ROR1 may compete with ROR1-directed cellular therapies, such as chimeric antigen receptor-modified T-cells (T-cells collected from a patient's own blood and genetically modified to express chimeric antigen receptors that allow the T-cells to recognize specific tumor cells), also known as CAR-T, that are under current clinical development by MD Anderson Cancer Center as well as a separate program under pre-clinical development by Juno Therapeutics, Inc.
- ***APVO436***. If approved for AML, we anticipate that APVO436 would compete with other agents targeting CD123 that are in development if they are also approved. Bispecifics in development targeting CD123 include: MGD006 (Macrogenics), JNJ-63709178 (Janssen) and XmAb14045 (Xencor). There are at least two CAR-T therapies in development; CART123 (University of Penn.) and CARTCD123 (NCI/City of Hope). Other competitive products targeting CD123 are: SGN-CD123A (antibody drug conjugate, Seattle Genetics), SL-401 (antibody immunotoxin, Stemline), KHK2833 (monoclonal antibody, Kyowa Hakko Kirin Pharma), and CSL362 (monoclonal antibody, CSL/Janssen).

COLLABORATIONS AND LICENSES

We have entered into several significant collaborations and transactions to support our growth. These include the following:

Collaboration with MorphoSys AG to develop MOR209/ES414

In August 2014, we entered into a collaboration agreement with MorphoSys to co-develop and commercialize our novel oncology immunotherapeutic, MOR209/ES414, developed for treatment of metastatic castration-resistant prostate cancer. Under the collaboration agreement, we retain commercialization rights in the United States and Canada, with a tiered royalty obligation to MorphoSys, ranging from mid-single digit up to 20% of sales. MorphoSys has worldwide commercialization rights excluding the United States and Canada, with a low single digit royalty obligation to us. The royalty term is determined on a product-by-product and country-by-country basis and begins on the date at which a substantial amount of cumulative net sales has been reached and ends on the expiration of patents covering such licensed product in such country or twelve years after the initiation of royalty payments if there is no such valid claim.

In December 2015, after a joint review of data from the ongoing Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, we and MorphoSys concluded that the dosing regimen and administration required adjustment. The decision to adjust development of MOR209/ES414 was not based on safety aspects but was driven by the high complexity and properties of this first generation ADAPTIR bispecific molecule. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; this is called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug that could be given safely on a weekly basis. These antibodies bind to the drug, reduced the concentration of MOR209/ES414 in the blood and thus could potentially reduce its efficacy. 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 has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. As a result of the dosing regimen change and the impact to the overall development timeline and technical risk, we amended our co-development agreement with MorphoSys in December 2015. Under the terms of the amended agreement, MorphoSys' cost sharing in the years 2016 to 2018 was reduced and future milestone payments payable by MorphoSys to us were reduced to a total of up to $74.0 million. In addition, the amended collaboration agreement changed the total expected funding requirement for us to up to approximately $250 million. The MOR209/ES414 Phase I clinical trial under the amended protocol, providing continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA, commenced December 2016.

In December 2016, the collaboration agreement was further amended to adjust the allocation of certain manufacturing and development costs and extend MorphoSys's convenience termination rights. Under the amendment, we will bear 75% of all development costs with respect to MOR209/ES414, and MorphoSys will bear 25% of such costs, during the period from January 1, 2017 through June 30, 2017. During the period from July 1, 2017 through December 31, 2018, we will bear 49% of such development costs and MorphoSys will bear 51%.Beyond January 1, 2019, we will bear 36% and MorphoSys will bear 64% of such development costs. In addition, the timeframe for a one-time right to terminate the collaboration agreement by MorphoSys has been extended from December 31, 2016 to June 30, 2017, or within one week following the receipt and discussion of clinical data from the first six patients enrolled and dosed in the MOR209/ES414 Phase I clinical trial.

Product License and Trademark License Agreements with Emergent

In July 2016 in connection with the separation, we entered into a product license agreement with Emergent pursuant to which Emergent granted us a perpetual, exclusive royalty-free, nontransferable worldwide license, under certain licensed intellectual property rights, to research, develop, make, have made, use, sell, offer to sell and import WinRho SDF, HepaGam B and VARIZIG in their respective indications to support our hyperimmune products. Under the product license agreement, in the event we cease to use Emergent as a manufacturer of our hyperimmune products, we are only permitted to exercise rights with respect to Emergent's human hyperimmune platform manufacturing know-how through a third-party contract manufacturer which has either been approved by Emergent (in Emergent's sole and absolute discretion) or if there has been a manufacturing failure under the Emergent manufacturing services agreement. We may terminate our rights under the agreement at any time by providing written notice to Emergent. Emergent may terminate the agreement if we breach the agreement and the breach is not cured within a specified period of time or is incapable of cure. Each party may terminate the agreement if the other party experiences certain bankruptcy events.

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

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

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

MANUFACTURING AND SUPPORT SERVICES

In connection with our separation, we entered into a manufacturing services agreement with Emergent. Emergent owns facilities with manufacturing and other capabilities located in Winnipeg, Manitoba, Canada, where our hyperimmune specialty plasma products WinRho SDF, HepaGam B and VARIZIG are currently manufactured. Under the agreement, Emergent will continue to manufacture our hyperimmune specialty plasma products. Under this agreement, Emergent also provides third-party logistics services for our hyperimmune specialty plasma products and IXINITY.

The manufacturing services agreement with Emergent covers each step in the manufacturing process from raw materials procurement, bulk manufacturing, filling and finishing, testing, labeling, and packaging of final product, as well as third-party logistics services for delivery of such product to Aptevo customers on our behalf. We are reliant exclusively on Emergent for the provision of each of these services as it relates to WinRho SDF, HepaGam B and VARIZIG and as it relates to third-party logistics services for IXINITY. Emergent also serves as a distributor in Canada under the Canadian distributor agreement we entered into with Emergent. Pursuant to this arrangement, Emergent receives product intended for sale in Canada on our behalf and delivers it to our other Canadian distributors: Canadian Blood Services and Hema-Quebec.

In addition, Emergent is providing transition services to us and may provide such services for up to two years following the separation. These services cover such functions as regulatory, pharmacovigilance, clinical research and quality assurance under our supervision. Pharmacovigilance refers to the drug safety evaluation process during clinical trials or after market approval where the effects of therapeutics or medical drugs are monitored to identify and evaluate adverse reactions.

As more fully explained below, we rely primarily on CMC ICOS Biologics, Inc., or CMC, for drug substance manufacture of IXINITY, on Patheon UK Limited for fill-finish services of IXINITY and on Rovi Contract Manufacturing, S.L. for supply of the syringe pre-filled with water for injection packaged with IXINITY. IXINITY will be delivered to Aptevo customers by Emergent as part of the third-party logistics services it provides to Aptevo under the manufacturing services agreement. For additional information, see the section entitled "Risk Factors—Risks Related to Our Business" in this Annual Report on Form 10-K, Commercial packaging, packaging component procurement and release, ancillary procurement and distribution for IXINITY will be provided by Emergent and various other parties.

Sources and Availability of Raw Materials

We rely on Emergent for all supplies and raw materials used in the production of WinRho SDF, HepaGam B and VARIZIG.

Agreement with CMC Biologics. We rely on CMC, for the manufacture of the substance that becomes the active ingredient (the bulk drug substance) in the production of our IXINITY product. We have an exclusive Commercial Supply (Manufacturing Services) Agreement with CMC pursuant to which, subject to specified exceptions, we are obligated to purchase at least eight batches and CMC is obligated to maintain a maximum capacity for sixteen batches of IXINITY bulk drug substance per full year. The agreement has a six-year term expiring on June 17, 2017. CMC is obligated to use commercially reasonable efforts to perform services in accordance with our forecast and projected delivery dates. In the event there is a supply failure as defined under the agreement, the agreement becomes non-exclusive with respect to 50% of our forecasted demand (or up to the unsupplied quantities until supply reinstatement).

The agreement provides for milestone payments in addition to fees for services. The milestone payments set forth in the agreement have been paid. To the extent an invoice dispute is not resolved within sixty days of our original notice, if we have withheld payment, CMC is entitled to suspend the services until such time dispute is resolved in accordance with terms of the agreement. In addition to other limitations on damages (*e.g.* specific to replacement of defective product), with several exceptions, neither party is liable under the agreement for loss or damage in respect of indirect, special or consequential damages or losses. With several exceptions, CMC's aggregate liability to us for any loss or damage suffered by us under the agreement in respect of services in a calendar year is limited to an amount equal to 1.1 times the total price of the services performed under the agreement subject to a maximum of $30.0 million. Each party may terminate the agreement if the other party fails to pay any amount properly due and payable with ten days of notice demanding payment after the expiration of the original payment term or if the other party materially breaches the agreement and fails to remedy any such breach capable of remedy during a twenty business day notice period. Each party may terminate the agreement if the other party experiences certain bankruptcy events. This agreement may be terminated by either party in the event of a material breach by the other party; however, termination shall not affect the accrued rights of either party. We may also terminate our obligations under the agreement with a specified amount of prior notice, if CMC has any material permit or regulatory license permanently revoked preventing the performance of services by CMC, if CMC is subject to certain competitor change of control events, or where there is a supply failure prior to a supply reinstatement where CMC does not reinstate supply within twelve months of the supply failure.

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

Agreement with Rovi Contract Manufacturing, S.L. Rovi Contract Manufacturing, S.L., or Rovi, is currently the sole source third-party manufacturer that supplies the syringe pre-filled with water for injection, that is packaged with and required for reconstitution of our IXINITY product. We have a non-exclusive supply agreement with Rovi pursuant to which Rovi is obligated to use its best efforts to supply the quantity of syringes ordered by us. The agreement has a five-year term expiring on April 28, 2019, and thereafter renews for successive five-year terms, unless Rovi provides us with written notice of its intent not to renew at least twenty-four months prior to the expiration of the term or any renewal term. We may terminate the agreement for any reason on at least twelve months' prior notice. Each party may terminate the agreement if the other party breaches the agreement and the breach is not cured within a specified period of time. Neither party is liable under the agreement for loss or damage in respect of indirect, special or consequential damages or losses except to the extent such damages are caused by willful misconduct. Each party's liability under the agreement, annually and in the aggregate, is limited to three times the amount invoiced by Rovi under the agreement for products during the 12-month period preceding the incident with a maximum limit of six million Euros; provided that in respect of certain third-party claims or costs resulting or arising from defective or infringing products or claims for injunctive relief, each party's liability under the agreement, annually and in the aggregate, is limited to six million Euros.

INTELLECTUAL PROPERTY

We actively seek intellectual property protection for our products and product candidates. We own or exclusively license patent rights supporting IXINITY, the ADAPTIR platform and pipeline products including MOR209/ES414, ES210, and otlertuzumab. 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 occasionally 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 which 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 products 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 ADAPT IR platform intellectual property, except that we have a non-exclusive research license with Lonza to certain CHO cell lines, which are cells derived from the ovary of a Chinese hamster and often used in biological and medical research and commercially in the production of therapeutic proteins, for use in protein expression and the GS System. The GS System is a cell transfection and protein expression system that uses a robust viral promoter and selection via glutamine metabolism to provide rapid development of high-yielding and stable mammalian cell lines that express transfected proteins of therapeutic interest. The GS System is well known in the industry, and according to Lonza, is a familiar system that has been used by over 100 global pharmaceutical and biotechnology companies. Under our Lonza research license, we have an option to take a license to use the GS System to develop and manufacture therapeutic proteins for our commercial purposes.

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

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

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

Hyperimmune products, WinRho, HepaGam B and VARIZIG. We rely on the confidential nature of our in-licensed manufacturing know-how as well as trade secret protection to protect our licensed products to the extent we are able to do so. In connection with our separation from Emergent, we received a license from Emergent under certain of its proprietary human hyperimmune platform manufacturing know-how that we may exercise under specified circumstances. Our WinRho SDF, HepaGam B and VARIZIG products are protected by Emergent's manufacturing trade secrets. We rely on this intellectual property to protect our WinRho SDF, HepaGam B and VARIZIG products. We do not have patent protection for WinRho SDF, HepaGam B or VARIZIG.

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

MOR209/ES414. We have patents and pending patent applications supporting the MOR209/ES414 product candidate. We have foundational patents and patent applications in countries including the United States, Australia, Brazil, Canada, China, Egypt, Europe, Hong Kong, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Singapore, South Africa, United Arab Emirates and Vietnam. The foundational patents which grant in this patent family are estimated to expire in April 2032. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

ES210. We have patents and pending patent applications supporting our ES210 product candidate. We have foundational patents and patent applications in countries and territories, including the United States., Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Japan, Mexico, New Zealand, Singapore, South Africa and South Korea. The foundational patents which grant in this patent family are estimated to expire in October 2029. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

otlertuzumab. We have patents and pending patent applications supporting the otlertuzumab product candidate. We have foundational patents and patent applications in countries and territories, including the United States, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Russia, South Africa and South Korea. The foundational patents and patent applications which grant in these patent families are estimated to expire between July 2026 and April 2029. The estimated patent expirations are subject to change based on patent term adjustments, extensions or terminal disclaimers.

Corporate Trademarks. Where possible, we pursue registered trademarks for our marketed products in significant markets. In addition, we have pending trademark applications covering APTEVO, a graphic logo, APTEVO THERAPEUTICS, APTEVO BIOTHERAPEUTICS, APTEVO RESEARCH AND DEVELOPMENT and ADAPTIR.

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 to gather additional information relating to safety and potential adverse effects.

- Phase 3 clinical trials consist of expanded, large-scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product and dosing regimen. The safety and efficacy data generated from Phase 3 clinical trials typically form the basis for FDA approval of the product candidate.
- Phase 4 clinical trials, if conducted, are conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific population. As part of a product approval, the FDA may require that certain Phase 4 studies, which are called post-marketing commitment studies, be conducted post-approval.

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

Marketing Approval—Biologics

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

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

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

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

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

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

Post-Approval Requirements. Any biologic for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, current good manufacturing practices, or cGMP, and restrictions on advertising and promotion. Adverse events that are reported after marketing approval can result in additional limitations being placed on the product's distribution or use and, potentially, withdrawal or suspension of the product from the market. In addition, the FDA authority to require post-approval clinical trials and/or safety labeling changes if warranted. In certain circumstances, the FDA may impose a REMS after a product has been approved. Facilities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other laws. The FDA also closely monitors advertising and promotional materials we may disseminate for our products for compliance with restrictions on off-label promotion and other laws. We may not promote our products for conditions of use that are not included in the approved package inserts for our products. Certain additional restrictions on advertising and promotion exist for products that have boxed warnings in their approved package inserts, such as WinRho SDF.

Pricing, Coverage and Reimbursement

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

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

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. Sales of WinRho SDF, HepaGam B, VARIZIG and IXINITY that are reimbursed through Medicaid are subject to the obligations related to this program.

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

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

Foreign Regulation

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

Healthcare Fraud and Abuse and Anti-Corruption Laws

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

If we violate the healthcare fraud and abuse laws, we could be subject to sanctions, including civil and criminal penalties, damages, fines, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, individual imprisonment, integrity obligations, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Similar restrictions are imposed on the promotion and marketing of medicinal products in other countries. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct are often strictly enforced. Even in those countries where we are not directly responsible for the promotion and marketing of our products, inappropriate activity by our international distribution partners can have implications for us.

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

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

Health Care 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, in January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Although the Budget Resolution is not a law, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The first legislative proposal to repeal and replace the ACA was released in March 2017 by the House of Representatives titled, the "America Health Care Act", or AHCA. The AHCA would, among other changes, eliminate individual and employer mandates, freeze enrollment in Medicaid expansion, eliminate certain taxes such as the "Cadillac" tax on high-cost employer-sponsored health plans, and create refundable tax credits to assist individuals in buying health insurance.

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 paymen ts 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.

We anticipate additional legislative changes in the future, including legislation to repeal and replace certain provisions of the ACA. It remains to be seen, however, precisely what the new legislation will provide, when it will be enacted, and what impact it will have on the availability of healthcare and/or containing or lowering the cost of healthcare.

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

Aptevo employed 118 full-time persons as of December 31, 2016. 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.

AVAILABLE INFORMATION

The Aptevo investor website *www.AptevoTherapeutics.com* is currently operational. 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 Aptevo's results of operations, financial condition or financial prospects. The risk factors generally have been separated into nine groups: operating risks, commercialization risks, regulatory and compliance risks, product development risks, intellectual property risks, risks related to collaborations, financial risks, risks related to the separation, and risks related to our common stock.

RISKS RELATED TO OUR BUSINESS

Financial Risks

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

Our historical consolidated financial data prior to August 1, 2016 was prepared on a "carve-out" basis from the financial information of Emergent and shows that had we been a standalone company, we would have had a history of losses, and we may be unable to achieve profitability going forward.

For the year ended December 31, 2016, we incurred a net loss of $112.4 million and we had an accumulated deficit of $80.7 million as of December 31, 2016. For that same period, net cash used in our operating activities was $36.9 million. If we cannot achieve profitability or generate positive cash from operating activities, our business operations may be adversely impacted and the trading value of our common stock may decline.

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

As of December 31, 2016, we had cash, cash equivalents and marketable securities in the amount of $54.9 million. We will require significant additional funding to grow our business including to develop additional products, support commercial marketing activities or otherwise provide additional financial flexibility. In addition, we received an additional $20.0 million from Emergent pursuant to the terms of our separation on January 13, 2017. To enhance long-term financial flexibility, we entered into a credit facility for up to $35.0 million, $20.0 million of which was received on August 4, 2016. Our future capital requirements will depend on many factors, including:

- the level, timing and cost of product sales;
- the collection of accounts receivable from customers;
- the extent to which we invest in products or technologies;
- the ability to draw down on the second tranche of $15.0 million on the credit facility

- the ability to secure partnerships and/or collaborations that generate additional cash;
- capital improvements to new or existing facilities;
- the payment obligations under our current or any future indebtedness;
- the scope, progress, results and costs of our development activities;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the ongoing costs associated with the separation from Emergent and performance under agreements with Emergent; and
- the ongoing costs associated with replicating or outsourcing from other providers' certain facilities, systems, operational and administrative infrastructure, including information technology infrastructure, and personnel, to which we no longer have access after our separation from Emergent.

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

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

Our business depends on the continued success of our commercial product portfolio.

Our commercial portfolio consists of four revenue-generating products, consisting of WinRho SDF, HepaGam B, VARIZIG and IXINITY. We expect revenues from our product sales to continue to account for a significant portion of our revenue. The commercial success of our marketed products depends upon:

- the continued acceptance by regulators, physicians, patients and other key decision-makers of our products as safe, therapeutic and cost-effective options;
- our ability to further develop our products and obtain marketing approval for their use in additional patient populations and the clinical data we generate to support expansion of the product label;
- the ability of Emergent and our other third-party manufacturing partners to provide us with sufficient saleable quantities of our marketed products;
- the impact of competition from existing competitive products and from competitive products that may be approved in the future;
- the continued safety and efficacy of our marketed products;
- to what extent and in what amount government and third-party payors cover or reimburse for the costs of our marketed products; and
- our success and the success of our third-party distributors in selling and marketing our products, including in countries outside the United States.

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

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

To preserve the tax-free treatment of the distribution related to the separation, together with certain related transactions, we are restricted under the tax matters agreement that we entered into with Emergent, from taking any action that prevents such transactions from being tax-free for U.S. federal income tax purposes. In particular, for a period of two years following the separation, we are restricted from taking certain actions (including restrictions on share issuances, business combinations, sales of assets, amendments to organizational documents and similar transactions) that could cause the distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. These restrictions may limit our ability to pursue certain strategic transactions or engage in other transactions that might increase the value of our business, including use of our common stock to make acquisitions and equity capital market transactions. In addition, under the tax matters agreement, we are required to indemnify Emergent against any tax liabilities and related expenses arising from the failure of the distribution, together with certain related transactions, to be tax-free to the extent such failure is attributable to actions, events or transactions relating to our stock, assets or business, including the acquisition of our stock even if we did not participate in or otherwise facilitate the acquisition.

We may not achieve profitability in future periods or on a consistent basis.

Our ability to become profitable will be substantially dependent on our product sales revenues and revenues from collaboration and licensing arrangements. Accordingly, our ability to become profitable may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve profitability. In addition, we have incurred and anticipate incurring significant costs associated with the separation from Emergent and making substantial expenditures to further develop and commercialize our products and product candidates. We anticipate needing to generate greater revenue in future periods from our marketed products, our products in development or a sale of certain assets in order to achieve profitability in light of our planned expenditures. If we are unable to generate greater revenue, we may not achieve profitability in future periods, and may not be able to maintain any profitability we do achieve. If we are unable to generate sufficient revenues, we will not become profitable and may be unable to continue operations without additional funding.

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

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

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on borrowings under the Credit Agreement if market rates of interest increase;

- not complying with restrictive covenants restricting, among other things, indebtedness, liens, dividends and other distributions, repayment of subordinated indebtedness, mergers, dispositions, investments (including licensing), acquisitions, transactions with affiliates and modification of organizational documents or certain other agreements;
- not complying with affirmative covenants including payment, reporting and revenue covenants; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

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

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturns.

Our results of operations could be materially negatively affected by general economic conditions, both in the United States and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, and the availability and cost of credit have contributed to increased volatility and diminished expectations for the economy and the markets going forward. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds, if necessary, and our stock price may further decline.

Credit and financial market conditions may exacerbate certain risks affecting our business.

Sales of our products are made, in part, through direct sales to our customers, which include hospitals, physicians and other health care providers. As a result of adverse global credit and financial market conditions, our customers may be unable to satisfy their payment obligations for invoiced product sales or may delay payments, which could negatively affect our revenues, income and cash flow. In addition, we rely upon third parties for many aspects of our business, including our collaboration partners, wholesale distributors for our products, contract clinical trial providers, research organizations, manufacturers and third-party suppliers. Because of the tightening of global credit and the volatility in the financial markets, there may be a delay or disruption in the performance or satisfaction of commitments to us by these third parties, which could adversely affect our business.

The way that we account for our operational and business activities is based on estimates and assumptions that may differ from actual results.

The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, our management evaluates its critical estimates and judgments, including, among others: those related to revenue recognition, including product rebates, chargeback and return accruals; inventory; clinical research costs; business combinations; intangible assets and impairment; income taxes; stock-based compensation; and contingent consideration. Those critical estimates and assumptions are based on our historical experience, future projections, our observance of trends in the industry, and various other factors that are believed to be reasonable under the circumstances, and they form the basis for making judgments about the carrying values and fair values of assets and liabilities that may not be readily apparent from other sources. If actual results differ from these estimates as a result of unexpected conditions or events occurring which cause us to have to reassess our assumptions, there could be a material adverse impact on our financial results and the performance of our stock.

We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations.

The nature of our business exposes us to potential liability inherent in pharmaceutical products, including with respect to the sale of our products, any other products that we successfully develop and the testing of our product candidates in clinical trials. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise possess regulatory approval for commercial sale or study. We cannot predict the frequency, outcome or cost to defend any such claims.

If we cannot successfully defend ourselves against future claims that our products or product candidates caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand or withdrawal of a product;
- adverse publicity and/or injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- an inability to commercialize products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition and results of operations. The cost of defending any products liability litigation or other proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability claims, regardless of merit or eventual outcome, may absorb significant management time and result in reputational harm, potential loss of revenue from decreased demand for our products and/or product candidates, withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs, and could cause our stock price to fall.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims by individuals and third-party payors. In addition, product liability claims could result in an investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, the EMA, or the competent authorities of the EU Member States. Such investigations could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension, variation, or withdrawal of approval. Any such regulatory action by the FDA, the EMA or the competent authorities of the EU Member States could lead to product liability lawsuits as well.

We rely significantly on information technology systems and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively or result in data leakage of proprietary and confidential business and employee information.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employee error, malfeasance or other disruption—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others. A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to our proprietary and confidential business and employee information could result in financial, legal, business or reputational harm to us, any of which could adversely affect our business, financial condition and operating results.

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

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

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

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

Commercialization Risks

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

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

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

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

We face substantial competition.

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

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

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

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

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

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

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

Regulators in the EU review biosimilar products using a similar regulatory process. Our Biologic Products have not received marketing authorization by the European Medicines Agency, or EMA, and are not sold in Europe.

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

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

The success of our products, including our hyperimmune specialty products, will depend upon, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If any of our products do not achieve and maintain an adequate level of acceptance, we may not generate material revenues from sales of these products. The degree of market acceptance of our products will depend on a number of factors, including: our ability to provide acceptable evidence of safety and efficacy; the prevalence and severity of any side effects; availability, relative cost and relative efficacy of alternative and competing treatments; the ability to offer our products for sale at competitive prices; our ability to continuously supply the market without interruption; the relative convenience and ease of administration; the willingness of the target patient population to try new products and of physicians to prescribe these products; the strength of marketing and distribution support; publicity concerning our products or competing products and treatments; and the sufficiency of coverage or reimbursement by third parties.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

For example, CMC ICOS Biologics, Inc., or CMC, is the exclusive manufacturer of bulk drug substance for our IXINITY product. During 2015, we ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. During 2016, we ordered five manufacturing lots of bulk drug substance from CMC and none of these lots satisfied product release specifications. On October 4, 2016, we provided a Notice of Interruption in Manufacturing, or Notice, to the FDA, notifying the FDA of a potential interruption in the supply of IXINITY® coagulation factor IX (recombinant) due to the ongoing manufacturing challenges with the manufacturer of the bulk drug. On March 15, 2017, we announced the successful manufacture of a recent bulk drug substance batch of IXINITY and we anticipate that the new supply will be available beginning in May 2017, after the completion of routine final drug product (FDP) manufacturing activities. While we do not currently anticipate or foresee a supply shortage or supply interruption occurring, any supply shortage or supply interruption of IXINITY would adversely affect its sales and could adversely affect its market position, commercial viability and the trading price of our common stock.

Emergent owns the manufacturing know-how necessary for the manufacture of WinRho SDF, HepaGam B and VARIZIG. An inability to manufacture these products would lead to lost revenue.

Emergent owns its human hyperimmune platform manufacturing know-how, which is necessary for the manufacture of WinRho SDF, HepaGam B and VARIZIG. We have entered into a manufacturing services agreement with Emergent with respect to the manufacturing of these products. We also entered into a product license agreement with Emergent pursuant to which Emergent has granted us an exclusive royalty-free, worldwide license, under certain licensed intellectual property rights, to research, develop, make, have made, use, sell, offer to sell and import WinRho SDF, HepaGam B, and VARIZIG. Under the product license agreement, we are only permitted to exercise rights with respect to Emergent's human hyperimmune platform manufacturing know-how through a third-party contract manufacturer, under limited conditions, including a requirement that the manufacturer is bound to protect the manufacturing know-how, and is either approved by Emergent (in Emergent's sole and absolute discretion) or, there has been a manufacturing failure under the manufacturing services agreement.

Emergent has the right to terminate the product license agreement upon breach by us of any of its terms, including our confidentiality obligations and other obligations, if such breach is not cured within a specified period of time or is incurable. If the product license agreement is terminated, we will no longer be able to research, develop, make, have made, use, sell, offer to sell and import WinRho SDF, HepaGam B and VARIZIG, which would lead to lost revenue and otherwise materially and adversely affect our business, financial condition, results of operations and growth prospects.

Manufacturing biologic products, especially in large quantities, is complex and time consuming.

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

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

We rely on third parties to manufacture all clinical trial materials for our product candidates, and we will rely on third parties to manufacture commercial supplies, if any such product candidates are ultimately approved for commercial sale. Our product candidates, including MOR209/ES414, ES210, otlertuzumab, APVO436 and proof of concept bispecific immunotherapeutic protein targeting ROR1, will not be approved for marketing by the FDA or other foreign regulatory authorities unless the FDA or their foreign equivalents also approve the facilities used by our third-party manufacturers to produce them for commercialization. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, the FDA or their foreign counterparts will not approve their manufacturing facilities, which would result in significant delays in obtaining FDA or foreign marketing approvals for our product candidates. In order to successfully develop and commercialize our product candidates in a timely manner, we and our third-party manufacturers must be able to develop and execute on manufacturing processes, and reach agreement on contract terms.

We and our third-party manufacturers may not be able to meet these manufacturing process requirements for any of our current product candidates, including MOR209/ES414, ES210, otlertuzumab, and a proof of concept bispecific immunotherapeutic protein that targeting ROR1, all of which have complex manufacturing processes, which make meeting these requirements even more challenging. If we are unable to develop manufacturing processes for our clinical product candidates that satisfy these requirements, we will not be able to supply sufficient quantities of test material to conduct our clinical trials in a timely or cost effective manner, and as a result, our development programs will be delayed, our financial performance will be adversely impacted and we will be unable to meet our long-term goals.

Development and commercialization of our products may be terminated or delayed.

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

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

If any third-party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to commit sufficient resources to our collaboration or conduct its activities in a timely manner, or fails to comply with regulatory requirements, such breach, termination or failure could delay or otherwise adversely impact the manufacturing, development or commercialization of our products, our products in development or any additional products or product candidates that we may develop; require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or result in the termination of the development or commercialization of our products.

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

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

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

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

Regulatory and Compliance Risks

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

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

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

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

The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review for a submitted product application may cause delays in the approval or rejection of an application.

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

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

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells and, a component of the TCR complex expressed on all T-cells. The mechanism of action of MOR209/ES414 is RTCC. It is being developed under our collaboration with MorphoSys AG for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies;
- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease and other autoimmune and inflammatory diseases;
- otlertuzumab, a monospecific ADAPTIR protein therapeutic currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL;
- a proof of concept bispecific immunotherapeutic ADAPTIR protein targeting ROR1 (preclinical candidate) are built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies and an antigen found on solid tumors and hematologic or blood-related, malignancies;
- APVO436, a bispecific ADAPTIR protein therapeutic currently in pre-clinical development targeting CD123, a cell surface receptor highly expressed on several hematological malignancies and CD3, a component of the T-cell receptor. Similar to MOR209/ES414 and the ROR1 preclinical program, APVO436 utilizes redirected RTCC to initiate killing of tumor cells; and
- other protein therapeutic product candidates primarily targeting tumor based on mechanisms of action that modulate the immune system (immuno-oncology based mechanism of action).

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

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

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

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

Delays in obtaining or failure to obtain regulatory approvals may: delay or prevent the successful commercialization of any of the products or product candidates in the jurisdiction for which approval is sought; diminish our competitive advantage; and defer or decrease our receipt of revenue.

Certain of our products in development have experienced regulatory and/or clinical setbacks in the past. For example, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; which are called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug that could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol has been amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA. The procedures to obtain marketing approvals vary among countries and can involve additional clinical trials or other pre-filing requirements. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all the risks associated with obtaining FDA approval, or different or additional risks. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. Accordingly, approval by the FDA does not ensure approval by the regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by the FDA or regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products and products in development in any market on a timely basis, if at all.

The MOR209/ES414 Phase I clinical trial under the amended protocol, providing continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA, commenced December 2016. As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. Under the terms of the restructured agreement, MorphoSys' cost sharing in the years 2016 to 2018 was reduced and future milestone payments payable by MorphoSys to us were reduced to a total of up to $74.0 million. As a result of the required change in dosing regimen for MOR209/ES414, the lead RTCC candidate, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial. The requirement for further adjustments to the dosing regimen or other parts of the program could delay our development timeline or delay or prevent our ability to receive regulatory approval for MOR209/ES414. In December 2016, the agreement was modified to adjust the allocation of certain manufacturing and development costs and extend MorphoSys' convenience termination rights. Under the amendment, the timeframe for a one-time right to terminate the collaboration agreement by MorphoSys has been extended from December 31, 2016 to June 30, 2017, or after review of clinical data from the first six patients enrolled and dosed in the MOR209/ES414 Phase I clinical trial.

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

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

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

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

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

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

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

Any drug or, biologic for which we receive FDA approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, current good manufacturing practices, or cGMP, and restrictions on advertising and promotion. Adverse events that are reported after marketing approval can result in additional limitations being placed on the product's distribution or use and, potentially, withdrawal or suspension of the product from the market. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Because of the breadth of these laws, it is possible that some of our business activities, or those of our third-party manufacturers and distributors, could be subject to challenge under one or more of such laws.

In addition, the FDA has post-approval authority to require post-approval clinical trials and/or safety labeling changes if warranted by the appearance of new safety information. In certain circumstances, the FDA may impose a Risk Evaluation and Mitigation Strategy, or REMS, after a product has been approved. Facilities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other laws. The FDA also closely monitors advertising and promotional materials we may disseminate for our products for compliance with restrictions on off-label promotion and other laws. We may not promote our products for conditions of use that are not included in the approved package inserts for our products. Certain additional restrictions on advertising and promotion exist for products that have so-called boxed warnings in their approved package inserts, such as WinRho® SDF.

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

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

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a biotechnology company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid or other third-party payors for our products, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase, prescribing or recommendation of an item or service reimbursable under federally funded healthcare programs, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims and false statement laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other payors that are false or fraudulent or making any materially false statement in connection with the delivery or payment for healthcare benefits, items or services;
- Health Insurance Portability and Accountability Act of 1996, or HIPAA, which creates federal criminal and civil statutes that prohibit executing a scheme to defraud any healthcare benefit program; and Health Information Technology for Economic and Clinical Health, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal physician self-referral laws, such as the Stark law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral;
- the Physician Payment Sunshine Act, which imposes disclosure requirements on pharmaceutical manufacturers of payments made to physicians, healthcare providers and institutions; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Moreover, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes, so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Recently, several pharmaceutical and other healthcare companies have been prosecuted under the federal false claims laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations.

Further, there has been a recent trend in the increase of federal and state laws and regulations regarding financial arrangements with physicians. The Affordable Care Act imposes new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any ownership or investment interests held by physicians and their immediate family members during each calendar year, subject to federal implementation and enforcement policies.

In addition, certain states mandate that we comply with a state code of conduct, adopt a company code of conduct under state criteria, disclose marketing payments made to physicians, and/or report compliance information to the state authorities. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and reporting requirements increase the possibility that a pharmaceutical company may violate one or more of the requirements. Any failure to comply with these reporting requirements could result in significant fines and penalties.

The risks of complying with these laws cannot be entirely eliminated. The risk of violation of such laws is also increased because many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly. If our past or present operations, or those of our distributors are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Similarly, if healthcare providers, distributors or other entities with whom we do business are found to be out of compliance with applicable laws and regulations, they may be subject to sanctions, which could also have a negative impact on us.

If we fail to comply with our obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines.

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

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

Pricing and rebate calculations vary among products and programs, involve complex calculations and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current AMP and "best price" for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Price recalculations also may affect the "ceiling price" at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B/PHS drug pricing program.

In addition to retroactive rebate liability and the potential for 340B program refunds, if we are found to have made a misrepresentation in the reporting of ASP, we are subject to civil monetary penalties in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied. If we are found to have knowingly submitted false AMP or "best price" information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification also would subject us to $100,000 in civil monetary penalties. In addition, our failure to submit monthly/quarterly AMP or "best price" information on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

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

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and certain federal grantees, we also must participate in the DVA FSS pricing program. To participate, we are required to enter into an FSS contract with the DVA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies—the DVA, the U.S. Department of Defense, or the DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard—at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the Non-Federal Average Manufacturer Price, or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the DVA. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to penalties of $100,000 for each item of false information. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to disclose the error and refund the difference to the government. The failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The failure to obtain or maintain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business.

We currently sell and intend to continue to sell our products outside the United States. To market our products in the EU and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review. We and our collaborative partners may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to commercialize our products internationally. The failure to obtain these approvals could harm our business.

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

As we expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the FCPA, the U.K. Bribery Act of 2010, Canada's Corruption of Foreign Public Officials Act, or other similar foreign laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices outside the United States are found to be in violation of the FCPA or similar foreign laws, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

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

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

EU Member States, Switzerland and other countries have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the European Union, and guidance on implementation and compliance practices are often updated or otherwise revised. Our failure to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. The revised EU Data Protection Directive adopted in April 2016 may also increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

Product Development Risks

Our business depends on our success in developing and commercializing our product candidates.

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

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

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

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain.

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

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

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

For example, in December 2015, after a joint review of data from the Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys concluded that the dosing regimen and administration required adjustment. Patients receiving weekly doses of MOR209/ES414 developed ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, we observed no safety issues related to the development of ADA. The cause of these antibodies is unclear but could be due to the weekly administration of the drug. We and MorphoSys amended to continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. There is no guarantee that this change in administration will enable higher dosing and/or prevent the development of ADA. Further adverse or inconclusive clinical results could require additional adjustments to the dosing regimen or other parts of the program and could delay or prevent our ability to receive regulatory approval for MOR209/ES414.

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

Even if we are successful in advancing a product candidate into the clinical development stage, before obtaining regulatory and marketing approvals, we must demonstrate through extensive human clinical trials that the product candidate is safe and effective for its intended use. Human clinical trials must be carried out under protocols that are acceptable to regulatory authorities and to the independent committees responsible for the ethical review of clinical studies. There may be delays in preparing protocols or receiving approval for them that may delay the start or completion of the clinical trials. This is applicable both domestically and internationally. Clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global trials increasingly complex.

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

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

For example, as noted above, MOR209/ES414 is currently being tested in its first clinical trial in humans. Fifteen patients have received the drug. One of the significant serious adverse events associated with the drug is infusion reactions. Infusion reactions are often associated with the infusion of a protein and are expected with this drug that activates T-cells. The events that have been reported with infusion of the drug include: fever, fatigue, hypertension, bronchospasm, chills and rigors. The severity of these reactions varied by patient and were managed medically and resolved. In addition, in December 2015, we discovered that patients receiving weekly doses of our product candidate MOR209/ES414 developed ADA during use. This ADA, which was not associated with safety issues, developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. Undesirable side effects, such as this, or other unexpected adverse events or properties of any of our candidates, could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our other product candidates. If such an event occurs, a number of potentially significant negative consequences may result, including:

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

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

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

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

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

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

In certain cases, government entities conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. These government entities have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time.

If we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. This could require changes in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

Our decisions to allocate our research and development, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also prove to be incorrect and could cause us to miss valuable opportunities.

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

We do not have patent protection for WinRho SDF, HepaGam B or VARIZIG. Because not all of our drugs have patent protection, orphan drug designation is particularly important for our products that are eligible for orphan drug designation. VARIZIG is approved in the United States to reduce the severity of varicella (chickenpox) following exposure in high-risk patient groups, including adults and children with compromised immune systems, newborns of mothers with varicella shortly before or after delivery, neonates and infants less than one year of age, and pregnant women. VARIZIG has orphan drug exclusivity in the United States through December 2019. We plan to rely on this exclusivity period under the orphan drug designation for VARIZIG to maintain a competitive position. Our product candidate otlertuzumab was granted orphan drug designation by the FDA in November 2011 and received orphan medicinal product designation from the European Commission in December 2012 for the treatment of CLL. Orphan drug designation in Europe qualifies a drug for certain development and commercial incentives, including protocol assistance, access to centralized authorization procedures, reduced fees for regulatory activities, and ten years of market exclusivity after approval, but exclusivity may be reduced to six years if a drug no longer meets the criteria for orphan drug designation, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified .

Intellectual Property Risks

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

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

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

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may inadvertently lapse or be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our products. In the past, we have abandoned the prosecution and/or maintenance of patent applications related to patent families in the ordinary course of business. In the future we may choose to abandon such prosecution and/or maintenance in a similar fashion. If these patent rights are later determined to be valuable or necessary to our business, our competitive position may be adversely affected. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and in other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defensive measures.

The cost of litigation to uphold the validity of patents, once obtained, to prevent infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subject to patent office proceedings. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume management's time and attention and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions covered by or incorporating them. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially and adversely affected.

In addition to patent litigation, we may be a party to adversarial proceedings before the Patent Trial and Appeal Board of the US Patent and Trademark Office, or the PTAB. Potential proceedings before the PTAB include inter partes review proceedings, post-grant review proceedings and interference proceedings. Depending on our level of success at the PTAB, these proceedings could adversely impact our intellectual property rights with respect to our products and technology.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. Depending on decisions by the U.S. Congress, the federal courts, and the PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

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

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

A European Patent Opposition is a European Patent Office proceeding that allows for an opponent to challenge the validity of an issued patent. A European Patent Opposition is a proceeding that determines only the validity of a patent and does not determine whether a party infringes a patent. To initiate an Opposition at the European Patent Office, an opponent files a notice that it wishes to oppose the patent within a nine-month period following the publication of the patent grant. After the opponent files the notice, it may be a few years before the merits of the opposition are heard and decided by the European Patent Office Opposition Division and several more years before the Boards of Appeal hears and decides on any appeals. We are currently involved in three opposition proceedings in Europe relating to factor IX proteins such as IXINITY. We were previously involved in five opposition proceedings in Europe relating to factor IX proteins, but two of the opposition proceedings were decided in our favor and cannot be further appealed. Baxter International Inc. (or Baxalta) is or was the sole counter-party in all proceedings. Of the five European Patent Office Proceedings, all have now gone before the European Patent Office Opposition Division. Of these oppositions, four were decided in our favor (in the name of UNC, our licensor, or Cangene Corporation when acting as an opponent) and one was decided in favor of Baxalta. Three of these oppositions have been appealed (including one which has now been settled in our favor by the Board of Appeal and can no longer be contested by Baxalta centrally at the European Patent Office), and we expect Baxalta to appeal the fourth. It may be several years before these oppositions go before the Boards of Appeal for a final decision. Depending on the final outcome of these proceedings, we may be unable to continue to conduct our current IXINITY fill/finish manufacturing activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

Third party may file trademark infringement claim against us.

Defending ourselves against such trademark infringement claims could be costly, time-consuming and distracting to management, and if we are unsuccessful in our defense, we could face an injunction and damages.

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

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

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

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

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

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

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

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

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

Risks Related to Collaborations

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

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

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

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

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

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

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

Risks Related to the Separation

We may not realize some or all of the anticipated benefits of the separation from Emergent due to a number of factors.

We may not realize some or all of the anticipated strategic, financial or other benefits from the separation from Emergent. We are smaller, less diversified and with a narrower business focus than the previously consolidated company, and may be more vulnerable to changing market conditions, which could materially and adversely affect our business, financial condition and results of operations. The spin-off transactions presented a number of significant risks to our internal processes, including the failure to maintain an adequate control environment due to changes to our information technology systems and financial reporting processes. We may discover as a result of the separation, a negative impact on the financial condition and results of operations of our business. There also can be no assurance that the separation will not adversely affect our business.

Emergent may fail to perform under various transaction agreements that were executed as part of the separation or we may fail to have necessary systems and services in place when certain of the transaction agreements expire.

In connection with the separation, we entered into a separation and distribution agreement and various other agreements with Emergent, including a non-negotiable promissory note, a transition services agreement, a tax matters agreement, an employee matters agreement, a manufacturing services agreement, a Canadian distributor agreement, a trademark license agreement and a product license agreement. Certain of these agreements provide for the performance of services by Emergent for a period of time after the separation. We will rely on Emergent to satisfy its performance obligations under these agreements. If Emergent is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could incur operational difficulties or losses.

If we do not have in place our own systems and services, or if we do not have agreements with other providers of these services when the transition services or longer-term agreements terminate, we may not be able to operate our business effectively and our results of operations may be adversely affected. We are in the process of creating our own, or engaging third parties to provide, systems and services to replace systems and services Emergent provided to us. We may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Emergent's systems to ours. These systems and services may also be more expensive or less efficient than the systems and services Emergent is expected to provide during the transition period.

Our accounting and other management systems and resources may not be adequately prepared to meet the ongoing financial reporting and other requirements of a standalone publicly-traded company.

Prior to our separation from Emergent, our financial results were included within the consolidated results of Emergent. We are now directly subject to substantial reporting and other obligations under the Securities Exchange Act of 1934, or Exchange Act. These reporting and other obligations place significant demand on our management, administrative and operational resources, including accounting resources. We may not have sufficient time to meet these obligations by the applicable deadlines.

Moreover, to comply with these requirements, we have migrated our systems, including information technology systems, implement additional financial and management controls, reporting systems and procedures. We expect to incur additional annual expenses related to these steps, and those expenses may be significant. If we are unable to upgrade our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies under the Exchange Act could be impaired. Any failure to achieve and maintain effective internal controls could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

We and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting as of and for the years ended December 31, 2015 and for quarters through September 30, 2016. A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Specifically, it was determined that a deferred tax liability should have been recorded associated with the difference between the book basis and the tax basis of the in-process research and development asset that was recorded as a part of an acquisition in 2010. As a result, we were required to restate our previously issued audited financial statements for the year ended December 31, 2015 and unaudited financial information for the quarter ended March 31, 2016, included in the Company's Registration Statement on Form 10, and unaudited financial information for the quarters ended June 30, 2016 and September 30, 2016 included in the Company's Quarterly Report on Form 10-Q for the quarters ended June 30, 2016 and September 30, 2016.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, beginning in 2018, Section 404 of the Sarbanes-Oxley Act, or Section 404, will require us to perform

system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. As an emerging growth company, we expect to avail 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, Emergent agreed to indemnify us for certain liabilities. The Emergent indemnity may not be sufficient to hold us harmless from the full amount of liabilities for which Emergent will be allocated responsibility, and Emergent may not be able to satisfy its indemnification obligations in the future.

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

If the distribution, together with certain related transactions, does not qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, our stockholders could be subject to significant tax liabilities, and, in certain circumstances, we could be required to indemnify Emergent for taxes and related expenses resulting from the failure of the transaction to so qualify.

It is intended that the distribution, together with certain related transactions, will generally be tax-free to Emergent and its stockholders for U.S. federal income tax purposes. Emergent has received a favorable private letter ruling from the IRS regarding certain U.S. federal income tax matters relating to the distribution and certain related transactions. It was a condition to the distribution that (i) the private letter ruling from the IRS continue to be valid and in full force and effect and (ii) Emergent receive an opinion from WilmerHale LLP, in a form and substance satisfactory to Emergent, substantially to the effect that, for U.S. federal income tax purposes, the distribution and certain related transactions, taken together, will qualify as a transaction described under Sections 355(a) and 368(a)(1)(D) of the Internal Revenue Code, or the Code. The IRS private letter ruling is based upon certain facts and representations submitted by Emergent to the IRS. In addition, the opinion from WilmerHale LLP was based upon and rely on, among other things, the IRS private letter ruling and certain facts and assumptions, as well as certain representations and covenants of Emergent and Aptevo contained in the tax matters agreement and certain representations contained in representation letters provided by Emergent, Aptevo and certain stockholders to WilmerHale LLP, including representations and covenants relating to the past and future conduct of Emergent, Aptevo and such stockholders. If any of these facts, assumptions, representations, or covenants is, or becomes, inaccurate or incomplete, the IRS private letter ruling and/or the opinion of WilmerHale LLP may be invalid and the conclusions reached therein could be jeopardized. In addition, the IRS private letter ruling only addresses certain limited matters relevant to determining whether the distribution, together with certain related transactions, qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, and the opinion of WilmerHale LLP represents the judgment of such counsel which is not binding on the IRS or any court. Accordingly, notwithstanding the IRS private letter ruling and the opinion of WilmerHale LLP, there can be no assurance that the IRS will not assert that the distribution and/or certain related transactions should be treated as a taxable transaction for U.S. federal income tax purposes or that a court would not sustain such a challenge.

If the distribution, together with certain related transactions, does not qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, in general, (i) Emergent would recognize taxable gain on the distribution equal to the amount by which the fair market value of the Aptevo common stock distributed to Emergent stockholders exceeds Emergent's tax basis in its shares of our common stock and (ii) each Emergent stockholder would be treated as receiving a taxable distribution in an amount equal to the fair market value of the Aptevo common stock received by such stockholder.

Under the tax matters agreement that we entered into with Emergent, we may be required to indemnify Emergent against any tax liabilities and related expenses resulting from the failure of the distribution, together with certain related transactions, to qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code to the extent that the failure to so qualify is attributable to actions, events or transactions relating to our stock, assets or business, or a breach of the relevant representations or covenants made by us in the tax matters agreement or the IRS private letter ruling or in the representation letters provided to WilmerHale LLP.

We have incurred and expect to incur both one-time and ongoing material costs and expenses as a result of our separation from Emergent, which could adversely affect our results of operations.

We have incurred and expect to incur both one-time and ongoing costs and expenses as a result of our separation from Emergent. These increased costs and expenses may arise from various factors, including financial reporting, costs associated with complying with federal securities laws (including potential future compliance with the Sarbanes-Oxley Act of 2002), tax administration, and legal and human resources related functions, and it is possible that these costs will be material to our business.

Certain of our executive officers and/or directors may have actual or potential conflicts of interest because of their previous positions at Emergent.

The ownership by our executive officers and/or directors of shares of Emergent common stock, stock options or other equity awards may create, or may create the appearance of, conflicts of interest. Because of their current or former positions with Emergent, certain of our executive officers and/or directors own shares of Emergent common stock, stock options to purchase Emergent common stock or other equity awards. Shares of Emergent common stock, stock options to purchase Emergent common stock or other equity awards may comprise a significant portion of some of these individuals' total personal financial assets. Even though our executive officers and/or directors who were previously employees of Emergent have ceased to be employees of Emergent, some of our executive officers and/or directors will continue to have a financial interest in Emergent common stock, which may create, or may create the appearance of, conflicts of interest when these individuals are faced with decisions that could have different implications for Emergent than the decisions have for us.

Risks Related to Our Common Stock

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

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

Our stock price has fluctuated in the past and is likely to be volatile in the future. Since August 1, 2016, the reported sale price of our common stock has fluctuated between $1.83 and $3.33 per share. The stock market in general, and the market for biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a number of factors, some of which may be beyond our control or unrelated to our operations, including, among others:

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

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

The restatement of our previously issued financial statements, the misstatements that resulted in such restatement, and the material weakness that has been identified in our internal control over financial reporting, could expose us to additional risks that could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline.

As discussed in this Annual Report on Form 10-K, we have restated our previously issued audited consolidated financial statements for the year ended December 31, 2015 and the unaudited financial information related to March 31, 2016 and June 30, 2016 and the three and nine months ended September 30, 2016. This restatement, along with the material weakness that has been identified in our internal control over financial reporting, could expose us to potential claims and additional risks that could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline. We have implemented actions with respect to our internal controls but to the extent these steps are not successful, we could be forced to incur additional time and expense or we may not be able to produce accurate and timely financial results. As a result of the restatement and the material weakness in our internal controls, we could be subject to shareholder, governmental, or other actions in connection with the restatement or related or other matters. Any such proceedings would, regardless of the outcome, consume a significant amount of management's time and attention and would result in additional legal, accounting and other costs. If we were not to prevail in any such proceedings, we could be required to pay substantial damages or settlement costs. In addition, the restatement and related matters could impair our reputation or could lead to a loss of investor confidence.

The public announcement of data from clinical studies or news of any developments related to our product pipeline may cause significant volatility in our stock price.

The announcement of data from clinical studies by us or our collaborative partners or news of any developments related to our key pipeline products may cause significant volatility in our stock price. Furthermore, the announcement of any negative or unexpected data or the discontinuation of development of any of our key pipeline products, or any delay in our anticipated timelines for filing for regulatory approval, could cause our stock price to decline significantly. There can be no assurance that data from clinical studies will support a filing for regulatory approval or even if approved, that any of our key pipeline products will become commercially successful.

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

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

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

Fuad El-Hibri, the chairman of our Board of Directors, has significant influence over us through his substantial beneficial ownership of our common stock, including an ability to influence the election of the members of our Board of Directors, or delay or prevent a change of control of us.

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of December 31, 2016, Mr. El-Hibri was the beneficial owner of approximately 15% of our outstanding common stock. As a result, Mr. El-Hibri could delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions. In addition, Mr. El-Hibri's significant beneficial ownership of our shares could present the potential for a conflict of interest.

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

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

These provisions include:

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

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

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

In addition, under the tax matters agreement, for a period of two years following the separation, we are restricted from taking certain actions (including restrictions on business combinations and share issuances) that could cause the distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. We would be required to indemnify Emergent for any taxes and related expenses resulting from the failure of the transactions to so qualify to the extent that the failure is attributable to actions, events or transactions relating our stock, assets or business, and this indemnity obligation might discourage, delay or prevent a change of control that you may consider favorable.

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

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

Because we currently do not expect to pay dividends, investors will benefit from an investment in our common stock only if it appreciates in value.

We anticipate that we will retain all our future earnings, if any, to support our operations and our proprietary drug development programs and product candidates and pursue other opportunities. In addition, our credit facility limits our ability to pay dividends. As a result, we currently do not expect to pay dividends for the foreseeable future. Any future determination to pay dividends will be at the sole discretion of our Board of Directors and will depend upon our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments and such other factors as our Board of Directors deems relevant. We cannot guarantee that we will pay any dividends in the future or continue to pay any dividend if we were to commence paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

If our stockholders sell a substantial number of shares of our common stock in the public market, our market price could decline. In addition, holders of an aggregate of approximately [three million shares of our common stock] have the right to require us to register these shares of common stock under the Securities Act of 1933, as amended, under specified circumstances.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease our headquarters office and laboratory space in Seattle, Washington. The Seattle facility is approximately 51,000 square feet. The Seattle lease expires in April 2020. We also lease approximately 5,000 square feet of satellite office space in Berwyn, Pennsylvania. The Berwyn lease expires in May 2017.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our common stock has been listed on The NASDAQ Global Market under the symbol "APVO" since August 1, 2016. Prior to that date, there was no public trading market for our common stock. The following table sets forth the high and low intraday sales price per share of our common stock as reported on The NASDAQ Global Market for the period indicated:

Year Ended December 31, 2016	High	Low
First Quarter	n/a	n/a
Second Quarter	n/a	n/a
Third Quarter	$ 3.33	$ 2.20
Fourth Quarter	$ 2.83	$ 1.83

Holders of Common Stock and Outstanding Equity Awards

As of March 24, 2017, there were 17 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.

As of February 28, 2017, the Company had options covering 2,515,209 shares of common stock outstanding under the 2016 Stock Incentive Plan and the 2016 Converted Stock Incentive Plan (the Plans), unvested RSUs covering 2,030,608 shares of common stock outstanding under the Plans, and 20,918,290 shares of common stock outstanding.

Dividend Policy

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

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the year ended December 31, 2016.

Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the year ended December 31, 2016.

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.

Restatement

The accompanying Management's Discussion and Analysis of Financial Condition and Results of Operations gives effect to the restatement adjustments made to the previously reported consolidated financial statements that are discussed in Note 2 in the notes to consolidated financial statements in Item 8 of this Form 10-K. Additionally, in part as a result of these restatements, management has concluded that our deferred income tax account controls and procedures were not effective as of December 31, 2015, and September 30, 2016 following the August 1, 2016 spin-off resulting in a material weakness around these tax controls. Subsequent to the date of the spin-off, we enhanced our deferred income tax account-related internal controls over financial reporting to ensure the proper determination of the effect on deferred income tax accounts from certain purchase accounting transactions prior to Aptevo's spin-off. While these controls are not subject to an audit by our Independent Registered Public Accounting Firm, management has evaluated these controls and concluded that the material weakness has been sufficiently remediated, refer to Item 9A -- Controls and Procedures in this Form 10-K

Overview

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

In August 2015, Emergent BioSolutions Inc., or Emergent, announced a plan to separate into two independent publicly traded companies, one a biotechnology company focused on novel oncology and hematology therapeutics to meaningfully improve patients' lives and the other a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats. To accomplish this separation, Emergent created a new company, Aptevo Therapeutics Inc., or Aptevo, to be the parent company for the development-based biotechnology business focused on novel oncology and hematology therapeutics. We were incorporated in Delaware in February 2016 as a wholly owned subsidiary of Emergent. To effect the separation, Emergent made a pro rata distribution of Aptevo's common stock to Emergent's stockholders on August 1, 2016.

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

Our historical consolidated financial statements for the periods prior to August 1, 2016 have been prepared on a standalone basis and are derived from Emergent's consolidated financial statements and accounting records. The consolidated financial statements reflect our financial position, results of operations, and cash flows as our business was operated as part of Emergent prior to the separation, in conformity with U.S. Generally Accepted Accounting Principles (GAAP).

The consolidated financial statements include the allocation of certain assets and liabilities that have historically been held at the Emergent corporate level but which are specifically identifiable or allocable to us. Cash and cash equivalents held by Emergent were not allocated to us unless the cash was held by an entity that was transferred to us in the distribution. All of our intracompany transactions and accounts for the periods prior to August 1, 2016 have been eliminated. Most intercompany transactions between us and Emergent for the periods prior to August 1, 2016 were considered to be effectively settled in the consolidated financial statements at the time the transaction was recorded but for those transition related services. The total net effect of the settlement of these intercompany transactions is reflected in the consolidated statement of cash flows as payment from former parent upon spin-off, net of receivable and net transfer from former parent, prior to spin-off as a financing activity and in the consolidated balance sheet as former parent investment in subsidiary.

The historical financial statements do not necessarily include all of the expenses that would have been incurred had we been a separate, standalone entity and may not necessarily reflect our results of operations, financial position and cash flows had we been a standalone company during the periods presented. Our consolidated financial statements for the periods prior to August 1, 2016 include an allocation of expenses related to certain Emergent corporate functions, including senior management, legal, human resources, finance, information technology, and quality assurance. These expenses have been allocated to us based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, square footage, or other measures. We consider the expense allocation methodology and results to be reasonable for all periods presented. However, the allocations may not be indicative of the actual expense that would have been incurred had we operated as an independent, publicly traded company for the periods presented.

For the year ended December 31, 2016, we incurred a net loss of $112.4 million and we had an accumulated deficit of $80.7 million as of December 31, 2016. For that same period, net cash used in our operating activities was $36.9 million. We expect to experience operating losses and negative cash flows from operations for the foreseeable future. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, suspend or eliminate one or more of research and development programs. We will not generate revenues from our development stage product candidates unless and until we or our collaborators successfully complete development and obtain regulatory approval for such product candidates, which we expect will take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for one of our development stage product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such costs are not paid by collaborators. We do not have sufficient cash to complete the clinical development of any of our development stage product candidates and will require additional funding in order to complete the development activities required for regulatory approval of such product candidates.

Highlights for Year Ended December 31, 2016

Commercial Portfolio:

- Achieved 30% increase in year-over-year product sales revenue
- Continued to expand awareness of IXINITY within the Hemophilia B community following its U.S. launch in mid-2015
- Resolved ongoing bulk drug substance manufacturing challenges and resumed routine manufacturing operations, which the company believes will avert a supply interruption of IXINITY

Pipeline:

- Initiated the amendment to a Phase 1 continuous infusion, dose escalation study of MOR209/ES414 to evaluate safety and tolerability in patients with metastatic castration-resistant prostate cancer
- Published positive Phase 2 data from a study of otlertuzumab combined with bendamustine in the British Journal of Haematology showing a significant increase in median progression free survival, from approximately 10 to 16 months in patients receiving combination therapy

- Prepared to begin a Phase 1b study of otlertuzumab in combination with ibrutinib in patients with relapsed/refractory chronic lymphocytic leukemia (CLL)
- Optimized new preclinical ADAPTIR candidate, APVO436, targeting the cell-surface receptor CD123, which is highly expressed in multiple hematological malignancies
- Presented preclinical data at the American Association for Cancer Research annual meeting showing inhibition of tumor growth and an improvement in overall survival in preclinical models of triple negative breast cancer with a ROR1 ADAPTIR bispecific candidate

Corporate:

- Completed the spin-off from Emergent in August 2016
- Secured $65 million in non-dilutive funding from Emergent to support advancement of Aptevo's commercial and pipeline programs
- Strengthened Aptevo's financial position securing an additional $35 million in a term-loan financing with MidCap Financial; received the first tranche ($20 million) in August 2016

Program Highlights

Our pipeline is composed of marketed products for hematology indications and investigational stage candidates based on our ADAPTIR™ (modular protein technology) platform. Our investigational stage product candidates otlertuzumab, MOR209/ES414, ES210, APVO436 and a proof of concept bispecific immunotherapeutic protein targeting ROR1 are built on our novel ADAPTIR platform, which is designed to expand on the utility and effectiveness of therapeutic antibodies. The technology can produce monospecific and multispecific immunotherapeutic proteins that specifically bind to one or more targets, for example, bispecific therapeutic molecules, which may have structural and functional advantages over monoclonal antibodies. The mechanisms of action for otlertuzumab, MOR209/ES414, ES210, APVO436 and a proof of concept bispecific immunotherapeutic protein targeting ROR1 include direct tumor cytotoxicity, antibody-dependent cell-cytotoxicity, RTCC and targeted cytokine delivery. The structural differences of ADAPTIR molecules over monoclonal antibodies allow for the development of other ADAPTIR immunotherapeutics that engage immune effector cells and disease targets in a novel manner to produce unique signaling responses. We are skilled at product candidate generation, validation and subsequent pre-clinical and clinical development using the ADAPTIR platform. We have the ability to progress ADAPTIR molecules from concept to marketed product by way of our protein engineering, pre-clinical development and process development capabilities, cGMP manufacturing oversight and clinical development capabilities. We also have the ability to launch, market and commercialize these product candidates upon approval.

Our marketed products are:

- IXINITY®® coagulation factor IX (recombinant), indicated in adults and children 12 years of age and older with hemophilia B for control and prevention of bleeding episodes, and management of bleeding during operations;
- WinRho® SDF Rho(D) Immune Globulin Intravenous (Human), for treatment of autoimmune platelet disorder, also called immune thrombocytopenic purpura, or ITP, and, separately, for the treatment of hemolytic disease of the newborn, or HDN;
- HepaGam B® Hepatitis B Immune Globulin Intravenous (Human), for prevention of Hepatitis-B recurrence following liver transplantation in HBsAg-positive liver transplant patients, and for treatment following exposure to Hepatitis-B; and
- VARIZIG® Varicella Zoster Immune Globulin (Human), for treatment following exposure to varicella zoster virus, which causes chickenpox, in high-risk individuals.

Our investigational stage product candidates include:

- MOR209/ES414, a bispecific immunotherapeutic ADAPTIR protein, currently in Phase 1, targeting prostate specific membrane antigen, or PSMA, an enzyme that is expressed on the surface of prostate cancer cells and, a component of the TCR complex expressed on all T-cells, RTCC against tumors expressing ROR1. The mechanism of action of MOR209/ES414 is RTCC. It is being developed under our collaboration with MorphoSys AG for metastatic castration-resistant prostate cancer, which is advanced prostate cancer that has spread to other organs and no longer responds to hormone blocking therapies.
- ES210, a bispecific ADAPTIR protein therapeutic that is currently in pre-clinical development for inflammatory bowel disease and other autoimmune and inflammatory diseases.
- otlertuzumab, a monospecific ADAPTIR protein therapeutic that is currently in Phase 2 clinical development for chronic lymphocytic leukemia, or CLL.
- a proof of concept bispecific immunotherapeutic protein targeting ROR1 is an antigen found on several solid tumors and hematologic, or blood-related, malignancies. One pair of binding domains bind to ROR1 on tumors; the other pair of binding domains bind to CD3, an invariant component of the TCR complex. Initial preclinical data demonstrates RTCC activity in vitro and killing of tumors in animal models demonstrating that ROR1 can be targeted with an ADAPTIR bispecific.
- APVO436, a bispecific ADAPTIR protein therapeutic currently in pre-clinical development targeting CD123, a cell surface receptor highly expressed on several hematological malignancies and CD3, a component of the T-cell receptor. Similar to MOR209/ES414 and the ROR1 preclinical program, APVO436 utilizes redirected RTCC to initiate killing of tumor cells.
- Other therapeutic protein product candidates primarily targeting cancer based on mechanisms of action that modulate the immune system (immuno-oncology based mechanism of action).

Collaboration with MorphoSys AG

In August 2014, we entered into a collaboration agreement, or MorphoSys Agreement, with MorphoSys AG, or MorphoSys, for the joint worldwide development and commercialization of MOR209/ES414, a targeted immunotherapeutic protein, which activates host T-cell immunity specifically against cancer cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells. MOR209/ES414 was constructed using our proprietary ADAPTIR™ platform technology.

In accordance with the initial terms of the MorphoSys Agreement, we received a nonrefundable $20.0 million upfront payment and could have received up to $163.0 million in additional contingent payments, comprised of up to $80.0 million and up to $83.0 million, respectively, due upon the achievement of specified development and regulatory milestones. MorphoSys and Aptevo agreed to jointly fund further development of MOR209/ES414, with us responsible for 36% of the total development costs and MorphoSys responsible for the remainder, with our funding requirement capped at $186.0 million. Our development effort includes the performance of non-clinical, clinical, manufacturing and regulatory activities. We retain commercialization rights in the United States and Canada, with a tiered royalty obligation to MorphoSys, ranging from mid-single digit up to 20% of sales. MorphoSys has worldwide commercialization rights excluding the United States and Canada, with a low single digit royalty obligation to us.

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

As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. In December 2015, we and MorphoSys amended the collaboration agreement to (1) decrease the additional contingent payments due to us upon the achievement of specified development and regulatory milestones of up to $32.5 million and up to $41.5 million, respectively, (2) change the total funding requirement cap for us to up to approximately $250 million and (3) change the jointly funded development cost allocation. In addition, the termination provisions under the MorphoSys collaboration agreement were amended to give MorphoSys a one-time right to terminate the collaboration agreement, without notice, at either the end of 2016 or after review of clinical data from the first six patients enrolled and dosed in the Phase 1 trial. The requirement for further adjustments to the dosing regimen or other parts of the program could delay our development timeline or delay or prevent our ability to receive regulatory approval for MOR209/ES414. In December 2016, the collaboration agreement was further amended to adjust the allocation of certain manufacturing and development costs and extend MorphoSys's convenience termination rights. Under the amendment, the timeframe for a one-time right to terminate the collaboration agreement by MorphoSys has been extended from December 31, 2016 to June 30, 2017, or after review of clinical data from the first six patients enrolled and dosed in the MOR209/ES414 Phase I clinical trial.

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

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

IXINITY

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

Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, we made a separate determination as to the then useful life of the asset and begin amortization. In April 2015, the Food and Drug Administration, or FDA, approved IXINITY for the treatment of Hemophilia B in adults and children. As a result, the $8.3 million IXINITY IPR&D asset was reclassified as a definite-live intangible asset and is being amortized over ten years. Since April 2015, we have incurred approximately $9 million in research and development expense related to IXINITY, primarily for clinical trial activities (approximately $4 million) and development and qualification activities (approximately $5 million). The clinical trial activities are associated with: (1) obtaining licensure of IXINITY for pediatric use (children under the age of 12); and (2) continued treatment of clinical subjects as part of a post-licensure extension clinical study required by the FDA. The development and qualification expenses are primarily associated with: (1) ongoing non-clinical process development studies related to the optimization of the manufacturing of drug substance (2); continuation of pre-licensure stability study commitments; (3) developing fill/finish capabilities at Emergent's Baltimore, MD fill/finish contract manufacturing facility.

CMC ICOS Biologics, Inc., or CMC, is the exclusive manufacturer of bulk drug substance for our IXINITY® product. During 2015, we ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. During 2016, we ordered five manufacturing lots of bulk drug substance from CMC and none of these lots satisfied product release specifications. We continue to work with CMC toward the successful release of product. Additionally, Patheon UK Limited, through an affiliate, is currently the sole source fill-finish service manufacturer for our IXINITY® product.

On October 4, 2016, we provided a Notice of Interruption in Manufacturing, or Notice, to the FDA, notifying the FDA of a potential interruption in the supply of IXINITY® coagulation factor IX (recombinant) due to the ongoing manufacturing challenges with the manufacturer of the bulk drug. On March 15, 2017, we announced the successful manufacture of a recent bulk drug substance batch of IXINITY and we anticipate that the new supply will be available beginning in May 2017, after the completion of routine final drug product (FDP) manufacturing activities.

While we do not currently anticipate or foresee a supply shortage or supply interruption occurring, any supply shortage interruption of IXINITY would adversely affect its sales and could adversely affect its market position, commercial viability and the trading price of our common stock.

Results of Operations

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

Revenue

Product Sales

Sales by product are shown in the following table:

(in thousands)	Twelve Months Ended December 31, 2016	2015	Change
WinRho	$ 14,434	$ 14,218	$ 216
HepaGam	8,604	10,345	(1,741)
IXINITY	9,796	993	8,803
VARIZIG	3,410	2,311	1,099
Other	10	80	(70)
Total	$ 36,254	$ 27,947	$ 8,307

Product sales revenue increased by $8.3 million, or 30%, to $36.3 million for the year ended December 31, 2016 from $27.9 million for the year ended December 31, 2015. This increase was primarily related to revenue associated with IXINITY which increased by $8.8 million for the year ended December 31, 2016 following IXINITY's FDA approval in the second quarter of 2015 and an increase in unit sales of our VARIZIG product. Increased revenue from these two products however, was offset by a decrease in revenue for HepaGam B as a greater percentage of sales of this product occurred overseas where the price is lower due to contractual pricing agreements.

Collaborations

Collaborations revenue decreased by $5.5 million, or 97%, to $0.2 million for the year ended December 31, 2016 from $5.7 million for the year ended December 31, 2015. Collaboration revenue in 2016 decreased primarily due to recognition and payment of a $5.0 million development milestone achievement during the third quarter of 2015.

Cost of Product Sales

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

The following table provides information regarding our cost of products sales, including gross margin for the years ended December 31, 2016 and 2015:

	Twelve Months Ended December 31, 2016	2015	Change
Revenues:			
Product sales	$ 36,254	$ 27,947	$ 8,307
Contracts, grants and collaborations	180	5,654	(5,474)
Total revenues	36,434	33,601	2,833
Costs and expenses:			
Cost of product sales	24,182	16,933	7,249
Gross profit	$ 12,252	$ 16,668	$ (4,416)
Gross margin percent	34%	50%	

Cost of product sales increased by $7.2 million, or 43%, to $24.2 million for the year ended December 31, 2016 from $16.9 million for the year ended December 31, 2015. Gross margin decreased due to the ongoing challenges with the manufacture of our IXINITY product. In 2016, $7.1 million in manufacturing costs associated with unsuccessful manufacturing of our product were written off and included in cost of product sales. The remaining increase in cost of product sales for the year was primarily due to costs related to increased IXINITY product sales.

Research and Development Expenses

We expense research and development costs as incurred. These expenses consist primary of personnel-related costs, fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies, costs of contract manufacturing services for clinical trial material, and costs of materials used in clinical trials and research and development.

We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, and the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials. These research and development costs may be partially offset by cost-sharing arrangements with collaborative partners, such as our collaboration with MorphoSys AG.

Our principal research and development expenses by program for the year ended December 31, 2016 and 2015 are shown in the following table:

	Twelve Months Ended December 31,		
(in thousands)	**2016**	**2015**	**Change**
ADAPTIR related programs [1]	$ 10,749	$ 7,642	$ 3,107
ROR1	5,992	2,688	3,304
IXINITY	4,843	16,278	(11,435)
MOR209/ES414	4,526	2,406	2,120
otlertuzumab	1,733	3,399	(1,666)
Other	1,675	2,313	(638)
Total	$ 29,518	$ 34,726	$ (5,208)

[1] Other non-disclosed candidates are also included in the ADAPTIR related programs expense.

Research and development expenses decreased by $5.2 million, or 15%, to $29.5 million for the year ended December 31, 2016 from $34.7 million for the year ended December 31, 2015. This change was primarily comprised of:

- an increase in expense for ADAPTIR related programs primarily due to an increase in characterization studies and non-clinical activities;
- an increase in ROR1 is primarily due to an increase in lead construct selection and characterization studies;
- decrease in expense for our IXINITY product candidate (which was approved by the FDA in April 2015) due to a decrease in manufacturing process development activities in 2016 and the timing of clinical trial activities;
- an increase in expense for our MOR209/ES414 product candidate primarily due to the timing of manufacturing activities along with decreased reimbursement from MorphoSys for development activities under our collaboration agreement;

- a decrease in expense for our otlertuzumab product candidate related to the timing of clinical trial activities; and
- the expenses for our other activities, which decreased, were primarily related to centralized research and development activities not otherwise attributable to specific product candidates or programs.

Selling, General and Administrative Expenses

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

For the year ended December 31, 2016 selling, general and administrative expenses decreased by $4.4 million, or 13%, to $38.7 million for 2016 from $43.0 million for 2015. This decrease was primarily due to higher costs in 2015 associated with IXINITY sales and marketing and Emergent's pre-spin overhead allocation to Aptevo. These were slightly offset by increased initial costs associated with our spin-off activities in 2016.

Impairment of Goodwill and Intangible Asset

In 2016 we recorded impairments of approximately $71.0 million of long-term assets, which consisted of $41.8 million of intangible assets and $29.2 million of goodwill. Impaired intangible assets consisted of certain of our indefinite-lived in process research and development. For additional information about our impairments, see Note 8— Impairment of Intangible Assets, In-Process Research and Development and Goodwill in the notes to consolidated financial statements.

Other Income (Expense), Net

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

Income Taxes

Benefit from income taxes increased by $13.3 million, or 659%, to $15.3 million for the year ended December 31, 2016 from $2.0 million for the year ended December 31, 2015 due to the restatement of our deferred tax liability, (see Note 2 – Restatement). This deferred tax liability was released to benefit from income taxes upon the impairment of the related IPR&D asset.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements at December 31, 2016.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2016, we had cash, cash equivalents and short-term investments in the amount of $54.9 million.

On August 1, 2016, in connection with the spin-off of the Company from Emergent, we issued 20.2 million shares to Emergent stockholders and recorded a contribution from Emergent of $71.2 million. This contribution included a one-time payment of $45.0 million, and a working capital reimbursement for outstanding payments of $1.4 million, which we received in the fourth quarter of 2016, a noncash transfer of an intangible asset of $0.7 million, and a net transfer of cash from Emergent of $24.2 million. In addition, we recorded a promissory note to receive $20.0 million from Emergent, which we received in the first quarter of 2017.

In addition, on August 4, 2016, we entered into a $35.0 million Credit and Security Agreement, or the Credit Agreement, with MidCap Financial Trust. The Credit Agreement provides us with up to $35.0 million of available borrowing capacity composed of two tranches of $20.0 million and $15.0 million. The first tranche of $20.0 million was made available to us, and drawn, on the closing date of the Credit Agreement and the second tranche of $15.0 million will be available (subject to certain conditions) following the date we: (1) achieve net commercial product revenue of $40.0 million on a trailing twelve-month basis, and (2) receive payment of the additional $20.0 million in cash committed by Emergent. Emergent's promise to pay such $20.0 million in cash was evidenced by a non-negotiable, unsecured promissory note issued to us and was paid in the first quarter of 2017. Once drawn, interest is paid monthly while principal will be paid on a monthly basis commencing in August 2018. The credit agreement will mature on February 1, 2021. Amounts drawn under the Credit Agreement accrue interest at a rate of LIBOR plus 7.60% per annum.

The Credit Agreement covenants require us and our subsidiaries to maintain increasing minimum net commercial product revenue for each twelve-month period ending on the last day of each calendar quarter. An event of default could result in the acceleration of the amounts owed under the Credit Agreement, and we may not have sufficient funds or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests in our assets securing our indebtedness. A decrease in manufacturing development activities in 2016 due to a shortage of IXINITY, resulted in a reduction in revenue, which may result in the violation of the covenants under our Credit Agreement with MidCap Financial Trust unless the parties agree to a waiver or amendment to the Credit Agreement.

Capital Requirements

Aptevo expects to incur losses from operations for the foreseeable future primarily due to research and development expenses, including expenses related to conducting clinical trials. Aptevo's future capital requirements will depend on a number of factors, including:

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

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

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2016 and 2015:

	Twelve months ended December 31,	
(in thousands)	**2016**	**2015**
Net cash provided by (used in):		
Operating activities	(36,862)	(48,760)
Investing activities	(47,394)	(1,527)
Financing activities	89,295	51,331
Increase in cash and cash equivalents	$ 5,039	$ 1,044

Net cash used in operating activities of $36.9 million for the year ended December 31, 2016 was primarily due to our net loss of $112.4 million, offset by the noncash impairment of goodwill and intangible assets of $71.0 million and the write-down of nonsaleable IXINITY inventory. Net cash used in operating activities of $48.8 million for the year ended December 31, 2015 was primarily due to our net loss of $59.3 million.

Net cash used in investing activities for the periods presented was primarily due to the purchase of short term investment of $44.8 million in 2016 and the purchases of property and equipment.

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

Contractual Obligations

Our contractual obligations as of December 31, 2016 were as follows:

	Payments due by period				
(in thousands)	Total	Less than 1 year	1 to 3 Years	4 to 5 Years	More than 5 years
Contractual obligations:					
Operating lease obligations	$ 5,482	$ 1,664	$ 3,264	$ 554	$ —

Critical Accounting Policies and Significant Judgements and Estimates

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

Revenue Recognition

We recognize revenue if four basic criteria have been met: (1) there is persuasive evidence of an arrangement, (2) delivery has occurred or services have been rendered, (3) the fee is fixed or determinable, and (4) collectability is reasonably assured. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time as all criteria are met.

Collaborations

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

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

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

Research and Development

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

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

Stock-Based Compensation

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

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

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

Income Taxes

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

Our 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. We consider future taxable income and ongoing tax planning strategies in assessing the need for valuation allowances. In general, if we determine that it is more likely than not to realize more than the recorded amounts of net deferred tax assets in the future, we 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 we determine that it is not more likely than not to realize all or part of the net deferred tax asset in the future, we 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, we make certain estimates and assumptions, in (1) calculating our 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. Our estimates and assumptions may differ significantly from tax benefits ultimately realized.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, which deferred the effective date of the new revenue standard for periods beginning after December 15, 2016 to December 15, 2017, with early adoption permitted but not earlier than the original effective date. Accordingly, the updated standard is effective for the Company in the first quarter of fiscal 2018. We continue to evaluate the effect that the standard will have on its consolidated financial statements and related disclosures including the areas of variable consideration and new disclosure requirements. We currently expect to use the modified retrospective method to adopt this standard.

In August 2014, the FASB issued ASU No.2014-15 Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management is required to assess an entity's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. The provisions of this standard are effective for annual periods ending after December 31, 2016, and for annual and interim periods thereafter. We adopted this guidance for the year ended December 31, 2016 and management believes that our existing cash and cash equivalents will be sufficient to fund our operations through the first quarter of 2018.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize a lease liability and a right-of-use asset for all leases (with the exception of short term leases) at the commencement date. Lessor accounting under ASU 2016-02 is largely unchanged. ASU 2016-02 is effective for annual and interim periods beginning on or after December 15, 2018 and early adoption is permitted. Under ASU 2016-02, lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. Lessees and lessors may not apply a full retrospective transition approach. We have not yet selected an implementation date nor have we determined the effect of the standard on our ongoing financial reporting.

In March 2016, the FASB issued ASU 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." ASU 2016-09 simplifies the accounting for share-based payment award transactions including the financial statement presentation of excess tax benefits and deficiencies, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the requirements of ASU 2016-09 and have not yet determined the impact on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments," which clarifies the classification and presentation of eight specific cash flow issues in the statement of cash flows. This standard is effective beginning January 1, 2018, with early adoption permitted. The new standard requires a retrospective transition. We are currently evaluating the requirements of ASU 2016-09 and have not yet determined the impact on our consolidated statement of cash flows.

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

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

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APTEVO THERAPEUTICS INC.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Aptevo Therapeutics Inc.

We have audited the accompanying consolidated balance sheets of Aptevo Therapeutics Inc. as of December 31, 2016 and 2015 (as restated) and 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, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Aptevo Therapeutics Inc. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the 2015 financial statements have been restated to correct an error in deferred tax liabilities and corresponding goodwill.

/s/ Ernst & Young LLP
Seattle, Washington
March 31, 2017

Item 8. Financial Statements and Supplementary Data.

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

	December 31,	
	2016	2015 (Restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,676	$ 4,637
Restricted cash	400	—
Short-term investments	44,849	—
Accounts receivable, net	4,284	6,456
Inventories	6,639	20,322
Income tax receivable, net	—	1,376
Prepaid expenses and other current assets	5,566	2,343
Total current assets	71,414	35,134
Property and equipment, net	5,910	4,179
In-process research and development	—	41,800
Intangible assets, net	14,534	17,441
Goodwill	—	29,213
Total assets	$ 91,858	$ 127,767
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 11,489	$ 10,084
Accrued compensation	4,009	3,334
Contingent consideration, current portion	—	444
Sales rebates and discounts	3,235	2,238
Deferred revenue, current portion	811	3,843
Total current liabilities	19,544	19,943
Deferred revenue, net of current portion	2,896	3,318
Long-term debt, net	18,383	—
Deferred income taxes	—	15,817
Other liabilities	469	71
Total liabilities	41,292	39,149
Stockholders' equity:		
Preferred stock: $0.001 par value; 15,000,000 shares authorized, zero shares issued or outstanding	—	—
Common stock: $0.001 par value; 500,000,000 shares authorized; 20,271,737 and zero shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	20	—
Additional paid-in capital	151,271	—
Accumulated other comprehensive income	(33)	—
Contribution receivable from former parent	(20,000)	—
Former parent investment in subsidiary	—	320,606
Accumulated deficit	(80,692)	(231,988)
Total stockholders' equity	50,566	88,618
Total liabilities and stockholders' equity	$ 91,858	$ 127,767

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)

	Year Ended December 31,	
	2016	**2015**
Revenues:		
Product sales	$ 36,254	$ 27,947
Collaborations	180	5,654
Total revenues	36,434	33,601
Costs and expenses:		
Cost of product sales	24,182	16,933
Research and development	29,518	34,726
Selling, general and administrative	38,666	43,042
Impairment of goodwill and intangible assets	71,013	—
Loss from operations	(126,945)	(61,100)
Other income (expense):		
Other income (expense), net	(810)	(237)
Total other income (expense), net	(810)	(237)
Loss before income taxes	(127,755)	(61,337)
Benefit from income taxes	15,340	2,020
Net loss	(112,415)	(59,317)
Net loss per share - basic and diluted	$ (5.55)	$ (2.93)
Shares used to compute net loss per share - basic and diluted	20,239,160	20,229,849

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

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

	Year Ended December 31,	
	2016	2015
Net loss	(112,415)	(59,317)
Other comprehensive loss:		
Unrealized losses on available-for-sale investments, net	(33)	—
Total comprehensive loss	$ (112,448)	$ (59,317)

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

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

	Year Ended December 31,	
	2016	**2015**
Operating Activities		
Net loss	$ (112,415)	$ (59,317)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,809	1,107
Depreciation and amortization	3,362	2,907
Impairment of goodwill and intangible assets	71,013	—
Restricted cash	(400)	—
Income taxes	(15,817)	(1,361)
Provision for allowance for doubtful accounts	200	3,481
Change in fair value of contingent consideration	(444)	214
Changes in operating assets and liabilities:		
Accounts receivable	1,972	3,884
Inventories	13,683	(2,697)
Income taxes	1,376	(66)
Prepaid expenses and other current assets	(3,223)	2,860
Accounts payable, accrued compensation and other liabilities	2,479	(2,384)
Sales rebates and discounts	997	(8)
Deferred revenue	(3,454)	2,620
Net cash used in operating activities	(36,862)	(48,760)
Investing Activities		
Purchases of property and equipment	(2,512)	(1,527)
Purchases of investments	(44,882)	—
Net cash used in investing activities	(47,394)	(1,527)
Financing Activities		
Common stock issued upon exercise of stock options	20	—
Common stock issued upon vesting of restricted stock units	18	—
Proceeds from long-term debt	20,000	—
Debt issuance costs	(1,962)	—
Transfer from former parent, prior to spin-off	71,219	52,220
Contingent consideration payments	—	(889)
Net cash provided by financing activities	89,295	51,331
Increase in cash and cash equivalents	5,039	1,044
Cash and cash equivalents at beginning of period	4,637	3,593
Cash and cash equivalents at end of period	$ 9,676	$ 4,637
Supplemental disclosures:		
Contribution receivable from former parent	$ 20,000	$ —
Cash paid for interest	$ 537	$ —
Cash paid for taxes	$ 162	$ —

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		Former Parent Investment in Subsidiary	Additional Paid-In Capital	Accumulated Deficit	Contribution Receivable from Former Parent	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount						
Balance at December 31, 2014	—	$ —	$ —	$ —	$ —	$ —	$ —	$ 94,608
Net transfers from former parent	—	—	53,327	—	—	—	—	53,327
Net loss for the period	—	—	—	—	(59,317)	—	—	(59,317)
Balance at December 31, 2015	—	$ —	$ 320,606	$ —	$ (231,988)	$ —	$ —	$ 88,618
Capitalization upon spinoff	20,229,849	20	—	—	—	—	—	20
Transfers from former parent	—	—	(288,883)	147,424	231,988	(20,000)	—	70,529
Unrealized losses on available-for-sale investments	—	—	—	—	—	—	(33)	(33)
Common stock issued upon exercise of stock options	9,144	—	—	20	—	—	—	20
Common stock issued upon vesting of restricted stock units	32,744	—	—	18	—	—	—	18
Stock-based compensation	—	—	—	3,809	—	—	—	3,809
Net loss for the period	—	—	(31,723)	—	(80,692)	—	—	(112,415)
Balance at December 31, 2016	$ 20,271,737	$ 20	$ —	$ 151,271	$ (80,692)	$ (20,000)	$ (33)	$ 50,566

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

Note 1. Nature of Business and Significant Accounting Policies

Organization and Basis of Presentation

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

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

At the closing of the spin-off Aptevo recorded a contribution from Emergent of $71.2 million. This contribution included a one-time payment of $45.0 million, and a working capital reimbursement for outstanding payments of $1.4 million, which we received in the fourth quarter of 2016, a noncash transfer of an intangible asset of $0.7 million, and a net transfer of cash from Emergent of $24.2 million. Also recorded was a promissory note to receive $20.0 million from Emergent, which was received in the first quarter of 2017. In addition, on August 4, 2016, we entered into a $35.0 million Credit and Security Agreement, or the Credit Agreement, with MidCap Financial Trust. The Credit Agreement provides us with up to $35.0 million of available borrowing capacity, which will be available (subject to certain conditions) to us in two tranches of $20.0 million and $15.0 million, respectively, through August 31, 2017. See Note 10 — Debt.

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles or GAAP.

Prior to August 1, 2016, the consolidated financial statements were prepared on a "carve-out" basis for the purpose of presenting Aptevo's financial position, results of operations, and cash flows, and were derived from Emergent's consolidated financial statements and accounting records. Aptevo did not operate as a standalone entity in the past and accordingly the selected financial data presented herein is not necessarily indicative of Aptevo's future performance and does not reflect what Aptevo's performance would have been had Aptevo operated as an independent publicly-traded company prior to August 1, 2016. The consolidated financial statements reflect Aptevo's financial position, results of operations, and cash flows as a separately operated business in conformity with GAAP post the August 1, 2016 spin-off.

Prior to August 1, 2016, the consolidated financial statements included an allocation of certain assets and liabilities that have historically been held at the Emergent corporate level but which were specifically identifiable or allocable to Aptevo. All Aptevo intracompany transactions and accounts have been eliminated. All intercompany transactions between Aptevo and Emergent are considered to be effectively settled in the consolidated financial statements at the time the transaction is recorded. The total net effect of the settlement of these intercompany transactions is reflected in the consolidated statement of cash flows as a financing activity and in the consolidated balance sheet as a net investment from Emergent. As of August 1, 2016, in connection with the separation and distribution, Emergent's investment in the Company's business was redesignated as stockholder's equity and allocated between common stock and additional paid-in capital based on the number of shares issued at the distribution date.

Prior to August 1, 2016, Aptevo's consolidated financi al statements included an allocation of expenses related to certain Emergent corporate functions, including senior management, legal, human resources, finance, information technology, and quality assurance. These expenses were allocated to Aptevo based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, square footage, or other measures. Aptevo considers the expense allocation methodology and results to be reasonable for all periods presented. However, the allocations may not be indicative of the actual expense that would have been incurred had Aptevo operated as an independent, publicly-traded company for the periods presented.

Prior to August 1, 2016, the income tax amounts in these consolidated financial statements were calculated based on a separate return methodology and presented as if Aptevo's operations were a standalone taxpayer in each of its tax jurisdictions.

Significant Accounting Policies

Use of Estimates

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

Principles of Consolidation

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

The majority of our transactions occur in U.S. dollars, however we do have an agreement with Emergent for sales to two Canadian distributors. These sales are translated into U.S. dollars, the reporting currency, at the exchange rate prevailing at the balance sheet date.

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. In addition, was have restricted cash in the amount of $0.4 million maintained in depository as collateral for corporate credit cards.

Short-Term Investments

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

Concentrations of Credit Risk

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

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. At December 31, 2016 and December 31, 2015, we had an allowance for doubtful accounts balance of $3.3 million and $3.5 million, respectively.

Inventories

Inventories, including purchased 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) and includes the services and products of third-party suppliers. Aptevo analyzes its inventory levels quarterly and writes down, in the applicable period, inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. Aptevo also writes off, in the applicable period, the costs related to expired inventory and unsuccessful manufacturing runs.

Property and Equipment

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

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

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

In-Process Research and Development and Long-lived Assets

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

Aptevo assesses the recoverability of its long-lived assets or asset groups for which an indicator of impairment exists by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If Aptevo concludes that the carrying value will not be recovered, Aptevo measures the amount of such impairment by comparing the fair value to the carrying value of the assets or asset groups. See Note 8 — Impairment of Intangible Assets, In-Process Research and Development and Goodwill.

Goodwill

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

A two-step test would first compare Aptevo's fair value to its carrying value. If the carrying value exceeds its fair value, then the second step of the impairment test is performed in order to determine the implied fair value of goodwill. If the carrying value of goodwill exceeds its implied fair value, an impairment loss is recognized.

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

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

The determination of the fair value of is judgmental in nature and involves the use of significant estimates and assumptions. The estimates and assumptions used in calculating fair value include identifying future cash flows, which requires that Aptevo make a number of critical legal, economic, market and business assumptions that reflect best estimates as of the testing date. Aptevo's assumptions and estimates may differ significantly from actual results, or circumstances could change that would cause Aptevo to conclude that an impairment now exists or that it previously understated the extent of impairment. See Note 8 — Impairment of Intangible Assets, In-Process Research and Development and Goodwill.

Contingent Consideration

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

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

Fair Value of Financial Instruments

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

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

Sales Rebates and other Discounts

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

All revenues from product sales are also recorded net of applicable allowances for sales and government rebates, special promotional programs, and discounts. Management does not believe there to be a legal right of offset related to these allowances and the receivables from wholesalers; accordingly, allowances are classified as a current liability in the accompanying balance sheets 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 amortize these cost to interest expense over the term of the debt, using the effective interest method. Debt issuance costs are presented in the balance sheet as a reduction of the carrying amount of the debt liability.

Revenue Recognition

Aptevo recognizes revenue if four basic criteria have been met: (1) there is persuasive evidence of an arrangement, (2) delivery has occurred or services have been rendered, (3) the fee is fixed or determinable, and (4) collectability is reasonably assured. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time as all criteria are met.

Collaborations

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

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

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

Product Sales

The Company markets and sells its products through commercial wholesalers (direct customers) who purchase the products at a price referred to as the wholesale acquisition cost (WAC). Additionally, the Company may enter into separate agreements with indirect customers to acquire its products for a contracted price that is less than the product's WAC. The indirect customers, such as group-purchasing organizations, physician practice-management groups and hospitals, continue to purchase the Company's products from the wholesalers, but at their respective contractual prices. Per its wholesaler agreements, the Company guarantees to credit the wholesaler for the difference between the WAC and the indirect customers' contracted price. This credit is referred to as a chargeback and revenues from product sales are recorded net of estimated chargebacks. Adjustments to the chargeback provisions are made periodically to reflect new facts and circumstances that may indicate that 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, the Company 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.

The Company defers the recognition of revenue from the sales of new product introductions until the commercial wholesalers resell the product to the healthcare providers. This is due to the inherent uncertainties in estimating normal wholesaler inventory levels of new products in addition to possible product launch incentives such as extended payment terms and expanded return rights that allow the wholesalers to return the product. Once the Company gains enough historical experience to reasonably estimate allowances for chargebacks, rebates and other discounts, revenue from sales and the related allowances are recognized upon sale to the wholesaler.

Research and Development

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

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

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, restricted stock units (RSUs), and stock options granted to our employees and directors based on the fair value of the awards on the date of grant. The fair value of stock options is estimated at the date of grant using the Black-Scholes option pricing model that requires management to apply judgment and make estimates, including:

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

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

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

Income Taxes

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

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

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

Segment Reporting

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

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, which deferred the effective date of the new revenue standard for periods beginning after December 15, 2016 to December 15, 2017, with early adoption permitted but not earlier than the original effective date. Accordingly, the updated standard is effective for the Company in the first quarter of fiscal 2018. Aptevo is continuing to evaluate the effect that the standard will have on its consolidated financial statements and related disclosures including the areas of variable consideration and new disclosure requirements. Aptevo is currently expecting to use the modified retrospective method to adopt this standard.

In August 2014, the FASB issued ASU No.2014-15 Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management is required to assess an entity's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. The provisions of this standard are effective for annual periods ending after December 31, 2016, and for annual and interim periods thereafter. We adopted this guidance for the year ended December 31, 2016 and management believes that our existing cash and cash equivalents will be sufficient to fund our operations through the first quarter of 2018.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize a lease liability and a right-of-use asset for all leases (with the exception of short term leases) at the commencement date. Lessor accounting under ASU 2016-02 is largely unchanged. ASU 2016-02 is effective for annual and interim periods beginning on or after December 15, 2018 and early adoption is permitted. Under ASU 2016-02, lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. Lessees and lessors may not apply a full retrospective transition approach. The Company has not yet selected an implementation date nor has it determined the effect of the standard on the Company's ongoing financial reporting.

In March 2016, the FASB issued ASU 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." ASU 2016-09 simplifies the accounting for share-based payment award transactions including the financial statement presentation of excess tax benefits and deficiencies, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted. Aptevo is currently evaluating the requirements of ASU 2016-09 and have not yet determined the impact on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments," which clarifies the classification and presentation of eight specific cash flow issues in the statement of cash flows. This standard is effective beginning January 1, 2018, with early adoption permitted. The new standard requires a retrospective transition. Aptevo is currently evaluating the impact of the new standard on its consolidated financial statements.

Note 2. Restatement

Restatement Background

Our December 31, 2015 financial statements include $41.8 million of intangible assets which resulted from the acquisition of IPR&D programs related to TRU-016, a novel CD37-directed therapy for B-cell malignancies, such as chronic lymphocytic leukemia and non-Hodgkin's lymphoma. This amount was deemed to be an indefinite-lived asset, to remain as an indefinite-lived asset on the balance sheet until completion or abandonment of the associated research and development efforts. Following the spin-off of the Company in August 2016, the Company conducted an internal review of all deferred tax assets and liabilities acquired and it was determined that a deferred tax liability should have been recorded associated with the difference between the book basis and the tax basis of the asset as a part of the acquisition in 2010. The error has no effect on the net assets distributed in the spin-off.

Impact of Restatement on Consolidated Balance Sheets

The Company has restated its consolidated balance sheet as of December 31, 2015. The restatement resulted in an increase in deferred tax liabilities of $15.3 million and a corresponding $15.3 million increase in goodwill. The restatement had no impact on total stockholders' equity.

The impact of the restatement on the Company's consolidated balance sheets is reflected and quantified for 2015 in the below table.

Balance Sheet Impact:
(1)

(in thousands)	December 31, 2015 (As previously reported)	Restatement Adjustment	December 31, 2015 (Restated)
Goodwill	$ 13,902	$ 15,311	$ 29,213
Total assets	112,456	15,311	127,767
Deferred tax liability	506	15,311	15,817
Total liabilities	$ 23,838	$ 15,311	$ 39,149
Total stockholders equity	$ 88,618	$ —	$ 88,618

See Note 17 for unaudited information on the impact of this restatement to unaudited interim periods.

Note 3. MorphoSys Collaboration Agreement

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

In accordance with the initial terms of the MorphoSys Agreement, Aptevo received a nonrefundable $20.0 million upfront payment and could receive up to $163.0 million in additional contingent payments, comprised of up to $80.0 million and up to $83.0 million, respectively, due upon the achievement of specified development and regulatory milestones. MorphoSys and Aptevo jointly agreed to fund further development of MOR209/ES414, with Aptevo responsible for 36% of the total development costs and MorphoSys responsible for the remainder, with Aptevo's funding requirement capped at $186.0 million. Aptevo's development effort includes the performance of non-clinical, clinical, manufacturing and regulatory activities. Aptevo retains commercialization rights in the U.S. and Canada, with a tiered royalty obligation to MorphoSys, ranging from mid-single digit up to 20% of sales. MorphoSys has worldwide commercialization rights excluding the U.S. and Canada, with a low single digit royalty obligation to Aptevo.

In December 2015, after a joint review of data from the ongoing Phase 1 dose escalation study of MOR209/ES414 in prostate cancer patients, Aptevo and MorphoSys decided to adjust the dosing regimen and administration of MOR209/ES414. Patients receiving weekly doses of MOR209/ES414 developed antibodies against the drug; this is called anti-drug antibodies, or ADA. ADA developed in most patients including those receiving the maximum tolerated dose of drug which could be given safely on a weekly basis. These antibodies bind to the drug and reduce the concentration of active MOR209/ES414 in the blood and thus could potentially reduce its efficacy. However, no safety issues related to the development of ADA were observed.

The cause of these antibodies is unclear but could be due to the weekly administration of the drug. Hence, the protocol was amended to a continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA. The MOR209/ES414 Phase I clinical trial under the amended protocol, providing continuous intravenous infusion as a way to administer higher levels of drug and prevent the development of ADA, commenced December 2016.

As a result of the required dosing regimen change and the impact to the overall development timeline and technical risk, our co-development agreement with MorphoSys was restructured. In December 2015, Aptevo and MorphoSys amended the collaboration agreement to decrease the additional contingent payments due to Aptevo upon the achievement of specified development and regulatory milestones of up to $32.5 million and up to $41.5 million, respectively and change the total funding requirement cap for Aptevo to up to approximately $250.0 million. In December 2016, the collaboration agreement was further amended to adjust the allocation of certain manufacturing and development costs and extend MorphoSys's convenience termination rights. Under the amendment, we will bear 75% of all development costs with respect to MOR209/ES414, and MorphoSys will bear 25% of such costs, during the period from January 1, 2017 through June 30, 2017. During the period from July 1, 2017 through December 31, 2018, we will bear 49% of such development costs and MorphoSys will bear 51%. Beyond January 1, 2019, we will bear 36% and MorphoSys will bear 64% of such development costs. In addition, the timeframe for a one-time right to terminate the collaboration agreement by MorphoSys has been extended from December 31, 2016 to June 30, 2017, or within one week following the receipt and discussion of clinical data from the first six patients enrolled and dosed in the MOR209/ES414 Phase I clinical trial.

Aptevo evaluated the MorphoSys Agreement and determined that it was a revenue arrangement with multiple deliverables or performance obligations. Aptevo determined there were two units of accounting under the MorphoSys Agreement: (1) the delivered license to further develop and commercialize MOR209/ES414, and (2) undelivered items related to development services. Aptevo determined that the license had standalone value as the drug candidate has been: (1) developed and is currently Phase 1 clinical trial ready, (2) MorphoSys possesses the knowledge, technology, skills, experience and infrastructure necessary to complete all further development of the drug through commercialization, and (3) MorphoSys has the right to further sublicense the product. In 2014, Aptevo allocated the $20.0 million upfront payment to the two units of accounting using the relative selling price method. Aptevo determined the estimated selling price for the license using the income approach and an appropriate discount rate. The estimated selling price includes unobservable inputs (Level 3), such as estimates of revenues and operating margins; the time and resources needed to complete the development and approval of the product candidate; and the risk related to the viability of and potential for alternative treatments. Aptevo determined the estimated selling price of the development services unit of accounting based on the estimated number of full-time equivalent personnel at the contractual rate as defined in the MorphoSys Agreement, whose rates and terms approximate those of other Emergent or Aptevo service related contracts and those observed generally through other collaboration negotiations. The allocation resulted in $15.3 million of the $20.0 million upfront payment being allocated to the license and $4.7 million being allocated to the development services. Aptevo determined the license fee unit of accounting was delivered and completed on the date the MorphoSys Agreement was executed and thus recognized $15.3 million of license revenue in August 2014. Revenue related to the development services is recognized as the services are performed with $0.1 million and $0.5 million, respectively, recognized in the year ended December 31, 2016 and 2015. The current estimated service period for the undelivered development services under the MorphoSys Agreement is through 2023.

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

The MorphoSys Agreement provides for the sharing of development and clinical costs related to MOR209/ES414. In the event Aptevo's share of the total cost incurred for a given quarter exceeds its pro rata limit, Aptevo records a receivable from MorphoSys for the excess and reduces research and development expense by this amount. For the year ended December 31, 2016 Aptevo recorded a reduction to research and development expense of $0.1 million and for the year ended December 31, 2015 Aptevo recorded a reduction to research and development expense of $4.3 million.

As of December 31, 2016, the MorphoSys Agreement related accounts receivable balance was $0.0 million and the related total deferred revenue balance was $3.7 million.

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

	December 31, 2016			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 5,215	$ —	$ —	$ 5,215
Corporate bonds	—	9,951	—	9,951
US government and agency debt securities	—	34,898	—	34,898
Total assets	$ 5,215	$ 44,849	$ —	$ 50,064

If quoted market prices in active markets for identical assets are not available to determine fair value, then the Company uses quoted prices of similar instruments and other significant inputs derived from observable market data obtained from third-party data providers. These investments are included in Level 2 and consist of debt securities of U.S government agencies and corporate bonds. There were no transfers between Levels 1 and 2 during the twelve-month period ended December 31, 2016.

The following table is a reconciliation of the beginning and ending balance of the liabilities (contingent consideration) measured at fair value using significant unobservable inputs (Level 3) during the year ended December 31, 2016. The royalty agreement associated with HepaGam B expired on June 30, 2016, and no future royalty payments are expected on sales after that date.

(in thousands)	
Balance at December 31, 2015	$ 444
Expense included in earnings	19
Settlements	(463)
Balance at December 31, 2016	$ —

Note 5. Investments

Investments are classified as available-for-sale securities and are carried at fair value with unrealized temporary holding gains and losses excluded from net income or loss and reported in other comprehensive income or loss and also as a net amount in accumulated other comprehensive income or loss until realized. Available-for-sale securities are written down to fair value through income whenever it is necessary to reflect other than temporary impairments. The Company determined that the unrealized gains on its marketable securities as of December 31, 2016 were temporary in nature, and the Company currently does not intend to sell these securities before recovery of their amortized cost basis. All short-term investments are limited to a final maturity of less than one year from the reporting date.

	December 31, 2016			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding (Losses)	Estimated Fair Value
Cash equivalents:				
Money market fund	$ 5,215	$ —	$ —	$ 5,215
Total cash equivalents	$ 5,215	$ —	$ —	$ 5,215
Short-term investments:				
Corporate bonds	$ 9,959	$ 1	$ (9)	$ 9,951
US government and agency debt securities	34,923	—	(25)	34,898
Total short-term investments	$ 44,882	$ 1	$ (34)	$ 44,849

Note 6. Inventories

Inventories consist of the following:

(in thousands)	December 31, 2016	December 31, 2015
Raw materials and supplies	$ 260	$ 6,520
Work-in-process	1,165	4,730
Finished goods	5,214	9,072
Total inventories	$ 6,639	$ 20,322

CMC ICOS Biologics, Inc., (CMC), is the exclusive manufacturer of bulk drug substance for the IXINITY product. During 2015, we ordered nine manufacturing lots of bulk drug substance from CMC and only one of those lots was successfully manufactured and released in 2015. On October 4, 2016, we provided a Notice of Interruption in Manufacturing, or Notice, to the FDA, notifying the FDA of a potential interruption in the supply of IXINITY® coagulation factor IX (recombinant) due to the ongoing manufacturing challenges with the manufacturer of the bulk drug. On March 15, 2017, we announced the successful manufacture of a recent bulk drug substance batch of IXINITY and we anticipate that the new supply will be available beginning in May 2017, after the completion of routine final drug product (FDP) manufacturing activities. While we do not currently anticipate or foresee a supply shortage or supply interruption occurring, any supply shortage or supply interruption of IXINITY would adversely affect its sales and could adversely affect its market position, commercial viability and the trading price of our common stock.

Due to the challenges with the manufacture of our IXINITY product that meets release specifications for the final drug product, we wrote off unsaleable IXINITY inventory that was in the process of being manufactured in the amount of $7.1 million in 2016. This cost is included in cost of product sales.

Note 7. Property and equipment, net

Property, plant and equipment consist of the following:

(in thousands)	December 31, 2016	December 31, 2015
Leasehold improvements	$ 2,265	$ 2,152
Furniture and equipment	10,283	7,884
Property and equipment, gross	12,548	10,036
Less: Accumulated depreciation	(6,638)	(5,857)
Total property and equipment, net	$ 5,910	$ 4,179

Note 8. Impairment of Intangible Assets, In-Process Research and Development and Goodwill

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

We measured the fair value of both our indefinite-lived and definite lived intangible assets using accepted valuation techniques. The significant estimates used included our weighted average cost of capital, long-term rate of growth and profitability of our business, and working capital effects. Our assumptions are based on actual historical performance, expected results after commercial launch of our otlertuzumab product, and implied risk premiums based on market prices of our equity and debt as of the assessment date. To validate the reasonableness of the fair values, we reconciled the aggregate fair values of the business determined in step one to the enterprise market capitalization. Enterprise market capitalization includes, among other factors, the market capitalization of our stock and an acquisition premium based on historical data from acquisitions within the same or similar industries. In performing the reconciliation, we used the market value of our stock price, the stock price on the valuation date and considered such other quantitative and qualitative factors we considered relevant. This assessment resulted in the recognition in the third quarter of 2016 of a loss on impairment of in process research and development costs related to our otlertuzumab candidate of approximately $41.8 million and $29.2 million of goodwill.

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

Note 9. Intangible Assets, Net

Intangible assets, net, are comprised of licenses for our suite of commercial products. For the years ended December 31, 2016 and 2015, the Company recorded $2.2 million and $3.4 million, respectively, of intangible asset amortization expense. As of December 31, 2016, the weighted average amortization period remaining for intangible assets was 85 months.

Future amortization expense as of December 31, 2016 is as follows:

(in thousands)	
2017	$ 2,083
2018	2,083
2019	2,083
2020	2,083
2021 and beyond	6,202
Total remaining amortization	$ 14,534

Note 10. Debt

Credit Facility

On August 4, 2016, we entered into a $35.0 million Credit and Security Agreement (the Credit Agreement), with MidCap Financial Trust. The Credit Agreement provides us with up to $35.0 million of available borrowing capacity, available (subject to certain conditions) in two tranches of $20.0 million and $15.0 million, respectively, through August 31, 2017. The loan repayment will include interest (no principal) through August 2018. Commencing in August 2018, the payments will include principal and interest and will be repaid in full on February 1, 2021 (54 months). Amounts drawn under the Credit Agreement bear interest at a rate of LIBOR plus 7.60% per annum. The first tranche of $20.0 million was funded on the closing date of the Credit Agreement with the second tranche of $15.0 million will be available (subject to certain conditions) following the date Aptevo and its subsidiaries: (1) achieve net commercial product revenue of $40.0 million on a trailing twelve-month basis, and (2) receive an additional $20.0 million in cash from Emergent. Emergent's promise to pay this $20.0 million in cash is evidenced by a non-negotiable, unsecured promissory note issued to Aptevo from Emergent which was paid in the first quarter of 2017. We paid debt issuance costs of $1.9 million.

Five year payments on debt as of December 31, 2016 is as follows:

(in thousands)	
2017	$ 1,620
2018	4,908
2019	9,053
2020	8,405
2021	671
Total principal and interest payments	$ 24,657

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, in each case applicable to us and our subsidiaries. The negative covenants include restrictions on, among other things, indebtedness, liens, dividends and other distributions, repayment of subordinated indebtedness, mergers, dispositions, investments (including licensing), acquisitions, transactions with affiliates and modification of organizational documents or certain other agreements. The Credit Agreement contains financial covenants that require us and our subsidiaries to maintain increasing minimum net commercial product revenue for each twelve-month period ending on the last day of each calendar quarter, commencing with the twelve-month period ending September 30, 2016. The Credit Agreement also includes provision related to events of default and occurrence of material adverse effect. The occurrence of an event of default could result in the acceleration of the Credit Agreement. There was no event of default under the Credit Agreement as of December 31, 2016.

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

The related financing documents contain: (1) a customary agency fee, (2) an exit fee of up to 5.75% of the aggregate principal amount under the Credit Agreement for repayment or prepayment other than scheduled amortization payments and the final payment of principal and (3) a prepayment fee of up to 4% of the amount prepaid for the first year, decreasing over time, for any amounts prepaid prior to the maturity date, whether voluntary or by reason of the occurrence of an event of default or acceleration of the loan, other than certain mandatory prepayments.

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

Note 11. Net Loss per Share

Net loss per share is calculated by dividing the net loss of the Company by the number of weighted shares outstanding on December 31, 2016, and the number of shares issued during the spin-off for prior periods. Prior to the spin-off, Aptevo did not operate as a separate entity and as a result did not have any common stock outstanding other than 1,000 shares held by Emergent. The calculation of basic and diluted net loss per share assumes that the 20,229,849 ordinary shares issued to Aptevo stockholders in connection with the spin-off were outstanding from the beginning of the periods presented. Diluted earnings per share is calculated using the weighted average number of common shares outstanding plus dilutive common stock equivalents outstanding during the period. Common stock equivalents are excluded for the twelve-month periods ended December 31, 2016 and 2015, since the effect is anti-dilutive due to the Company's net losses. Common stock equivalents include stock options and unvested RSUs.

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

(in thousands, except for per share amounts)	As of December 31, 2016
Outstanding options to purchase common stock	2,069
Unvested RSUs	3,034

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

Note 12. Equity

Capitalization Upon Spin-off

On August 1, 2016, in connection with the spin-off of the Company from Emergent, we issued 20.2 million shares to Emergent shareholders and recorded a contribution from Emergent of $71.2 million. This contribution included a one-time payment of $45.0 million, and a working capital reimbursement for outstanding payments of $1.4 million, which we received in the fourth quarter of 2016, a noncash transfer of an intangible asset of $0.7 million, and a net transfer of cash from Emergent of $24.2 million. In addition, we recorded a promissory note to receive $20.0 million from Emergent, which we received in the first quarter of 2017.

Converted Equity Awards Incentive Plan

The Company had no stock-based compensation plans prior to spin off from Emergent; however certain Aptevo employees participated in Emergent's stock-based compensation plans (Emergent Plans), which provided for the grants of stock options and restricted stock units (RSUs). The expense associated with Aptevo employees who participated in the Emergent Plans was allocated to the Company in the accompanying Statements of Operations for the associated periods prior to the spin off.

In connection with the spin off and the employee matters agreement, the Company adopted the Converted Equity Awards Incentive Plan (the Converted Plan) and outstanding equity awards of Emergent held by Aptevo employees (the Converted Awards) were converted into or replaced with equity awards of Aptevo (the Conversion Awards) under the Converted Plan and were adjusted to maintain the economic value before and after the distribution date using the relative fair market value of the Emergent and Aptevo common stock based on the closing prices as of August 1, 2016. There was no significant incremental stock-based compensation expense recorded as a result of the equity award conversion. A total of 1.3 million shares of Aptevo common stock have been authorized for issuance under the Converted Plan.

2016 Stock Incentive Plan

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

Stock options under the 2016 SIP generally vest pro rata over a three-year period and terminate 7 to 10 years from the grant date, though the specific terms of each grant are determined individually. The Company's executive officers and certain other employees may be awarded options with different vesting criteria, and options granted to non-employee directors also vest over a three-year period. Option exercise prices for new options granted by the Company equal the closing price of the Company's common stock on the NASDAQ Global Market on the date of grant, while options issued as Conversion Awards were priced according to the Converted Plan.

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

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

Issuance of Shares

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

Stock-Based Compensation Expense

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

(in thousands)	December 31, 2016	December 31, 2015
Research and development	$ 2,693	$ 1,107
General and administrative	1,116	—
Total stock-based compensation expense	$ 3,809	$ 1,107

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:

	December 31, 2016
Expected dividend yield	0.00%
Expected volatility	75.00%
Risk-free interest rate	1.23%
Expected average life of options	6 years

Management applied an estimated forfeiture rate for the 2016 plan period of 10%.

The following is a summary of option activity for the year ended December 31, 2016:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Term	Aggregate Intrinsic Value
Outstanding Aptevo Options at December 31, 2015	—	$ —		$ —
Aggregate impact of conversion related to spin-off	1,672,177	2.49		127,520
Granted	456,075	2.83		35,306
Exercised	(9,144)	2.15		(8,839)
Forfeited	(33,894)	2.48		(5,369)
Outstanding at December 31, 2016	2,085,214	$ 2.57	6.20	$ 153,987
Exercisable at December 31, 2016	514,045	$ 2.25	4.30	$ 119,169

As of December 31, 2016, we had $1.1 million of unrecognized compensation expense related to options expected to vest over a weighted average period of 2.0 years. The weighted average remaining contractual life of outstanding and exercisable options is 6.1 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 2016 and the exercise price, multiplied by the number of in the money options) that would have been received by the option holders had all the option holders exercised their options on December 31, 2016. The amount of aggregate intrinsic value will change based on the price of Aptevo's common stock.

Restricted Stock Units

The following is a summary of restricted stock activity for the year ended December 31, 2016:

	Number of Units	Weighted Average Fair Value per Unit	Aggregate Fair Value
Outstanding Aptevo RSU's at December 31, 2015	—	$ —	$ —
Aggregate impact of conversion related to spin-off	1,223,215	2.76	—
Granted	2,115,772	2.94	—
Converted	(140,882)	2.42	—
Forfeited	(163,910)	2.90	—
Outstanding at December 31, 2016	3,034,195	$ 2.88	$ 7,403,435
Expected to Vest	2,801,201	$ 2.88	$ 6,834,930

As of December 31, 2016, we had $4.6 million of unrecognized compensation expense related to RSU's expected to vest over a period of 1.3 years. The weighted average remaining contractual life of unvested RSU's is 3.2 years.

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

Note 13. 401(k) savings plan

Aptevo has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers all employees. Under the 401(k) Plan, employees may make elective salary deferrals. Aptevo currently provides for matching of qualified deferrals up to 50% of 401(k) employee deferral contributions, based on a maximum employee deferral rate of 6% of compensation. During the year ended December 31, 2016 and December 31, 2015, Aptevo's related share of matching contributions was approximately $0.3 million and $0.3 million.

Note 14. Leases and Contingencies

The Company leases laboratory and office facilities, and office equipment under operating lease agreements. The Company recognizes rent expense under such arrangements on a straight-line basis over the term of the lease. During the year ended December 31, 2016 and December 31, 2015 total lease expense was $1.8 million and $1.8 million, respectively.

We are committed to future minimum lease payments under operating lease agreements as follows:

Year ending December 31, 2016 (in thousands)	
2017	$ 1,664
2018	1,620
2019	1,644
Thereafter	554
Total	$ 5,482

Note 15. Income Taxes

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

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

	Year ended December 31,	
(in thousands)	2016	2015
Current		
International	$ (29)	$ (660)
Total current	(29)	(660)
Deferred		
Federal	(14,630)	—
State	(681)	—
International	—	(1,360)
Total deferred	(15,311)	(1,360)
Total benefit from income taxes	$ (15,340)	$ (2,020)

The Company's net deferred tax asset (liability) consists of the following:

(in thousands)	December 31, 2016	2015 (Restated)
Federal losses carryforward	$ 7,237	$ 90,121
Other tax credits	384	13,026
Scientific research and experimental development credit carryforward	—	3,460
State losses carryforward	371	—
Intangible assets	17,464	—
Stock compensation	1,726	1,167
Foreign deferrals	—	17,755
Inventory reserves	—	1,716
Fixed assets	160	1,357
Other	3,050	3,910
Deferred tax asset	30,392	132,512
Intangibles	—	(13,043)
Other	(575)	(797)
Deferred tax liability	(575)	(13,840)
Valuation allowance	(29,817)	(134,489)
Net deferred tax liabilities	$ —	$ (15,817)

For the year ended December 31, 2015, deferred assets and liabilities are a result of the separate return calculation presentation and may not represent deferred assets and liability balances after the distribution. Certain deferred items may not have existed due to utilization by the Emergent group prior to the distribution, together with certain related transactions, or may hold no future value subsequent to the distribution due to the Company's future jurisdictional income projections. Federal net operating losses and research and development credit carryforwards are examples of deferred items that have been previously utilized or will have no future value to the Company as the distribution, together with certain related transactions, did not result in the transfer of loss carryforwards or tax credit carryforwards to the Company. The Company has determined a valuation allowance is required for financial reporting purposes due to cumulative historic losses on a separate tax return basis as well as the expiration of certain attributes.

As of December 31, 2016 and 2015, the Company has recorded federal net operating losses of approximately $20.7 and $257.4 million, respectively, state tax losses of $10.5 million and $0.0, respectively, and tax credits of $0.4 million and $13.2 million, respectively. In addition, the Company has recorded Canadian loss carryforwards of approximately $0.0 and $68.3 million, respectively, and Canadian scientific research and experimental development credits in the amount of $0.0 and $3.5 million, respectively. On a separate return basis, the US losses and credits would begin to expire in 2037. The state net operating losses will begin to expire in varying periods. The Emergent group retained the Canadian losses, Canadian tax credits and pre-spin federal losses and research and development tax credits. Carryforwards of net operating losses are subject to possible limitation, should a change in ownership occur, as defined by Internal Revenue Code Section 382.

The valuation allowance as of December 31, 2016 is primarily related to net operating losses and intangibles. The net change in valuation allowance was a decrease of $83.3 million.

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

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits:

(in thousands)	December 31, 2016	2015
Balance at the beginning of the year	$ —	$ —
Increases (decreases) related to prior period tax positions	76	—
Increases (decreases) related to current period tax positions	—	—
Balance at the end of the year	$ 76	$ —

We recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense. To date, no interest and penalties have been recognized related to the underpayment of income taxes.

The benefit from income taxes differs from the amount of taxes determined by applying the U.S. federal statutory rate to loss before benefit from income taxes as a result of the following

(in thousands)	Year ended December 31, 2016	2015
US	$ (123,199)	$ (41,648)
International	(4,556)	(19,689)
Loss before benefit from income taxes	$ (127,755)	$ (61,337)
Federal tax at statutory rates	$ (44,714)	$ (21,467)
State taxes, net of federal benefit	(1,189)	419
Impact of foreign operations	(29)	1,828
Change in valuation allowance	9,549	20,563
Separation related adjustment	11,055	—
Tax credits	(460)	(3,898)
Unrecognized tax benefits of tax credits	76	—
Permanent differences	10,372	535
Benefit from income taxes	$ (15,340)	$ (2,020)

Note 16. Subsequent Events

On January 5, 2017, Aptevo received a $20.0 million payment that had been committed to by Emergent in the form of a promissory note at the closing of the spin-off.

Note 17. Selected Quarterly Financial Data (unaudited)

Impact of Restatement

As detailed in Note 2, the Company has restated its consolidated balance sheet as of December 31, 2015. Accordingly, the Company has restated its consolidated balance sheet as of March 31, 2016 and June 30, 2016. In addition, the Company has restated its statements of operations for the quarterly and nine month periods ended September 30, 2016. The restatement resulted in the recognition of a $15.3 million benefit from income taxes equal to the amount of the deferred tax liability recorded associated with the TRU-016 IPR&D asset when the $41.8 million was impaired. The restatement also resulted in an increase in the impairment expense recognized in the third quarter of 2016 due to the impairment of all goodwill, by the amount that goodwill would have been increased. These two restated captions on the statements of operations have the effect of offsetting each other, resulting in no impact to net loss for the quarter and nine months ended September 30, 2016. The restatement adjustment did not impact the consolidated statement of operations for any periods prior to the third quarter of 2016.

The impact of the restatement on the Company's consolidated balance sheets and statements of operations is reflected and quantified for all interim periods affected, as applicable, in the below tables.

Balance Sheets Impact:

(in thousands)	March 31, 2016 (As previously reported)	Restatement Adjustment	March 31, 2016 (Restated)	June 30, 2016 (As previously reported)	Restatement Adjustment	June 30, 2016 (Restated)
Goodwill	$ 13,902	$ 15,311	$ 29,213	$ 13,902	$ 15,311	$ 29,213
Total assets	112,605	15,311	127,916	118,159	15,311	133,470
Deferred tax liability	506	15,311	15,817	506	15,311	15,817
Total liabilities	$ 22,743	$ 15,311	$ 38,054	$ 20,962	$ 15,311	$ 36,273
Total stockholders equity	$ 89,862	$ —	$ 89,862	$ 97,197	$ —	$ 97,197

Statement of Operations Impact:

	Three Months Ended			Nine Months Ended		
(in thousands)	September 30, 2016 (As previously reported)	Restatement Adjustment	September 30, 2016 (Restated)	September 30, 2016 (As previously reported)	Restatement Adjustment	September 30, 2016 (Restated)
Impairment expense	$ 55,702	$ 15,311	$ 71,013	$ 55,702	$ 15,311	$ 71,013
Loss from operations	(71,254)	(15,311)	(86,565)	(97,081)	(15,311)	(112,392)
Loss before income taxes	(71,747)	(15,311)	(87,058)	(97,498)	(15,311)	(112,809)
Benefit from income taxes	6	15,311	15,317	29	15,311	15,340
Net loss	$ (71,741)	$ —	$ (71,741)	$ (97,469)	$ —	$ (97,469)

The following table sets forth our unaudited quarterly consolidated statement of operations data for the eight quarters ended December 31, 2016:

2016 (in thousands, except per share amounts)	March 31,	June 30,	September 30, (Restated) (1)	December 31,
Revenue	$ 8,067	$ 10,193	$ 9,405	$ 8,769
Loss from operations	(12,982)	(12,845)	(86,565)	(14,553)
Loss before income taxes	(12,902)	(12,849)	(87,058)	(14,946)
Benefit from income taxes	12	11	15,317	—
Net loss	$ (12,890)	$ (12,838)	$ (71,741)	$ (14,946)
Net loss per share - basic and diluted	$ (0.64)	$ (0.63)	$ (3.55)	$ (0.74)

2015 (in thousands, except per share amounts)	March 31,	June 30,	September 30,	December 31,
Revenue	$ 11,663	$ 7,090	$ 6,562	$ 8,286
Loss from operations	(11,102)	(18,310)	(13,188)	(18,500)
Loss before income taxes	(11,397)	(18,328)	(13,104)	(18,508)
Benefit from income taxes	375	612	424	610
Net loss	$ (11,022)	$ (17,716)	$ (12,680)	$ (17,898)
Net loss per share - basic and diluted	$ (0.54)	$ (0.88)	$ (0.63)	$ (0.88)

(1) These amounts reflect a benefit from income taxes after giving effect to the goodwill and deferred tax liability restatement discussed above. The impairment of the Company's IPR&D in the quarter ended September 30, 2016 resulted in a benefit from income taxes of $15.3 million related to the reversal of the associated deferred tax liability in that quarter. The Company's interim financial statements included in Form 10-Q for the quarter ended September 30, 2016 did not reflect this benefit from income taxes or the increase in impairment of goodwill.

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, 2016, 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, 2016, 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.

Although the Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies, management has identified a material weakness in our internal controls over financial reporting related to the review of certain deferred income tax accounts in connection with the material error correction discussed in Note 2 to the financial statements. As a result of this material weakness, management has concluded that our deferred income tax account controls and procedures were not effective as of December 31, 2015, March 31, 2016, June 30, 2016 and September 30, 2016. In establishing the Aptevo finance organization's year end controls following the August 1, 2016 spin-off from Emergent, we enhanced our deferred income tax account-related controls to ensure the proper determination of the effect on deferred income tax accounts from certain purchase accounting transactions prior to Aptevo's spin-off from Emergent. While these controls are not subject to an audit by our independent registered public accounting firm, management has evaluated these controls and concluded that the material weakness has been sufficiently remediated.

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 2017 Annual Meeting of Stockholders (the Proxy Statement), which is expected to be filed not later than 120 days after December 31, 2016, under the headings "Executive Officers," "Proposal 1 -Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," and "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

Item 11. Executive Compensation.

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

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

Information required by this item will be contained in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Proposal 2 – Approval of the Amendment to the 2016 Stock Incentive Plan" 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 3 – Ratification of the Selection of Independ," and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

1. Consolidated Financial Statements

See Index to Consolidated Financial Statements at Item 8 herein.

2. Consolidated Financial Statement Schedules

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

3. Exhibits

See the Exhibit Index immediately following the signature page of this report. (b) Registrants shall file, as exhibits to this form, the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

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 31, 2017

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 31, 2017
/s/Jeffrey G. Lamothe **Jeffrey Lamothe**	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2017
/s/Fuad El-Hibri **Fuad El-Hibri**	Chairman of the Board of Directors	March 31, 2017
/s/Daniel J. Abdun-Nabi **Daniel J. Abdun-Nabi**	Director	March 31, 2017
/s/Grady Grant, III **Grady Grant, III**	Director	March 31, 2017
/s/Zsolt Harsanyi, Ph. D. **Zsolt Harsanyi, Ph. D.**	Director	March 31, 2017
/s/Barbara Lopez Kunz **Barbara Lopez Kunz**	Director	March 31, 2017
/s/John E. Niederhuber, M.D. **John E. Niederhuber, M.D.**	Director	March 31, 2017

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. (schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Aptevo hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the Securities and Exchange Commission.)	8-K	2.2	August 2, 2016	001-37746	
3.1	Restated Certificate of Incorporation of Aptevo Therapeutics Inc.	8-K	3.1	August 2, 2016	001-37746	
3.2	Amended and Restated By-Laws 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		
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	
10.1	Promissory Note, dated July 29, 2016, made by Emergent BioSolutions Inc. in favor of Aptevo Therapeutics Inc.	8-K	10.1	August 2, 2016	001-37746	
10.2	Transition Services Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.2	August 2, 2016	001-37746	
10.3	Tax Matters Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.3	August 2, 2016	001-37746	
10.4	Employee Matters Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.4	August 2, 2016	001-37746	
10.5	Manufacturing Services Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.5	August 2, 2016	001-37746	
10.6	Canadian Distributor Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.6	August 2, 2016	001-37746	
10.7	Trademark License Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.7	August 2, 2016	001-37746	
10.8	Product License Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc.	8-K	10.8	August 2, 2016	001-37746	
C 10.9	Aptevo Therapeutics Inc. 2016 Stock Incentive Plan	8-K	10.9	August 2, 2016	001-37746	
C 10.10	Aptevo Therapeutics Inc. Converted Equity Awards Incentive Plan	8-K	10.10	August 2, 2016	001-37746	
C 10.11	Aptevo Therapeutics Inc. Senior Management Severance Plan	8-K	10.11	August 2, 2016	001-37746	
C 10.12	Form of Indemnity Agreement for directors and senior officers	10	10.9	April 15, 2016	001-37746	

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
10.13	Fourth and Battery Office Lease, dated as of April 28, 2003, by and between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc. and Genecraft, Inc.) and Selig Real Estate Holdings Eight L.L.C. , or the Seattle Office Lease	10	10.12	April 15, 2016	001-37746	
10.14	Seattle Office Lease Amendment, dated December 8, 2004	10	10.13	April 15, 2016	001-37746	
10.15	Seattle Office Lease Amendment, dated February 1, 2006	10	10.14	April 15, 2016	001-37746	
10.16	Seattle Office Lease Amendment, dated February 2, 2007	10	10.15	April 15, 2016	001-37746	
10.17	Seattle Office Lease Amendment, dated June 7, 2010	10	10.16	April 15, 2016	001-37746	
10.18	Seattle Office Lease Amendment, dated December 21, 2010	10	10.17	April 15, 2016	001-37746	
10.19	Seattle Office Lease Amendment, dated July 17, 2012	10	10.18	April 15, 2016	001-37746	
10.20	Seventh Amendment to Seattle Office Lease, dated December 5, 2014	10	10.19	April 15, 2016	001-37746	
†10.21	License and Co-Development Agreement, dated as of August 19, 2014, by and between Emergent Product Development Seattle, LLC and MorphoSys AG, or the MorphoSys Collaboration Agreement	10	10.20	June 29, 2016	001-37746	
†10.22	First Amendment to MorphoSys Collaboration Agreement, dated June 19, 2015	10	10.21	April 15, 2016	001-37746	
†10.23	Second Amendment to MorphoSys Collaboration Agreement, dated December 7, 2015	10	10.22	April 15, 2016	001-37746	
10.23	Third Amendment to MorphoSys Collaboration Agreement, dated December 12, 2016	8-K	10.1	December 15, 2016	001-37746	
†10.25	Amended and Restated License Agreement, dated as of November 28, 2008, by and between Cangene Corporation (as successor-in-interest to Inspiration Biopharmaceuticals, Inc.) and The University of North Carolina at Chapel Hill, as amended on June 14, 2012	10	10.23	April 15, 2016	001-37746	
†10.26	CMC Commercial Supply (Manufacturing Services) Agreement, dated June 17, 2011, between CMC ICOS Biologics, Inc. and Aptevo BioTherapeutics LLC (as successor-in-interest to Inspiration Biopharmaceuticals, Inc.)	10	10.24	May 31, 2016	001-37746	
†10.27	Settlement and Amendment, dated November 20, 2012, Concerning a Manufacturing Agreement dated December 2, 2005 and a Commercial Supply Agreement dated June 20, 2011 between CMC ICOS Biologics, Inc. and Aptevo BioTherapeutics LLC (as successor-in-interest to Inspiration Biopharmaceuticals, Inc.)	10	10.25	May 31, 2016	001-37746	
†10.28	Supply Agreement, dated April 29, 2014, between Aptevo BioTherapeutics LLC and Rovi Contract Manufacturing, S.L.	10	10.26	May 31, 2016	001-37746	
†10.29	Manufacturing Services Agreement, dated May 27, 2015, Aptevo BioTherapeutics LLC and Patheon UK Limited	10	10.27	May 31, 2016	001-37746	

Exhibit Number	Description	Form	Exhibit	Filing Date	File No.	Filed Herewith
10.30	Credit and Security Agreement, dated August 4, 2016 by and among Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC, Aptevo Research and Development LLC and MidCap Financial Trust, as agent, and the lenders from time to time party thereto.	8-K	10.1	August 5, 2016	001-37746	
10.31	Fee Letter dated August 4, 2016 by and among Aptevo Therapeutics Inc., Aptevo Biotherapeutics LLC, Aptevo Research and Development LLC and MidCap Financial Trust, as agent.	8-K	10.2	August 5, 2016	001-37746	
10.32	Third Amendment to License and Co-Development Agreement, dated as of December 12, 2016 by and between Aptevo Research and Development LLC and MorphoSys AG.	8-K	10.1	December 15, 2016	001-37746	
21.1	Subsidiaries of Aptevo Therapeutics Inc.	10	21	June 29, 2016	001-37746	
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
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 requested 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.

Exhibit 23.1

Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-333-213108) pertaining to the 2016 Stock Incentive Plan and the Converted Equity Awards Incentive Plan of Aptevo Therapeutics Inc. of our report dated March 31, 2017, with respect to the consolidated financial statements of Aptevo Therapeutics Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Seattle, Washington
March 31, 2017

EXHIBIT 31.1

CERTIFICATION

I, Marvin L. 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the 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) 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 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 31, 2017

By: /s/ Marvin White

Marvin White
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Jeffrey G. 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the 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) 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 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 31, 2017

By: /s/ Jeffrey G. Lamothe

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

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Aptevo Therapeutics Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Marvin L. White, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report to which this Certification is attached as Exhibit 32.1 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 31, 2017

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 10-K), irrespective of any general incorporation language contained in such filing."

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Aptevo Therapeutics Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jeffrey G. Lamothe, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report to which this Certification is attached as Exhibit 32.2 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 31, 2017

By: /s/ Jeffrey G. Lamothe

Jeffrey G. 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 10-K), irrespective of any general incorporation language contained in such filing."