EAGLE PHARMACEUTICALS, INC.
Form 10-K
February 28, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
o 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 001-36306
Eagle Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	2834	20-8179278
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677
(201) 326-5300
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)
Securities registered pursuant to Section 12(b) of the Act:
Common Stock (par value $0.001 per share), NASDAQ Global Market
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
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 x No o
Indicate by check mark whether the registrant has submitted electronically 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 such files). Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company” and “emerging growth company” in 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o

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

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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant was approximately $703,596,009 computed by reference to the last reported sale price of $75.66 per share as reported by The NASDAQ Global Market, as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2018. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares outstanding of the registrant's common stock, $0.001 par value per share, as of February 22, 2019 was 13,924,296 shares.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2019 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2018, are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III.

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EAGLE PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
For the fiscal year ended December 31, 2018

Eagle Pharmaceuticals, Inc.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

 References to the "Company," "Eagle Pharmaceuticals," "Eagle," "we," "us" or "our" mean Eagle Pharmaceuticals, Inc., a Delaware corporation and its subsidiary, and references to "Eagle Biologics" mean Eagle Biologics, Inc.

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- our ability to obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our products and product candidates and our ability to successfully commercialize our products and product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our products and product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our products and product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the performance of our strategic collaborators and success of our current strategic collaborations;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing drugs that are or become available;
- the loss of key scientific or management personnel;
- our use of the proceeds from our initial public offering; and subsequent follow-on offering;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; and
- our ability to prevent or minimize the effects of Paragraph IV patent litigation.

Forward-looking statements are statements that are not historical facts. Words such as “believes,” “potential,” “will,” “could,” “would,” “should,” “may,” “intends,” “anticipates,” “plans,” “enables,” “potential,” “entitles,” “estimates,” “projects,” “predict expressions are intended to identify forward-looking statements.

These forward-looking statements reflect our management’s beliefs and views with respect to future events, are based on estimates and assumptions as of the date of this Annual Report on Form 10-K, and are subject to risks and uncertainties. Additionally, these statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted

an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Some of these important factors include our "critical accounting estimates" described in Item 7 in Part II of this Annual Report on Form 10-K and the factors set forth under the caption "Risk Factors" in Item 1A in Part I of this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation

to do so (unless required by law), even if our estimates change, and readers should not rely on our forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I
Item 1. Business

Company Overview

Organization

Eagle Pharmaceuticals, Inc. is a specialty pharmaceutical company registered at and with principal offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677. On November 16, 2016, we purchased all of the outstanding capital stock of Arsia Therapeutics, Inc. (“Arsia”), and subsequently changed its name to Eagle Biologics, Inc. ("Eagle Biologics").

Business

Our business model is to develop proprietary innovations to FDA-approved, injectable drugs, that offer commercial and/or functional advantages to currently available alternatives. We have historically been, and will continue to primarily be, focused on developing and commercializing injectable drugs, primarily in the critical care and oncology areas, using the United States Food and Drug Administration (“FDA”)'s 505(b)(2) New Drug Application (“NDA”) regulatory pathway. With our addition of Eagle Biologics, we hope to apply our market strategy to offer “biobetter” formulations, and to develop novel biologic products under the pathway provided by the Biologics Price Competition and Innovation Act ("BPCIA"). In addition, we plan to continue to market and/or commercialize our products through marketing partners and/or through our internal direct sales force.

For each of our current and future pre-commercial products, we target market entry no later than the entry of the first generic or biosimilar drug with the goal of substantially converting the market by addressing the needs of stakeholders who ultimately use our products. We believe we can further extend commercial duration through new intellectual property protection and/or orphan drug exclusivity and three years of non-patent regulatory exclusivity for future product candidates, as provided under applicable law and regulations. We strive to enhance branded reference drugs to optimize their ease and safety of use for healthcare providers, produce less drug waste, lower cost to stakeholders, and create the opportunity for label expansion to additional indications.

Our 505(b)(2) model has been validated by the approval and successful launches of our novel formulations of Argatroban and Ryanodex® (dantrolene sodium) (“Ryanodex”) and Eagle's bendamustine ready-to-dilute ("RTD") 500ml solution (“Big Bag” or "Belrapzo"); marketed by Eagle, and rapidly infused bendamustine RTD (“Bendeka”); marketed by Teva, licensed to and launched jointly with Teva Pharmaceutical Industries Ltd. (“Teva”) in January 2016. We are in the early stages of development with our biologics strategy and do not currently have any commercially approved biologics products.

Our product portfolio now includes four approved products: Argatroban; Ryanodex; Belrapzo; and Bendeka. We have three commercial partners: Teva, which through its subsidiary Cephalon, Inc. ("Cephalon") markets Bendeka, and Chiesi USA, Inc. ("Chiesi") and Sandoz Inc. (“Sandoz”), who pursuant to separate agreements market Argatroban.

We currently have multiple product candidates in advanced stages of development, and/or under review for approval by the FDA. Additionally, we have other exploratory candidates under a collaborative agreement entered into in January 2016 with Albany Molecular Research, Inc. (“AMRI”). Our advanced product candidates are EP-4104 (dantrolene sodium for exertional heat stroke (“EHS”)) (“EP-4104”), EP-5101 (PEMFEXY™), a pemetrexed injection ready-to-dilute formulation (“EP-5101”) and EGL-5385-C-1701 (fulvestrant). EP-5101 has been tentatively approved by the FDA. EGL-5385-C-1701 and EP-4104, both unapproved, may address unmet medical needs in major specialty markets.

In 2018, we accomplished the following with respect to our product portfolio:

- On April 16, 2018, we announced the FDA's acceptance of our Abbreviated New Drug Application ("ANDA") filing for vasopressin injection, 1ml. This product is the generic version of Endo International plc's original Vasostrict® formulation, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

- On May 15, 2018, the FDA granted final approval for our ready-to-dilute bendamustine hydrochloride solution in a 500ml admixture ("Big Bag") for the treatment of patients with chronic lymphocytic leukemia (“CLL”) and patients with indolent B-cell non-Hodgkin lymphoma (“NHL”) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. We immediately launched this product upon FDA approval.

- On August 30, 2018, we announced the completion of enrollment of our second clinical study to further evaluate the safety and efficacy of Ryanodex (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke, an investigational new indication for the product.

- On October 3, 2018, we announced we had entered into an agreement with the United States Army Medical Research Institute of Chemical Defense, the nation’s leading science and technology laboratory in the area of medical chemical countermeasures research and development, to conduct a study to evaluate the neuroprotective effects of Ryanodex.

- On November 27, 2018, we announced positive results of a pre-clinical study conducted to evaluate the effects of Ryanodex in Acute Radiation Syndrome.

In addition to building our product portfolio, we continue to develop our commercial organization. We have built an internal commercial team consisting of approximately 50 direct sales representatives, support staff and management who are a part of our independent commercial organization.

Product Portfolio

Our product portfolio consists of:

Product	U.S. Brand Reference Drug	Description	Indication	Estimated Market Opportunity (amounts in millions)	Status
Ryanodex® (dantrolene sodium)	Dantrium®/ Revonto®	Muscle relaxant	Malignant hyperthermia	$75[2]	Approved (U.S.)/ launched August 2014; orphan drug exclusivity received for MH (U.S.)
Argatroban	Argatroban	Anti-coagulant; thrombin inhibitor	Heparin-induced thrombocytopenia	$99[2]	Approved (U.S.); marketed by Chiesi USA, Inc. and Sandoz
BENDEKA™	BENDEKA™	Chemotherapeutic agent	CLL; Indolent NHL	$642[1] [3]	Approved (U.S.) in December 2015; licensed to and marketed by Teva; orphan drug designation for CLL and NHL (U.S.)
Belrapzo (bendamustine RTD)	Treanda®	Chemotherapeutic agent	(CLL); Indolent (NHL)	$642[1] [3]	Approved (U.S.) and launched for CLL and NHL in May 2018
EP-4104 (dantrolene sodium)	No drug currently approved	Muscle relaxant	Exertional heat stroke	$400[2]	Orphan drug designation received for heat stroke (U.S.); IND submission in 2015; completed safety and efficacy study in December 2015; FDA granted fast track designation and NDA submitted in January 2016; additional clinical trial requested by FDA in 2017
EP-5101 (PEMFEXY™)	Alimta	Chemotherapeutic agent	Lung cancer and mesothelioma	$1,131[1]	NDA submitted December 2016; tentative approval received in October 2017
EGL-5385-C-1701 (fulvestrant)	Faslodex	Selective estrogen receptor degrader	Metastatic breast cancer	$537[1]	Pre-NDA submission

Vasopressin injection 1ml	Vasostrict	Crash cart item in hospital settings	Indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines	$454 [1]	FDA accepted our ANDA filing

[1]Based on publicly filed reports with the SEC.
[2]Based on independent market research and management's estimates extrapolated there from.
[3]Benedeka and Belrapzo are part of the same estimated market opportunity.

Our Competitive Strengths
Our Purpose

We believe that many currently available critical care and oncology injectable drugs and biopharmaceuticals have suboptimal characteristics that do not meet the needs of patients, physicians, nurses or pharmacists. These characteristics can impact safety, shelf life, convenience, waste, cost, and ease of use by practitioners and pharmacy staff. For instance, existing drugs may be

packaged inefficiently or come in formulations that require reconstitution or dilution, or which are otherwise difficult or inconvenient to prepare, and which could expose workers to cytotoxic compounds and can result in dosing errors. This can also lead to wasted quantities of drug, inefficiencies in staff time and constrained work flow, reduced shelf life and the need for multiple dosing of individual patients to complete treatment. Likewise the viscosity of many biologic products requires them to be delivered intravenously often in time consuming and sometimes painful treatments for patients. We believe there is a large and unmet market for developing injectable drugs that address the specific needs of patients, physicians, nurses and pharmacists to simplify their use, reduce waste and lower healthcare costs.

We believe that our management's unique knowledge of the industry as well as the biopharmaceutics formulation acumen presented by Eagle Biologics combine to enable us to compete effectively in the market for injectable therapeutics in both small and large molecule markets. We look to continue to exploit these strengths in order to build upon our portfolio of attractive assets.

We have and continue to engage physicians, nurses, pharmacists and key opinion leaders, to identify specific products where the characteristics described above present opportunities for product improvement. We evaluate the product opportunities presented by the stakeholders and determine whether or not they conform to our research and development planning. A key aspect of our evaluation is the intellectual property landscape for each product opportunity, including our ability to avoid infringing existing patents and the potential patentability of our modified version of the drug. We utilize our experienced team of formulators with extensive experience with injectable pharmaceuticals, and a track record of success in product development, regulatory relations, and quality assurance to develop improved products.

Because our products are differentiated from the branded reference drugs, we believe we are able to avoid infringing existing patents covering the branded reference drug allowing us to enter the existing market no later than applicable generic drugs, which may be subject to protracted patent litigation that delays market entry. Protracted litigation is a significant barrier to entry for competitors seeking approval of an ANDA referencing the branded reference product, and our early entry into the market leads to less price erosion due to constrained competition. Our patent estate includes over 30 owned or exclusively-licensed U.S. issued patents and over 10 filed U.S. patent applications, as well as several patents and patent applications that have been filed in various worldwide territories, that we believe protect or will protect, as applicable the market value of our current portfolio of products. We believe that other potential barriers to entry for our competitors consist of the following:

- our early entry into the market allows us to influence usage patterns when fewer, if any, competitors exist and allows us to market our products as improved versions of the branded reference drug prior to or concurrent with any generic entry, thereby giving us the opportunity to capture significant market share at this early stage. We believe that such early entry into the market will limit later conversions into generic versions of the branded reference drugs, deterring competition and allowing us to maintain market share and favorable pricing;
- the potential for seven years of exclusivity upon approval of a 505(b)(2) NDA that receives orphan drug status; and
- the potential for three years of regulatory exclusivity for our future product candidates upon approval, if any, of a 505(b)(2) NDA supported by new clinical investigations (other than bioequivalence and bioavailability studies) essential to approval of the application.

Our product portfolio is focused on oncology, critical care, and orphan diseases and includes four approved products, a tentative approval, and several distinct product candidates in advanced development. Additionally, we have other exploratory candidates under our collaborative agreement with AMRI, and are developing a “biobetters” pipeline at our subsidiary, Eagle Biologics. We believe that we can leverage our formulation and development expertise to achieve improved product attributes in terms of potential for longer stability, shorter infusion times, less waste and/or ease and safety of use for healthcare professionals and achieve longer commercial duration compared to generic competitors. We believe that our products may offer certain benefits as compared to existing injectable drugs which may include

one or more of the following:

- improved safety through elimination of reconstitution in the pharmacy or in the acute care setting;
- reduction in the number of injections required;
- reduction in the volume of drug needed to be injected, potentially expanding the application to additional medical situations;
- reduction in the amount of diluent required to administer the drug;
- reduction in drug waste;
- reduction in drug infusion time; and
- potential label expansion to include additional indications.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company focused on the development and commercialization of injectable

pharmaceutical products for use in acute care settings that represent an improvement over the currently marketed reference drug. Our strategy to achieve this goal includes:

Enter the market no later than the first generic drug. We intend to enter the market no later than the first generic or biosimilar of the branded reference drug. During this period, the number of competitors is lowest and branded drugs are generally at peak or near peak value. This will allow us to influence usage patterns and market our products as improved versions, thereby achieving favorable pricing. Even if we enter the market simultaneously with, or after, the first generic drug, as a 505(b)(2) applicant, we would be able to enter the market without regard to any generic drug's 180-day exclusivity period.

Retain commercial rights in the United States and selectively partner outside of the United States. In general, we believe that we can cost-effectively commercialize our products in the United States internally or through a contracted sales force and selected commercial arrangements, and thereby retain the commercial value of these products. We have established a small, contract specialty sales force focusing on GPOs, hospital systems and key stakeholders in acute care settings, primarily hospitals. Outside of the United States, we may utilize partners for the commercialization of our products.

Strengthen our product portfolio. We intend to continue to strengthen our product portfolio in the areas of oncology, critical care and orphan diseases. We will continue to develop our current product portfolio and leverage our expertise to identify new products with suboptimal characteristics that present us with significant opportunity for revenue generation. In addition to our internal efforts, we will opportunistically in-license or acquire product candidates that fit our therapeutic areas of focus and meet our rigorous evaluation process.

Continue to build a robust intellectual property portfolio. Our patent estate includes over 30 owned or exclusively-licensed U.S. issued patents and over 10 filed U.S. patent applications, as well as several that have been filed in various worldwide territories, that protect or will protect, as applicable the market value of our approved and pipeline products. We intend to continue to build our patent portfolio by filing for patent protection on new developments with respect to our product candidates that will not infringe patents that cover the branded reference drugs. We expect that these will, if issued, allow us to list our own patents in the Orange Book, to which potential competitors will be required to certify upon submission of their applications referencing our products, if approved.

Our Products and Product Portfolio

Belrapzo and Bendeka (Licensed to Teva and SymBio) for Chronic Lymphocytic Leukemia and Non-Hodgkin's Lymphoma

Overview

Bendamustine is an alkylating agent approved for use in CLL, and indolent B-cell NHL, that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen (which we refer to herein as the NHL indication).

U.S. Marketed Bendamustine Products

Teva currently markets its lyophilized bendamustine product under the trade name Treanda®. Teva ceased distribution of Treanda® liquid on March 30, 2016.

Limitations of Marketed Bendamustine Products

Treanda® is a lyophilized powder that requires reconstitution in water prior to use. A 500 mL intravenous (IV) administration is used over 30 or 60 minutes for CLL and NHL patients, respectively. The product is sold in single use vials creating an opportunity for product waste in certain applications.

Eagle's Solution: Belrapzo and Bendeka

The Belrapzo and Bendeka liquid formulations eliminate the need to reconstitute the drug prior to use, relative to the lyophilized presentation of Treanda®. As a result, we believe that relative to the lyophilized presentation of Treanda® there is less potential for dosing errors, less exposure to cytotoxic powders and a more efficient work flow.

Additionally, admixtures prepared with Bendeka contain lower sodium as compared with Treanda® which could be of benefit to the predominantly elderly, renally impaired and cardiovascular compromised patients. Also, Bendeka is available in a multi-use

vial, which allows infusion centers and hospitals to avoid needless waste of unused drug remaining after procedures with single use vials.

Big Bag

On May 15, 2018, the FDA granted final approval for Big Bag, a ready-to-dilute (“RTD”), multi-dose liquid with extended drug stability for use with a 500mL intravenous, or IV, infusion bag.

Teva License- Bendeka

Bendeka is the same RTD, multi-dose liquid formulation as Belrapzo, with extended drug stability, but for use with a 50 mL IV infusion bag, which enables it to be administered in a shorter time-period than current drugs on the market and represents a label expansion from Belrapzo. We received orphan drug designation for Bendeka for CLL and NHL in July 2014. We entered into the Cephalon License to market this product. See License Agreements - Bendamustine License Agreement, below.

Argatroban for Heparin-Induced Thrombocytopenia

Argatroban is an anti-coagulant originally developed for the treatment of heparin-induced thrombocytopenia ("HIT"). Our formulation of Argatroban, was our first product approved by the FDA and is marketed by Chiesi and Sandoz under separate agreements with us. See License Agreements - License and Distribution Agreement - Chiesi; and Settlement Agreement and Related Supply and Distribution Agreement with Sandoz, below.

Currently-Marketed Argatroban Products

Argatroban is currently sold by GlaxoSmithKline (“GSK”), West-ward, Chiesi and Sandoz. It is sold in 250mL (GSK and West-ward), 125mL (Sandoz) and 50mL (Chiesi and Sandoz) presentations. According to IQVIA Holdings Inc., Argatroban had U.S. annual sales of $39 million in 2018.

Limitations of Argatroban Marketed Products

The branded form of argatroban from GSK and West-ward is supplied in a 2.5 mL vial with 100 mg/mL of active pharmaceutical ingredient. In this formulation, the current product requires 100-fold dilution for infusion, requiring the use of a 250 mL intravenous bag, typically resulting in approximately 30% waste primarily driven by prophylactic administration while waiting for HIT testing results, common infection control policies requiring change of intravenous bags every 24 hours and patient release from hospital prior to complete administration.

Eagle's Solution: Argatroban Injection

Our formulation of Argatroban is supplied in a single-use vial, containing 50mg of drug in a 50mL aqueous solution, where only 1% of the drug is wasted. Argatroban is ready to use and the vial label contains a ring sling for convenient IV pole administration. It was approved by the FDA on June 29, 2011, for treatment of HIT in patients.

Ryanodex® for Malignant Hyperthermia

Overview

Dantrolene was first introduced to the U.S. market in 1979 and is currently the only drug approved to treat a rare genetic disorder called malignant hyperthermia ("MH"). There are only 500 to 800 cases of MH in the United States each year, qualifying dantrolene for orphan drug designation. This disease is triggered when a patient with this genetic

predisposition has a surgical procedure and is exposed to certain inhaled anesthetics or the muscle relaxant, succinylcholine. When this exposure occurs, a metabolic response can be triggered in the patient resulting in an episode of MH that can be fatal if not treated immediately. Because dantrolene is the only approved drug available to treat MH, the Joint Commission on Accreditation of Healthcare Organizations, (the "Joint Commission") requires that all hospitals stock vials of this product at all times, generally in the operating room area.

Currently-Preexisitng Dantrolene Products for MH

The two preexisting injectable dantrolene drugs on the market for the treatment of MH, Dantrium® and Revonto®, are offered in a vial containing 20mg of lyophilized powder that requires mixing with 60mL of sterile water. We estimate that the addressable

U.S. market opportunity for MH drugs is approximately $75 million per year.

Limitations of Dantrium® and Revonto®

When an MH crisis occurs during surgery, the surgical procedure is immediately discontinued and the anesthesiologist and others in the operating room quickly begin reconstituting dantrolene, often at the same time as performing other resuscitative efforts, in order to administer the drug to the patient as an IV push. Based on recommendations from the Malignant Hyperthermia Association of the United States ("MHAUS"), the recognized authority on treating MH in the United States, the recommended dose is 2.5mg/kg or higher. It is critically important that the drug be administered as rapidly as possible, as MH symptoms include tachycardia, elevated blood pressure, raised CO_2 levels and very high body temperature levels. If not treated immediately, the disease can be fatal.

Because of the dosing required in adult patients to reverse the MH symptoms and the current formulations of Dantrium® and Revonto®, it is often necessary to reconstitute 10 to 20 vials of dantrolene. As the current formulations are also poorly water soluble, this process generally takes up to 15 to 20 minutes at a point when time is critical and the patient is extremely unstable. Furthermore, the volume of diluent required to reconstitute Dantrium® and Revonto® means that the adult patient receives a significant volume of fluid (600mL to 1,200mL) as an IV infusion, which on occasion can result in detrimental secondary physiological consequences for the patient, such as pulmonary edema and extravasation, which can lead to tissue necrosis.

Eagle's Solution: Ryanodex®

We have developed a differentiated formulation of dantrolene sodium that was approved by the FDA in July 2014 and is currently sold under the brand name, Ryanodex®, for the treatment of MH. The presentation is a 5ml vial containing 250mg of dantrolene sodium in lyophilized powder form.

We believe that the immediate benefits of our Ryanodex® formulation are clinically significant in critical care situations. Specifically, Ryanodex® reduces the amount of time to reconstitute and administer dantrolene from 15 to 20 minutes with Dantrium® and Revonto®, to 1 minute, as the anesthesiologist will be able to mix and administer a dose of 250mg from a single vial of Ryanodex® in contrast to mixing and administering up to 12 or more vials of Dantrium® or Revonto®. A recent retrospective study conducted by MHAUS demonstrated that every 15-minute delay in treating MH resulted in a 7.8% increase in patient complications.

EP-4104 (dantrolene) for Exertional Heat Stroke ("EHS")

EHS is a rare, sudden and unpredictable life-threatening medical condition. It is thought that symptoms and effects are correlated to MH and our research and development efforts suggest dantrolene may be beneficial for treating EHS.

EHS is one of the leading causes of death in athletes, including college and high-school students. EHS is also a leading cause of non-combat death in the military. EHS is a state of extreme hyperthermia (above 104°F) that occurs when heat that is generated by muscular exercise exceeds the body's ability to dissipate it. EHS typically affects seemingly healthy individuals during exercise and manifests within a few minutes to hours of such activity and is characterized by an increased core body temperature and central nervous system dysfunction including delirium, convulsions, and coma. Predisposing factors to EHS include a lack of heat acclimatization, poor physical fitness, dehydration, recent infection, exercising in warm and humid conditions and concurrent illness.

Limitations of Current EHS Therapies

There are currently no FDA-approved products that treat EHS, and patients continue to die or suffer significant morbidity from the condition. The current treatment regimen for EHS is not directed at the underlying cause of the

disease, but is essentially symptomatic therapy. Currently, to treat EHS, the standard treatment includes body surface cooling by water immersion or ice packs and support of organ system function with a goal of accelerating the transfer of heat from the skin to the environment. Even if these cooling techniques are properly implemented patients are still subject to risk of brain damage, irreversible organ damage and death.

Eagle's Solution: EP-4104

EP-4104's presentation will initially be a 5mL vial containing 250mg of dantrolene in lyophilized powder form requiring reconstitution. We believe that EP-4104 may provide significant benefits over the current standard of care, which may not be

readily available in most settings. Independent market research commissioned by us suggests that the worldwide peak annual revenue for EHS could exceed $400 million.

EP-4104 Clinical Development and Regulatory Status

In February 2016, the FDA granted Fast Track designation to our product candidate EP-4104 (i.e. Ryanodex® for the treatment of EHS). The FDA's Fast Track program facilitates the development and review of drugs intended to treat serious conditions and address an unmet medical need. A drug development program with Fast Track designation is afforded greater access to the FDA for the purpose of expediting the drug's development, review and potential approval to get important new drugs to the patient earlier.
On July 11, 2016, the FDA determined that no additional human safety and efficacy data would be required for the submission of EP-4101. Following the completion of additional animal studies the NDA was submitted on January 20, 2017.

On July 26, 2017, we received a Complete Response Letter from the FDA regarding our 505(b)(2) NDA for Ryanodex for the treatment of exertional heat stroke (“EHS”), in conjunction with external cooling methods. Based on our meeting with the FDA, the Company conducted an additional clinical trial in August 2018 during the Hajj pilgrimage, similar to the study conducted during the Hajj in 2015. On August 30, 2018, we announced the completion of enrollment of our second clinical study to further evaluate the safety and efficacy of Ryanodex. During the 2018 Hajj, overall emergency room visits were dramatically decreased from previous years due to well-implemented crowd management, lower temperatures, lower humidity and other external factors. As a result, the number of EHS patients available for study enrollment was also significantly less than in previous years, and therefore much lower than anticipated. The preliminary assessment of patients enrolled is consistent with the data from the study conducted in 2015, in which patients dosed with Ryanodex plus Standard of Care (“SOC”) showed an additive benefit compared to patients receiving SOC only. We intend to complete the analysis of the data and meet with the U.S. Food and Drug Administration to discuss next steps in 2019.

EP-5101 (PEMFEXY™) for Lung Cancer

EP-5101 is an IV-administered cancer agent indicated for locally advanced or metastatic non-small cell lung cancer and mesothelioma. We are developing EP-5101 as a ready-to-use/dilute liquid form of pemetrexed that will be available in a 25mg/mL per vial. Because our product, if approved, will be available in liquid form, product reconstitution will not be required, making EP-5101 a preferred formulation under the Joint Commission guidelines.

Currently-Marketed Pemetrexed Product

The branded form of a pemetrexed product is marketed by Lilly Pharmaceuticals as Alimta. Alimta is approved for use to treat non-small cell lung cancer and mesothelioma. Alimta's lyophilized formulation utilizes pemetrexed disodium. The product presentations for Alimta are 100mg and 500mg single use vials containing lyophilized power that must be reconstituted before patient administration. Once mixed, Alimta must be used within 24 hours due to product stability concerns. According to Lilly Pharmaceuticals, worldwide sales of Alimta for the 2017 calendar year were approximately $1.0 billion.

Limitations of Alimta

Alimta, a lyophilized pemetrexed disodium formulation requiring reconstitution, adds time to administration, presents cytotoxic safety issues for healthcare professionals administering the drug and the potential for dosing errors. Because reconstitution of Alimta is generally not performed until the patient has cleared all tests necessary to receive the drug, this process contributes to a significant amount of time spent by such patients in infusion clinics. Additionally, this

method of administration limits the number of patients that may be treated on any given day by such clinics. Furthermore, as with any oncology drug, cytotoxic vapors released through reconstitution can be potentially harmful to pharmacists, physicians and nurses. Moreover, dosing errors may occur during reconstitution, as incorrect amounts of diluent may be used. As a result, lyophilized formulations are less preferred by the Joint Commission as compared to an RTD product.

Eagle's Solution: EP-5101 (PEMFEXY™)

EP-5101 is an RTD liquid formulation of pemetrexed. As an RTD liquid formulation, EP-5101 will not require additional time for reconstitution and may avoid certain safety concerns to healthcare professionals, including reducing exposure to the drug's cytotoxic

vapors during reconstitution by healthcare providers, and potential dosing errors during mixing. This could allow for a more efficient work flow within the infusion clinic and may result in an opportunity to reduce office staff and see more patients each day.

EP-5101 (PEMFEXY™) Development and Regulatory Status

We submitted an NDA for EP-5101 on December 30, 2016 for use in non-small cell lung cancer and mesothelioma. During February 2017, we received confirmation from the FDA that the filing was accepted. On October 27, 2017, we were granted tentative approval for EP-5101 by the FDA.

EGL-5385-C-1701 (fulvestrant) for Breast Cancer

Fulvestrant is an injectable estrogen receptor antagonist. It is used for the treatment of hormone receptor positive advanced breast cancer for post-menopausal women whose disease has progressed following treatment with prior endocrine therapy.

Currently-Marketed Fulvestrant Products

The branded form of fulvestrant is Faslodex, a 500mg injectable product marketed by AstraZeneca plc. Worldwide sales of Faslodex were $941 million in 2017, which included US sales of $492 million.

Limitations of Faslodex

Faslodex is administered in two deep intramuscular injections of high viscosity product per dose of treatment (5 ml each) over 1-2 minutes into each buttock. The procedure is painful and Faslodex injection reactions have been associated with peripheral nerve adverse reactions, including risk of damaging the sciatic nerve.

Eagle’s Solution: EGL-5385-C-1701

On October 30, 2018, we announced that the Company’s fulvestrant formulation has not met the primary pharmacokinetic endpoint evaluating the bioequivalence of the Company’s formulation compared to Faslodex in its open label, randomized, pharmacokinetic and safety study conducted in 600 healthy female volunteers across multiple U.S. sites. Eagle continues to pursue development of an innovative formulation that would require a single injection using a smaller needle thus requiring less time to dose the product while potentially reducing the pain and adverse reactions to injection. The 500 mg dose would be delivered in a single low viscosity 5 mL injection.

Additional Products in our Portfolio

Vasopressin
Vasopressin injection is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. We filed and ANDA in April 2018 for a generic version of VASOSTRICT® (vasopressin IV solution (infusion)), which variously covers either vasopressin-containing pharmaceutical compositions or methods of using a vasopressin-containing dosage form to increase blood pressure in humans. In May 2018, the NDA owner filed a lawsuit against us within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. In August 2018, Eagle filed an answer and a counterclaim for non-infringement and invalidity of asserted patents. A claim construction hearing is scheduled for May 2019, with a bench trial scheduled for May 2020.

Other Opportunities

We are pursuing several additional potential products and product indications that address broad indications such as oncology, emergency medicine, infectious diseases and others. We intend to use our novel and well-developed methods to identify ideal development candidates and to commercialize improved formulations of widely prescribed therapeutics.

In addition to our internal efforts, in January 2016 we entered into an agreement with AMRI to jointly develop and manufacture several select and complex parenteral drug products for registration and subsequent commercialization in the United States.

Under the terms of the agreement, AMRI will develop and initially provide cGMP manufacturing and analytical support for the registration of the new product candidates. We will be responsible for advancing the product candidates through clinical trials and regulatory submissions.

Eagle Biologics

On November 16, 2016, we acquired Arsia Therapeutics, Inc. and subsequently changed its name to Eagle Biologics, Inc. Eagle Biologics was founded in 2013 as an early stage corporation focused on using proprietary technology to significantly improve both approved and novel biologic pharmaceutical products. The technology we acquired in the acquisition enables low-viscosity, high-concentration monoclonal antibody (mAb) formulations to be delivered subcutaneously. Our aim is threefold: (i) to improve the formulation of biologic products thereby providing a market advantage with a differentiated product; (ii) to create IP around the formulation optimization extending market exclusivity, and (iii) to do so in an efficient manner, using as much reference-product data as possible to minimize clinical trial time and expense. The opportunity is driven by a library of patent protected excipients for use in pharmaceutical products.

Our plan for our biologics business is to partner with large pharmaceutical and biotech companies to improve the delivery of marketed biologics by eliminating IV infusions in favor of subcutaneous ("SC") routes of administration or, in cases where a SC product exists, to reduce the volume or number of injections. Currently, Eagle Biologics has feasibility study agreements in place with multiple partners to apply its technology to designated proteins. Once proof of concept has been established, and an opportunity is identified with a particular protein, Eagle Biologics plans to enter into a License and Development Agreement with the sponsor company to develop and seek FDA approval for the "biobetter." As of this filing, Eagle Biologics has no product in late stage development.

The formulation and development of biologic and/or biosimilar drugs is a highly competitive business and competition includes some of the industry's largest and well-funded pharmaceutical companies. Eagle Biologics will seek opportunities in this growing field to develop and market its "bio-better" products through collaborations with these companies.

Sales and Marketing

Historically, we have chosen to out-license the commercial rights for products we have developed, such as Argatroban and is sold by both Chiesi under an exclusive license from us, and by Sandoz as part of a settlement of a paragraph IV dispute between the parties and rights to our bendamustine rapid infusion product for treatment of patients with CLL and patients with NHL pursuant to the terms of the Cephalon License.

Other than with respect to products subject to existing commercialization arrangements, we intend to commercialize our product portfolio in the United States with our commercial organization. To expand our footprint in the Ryanodex® for MH market we have built an internal commercial team consisting of approximately 50 direct sales representatives, support staff and management who are a part of our independent commercial organization.

Manufacturing

We do not own any manufacturing facilities. The manufacture of sterile injectables is highly reliant on very complex sterile techniques and personnel aseptic techniques which present significant challenges and requires specialized expertise. Further, sterile processes have a high level of scrutiny by regulatory agencies. Consequently, we utilize a network of third party manufacturers for production of our products. All manufacturers are monitored and evaluated by our quality department to assess compliance with regulatory requirements and our internal quality standards and benchmarks.

Historically, sterile injectable manufacturers have, from time to time, had quality control difficulties. If non-conformances occur, remediation, such as temporary voluntary closure or renovations of major production facilities, could be costly and time consuming, resulting in cascading and persistent shortages. Moreover, high rates of capacity utilization may also limit the ability of manufacturers to perform routine maintenance and keep facilities in state of compliance which can lead to product recalls or other supply disruptions.

We have a highly experienced quality group that works with and regularly inspects or meets with our manufacturers to review the manufacturing process for our products and to provide input on quality issues. We have recognized the risk of such supply chain disruptions and approached the situation through risk management strategies designed to mitigate the effects of such disruptions. These include having our products and product candidates manufactured at more than one site around the world. While this creates additional effort and requires maintaining dialog and traveling to and overseeing production at a number of facilities, we believe our manufacturing risks are better managed by utilizing a range of third party manufacturers at diverse locations. We seek to minimize the risk of catastrophic events that could occur if our products were manufactured in a single location. Currently, with the exception of one site, no contract manufacturer produces more than one product for us. We currently utilize two manufacturing sites in India and four manufacturing site in the United States. We plan to manufacture the additional products in our portfolio at additional sites in the United States.

Intellectual Property and Exclusivity

We strive to protect and enhance the proprietary technologies that we believe are important to our business. We seek to obtain and maintain patents for any patentable aspects of our products or product candidates, their methods of use and any other inventions that are important to our business model and maintaining a competitive advantage over generic competitors. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our products and product candidates.

Patents and Patent Applications

We are the exclusive licensee under our license with Lyotropic to a family of patents and applications that relate to low volume formulations of dantrolene, and methods of treatment using dantrolene. There are eight issued U.S. patents, and several pending U.S. patent applications, along with foreign counterparts that include both issued patents and pending applications. The issued U.S. patents cover low volume formulations of dantrolene in reconstitutable and in ready to use liquid form. We expect that the issued patents will expire no later than July 1, 2025.

We are the sole owner of over 10 issued patents, several pending U.S. patent applications, and multiple patents and/or corresponding foreign filings for patent applications in a number of jurisdictions covering various formulations and methods of use of bendamustine. We are currently prosecuting these applications, which, if issued, would expire between 2031 and 2033.

We are the sole owner of a portfolio of issued U.S. patents and pending applications, and corresponding issued foreign patents and patent applications in a range of countries that cover various formulations and methods of use of Argatroban. We expect that our issued patents in the United States will expire no later than September 26, 2027, and our applications, if issued, will expire no later than October 9, 2027.

We are the owner of U.S. Patent 8,431,539 expiring July 20, 2031 and covering daptomycin.

Eagle also has a patent portfolio of issued and/or pending U.S. patent applications and corresponding foreign patent application in a range of countries that cover its biologics platform technologies. We are the sole owner of U.S. Patent Nos. 9,833,513, 9,913,905 and 9,925,263 expiring between 2034 and 2036.

Trade Secrets and Proprietary Information

Trade secrets play an important role in protecting our products and provide protection beyond patents and regulatory exclusivity. The scale-up and commercial manufacture of our products involves processes, custom equipment, and in-process and release analytical techniques that we believe are unique to us. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these security measures, individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our proprietary technology and processes may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors, contractors or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We seek to protect our proprietary

information, including our trade secrets and proprietary know-how, by requiring third parties with whom we contract for services related to our products, including manufacturing services to agree to terms in our agreements with such third parties that protect our confidential and trade secret information. We also require our employees, consultants and other advisors to execute proprietary information and confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention obligations. Further, we require confidentiality agreements from entities that receive our confidential data or materials.

License Agreements

License Agreement with Lyotropic Therapeutics, Inc.

In October 2008, we entered into a license and sublicense agreement with Lyotropic Therapeutics, Inc., ("Lyotropic"), under which we were granted an exclusive license under Lyotropic's intellectual property rights relating to dantrolene, and an exclusive worldwide sublicense under certain nanocrystal technology relating to a formulation of dantrolene licensed by Alkermes, Inc. (as successor in interest to Elan Pharma International Limited), or Alkermes, to Lyotropic under an August 2004 license agreement between Alkermes and Lyotropic. On August 3, 2016, the Company amended our agreement with Lyotropic Therapeutics, Inc. to reduce future royalties related to Ryanodex net sales to 3% (subject to further reduction upon the occurrence of certain triggering events) in exchange for $15 million.

License and Development Agreement with Chiesi

In September 2009, we entered into a license and development agreement with The Medicines Company which was assigned by the Medicines Company to Chiesi on September 24, 2016. Under the agreement, Chiesi has an exclusive license under our patent and other intellectual property rights in argatroban to commercialize Argatroban products in the United States and Canada, and a right of first negotiation to commercialize Argatroban in other countries (except the right of first negotiation does not apply to China unless and until we regain rights to commercialize Argatroban products in China).

Under this agreement, we received an upfront lump sum payment of $5.0 million. Additionally, we are obligated to share equally gross profits with Chiesi that we receive from Sandoz pursuant to the Sandoz Supply and Distribution Agreement and Chiesi is obligated to share equally with us the gross profits it receives from sales of Argatroban product in the United States.

Settlement Agreement and Related Supply and Distribution Agreement with Sandoz

In January 2013, we entered into a settlement agreement with Sandoz to resolve the lawsuit we brought against Sandoz claiming infringement of our issued U.S. patents 7,589,106 and 7,687,516, based on Sandoz's filing of ANDA No. 203743, in which Sandoz requested approval from the FDA for distribution of Argatroban prior to the expiration of such patents. In connection with, and at the same time as the settlement agreement, we also entered into a Supply and Distribution Agreement with Sandoz, under which we agreed to supply unbranded (generic) Argatroban in 50mg/50mL vials, which we define as an Authorized Generic Product, to Sandoz through our contract manufacturer for exclusive distribution to Sandoz's customers in the United States.

Under the terms of the Supply and Distribution Agreement, Sandoz is obligated to pay us a percentage in the range of 85 to 95 percent of the net profits for all Authorized Generic Product sold by Sandoz. Also, under the terms of the Supply and Distribution Agreement, Sandoz will continue to market argatroban in 125mg/125mL vials, which we define as a Sandoz Product, and Sandoz is obligated to pay us a percentage in the range of 60 to 70 percent of the net profits of all Sandoz Product sold by Sandoz.

Development and License Agreement with SciDose (Argatroban and bivalirudin)

In June 2007 we entered into a development and license agreement with SciDose, LLC ("SciDose") in which SciDose assigned us certain patents relating to Argatroban, bivalirudin, and two additional products under development or (the "SciDose Subject Products") and granted us an exclusive, sub-licensable, worldwide (excluding China for all products except ANDA products containing bivalirudin) license under SciDose's intellectual property rights to develop, make, use, sell and import parenteral formulations of the SciDose Subject Products (and including all other formulations for one of the additional products under development).

Under the terms of this Agreement, no further milestone payments are due to SciDose. We are required to make royalty payments based on gross profits of sales of the SciDose Subject Products by us and our affiliates (i) at 15% for Bivalirudin products, pursuant to an amendment in 2015, and at 50% for other SciDose Subject Products that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application (provided that we are entitled to recoup all of our expenses related to the development of a product commercialized under a 505(b)(2) application prior to splitting the profits we receive from such product), (ii) at 30% with respect to SciDose Subject Products that are commercialized on the basis of an ANDA application and (iii) at 20% with respect to other Scidose subject products. Our royalty obligations continue on a product-by-product basis until the later of ten years after the first commercial sale of each SciDose Subject Product and the expiration of the last valid claim covering such SciDose Subject Product, subject to certain customary reductions in the event that there is no valid patent claim covering the manufacture, use, import or sale of such SciDose Subject Product in a country in the territory.

Development and License Agreement with Robert One, LLC (bendamustine)

In March 2008 we entered into a development and license agreement with Robert One, LLC ("Robert One") in which Robert One assigned to us certain patents relating to bendamustine and four additional 505(b)(2) products and/or ANDA products under development (the "Robert One (bendamustine) Subject Products") and granted us an exclusive, sub-licensable, license under Robert One's intellectual property rights to develop make, use, sell and import Robert One (bendamustine) Subject Products worldwide (excluding China) with respect to bendamustine and other 505(b)(2) product applications and in North America with respect to ANDA product applications.

Under the terms of this Agreement no further milestone payments are due to Robert One. We are required to make royalty payments based on gross profits of sales of the Robert One (bendamustine) Subject Products by us and our affiliates in the Territory (i) at 10%, pursuant to an amendment in 2013, for bendamustine products and (ii) at 50% for products, other than bendamustine products, that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application (provided that we are entitled to recoup all of our expenses related to the development of a product commercialized under a 505(b)(2) application prior to splitting the profits we receive from such product), and (iii) at 30% with respect to products, other than bendamustine products, that are commercialized on the basis of an ANDA application. Our royalty obligations continue on a product-by-product basis until the later of ten years after the first commercial sale of each Robert One (bendamustine) Subject Product and the expiration of the last valid claim covering such Robert One (bendamustine) Subject Product, subject to certain reductions in the event that there is no valid patent claim covering the manufacture, use, import or sale of such Robert One (bendamustine) Subject Product in a country in the territory.

Development and License Agreement with Robert One, LLC (pemetrexed)

In February 2009 we entered into a development and license agreement with Robert One, in which Robert One assigned to us certain patents relating to pemetrexed and four additional 505(b)(2) products and/or ANDA products under development ("the Robert One 2009 Subject Products") and granted us an exclusive, sub-licensable, license under Robert One's intellectual property rights to develop make, use, sell and import Robert One 2009 Subject Products worldwide (excluding China) with respect to pemetrexed and other 505(b)(2) product applications and in North America with respect to ANDA product applications.

Under the terms of this Agreement no further milestone payments are due to Robert One. We are required to make royalty payments based on gross profits of sales of the Robert One 2009 Subject Product by us and our affiliates in the Territory (i) at 25% for pemetrexed parental formulation (ii) at 50% for Robert One 2009 Subject Products other than pemetrexed that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application (provided that we are entitled to recoup all of our expenses related to the development of a product commercialized under a 505(b)(2) application prior to splitting the profits we receive from such product), and (ii) at 30% with respect to Robert One 2009 Subject Products other than pemetrexed that are commercialized on the basis of an ANDA application. Our royalty obligations continue on a product-by-product basis until the later of ten years after the first commercial sale of each Robert One 2009 Subject Product and the expiration of the last valid claim covering such Robert One 2009 Subject Product, subject to certain reductions in the event that there is no valid patent claim covering the manufacture, use, import or sale of such Robert One 2009 Subject Product in a country in the territory.

Bendamustine License Agreement

On February 13, 2015, we submitted an NDA to the FDA for Bendeka which was approved by the FDA on December 8, 2015. Also, on February 13, 2015, we entered into the Cephalon License with Cephalon, for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Subsequently, with the consent of the Company, Cephalon assigned to Teva Pharmaceuticals International GmbH (“TPIG”) all of Cephalon’s rights and obligations under the Cephalon License. Accordingly, all references to “Cephalon” or to the “Cephalon License” and the

related supply agreements for Bendeka should be read and construed as references to TPIG and to the license agreement and supply agreements for Bendeka to which the Company and TPIG are now parties. Pursuant to the terms of the Cephalon License, Cephalon is responsible for all U.S. commercial activities for the product including promotion and distribution, and we are responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. Additionally, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million, received a $15 million milestone payment in January 2016 in connection with the FDA approval of Bendeka in December 2015, received a $40 million milestone in the fourth quarter of 2016 in connection with the receipt of the J-Code for Bendeka and in Q1 of 2017, Bendeka reached $500 million in cumulative net sales, triggering an additional $25 million sales-based milestone payment. In addition, the royalty payments of 20% of net sales of the product that the Company was entitled to receive increased to 25% on receipt of the J-Code. In connection with the Cephalon License, the Company has entered into a supply agreement with Cephalon, pursuant to which the Company is responsible for supplying product to Cephalon. During the quarter-ended September 30, 2016, the Company entered into an amendment to that certain Exclusive License Agreement

(the "Cephalon License") with Cephalon and the related supply agreements for Bendeka. The amendment expands the geographical scope of the rights granted under the original agreement to include certain territories outside the US and Canada. In accordance with this amendment, the Company recorded $1.75 million in license and other revenue on the statements of operations for the year-ended December 31, 2016. The Company is also eligible to receive up to $750.0 thousand on each regulatory approval received in certain additional territories, not to exceed $2.25 million, as well as royalties on future sales.

Cephalon Settlement and License Agreement

On February 13, 2015, we entered into the Cephalon Settlement Agreement with Cephalon, in connection with the Cephalon License, pursuant to which the parties agreed to settle the pending patent infringement claims against each other regarding Cephalon's US Patent No. 8,791,270, under which we agreed to enter into a Consent Judgment regarding the ‘270 patent. As part of the Cephalon Settlement Agreement, Cephalon has agreed to waive its orphan drug exclusivities for the treatment of patients with CLL and patients with NHL.

SymBio Product Collaboration and License Agreement

On September 20, 2017, we entered into the SymBio License with SymBio for the rights to develop and commercialize EP-3101 and Bendeka (collectively, the “Products”) in Japan. Under the SymBio License, SymBio will be responsible for all development of the Products in Japan and for obtaining and maintaining all regulatory approvals of the Products in Japan, with a target for regulatory approval of a Product in Japan in 2020. SymBio will bear all costs of development of the Products in Japan except that, if Japanese regulatory authorities require a certain clinical study to be conducted as a condition for approving one of the Products in Japan, we would share 50% of the out-of-pocket costs of that clinical study up to a specified dollar amount as a reduction to future royalty payments. Based on our assessment of the probability of additional costs, we have not deferred revenue on the SymBio License. SymBio will also be responsible, at its sole cost, for all marketing, promotion, distribution and sales of the Products in Japan and is obligated to launch the Products and meet certain minimum detailing, promotion and marketing commitments in connection with commercialization of the Products in Japan.

SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma (“MCL”), and as a first line treatment of low-grade NHL and MCL. Under the SymBio License, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Pursuant to the terms of the SymBio License, Eagle and SymBio will enter into a separate supply agreement, under which we will be responsible for manufacturing and supplying the Products to SymBio for development and commercialization in Japan. After a period of time following launch of a Product, SymBio will have the right to assume the responsibility for manufacturing of the Products in and for Japan. Under the SymBio License, we will retain the right to control the prosecution, maintenance and enforcement of our patents covering the Products, both inside and outside of Japan.

Under the SymBio License, we earned an upfront non-refundable cash payment of $12.5 million in the third quarter of 2017, and we are eligible to receive a milestone payment upon approval of a Product in Japan and a milestone payment upon achievement of certain cumulative net sales of the Products in Japan. After regulatory approval of a Product in Japan, we will also receive tiered, low double-digit royalties on net sales of the Products in Japan for so long as there are patents covering the Products in Japan or regulatory exclusivity for the Products in Japan.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than products that we are currently selling through partners or developing or that we may develop, which could render our products obsolete and noncompetitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability

of reimbursement from government and other third-party payors. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product portfolio in our target commercial markets.

Government Regulation

FDA Approval Process for Drugs and Biologics

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDCA, and in the case of biologics, the Public Health Service Act (“PHSA”) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of product from the market, injunctions, fines, civil penalties and criminal prosecution.

FDA approval is required before any new unapproved drug biologic or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States generally involves:

- completion of pre-clinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice ("cGLP") regulations;
- submission to the FDA of an Investigational New Drug ("IND") application for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board ("IRB") at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices ("cGCP") to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA or BLA.

The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including cGLPs. The results of preclinical testing are submitted to the FDA as part of an IND application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND application must also be made for each successive clinical trial

conducted during product development. Further, an independent IRB, covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator in accordance with cGCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA or BLA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

Phase 1: In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

Phase 2: Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.

Phase 3: Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an application is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most applications is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved application is also subject to annual product and establishment user fees.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under PDUFA the FDA has agreed to certain performance goals in the review of NDAs and BLAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA or a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the application contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter to indicate that the review cycle for an application is complete and that the application is not

ready for approval. A tentative approval is issued to a 505(b)(2) NDA if the sponsor must await the expiration of an Orange Book listed patent covering the reference product. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA or BLA approval, the FDA may require a Risk Evaluation and Mitigation Strategies ("REMS") program to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS program is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS program may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special

monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The requirement for a REMS program can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA/BLA or NDA/BLA supplement before the change can be implemented, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing supplements as it does in reviewing original applications.

Post-Approval Requirements

Once an NDA or BLA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion, including standards and regulations for direct to consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product’s FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced and announced inspections by the FDA and these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

In addition, the distribution of prescription pharmaceuticals is subject to the Prescription Drug Marketing Act ("PDMA") which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. A growing majority of states also

impose certain drug pedigree requirements on the sale and distribution of prescription drugs.

The FDA may require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Act, established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary

drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacological action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition

of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

FDA Approval for Biosimilars

In 2010, the Biologics Price Competition and Innovation Act (BPCIA) was enacted creating a statutory pathway for licensure of biological products that are biosimilar to, and possibly interchangeable with, reference biological products licensed under the PHSA. The BPCIA grants innovator manufacturers 12 years of exclusivity from the date of approval of the original, or reference, BLA before approving licenses for biosimilars. Innovators may also be entitled to a potential six-month extension of exclusivity if the results of pediatric studies are provided to the FDA. The BPCIA establishes procedures by which the biosimilar applicant is to provide information about its application and product to the reference product sponsor. The BPCIA also details how information about potentially relevant patents is shared between the sponsors and how litigation may proceed prior to approval of the biosimilar application. The BPCIA, like the Hatch Waxman Act, provides a period of exclusivity for the first biosimilar to obtain license from FDA as interchangeable with the reference product.

Orphan Drug Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat rare diseases or conditions, the FDA will grant orphan designation for that product for the orphan disease indication. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation provides manufacturers with research grants, tax credits and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. If a drug designated as an orphan product receives marketing approval for an indication broader than the orphan indication for which it received the designation, it will not be entitled to orphan drug exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, we may still be subject to competition. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or if our product candidate is

determined to be contained within the competitor's product for the same indication or disease.

International Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory

approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, marketing, sale and promotion of drug products and medical devices are subject to numerous regulations by various federal, state and local authorities in addition to the FDA including, but not limited to, the U.S. Federal Communications Commission, the U.S. Department of Justice, the U.S. Department of Health and Human Services (“HHS”) and its various enforcement divisions, such as the Centers for Medicare & Medicaid Services (“CMS”), the Office of Inspector General ("OIG"), the Office for Human Research Protections ("OHRP"), and the Office of Research Integrity ("ORI"), state Attorneys General, state Medicaid Fraud Control Units, or MFCUs, and other state and local government agencies. Healthcare laws and regulations that may govern our business include the following.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, including a prescription drug manufacturer, or a party acting on its behalf, from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce in return for either the referral of an individual, or the purchase, recommendation, leasing, ordering or furnishing of a good, facility, item, or service, for which payment may be made in whole or in part under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers, on one hand, and prescribers, purchasers, and formulary managers, on the other. The term "remuneration" expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution. Failure to meet all of the requirements of a particular applicable statutory exception or safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), among other things, amended the intent standard under the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The ACA also provided 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 federal civil False Claims Act (discussed below). Further, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state laws may be broader in scope in that some of these state laws extend to all payors and may not contain safe harbors.

Federal civil and criminal false claims laws and civil monetary penalty laws, including the federal civil False Claims Act, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval by the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The "qui tam" provisions of the federal civil False Claims Act allow a private individual to bring a civil action on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and potentially to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the federal civil False Claims Act. Many of these state laws are broader in scope and apply to all payors, and therefore, are not limited to only those claims submitted to the federal government. There are many potential bases for liability under the federal civil False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal civil False Claims Act has been used to assert

liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, and improper promotion of off-label uses not expressly approved by the FDA in a drug's label. Our future activities relating to the reporting of discount and rebate information and other information affecting federal, state and third party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws.

Also, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created several additional federal civil and
criminal statutes that prohibit healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the ACA amended certain of these federal criminal statutes such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed

a violation.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA and its implementing regulations established uniform standards for certain "covered entities," which are certain healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which expanded certain of HIPAA's privacy and security standards. Among other things, HITECH makes HIPAA's security standards and certain privacy standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Additionally, federal transparency laws, including the federal Physician Payments Sunshine Act created under Section 6002 of the ACA and its implementing regulations require that certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to "payments or other transfers of value" made or distributed to physicians (defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors), generally, with some exceptions, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals. Applicable manufacturers and applicable group purchasing organizations must also report annually to the CMS certain ownership and investment interests held by physicians (as defined above) and their immediate family members.

There are also an increasing number of analogous state laws that require manufacturers to file reports with states on pricing and marketing information, such as tracking and reporting of gifts, compensations, other remuneration and items of value provided to health care professionals and health care entities. Many of these laws contain ambiguities as to what is required to comply with the laws. Several states have also enacted legislation requiring pharmaceutical companies to, among other things, establish and implement commercial compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives. Certain state laws also regulate manufacturers' use of identifiable data. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including significant administrative, criminal and civil monetary penalties, damages, fines, imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government healthcare programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We are unable to predict whether we would be subject to actions under these laws or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance.

To the extent that any of our products are sold in a foreign country, we also may be subject to similar foreign laws and regulations, which may include, for instance, the U.S. Foreign Corrupt Practices Act, the U.K. Anti-Bribery Act, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Third-Party Payor Coverage and Reimbursement

The commercial success of our approved product portfolio, as well as our pre-clinical and clinical product portfolio, if and when approved, will depend, in part, upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product portfolio will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our product portfolio will be paid by health maintenance, managed care, pharmacy benefit, and/or similar healthcare management organizations, or are reimbursed

by government health administration authorities, such as Medicare and Medicaid, private health coverage insurers and other third-party payors. The market for our product portfolio will depend significantly on access to third-party payors' formularies, or lists of treatments for which third-party payors provide coverage and reimbursement.

Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Further, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained. The cost of pharmaceuticals and medical devices continues to generate substantial governmental and third-party payor scrutiny. We expect that the pharmaceutical industry will experience continued pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative and administrative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative and administrative reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product portfolio and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Healthcare Reform

In the United States and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that will likely affect our future operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs, improve access, and improve quality.

By way of example, in March 2010, the ACA was passed, which significantly changed health care financing by both governmental and private insurers. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry included, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extension products;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;
-

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- new requirements under the federal Physician Payments Sunshine Act for manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members; and,

- a new requirement to annually report certain drug samples that manufacturers and distributors provide to licensed practitioners, or to pharmacies of hospitals or other healthcare entities.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the U.S. Presidential administration to repeal or replace certain aspects of the ACA. Since January 2017, the U.S. President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (the "Tax Act") included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, the U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the U.S. Presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace ACA will impact ACA.

Other healthcare legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, following passage of subsequent legislation, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

In addition, the Drug Supply Chain Security Act signed into law on November 27, 2013 imposes on manufacturers of certain pharmaceutical products new obligations related to product tracking and tracing, among others, which will be phased in over ten years. Among the requirements of this new legislation, manufacturers subject to this federal law will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Covered manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, covered manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and

intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We expect that additional state and federal healthcare reform measures will be adopted in the future. For example, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in January 2016, CMS issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 1, 2016, among other things, revises the manner in which the “average manufacturer price” is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the ACA. Further, the current U.S. Presidential administration’s budget proposal for fiscal year 2019 contains further drug price control measures

that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the current U.S. Presidential administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the current U.S. Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any additional healthcare reform measures could further constrain our business and/or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product portfolio or additional pricing pressures.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Employees

As of December 31, 2018, we had a total of 96 employees and two full-time consultants. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced any work stoppage and consider our relations with our employees to be good.

Corporate Information

We were incorporated in Delaware in January 2007. Our principal executive offices are located at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677, and our telephone number is (201) 326-5300.

Available Information

Our corporate website address is www.eagleus.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only. We make our Annual Reports on Form 10-K, Quarterly reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file

such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC. You can access our filings through the SEC's internet site: www.sec.gov.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K, as well as our other public filings with the Securities and Exchange Commission. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall. In addition to the risk factors identified under the captions below, the operation and results of our business are subject to risks and uncertainties identified elsewhere in this Annual Report on Form 10-K as well as general risks and uncertainties such as those relating to general economic conditions and demand in the market for our products.

Risks Related to Our Financial Condition and Need for Additional Capital

We have a history of operating losses and have only recently achieved profitability. If we cannot sustain profitability, our business, prospects, operating results and financial condition would be materially harmed.

We have focused primarily on developing a broad product portfolio and currently have final regulatory approval for four products. Some of our product candidates will require substantial additional development time and resources before we would be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. Although we had net income of $31.9 million for the year ended December 31, 2018, $51.9 million for the year ended December 31, 2017 and $81.4 million for the year ended December 31, 2016, we incurred significant net losses prior to 2015.

We have devoted most of our financial resources to product development and may not generate significant revenue from sales of our product candidates in the near-term, if ever. As of December 31, 2018, we commercialize the following products, Argatroban, Ryanodex, Belrapzo and Bendeka.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses, but we expect to continue to incur substantial expenses, which we expect to increase as we expand our development activities and product portfolio. As a result of the foregoing, we may incur losses and negative cash flows in the future. We believe that our existing cash and cash equivalents, together with interest thereon, are sufficient to fund our operations for a minimum of twelve months.

If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, both internally and through our joint development agreement with AMRI. Changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our product commercialization or development efforts could encounter technical or other difficulties that could increase our development costs more than we expect. In any event, we may require additional capital prior to obtaining regulatory approval for, or commercializing, any additional product candidates.

In addition, attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize additional product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our products and product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or products, or to product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

The occurrence of any of these factors could have a material adverse effect on our business, operating results and prospects.

We may sell additional equity or incur debt to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or incur debt, which could adversely impact our stockholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness, including under the credit agreement we entered into in January 2017 and subsequently amended and restated in August 2017, which we refer to as the Credit Agreement, would result in increased fixed payment obligations. In addition, the incurrence of indebtedness could result in certain restrictive covenants, such as

limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required (causing a default under such indebtedness), which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Regulatory Approval

We cannot give any assurance that we will receive regulatory approval for our product candidates, which is necessary before they can be commercialized.

Our business and future success are substantially dependent on our ability to successfully and timely develop, obtain regulatory approval for, and commercialize our product candidates. Any delay or setback in the development of any of these product candidates could adversely affect our business. In addition, the process for obtaining regulatory approval to market biologic products is expensive, often takes many years, and can vary substantially based on the type, complexity and novelty of the product candidate involved. Our planned development, approval and commercialization of these product candidates may fail to be completed in a timely manner or at all. The FDA or other foreign regulatory agency may refuse or delay approval of our product candidates for failure to collect sufficient clinical or animal safety data and require us or our collaborators to conduct additional clinical or animal safety studies, which may cause lengthy delays and increased costs to our programs. We cannot provide assurance that we will be able to obtain approval for any of our product candidates from the FDA or any foreign regulatory authority or that we will obtain such approval in a timely manner. If we do not obtain regulatory approval of new products or additional indications for existing products, or are significantly delayed or limited in doing so, our revenue growth will be adversely affected, we may experience surplus inventory, or our business may be materially harmed and we may need to significantly curtail operations. For example, in March 2016 we received a Complete Response Letter from the FDA stating that while their initial review of our NDA for EP-6101 was complete, they could not approve the application in its present form and requested additional information. We have elected not to pursue the application further or seek to exploit EP-6101 for various reasons including the costs associated with addressing the information request in the FDA's Complete Response Letter and because additional generic bivalirudin products have entered or are entering the market. Additionally, in July 2017 we received a Complete Response Letter from the FDA regarding our 505(b)(2) NDA for EP-4104 for the treatment of EHS, in conjunction with external cooling methods. The FDA requested that the Company conduct an additional clinical trial for EP-4104. The Company conducted an additional clinical trial in August 2018 during the Hajj pilgrimage, similar to the study conducted during the Hajj in 2015. On August 30, 2018, the Company announced the completion of enrollment of the Company’s second clinical study to further evaluate the safety and efficacy of Ryanodex. During the 2018 Hajj, overall emergency room visits were dramatically decreased from previous years due to well-implemented crowd management, lower temperatures, lower humidity and other external factors. As a result, the number of EHS patients available for study enrollment was also significantly less than in previous years, and therefore much lower than anticipated. The preliminary assessment of patients enrolled is consistent with the data from the study conducted in 2015, in which patients dosed with Ryanodex plus Standard of Care (“SOC”) showed an additive benefit compared to patients receiving SOC only. The Company intends to complete the analysis of the data and meet with the U.S. Food and Drug Administration to discuss next steps in 2019.

If we are unable to differentiate our products or product candidates from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the ability to successfully commercialize our product candidates would be adversely affected.

Our strategy is to enter the market no later than the first generic or biosimilar to the applicable branded reference drug. We expect to compete against branded reference drugs and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our products and product candidates will be clinically differentiated from branded reference drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our products or product candidates against other drugs, the opportunity for our products and product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

In addition to existing branded reference drugs and the related generic products, the FDA or other applicable regulatory authorities may approve generic products that compete directly with our products or product candidates, if approved. Once an NDA, including a 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The Federal Food, Drug and Cosmetic Act ("FDCA"), FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as our products or product candidates and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our products or product candidates. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the

introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents of our products or product candidates would materially adversely impact our ability to successfully commercialize our product candidates or negatively impact our ability to gain market acceptance and market share for our products.

If the FDA does not conclude that our product candidates satisfy the requirements for the regulatory approval, or if the requirements for approval of any of our product candidates are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for those small molecule product candidates described in this Annual Report on Form 10-K and will likewise pursue an equivalent regulatory strategy for the biologic product candidates developed by Eagle Biologics. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA.

Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. While the regulatory pathway of a biobetter is less developed, we believe through collaborative deals we can achieve a similar result allowing us to rely on data previously generated.

If the FDA does not allow us to pursue the regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue such regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue our chosen regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA or BLA that we submit.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

Clinical testing, even when utilizing the 505(b)(2) pathway or its equivalent, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Our product candidates are in various stages of development, from early stage to late stage. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies. For example, the FDA has requested that the Company conduct an additional clinical trial for EP-4104. We are currently meeting with the FDA to seek agreement on such additional work, but there can be no assurance that the FDA will ultimately approve the NDA, or if so, in a timely fashion. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful.

We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long-term stockholder value will be limited.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates. We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them;
- delays in obtaining required institutional review board, or IRB, approval at each site;
- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

In addition, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment and completion of the trials is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any.

As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although our products or product candidates containing active ingredients that have already been approved and the side effects arising from the use of the active ingredient or class of drug in our products or product candidates are generally known, our products or product candidates may still cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have obtained regulatory approval for five NDA products, but no BLA products, and we have multiple NDA product candidates in advanced stages of development and other exploratory candidates under development. However, it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs or existing biologic drugs meet the criteria for our chosen regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or comparable to its branded reference product for its proposed indication;
- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We have no experience submitting BLAs and have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. For example, in March of 2016 we received a Complete Response Letter from the FDA stating that while their initial review of our NDA for EP-6101 was complete, they could not approve the application in its present form and requested additional information. We have elected not to pursue the application further or seek to exploit EP-6101 for various reasons including the costs associated with addressing the information request in the FDA's Complete Response Letter and because additional generic bivalirudin products have entered or are entering the market. Additionally, in July of 2017 we received a Complete Response Letter from the FDA regarding our 505(b)(2) NDA for Ryanodex for the treatment of EHS, in conjunction with external cooling methods. The FDA has requested that the Company conduct an additional clinical trial for EP-4104. We are currently meeting

with the FDA

to seek agreement on such additional clinical work, but there can be no assurance that the FDA will ultimately approve the NDA, or if so, in a timely fashion.

If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates.

Some of our product candidates will be submitted to the FDA for approval under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505(b)(2) application would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time-consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time-consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

Companies that produce branded reference drugs routinely bring litigation against abbreviated new drug application, or ANDA, or 505(b)(2) applicants that seek regulatory approval to manufacture and market generic and reformulated forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or 505(b)(2) applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic or reformulated products.

Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If patents are held to be valid and infringed by our product candidates in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, be required to cease selling in that jurisdiction and may need to relinquish or destroy existing stock in that jurisdiction. There may also be situations where we use our business judgment and decide to market and sell our approved products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is known as an "at-risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits

lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent and, to a lesser extent, 505(b)(2), products, patented branded products generally realize a substantially higher profit margin than bioequivalent and, to a lesser extent, 505(b)(2), products, resulting in disproportionate damages compared to any profits earned by the infringer. An adverse decision in patent litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. However, we may share truthful and not misleading information that is otherwise consistent with our products' FDA approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal and administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our business is subject to extensive regulatory requirements and our approved product and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA or BLA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the application. The holder of an approved NDA or BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program.

Manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the drug application. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters asserting that we are in violation of the law;
- impose restrictions on the marketing or manufacturing of the product;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal health care programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending application or supplements to an application submitted by us;
- seize product; or
- refuse to allow us to enter into government contracts.

Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in

response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates

or further restrict or regulate post-approval activities. For example, the Food and Drug Administration Safety and Innovation Act, or FDASIA, requires the FDA to issue new guidance on permissible forms of Internet and social media promotion of regulated medical products, and the FDA may soon specify new restrictions on this type of promotion. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) the laws of the United States FDA and similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (2) health care laws and regulations, including fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (3) laws requiring the reporting of financial information or data accurately. Specifically, the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Any relationships with health care professionals, principal investigators, consultants, customers (actual and potential) and third party payors, in addition to our general business operations, are and will continue to be subject, directly or indirectly, to federal and state health care fraud and abuse laws, marketing expenditure tracking and disclosure, or sunshine laws, government price reporting and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal, state and local fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as current, proposed and future sales, marketing and education programs. In addition, we may be subject to patient data privacy and security regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business, as well as transparency requirements. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal health care program, such as the Medicare and Medicaid programs. The Patient Protection and Affordable

Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal civil False Claims Act, which prohibit and impose penalties for, among other things, individuals or entities knowingly presenting, or causing to be presented, claims for payment or approval from the federal government including Medicare, Medicaid or certain other

governmental health care programs that are false or fraudulent or knowingly making or causing to be made a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, health care benefits, items or services relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain health care providers, health plans and health care clearinghouses, known as covered entities, as well as their respective business associates, independent contractors or agents of covered entities that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, created under Section 6002 of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services' Centers for Medicare & Medicare Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, changed by ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts;
- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities), and drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

In addition, any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not

comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations 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, without limitation, civil, criminal and administrative penalties, damages,

monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We are required to obtain regulatory approval for each of our products in each jurisdiction in which we intend to market such products, and the inability to obtain such approvals would limit our ability to realize their full market potential.

In order to market products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact our ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing product candidates. We may also acquire or in-license such product candidates. Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds or active ingredients, we do not have internal drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and delivery methods for existing FDA-approved products and/or select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Commercialization of Our Products and Product Candidates

Our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among physicians, nurses, pharmacists, patients and the medical community.

Even if we obtain regulatory approval for our product candidates, our products and product candidates may not gain market acceptance among physicians, nurses, pharmacists, patients, the medical community or third party payors, which is critical to commercial success. Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including:

- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the convenience and ease of administration to patients of the product candidate;
- the potential and perceived advantages of such product candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement by third party payors and government authorities;
- relative convenience and ease of administration;
- any negative publicity related to our or our competitors' products that include the same active ingredient;
-

the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA-approved labeling; and

- the effectiveness of sales and marketing efforts.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by physicians, nurses, pharmacists, patients and the medical community, we will be unable to generate significant revenues, and we may not become or remain profitable.

Guidelines and recommendations published by government agencies can reduce the use of our products and product candidates.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and health care providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

If we are unable to establish sales and marketing capabilities or if our commercial partners do not adequately perform, the commercial opportunity for our products may be diminished.

Although we intend to establish a commercial organization to promote certain of our approved products in the United States, we currently have limited experience, and the cost of establishing and maintaining such an organization may exceed the benefit of doing so. We have very limited prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team.

We and any other commercialization partner we engage in the future may not be able to attract, hire, train and retain qualified sales and sales management personnel. If we or our future partners, if any, are not successful in maintaining an effective number of qualified sales personnel, our ability to effectively market and promote our products may be impaired. Even if we are able to effectively build and maintain such sales personnel, such efforts may not be successful in commercializing our products.

The efforts of our partners in many instances would likely be outside our control. If any future partner is unsuccessful in their efforts, or we are unable to maintain such commercial partnerships or to effectively establish alternative arrangements for our products, our business could be adversely affected.

A substantial portion of our total revenues is derived from sales of a limited number of products.

We derive a substantial portion of our revenue from royalties derived from the sales of one product: Bendeka. This product is sold by our partner Teva Pharmaceuticals. During the year ended December 31, 2018, Bendeka accounted for approximately 75% of our total revenue. The sale of our products can be significantly influenced by the efforts of our partners, which are out of our control, as well as market conditions and regulatory actions. We may experience decreases in the sale of our products in the future as a result of actions taken by our competitors, such as price reductions or entry into the market for competing products, or as a result of regulatory actions related to our products or competing products, which could have a material impact on our results of operations and financial condition.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We may enter into agreements with third parties to market our products outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of our competitors both in the United States and internationally, include major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, Argatroban is currently marketed in the United States by, among others, GlaxoSmithKline, or GSK, and West-Ward Pharmaceuticals, or West-Ward. Dantrolene for malignant hyperthermia is marketed in the US by Par Pharmaceutical and US WorldMeds. Docetaxel in marketed in the US by, among others, Sanofi and Sandoz. While our formulations of these products are distinct, and we believe improvements, compared to those competitors mentioned, competition from these products on factors such as price and availability effect our commercial efforts. Additionally, we must compete with alternative drug treatments (as opposed to alternative formulations) for many of the indications that our products are approved to treat.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our products or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our products, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any application we submit.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our products and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect intellectual property rights related to our products and product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our products and product candidates that receive regulatory approval; and
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than our products or product candidates, or that reach the market sooner than our product candidates, we may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render

our technologies, products or product candidates obsolete, less competitive or not economical.

We could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.

We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal actions against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract or other legal theories. If we are forced to defend any such lawsuits, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our product candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered such market, which could adversely impact our potential revenue from such product candidates or negatively impact our ability to gain market acceptance and market share for our products.

Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a certain drug; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered.

Successful sales of our products and any other approved product candidates depend on the availability of adequate coverage and reimbursement from third party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Reimbursement by a third party payor may depend upon a number of factors, including but not limited to, the third party payor’s determination that use of a product is: a covered benefit under its health plan; safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; and/or neither cosmetic, experimental, nor investigational.

Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products and our product candidates will depend significantly on access to third party payors' drug formularies, or lists of medications for which third party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

Third party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. In addition, in the United States, no uniform policy requirement for coverage and reimbursement for drug products exists among third party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that could require us to provide scientific, clinical and cost effectiveness support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for our commercial products, and our pre-clinical and clinical product candidates for which we may receive regulatory approval, may not be available or

adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain for our products.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products and our product candidates profitably, once they are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding

access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the ACA was passed, which significantly changed health care financing by both governmental and private insurers. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the U.S. Presidential administration to repeal or replace certain aspects of the ACA.. Since January 2017, the U.S. President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. On January 22, 2018, the U.S. President of the U.S. signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the U.S. Presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace ACA will impact ACA and our business. We cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 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 proposals for spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, following passage of the Bipartisan Budget Act of 2015 as well as other legislative amendments, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, under the Drug Supply Chain Security Act signed into law on November 27, 2013, certain drug manufacturers will be subject to product identification, tracing and verification requirements, among others, that are designed to improve the detection and removal of counterfeit, stolen, contaminated or otherwise potentially harmful drugs from the U.S. drug supply chain. These requirements will be phased in over several years and compliance with this new law will likely increase the costs of the manufacture and distribution of drug products, which could have an adverse effect on our financial condition.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program

reimbursement methodologies for drugs. For example, in January 2016, CMS issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 1, 2016, among other things, revised the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the ACA. Further, the current U.S. Presidential administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the U.S. Presidential administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products

paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the U.S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the current U.S. Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these laws, as well as other new laws and reform measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other health care funding, or higher production costs which could have a material adverse effect on our customers and, accordingly, our financial operations.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA regulations and other laws regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Council for Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with

these third party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If any of our current strategic collaborators fail to perform their obligations or terminate their agreements with us, the development and commercialization of the product candidates under such agreements could be delayed or terminated and our business could be substantially harmed.

On February 13, 2015, we entered into the Cephalon License, with Cephalon for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Pursuant to the terms of the Cephalon License, Cephalon is responsible for all U.S. commercial activities for the product including promotion and distribution, and we are responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies.

This strategic collaboration may not be scientifically or commercially successful due to a number of important factors, including the following:

- If we fail to maintain any regulatory approvals, or otherwise materially breach the agreement, we may not receive all anticipated royalty payments.
- Cephalon has significant discretion in determining the efforts and resources that it will apply to their strategic collaboration with us. The timing and amount of any cash payments, and royalties that we may receive under such agreements will depend on, among other things, the efforts, allocation of resources and the commercialization of our product by Cephalon under the Cephalon License;
- Cephalon currently markets a competitive bendamustine product, Treanda®, in the United States. In addition, it is possible that Cephalon may develop and commercialize, either alone or with others, or be acquired by a company that has, products that are similar to or competitive with the product candidates that they license from us;
- Cephalon may change the focus of their commercialization efforts or pursue higher-priority programs;
- Cephalon may terminate its strategic collaboration with us on short notice, which could make it difficult for us to attract new strategic collaborators or adversely affect how we are perceived in the scientific and financial communities;
- Cephalon has the right to maintain or defend our intellectual property rights licensed to them in their territories, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if they do not, our ability to do so may be compromised by our strategic collaborators' acts or omissions; and
- Cephalon may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.
- If Cephalon fails to effectively commercialize our product, we may not be able to replace them with another collaborator.
- If our agreement with Cephalon terminates, we are required to pay them a portion of our future profits on the product.

Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

We rely on third parties to manufacture commercial supplies of our products and clinical supplies of our product candidates, and we intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

We do not own any manufacturing facilities, and we do not currently, and do not expect in the future, to independently conduct any aspects of our product manufacturing and testing, or other activities related to the clinical development and commercialization of our product candidates. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product candidate development and product commercialization activities. Our

reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates.

Our products and product candidates are highly reliant on very complex sterile techniques and personnel aseptic techniques. The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Quality problems in manufacturing are linked to a majority of shortages of sterile injectable drugs. Some of the largest manufacturers of sterile injectable drugs have had serious quality problems leading to the temporary voluntary closure or renovations of major production facilities. Further, as we scale up manufacturing of our product candidates and conduct required stability testing, product packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities to manufacture our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates.

More generally, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to make product candidates available for clinical trials and development purposes or to further commercialize our products or product candidates in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for approved products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects.

The design, development, manufacture, supply, and distribution of our products and product candidates is highly regulated and technically complex.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our products and product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products or product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our products, as well as our other product candidates, is highly regulated and

technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities.

We, or our contract manufacturers, must supply all necessary documentation in support of our regulatory filings for our products and product candidates on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must also pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the

regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biological product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

We rely on limited sources of supply for our products and product candidates, and any disruption in the chain of supply may impact production and sales of our products and cause delay in developing and commercializing our product candidates.

We currently have relationships with only one third party for the manufacture of each of our most advanced products and product candidates. Because of the unique equipment and process for manufacturing our products transferring manufacturing activities to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching finished drug suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of these single-source manufacturers breaches or terminates their agreements with us, we would need to identify an alternative source for the manufacture and supply of product candidates to us for the purposes of our development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, which could harm our financial position and commercial potential for our products. Any alternative vendor would also need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our product candidates that differs from the manufacturer used for clinical development of such product candidates. For our other product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. We may, however, be unable to advance the development of our products and product candidates in territories outside of the United States, which may limit the market potential for this product candidate. For example, our Eagle Biologics business strategy relies heavily on our ability to successfully consummate and execute under these collaboration agreements.

In situations where we enter into a development and commercial collaboration arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. We have entered into collaboration and promotion agreements with third parties, such as the Spectrum Agreement and the agreement with AMRI, but there is no assurance these arrangements will be successful. If we are unable to enter into any future development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

On February 13, 2015, we entered into the Cephalon License, with Cephalon for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. If we are able to establish additional collaboration arrangements, any such collaborations, in addition to the collaboration with Cephalon, may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we partner with a third party for development and commercialization of a product or product candidate, including Cephalon, we can expect to relinquish some or all of the control over the future success of that product or product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

We may be subject to a number of additional risks associated with our collaborations with third parties, the occurrence of which could cause collaboration arrangements to fail. Conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates and harm our business:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; and
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

If we are unable to maintain our group purchasing organization, or GPO, relationships, our revenues could decline and future profitability could be jeopardized.

Most of the end-users of injectable pharmaceutical products have relationships with GPOs whereby such GPOs provide such end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We currently derive, and expect to continue to derive, a large percentage of our revenue from end-user customers that are members of a small number of GPOs. Maintaining strong relationships with these GPOs will require us to continue to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with companies that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our GPO relationships, sales of our products and revenue could decline.

We rely on a limited number of pharmaceutical wholesalers to distribute our products.

As is typical in the pharmaceutical industry, we rely upon pharmaceutical wholesalers in connection with the distribution of our products. A significant amount of our products are sold to end-users under GPO pricing

arrangements through a limited number of pharmaceutical wholesalers. If we are unable to maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability.

Our approved products may not achieve expected levels of market acceptance.

Even if we are able to obtain regulatory approvals for our product candidates, the success of those products is dependent upon market acceptance. Levels of market acceptance for our product candidates could be affected by several factors, including:

- the availability of alternative products from our competitors;
- the price of our products relative to those of our competitors;
- the timing of our market entry;

- the ability to market our products effectively at the retail level;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety efficacy and benefits of our drug products compared to those of competing products; and
- the acceptance of our products by government and private formularies.

Some of these factors are not within our control, and our products may not achieve expected levels of market acceptance. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which may call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, which include our Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, and President and Chief Operating Officer. The loss of these executives' services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2018, we had a total of 96 employees in the United States and two full-time consultants in India. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. For example, on November 16, 2016, we acquired Arsia Therapeutics, Inc. (now Eagle Biologics). We may not be able to effectively manage the expansion of our operations, such as the Arsia acquisition, which may result in weaknesses in our infrastructure and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to sell our products and commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our acquisition of Arsia Therapeutics may not provide us with the long-term value we expected.

Our acquisition of Arsia Therapeutics, Inc. (now Eagle Biologics) and the purchase price of such was based on a series of long-term assumptions and estimates. However, there can be no assurance that these expectations will be completely realized, and we cannot ensure that we will be able to manage the risks associated with integrating Eagle Biologic’s operations and product candidates into our existing business and infrastructure. Unexpected difficulties may be disruptive to our ongoing development efforts, put a strain on our existing personnel, infrastructure and business

and divert management's time and attention. As a result of these or other problems and risks, we may never realize the full potential or we may never generate significant value from this transaction.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability. The use of our product candidates in clinical trials (if any), and the sale of our products and any product candidates for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products, other approved future products and our product candidates. If we cannot successfully defend against product liability claims, we

could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our products and our product candidates, if approved for commercial sale.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. The loss, theft or sabotage of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our sales of any products we may sell.

Our headquarters are located in Woodcliff Lake, New Jersey. If we encounter any disruptions to our operations at this building or if it were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

We may be constrained by our obligations under our Credit Agreement to operate our business to its full potential.

Our Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. Under the terms of the Credit Agreement, we are required to comply with (a) a maximum senior secured net leverage ratio, (b) a maximum total net leverage ratio and (c) a minimum fixed charge coverage ratio. These terms may restrict our ability to operate our business in the manner we deem most effective or desirable, and may restrict our ability to fund our operations through new public offerings of our common stock or strengthen our candidate development pipeline through acquisitions or licenses which cause us to exceed our maximum senior secured net leverage ratio.

Although we have not currently drawn on the Credit Agreement, failure to comply with the representations and warranties or affirmative and negative covenants could constitute an event of default which, if continued beyond the

cure period, would allow the administrative agent, at the request of or with the consent of the lenders holding a majority of the loans and commitments under the facility, to terminate the commitments of the lenders to make further loans and declare all the obligations of the loan parties under the Credit Agreement to be immediately due and payable, either of which could harm our business.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in foreign countries or territories. If this were to occur, early generic competition could be expected against our products and our product candidates in development. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any adverse outcome in these types of matters could result in one or more generic versions of our products being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of our products and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to our products or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our product candidates. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market our product candidates under patent protection could be reduced. If third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know-how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to our products and our product candidates. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is

not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office,

or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time-consuming, may divert our management's attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In particular, our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit

against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay.

In addition to paragraph IV litigation noted above, third-party owners of patents may generally assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products and/or our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation,

method of use, any method or process involved in the manufacture of any of our product candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. Additionally, one of our existing license agreements is a sublicense from a third party who is not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with their obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost or on reasonable terms, which may impact our ability to continue to develop and commercialize our product candidates and companion diagnostic incorporating the relevant intellectual property. If we fail to comply with our obligations under our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our important technology licenses were to be terminated by the licensor, we would likely cease further development of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not being issued. Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable

outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could

also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

The patents and the patent applications that we have covering our products are limited to specific formulations, methods of use and processes, and our market opportunity for our products and our product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and delivery methods that may be developed by competitors.

Patent protection on the active ingredients in our currently marketed products (Ryanodex, Bendeka, Argatroban and Non-Alcohol Docetaxel Injection) has expired, and there is therefore no composition of matter patent protection available for the active ingredient in such products. This is also the case with respect to our other product candidates. We have obtained, and continue to seek to obtain patent protection of other aspects of our products and our product candidates, including specific formulations, methods of use and processes, which may not be as effective as composition of matter coverage in preventing work-arounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations, methods of use and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval could be able to commercialize products with the same active ingredients as our product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products, subject to any regulatory exclusivity we may be able to obtain for our products.

The number of patents and patent applications covering products containing the same active ingredient as our products and our product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for our products and our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our products and our product candidates that are different from ours and do not infringe our issued patents covering our products.

Ryanodex® (dantrolene sodium), Argatroban, Bendeka ® and Non-Alcohol Docetaxel Injection have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. Once our products are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Ryanodex, Argatroban, Bendeka and Non-Alcohol Docetaxel Injection have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. One or more third parties may also challenge the patents that we control covering our products in court or the USPTO, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our products and product

candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products or product candidates and companion diagnostic. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business, financial condition and results of operations.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

Our stock price may continue to fluctuate significantly.

Our initial public offering was completed in February 2014 at a public offering price of $15.00 per share. The trading price of our common stock has fluctuated significantly in the past and is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully execute our commercialization strategy with respect to our approved products or any other approved product in the future;
- adverse results or delays in clinical trials, if any;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in the structure of healthcare payment systems;
- changes in laws or regulations applicable to our product candidates;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to the use of our products or any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- entry into new markets by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future;
- the trading volume of our common stock;
- changes in the collective short interest in our common stock; and
- additional repurchases of our common stock, if any, pursuant to our recently announced share repurchase program.

The stock market in general, and The Nasdaq Stock Market, or Nasdaq, in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

In addition, the market price of our shares of common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to short interest positions and/or inconsistent trading volume levels of our shares;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

In addition, the stock market in general, and NASDAQ and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. For example, in May 2016, we became party to a federal securities class action lawsuit, and although it was dismissed in October 2017, we incurred substantial costs defending such lawsuit. Such lawsuit, as well as similar lawsuits instituted in the future, could result in substantial additional costs to us and could also divert the time and attention of our management.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2018, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own the majority of our voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We have incurred significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company.

For example, as a public company, we are now subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation in filing of these reports. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and NASDAQ have imposed various other requirements on public companies and we have incurred and will continue to incur costs associated with compliance with such requirements. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

As of February 22, 2019 we had 13,924,296 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, are eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including volume limitations and manner of sale requirements.

In addition, shares issued upon exercise of vested options are eligible for sale. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming

freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2014 Equity Incentive Plan, or the 2014 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2014 Plan will automatically increase each year by 6% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2014 Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are at risk of securities class action and similar litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. On May 31, 2016, a federal securities class action suit was brought against us seeking compensatory damages in connection with, among other things, the EP-6101 Complete Response Letter, as described in more detail in Item 6, Legal Proceedings. Such lawsuit was dismissed with prejudice in August 2017, however, any similar litigation in the future, could result in substantial cost and a diversion of management's attention and resources, which could harm our business.

We have broad discretion in the use of the net proceeds from our recently completed initial public offering and follow-on offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our initial public offering and follow-on offering. Because of the number and variability of factors that will determine our use of the net proceeds from these offerings, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may continue to invest the net proceeds from our public offerings in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay cash dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including

our financial condition, results of operations, capital requirements, contractual restrictions (such as our Credit Facility), general business conditions, and any other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation of their stock.

There is no assurance that our stock repurchase program will result in repurchases of our common stock or enhance long term stockholder value.

Repurchases of our common stock pursuant to our stock repurchase program could affect our stock price and increase its volatility and will reduce the market liquidity for our stock. The existence of a stock repurchase program could also cause our stock price to be higher than it would be in the absence of such a program. Additionally, any future repurchases would diminish our cash reserves, which could impact our ability to pursue possible future strategic opportunities and acquisitions. There can be no assurance that any stock repurchases will, in fact, occur, or, if they occur, that they will enhance stockholder value.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

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

On December 22, 2017, the Tax Act was signed into law, significantly revising the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation on deductibility of executive compensation under regulation 162(m), limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2018 we conducted all of our commercial operations for Eagle Pharmaceuticals, Inc. at our 20,497 square foot leased office space located at 50 Tice Boulevard, Suite 315, Woodcliff Lake, NJ 07677. The term of the lease is for 60 months, expiring on June 30, 2020.

For Eagle Biologics, Inc. as of December 31, 2018, we conducted all of our non-outsourced operations at a leased space located at 47 Moulton St. Cambridge, MA 02138. The term of the lease is 60 months expiring on October 31, 2023.

We consider our current facilities suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

The disclosures under Note 14. Legal Proceedings in the Consolidated Financial Statements included in Part IV, Item 15 of this report are incorporated into this Part I, Item 3 by reference.

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

Market Information

Our common stock has been listed on the Nasdaq Global Market under the symbol "EGRX" since February 12, 2014. Prior to that date, there was no public trading market for our common stock.

Record Holders

As of February 22, 2019, we had 6 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities. The closing price per share of our common stock on February 22, 2019 was $46.23.

Dividends

We have never declared or paid a cash dividend on our common stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, our Credit Facility imposes contractual restrictions on us with respect to paying cash dividends. Any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and any other factors that our board of directors may deem relevant.

Stock Performance Graph

The following information shall not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934, as amended, or the Exchange Act, or to the liabilities of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference into any filing of Eagle Pharmaceuticals, Inc. under the Exchange Act or the Securities Act of 1933, as amended, or the Securities Act, except to the extent we specifically incorporate it by reference into such filing.

The following graph shows a comparison from February 12, 2014 (the date our common stock commenced trading on the Nasdaq Global Market) through December 31, 2018 of the cumulative total return for our common stock, and the Nasdaq Composite Index and The Nasdaq Biotechnology Index. The graph assumes that $100 was invested at the market close on February 12, 2014 in the common stock of Eagle Pharmaceuticals, Inc, the Nasdaq Composite Index and the Nasdaq Biotechnology Index and assumes reinvestments of dividends. The stock price performance of the following graph is not necessarily indicative of future stock price performance.

Company / Index	2/12/14	6/30/14	12/31/14	6/30/15	12/31/15	6/30/16	12/31/16	6/30/17	12/31/17	6/30/18	12/31/18
Eagle Pharmaceuticals, Inc	$ 100	$ 112	$ 138	$ 630	$ 691	$ 302	$ 618	$ 615	$ 416	$ 590	$ 314
NASDAQ Composite	$ 100	$ 105	$ 113	$ 119	$ 119	$ 115	$ 128	$ 146	$ 164	$ 179	$ 158
NASDAQ Biotechnology	$ 100	$ 99	$ 119	$ 144	$ 132	$ 101	$ 104	$ 121	$ 125	$ 129	$ 114

Recent Sales of Unregistered Securities

Pursuant to a Warrant to Purchase Common Stock, dated September 2018, the Company issued a warrant to FoxKiser LLP to purchase 7,467 shares of the Company's common stock at an exercise price of $66.96 per share in connection with certain services rendered to the Company. This warrant was issued in reliance on an exemption from registration under Section 4(2) of the Securities of 1933, as amended.

Use of Proceeds from Public Offerings of Common Stock

On February 18, 2014, we closed our initial public offering whereby we sold 3,350,000 shares of common stock, at a public offering price of $15.00 per share, before underwriting discounts and expenses. On March 18, 2014, the underwriters Piper Jaffray & Co. and William Blair & Company, L.L.C., acting as representatives of each of the underwriters, exercised an over-allotment option granted in connection with the offering of 100,000 shares of common stock at the initial public offering price, less the underwriter discount. The aggregate net proceeds received by us from the offering were approximately $46.1 million.

On March 20, 2015, we completed an underwritten public offering (the "Follow-on Offering") of 1,518,317 shares of common stock, including the exercise by the underwriters Piper Jaffray & Co. and William Blair & Company, L.L.C., acting as representatives of each of the underwriters, of a 30-day option to purchase an additional 198,041 shares of common stock. Of the shares sold, 1,388,517 shares were issued and offered by the Company and 129,800 shares were offered by certain selling stockholders. All of the shares were offered at a price to the public of $42.00 per share. The net proceeds from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $54.3 million. We did not receive any proceeds from the shares sold by the selling stockholders. The securities described above were offered by us pursuant to a shelf registration statement declared effective by the SEC on March 13, 2015.

We invested the net proceeds received from the above offerings in cash equivalents and other short-term investments in accordance with our investment policy. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

Issuer Purchases of Equity Securities

The following table provides information about purchases of our equity securities during the three months ended December 31, 2018:

Period	Total Number of Shares Purchased (1)(2)(3)(4)(5)	Average Price Paid per Share	Total Number of Shares Purchased as Part Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs
				(dollars in thousands)
October 1, 2018 to October 31, 2018	7,458	$ 63.99	7,458	150,000
November 1, 2018 to November 30, 2018	702,988	$ 49.99	702,988	110,000
December 1, 2018 to December 31, 2018	297,146	$ 49.99	297,146	100,000
Total	1,007,592	$ 50.10	1,007,592	

(1) All shares repurchased by the Company in this table were repurchased pursuant to the Share Repurchase Programs, described below and elsewhere in this Annual Report on Form 10-K.

(2) On August 9, 2016, the Company announced a share repurchase program approved by the Company's Board authorizing the repurchase of up to $75.0 million of the Company's common stock (the "2016 Share Repurchase Program"). Under the 2016 Share Repurchase Program, the Company was authorized to repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. The 2016 Share Repurchase Program was terminated by the Company's Board in connection with its approval of the 2018 Share Repurchase Program in October 2018.

(3) On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company may repurchase up to $100 million of its outstanding common stock (the "2017 Share Repurchase Program"). Under the 2017 Share Repurchase Program, the Company may repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. The 2017 Share Repurchase Program was terminated by the Company's Board in connection with its approval of the 2018 Share Repurchase Program in October 2018.

(4) On October 30, 2018, the Company announced a new repurchase program approved by the Board pursuant to which the Company may repurchase of up to $150 million of the its outstanding common stock, consisting of (i) up to $50 million in repurchases pursuant to an accelerated share repurchase agreement (the "ASR"), with JPMorgan Chase

Bank, N.A. (“JPMorgan”), and (ii) up to $100 million in additional repurchases (collectively, the “2018 Share Repurchase Program”). In connection with its approval of the 2018 Share Repurchase Program, the Board terminated the Company’s 2016 Share Repurchase Program and 2017 Share Repurchase Program in October 2018. Under the 2018 Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions, accelerated share repurchases or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. Under the 2018 Share Repurchase Program, the additional repurchases have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational

performance, market conditions, securities law limitations, and other factors. The repurchases will be made using the Company's cash resources.

(5) In connection with the 2018 Share Repurchase Program, on October 30, 2018, the Company entered into the ASR with JPMorgan to repurchase an aggregate of $50 million of the Company's common stock. Under the terms of the ASR, the Company paid $50 million to JP Morgan on November 1, 2018, and received 702,988 shares, representing approximately 80% of the notional amount of the ASR, based on the closing price of $56.90 on October 29, 2018. Upon settlement of the ASR, the final number of shares repurchased were trued up based on the average of the daily volume weighted average share prices of the Company's common stock, less a discount, during the term of the ASR. The Company received 297,146 shares on December 6, 2018, the termination date.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this annual report on Form 10-K.

Item 6. Selected Financial Data

The following table sets forth our selected financial data for the periods and as of the dates indicated. The following selected financial data should be read in conjunction with our audited financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K.

The statement of operations data for the years ended December 31, 2018, 2017, 2016, 2015, three months ended December 31, 2014, and the year ended September 30, 2014, respectively, and the balance sheet data as of December 31, 2018, 2017, 2016, 2015 and 2014, and September 31, 2014 are derived from our audited consolidated financial statements. All previously reported share and per share amounts of our common stock, including shares of common stock underlying stock options and warrants, throughout this Annual Report have been retroactively adjusted to reflect our 1-for-6.41 reverse stock split of our shares of common stock effective on February 18, 2014. Our audited consolidated financial statements have been prepared in U.S. dollars in accordance with U.S. GAAP.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results to be expected for a full fiscal year.

	Year Ended December 31,				Three Months Ended December 31,	Year Ended September 30,
Statement of Operations Data:	2018	2017	2016	2015	2014	2014
	(in thousands except share and per share amounts)					
Total revenue	$213,312	$236,707	$189,482	$66,227	$5,600	$19,099
Cost of product sales	42,374	33,714	35,785	7,762	1,782	5,042
Cost of royalty revenue	19,542	23,472	19,521	7,885	2,707	6,672
Research and development	44,419	32,607	28,289	27,855	3,986	16,816
Selling, general and administrative	60,509	71,416	53,329	20,165	3,690	9,326
Income (loss) from Operations	36,616	73,990	53,351	2,560	(6,565)	(18,757)
(Provision for) benefit from income taxes	(2,135)	(21,002)	28,026	(3)	1,059	1,295
Net income (loss) attributable to common stockholders	31,903	51,943	81,453	2,571	(5,506)	(19,643)
Income (loss) per share attributable to common stockholders- basic	$2.16	$3.44	$5.24	$0.17	$(0.39)	$(1.97)
Income (loss) per share attributable to common stockholders- diluted	$2.09	$3.27	$4.96	$0.16	$(0.39)	$(1.97)
Weighted average common shares outstanding-basic	14,768,625	15,102,890	15,533,681	15,250,154	14,032,828	9,955,937
Weighted average common shares outstanding-diluted	15,278,651	15,908,211	16,434,104	16,253,781	14,032,828	9,955,937

	December 31,					September 30,
Balance Sheet Data:	2018	2017	2016	2015	2014	2014
	(in thousands)					
Cash and cash equivalents	$78,791	$114,657	$52,820	$79,083	$34,869	$22,722
Short-term investments	—	—	—	—	—	19,999
Accounts receivable	66,486	53,821	42,194	26,267	11,956	7,296
Total assets	238,603	270,060	214,320	124,605	50,094	53,411
Total current liabilities	39,686	47,302	40,965	34,262	22,186	20,315
Retained earnings (Accumulated deficit)	58,187	26,284	(25,659)	(107,112)	(109,683)	(104,177)
Total stockholders' equity	$160,762	$179,144	$151,226	$90,343	$27,908	$33,096

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

The following discussion and analysis of financial condition and results of operations is provided to enhance the understanding of, and should be read in conjunction with, Part I, Item 1, “Business” and Item 8, “Financial Statements and Supplementary Data.” For information on risks and uncertainties related to our business that may make past performance not indicative of future results, or cause actual results to differ materially from any forward-looking statements, see “Special Note Regarding Forward-Looking Statements,” and Part I, Item 1A, “Risk Factors.”

Overview

Our business model is to develop proprietary innovations to FDA-approved, injectable drugs that offer commercial and/or functional advantages to currently available alternatives. We have historically been, and will continue to primarily be, focused on developing and commercializing injectable drugs, primarily in the critical care and oncology areas, using the United States Food and Drug Administration (“FDA”)'s 505(b)(2) New Drug Application (“NDA”) regulatory pathway. With our addition of Eagle Biologics, we hope to apply our market strategy to offer “biobetter” formulations, and to develop novel biologic products under the pathway

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provided by the Biologics Price Competition and Innovation Act. In addition, we plan to continue to market and/or commercialize our products through marketing partners and/or through our growing internal direct sales force. Our product portfolio now includes four approved products: Argatroban, Ryanodex® (dantrolene sodium) (“Ryanodex”), rapidly infused bendamustine RTD 50ml solution (“Bendeka”) and Eagle's bendamustine RTD 500ml solution (“Big Bag” or "Belrapzo"). We have three commercial partners: Chiesi USA, Inc. (“Chiesi”) and Sandoz Inc. (“Sandoz”), who, pursuant to separate agreements, market Argatroban and Teva Pharmaceutical Industries Ltd. ("Teva"), which, through its subsidiary Cephalon, Inc. (“Cephalon”), markets Bendeka®. Bendeka was commercially launched by Teva in January 2016. We launched Big Bag in May 2018 with our commercial team immediately after receiving FDA approval.

We currently have multiple product candidates in advanced stages of development and/or under review for approval by the FDA. Additionally, we have other product candidates under a collaborative agreement. Our advanced product candidates are EP-4104 (dantrolene sodium for exertional heat stroke (“EHS”)) (“EP-4104”), EP-5101 (PEMFEXY™, a pemetrexed injection ready-to-dilute formulation) (“EP-5101”) and EGL-5385-C-1701 (fulvestrant).

Recent Developments

On February 8, 2018, we entered into an amendment (the “Amendment”) to the stock purchase agreement dated November 10, 2016 (the “Arsia SPA”). Pursuant to the Arsia SPA, we acquired from Arsia Therapeutics, LLC (the “Seller”) all of the outstanding capital stock of Arsia Therapeutics, Inc. (now Eagle Biologics). Pursuant to the Amendment, our obligations to make four separate milestone payments pursuant to the Arsia SPA, which could have aggregated to a total of $48 million, were terminated in exchange for a single payment of $15 million to the Seller.

In March 2018, the Company announced that the United States Patent and Trademark Office (USPTO) issued a new patent to the Company's Eagle Biologics division. Patent number 9,925,263 will expire in March 2036 and is the third patent issued in the Eagle Biologics family of patents.

In March 2018, the FDA approved a second manufacturing site for Bendeka.

On April 16, 2018, the Company announced the FDA's acceptance of our ANDA filing for vasopressin injection, 1ml. This product is the generic version of Endo International plc's original Vasostrict® formulation, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Vasostrict had approximately $400 million in brand sales in 2017.

On May 15, 2018, the FDA granted final approval for Eagle's ready-to-dilute bendamustine hydrochloride solution in a 500ml admixture for the treatment of patients with chronic lymphocytic leukemia (CLL) and patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

On March 24, 2016 the FDA denied the Company's request for seven years of orphan drug exclusivity in the U.S., for Bendeka. In April 2016, the Company filed a lawsuit against the FDA arguing that Bendeka is entitled to orphan drug exclusivity as a matter of law (see Note 12. Legal Proceedings). On July 2, 2014, the FDA granted the Company orphan drug designations for Bendeka for the treatment of CLL and indolent B-cell NHL. The designations were based on a plausible hypothesis that Bendeka is “clinically superior” to a drug previously approved for the same indications. Generally, an orphan-designated drug is eligible for seven years of marketing exclusivity for the orphan-designated indications upon approval of the drug for those indications. On June 8, 2018, the U.S. District Court for the District of Columbia (the “Court”) issued a decision requiring the FDA to grant seven years of orphan drug exclusivity (ODE) in the U.S., for Bendeka, and on July 8, 2018 the FDA granted such ODE through December 2022. In addition, on July 8, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested the Court amend its decision to make clear that the decision does not affect any

applications referencing TREANDA. The FDA's motion was denied by the Court on August 1, 2018 on the grounds that FDA was seeking an inappropriate advisory opinion. On February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of exclusivity for Bendeka. Pursuant to the decision, no bendamustine product (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka. The Company expects to vigorously pursue the scope of its exclusivity grant.

In June 2018, as part of an ongoing organizational review, the Company began a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures include the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection and plans to rationalize research and development operations. The Company ceased selling Non-Alcohol Docetaxel Injection by September 30, 2018.

On July 26, 2017, we received a Complete Response Letter from the FDA regarding our 505(b)(2) NDA for Ryanodex for the treatment of exertional heat stroke ("EHS"), in conjunction with external cooling methods. Based on our meeting with the FDA, the Company conducted an additional clinical trial in August 2018 during the Hajj pilgrimage, similar to the study conducted during the Hajj in 2015. On August 30, 2018, we announced the completion of enrollment of our second clinical study to further evaluate the safety and efficacy of Ryanodex. During the 2018 Hajj, overall emergency room visits were dramatically decreased from previous years due to well-implemented crowd management, lower temperatures, lower humidity and other external factors. As a result, the number of EHS patients available for study enrollment was also significantly less than in previous years, and therefore much lower than anticipated. The preliminary assessment of patients enrolled is consistent with the data from the study conducted in 2015, in which patients dosed with RYANODEX plus Standard of Care ("SOC") showed an additive benefit compared to patients receiving SOC only. We intend to complete the analysis of the data and meet with the U.S. Food and Drug Administration to discuss next steps in 2019.

On September 26, 2018, we announced that the Compensation Committee of the Company's Board approved the appointment of David Pernock to the position of Chief Operating Officer effective as of September 1, 2018. In addition to his new role as Chief Operating Officer, Mr. Pernock has continued to serve as the Company's President.

On October 3, 2018, the Company announced that it entered into an agreement with the United States Army Medical Research Institute of Chemical Defense, the nation's leading science and technology laboratory in the area of medical chemical countermeasures research and development, to conduct a study to evaluate the neuroprotective effects of RYANODEX (dantrolene sodium).

On October 30, 2018, we announced that the Company's fulvestrant formulation has not met the primary pharmacokinetic endpoint evaluating the bioequivalence of the Company's formulation compared to Faslodex in its open label, randomized, pharmacokinetic and safety study conducted in 600 healthy female volunteers across multiple U.S. sites.

On October 30, 2018, the Company announced that its Board of Directors has approved a new share repurchase program providing for the repurchase of up to $150 million of the Company's outstanding common stock, consisting of (i) up to $50 million in repurchases pursuant to an accelerated share repurchase agreement (the "ASR") with JPMorgan Chase Bank, N.A. ("JPMorgan"), and (ii) up to $100 million in additional repurchases (the "2018 Share Repurchase Program"). In connection with its approval of the 2018 Share Repurchase Program, the Board terminated the Company's 2016 Share Repurchase Program and 2017 Share Repurchase Program in October 2018. During the fourth quarter of 2018, we repurchased 1,000,134 shares of outstanding common stock for $50 million pursuant to the ASR.

On November 27, 2018, the Company announced positive results of a pre-clinical study conducted to evaluate the effects of Ryanodex in Acute Radiation Syndrome.

Financial Operations Overview
Revenue

Our revenue consists of product sales, royalty revenue and license and other revenue.
Product Sales. Through the year ended December 31, 2018, we have recognized revenues from product sales of Bendeka, Argatroban, Ryanodex, Big Bag, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol. Sales of Bendeka are sold to our commercial partner Teva. Argatroban is sold directly to our commercial partners Chiesi and Sandoz. Sales to our commercial partners are typically made at little or no profit for resale. Ryanodex, Big Bag, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol have been sold directly to wholesalers, hospitals and surgery centers through a third party logistics partner. Diclofenac-misoprostol was divested in March 2016; however,

we continued to market diclofenac-misoprostol through the first quarter of 2018 until such time that the purchaser was able to launch the product. As part of a restructuring initiative, we ceased selling Non-Alcohol Docetaxel Injection by September 30, 2018.

We typically enter into agreements with group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of our direct commercial products. Based on these agreements, most of our hospital customers have contracted prices for products and volume-based rebates on product purchases. These amounts are estimated and recorded at the time of sale. In the case of discounted pricing, we typically pay a chargeback, representing the difference between the price invoiced to the wholesaler and the customer contract price.

Royalty revenue. We recognize revenue from royalties based on a percentage of Teva's net sales of Bendeka and Sandoz's and Chiesi's gross profit of Argatroban, both net of discounts, returns and allowances incurred by our commercial partners. Royalty

revenue is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured.

License and other revenue.

Our revenues may either be in the form of the recognition of deferred revenues upon milestone achievement for which cash has already been received or recognition of revenue upon milestone achievement, the payment for which is reasonably assured to be received in the future.

The primary factors that determine our revenues derived from Bendeka are:

- the level of orders submitted by our commercial partner, Teva;
- the rate at which Teva can convert the current market to Bendeka;
- the level of institutional demand for Bendeka;
- unit sales prices charged by our commercial partner, net of any sales reserves; and
- the level of orders submitted by wholesalers, hospitals and surgery centers.

The primary factors that may determine our revenues derived from Argatroban are:

- the level of orders submitted by our commercial partners, Sandoz and Chiesi;
- the level of institutional demand for Argatroban; and
- unit sales prices charged by our commercial partners, net of any sales reserves.

The primary factors that may determine our revenues derived from Ryanodex, Big Bag and our future products are:

- the effectiveness of our sales force;
- the level of orders submitted by wholesalers, hospitals and surgery centers;
- the level of institutional demand for our products; and
- unit sales prices, net of any sales reserves.

Cost of Revenues

Cost of revenue consists of the costs associated with producing our products for our commercial partners. In particular, our cost of revenue includes production costs of our products paid to a contract manufacturing organization coupled with shipping and customs charges, cost of royalty and the amortization of intangible assets. Cost of revenue may also include the effects of product recalls, if applicable.

Research and Development

Costs for research and development are charged to expense as incurred and include: employee-related expenses including salaries, benefits, travel and stock-based compensation expense for research and development personnel, expenses incurred under agreements with contract research organizations, contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies; costs associated with preclinical activities and development activities, costs associated with regulatory operations; and depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid expenses or accrued expenses as deemed appropriate.

Selling, General and Administrative

Selling, general and administrative costs consist primarily of salaries, benefits and other related costs, including stock-based compensation for executive, finance, sales and operations personnel. Selling, general and administrative expenses also include facility and related costs, professional fees for legal, consulting, tax and accounting services, insurance, selling, marketing, market research, advisory board and key opinion leaders, depreciation and general corporate expenses.

Income Taxes

We account for income taxes using the liability method in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 740, “Income Taxes” (“ASC 740”). Deferred tax assets and liabilities are

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determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is "more likely than not" that all or a portion of deferred tax assets will not be realized. ASC 740 also prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the Company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Results of Operations
Comparison of Years Ended December 31, 2018 and December 31, 2017

Revenues

	Year Ended December 31,		Increase / (Decrease)
	2018	2017	
	(in thousands)		
Product sales	$70,385	$45,327	$25,058
Royalty revenue	142,927	153,880	(10,953)
License and other revenue	—	37,500	(37,500)
Total revenue	$213,312	$236,707	$(23,395)

Product sales increased $25.1 million in the year ended December 31, 2018, primarily driven by the FDA approval and launch of Big Bag in May 2018 which generated $22.9 million of 2018 revenues accompanied by increases in product sales of Bendeka of $8.3 million and an increase for Ryanodex of $2.7 million. The increases were partially offset by decreases in product sales of Argatroban of $3.7 million, and in Non-Alcohol Docetaxel Injection of $3.8 million due to its discontinuation in September 2018.
Royalty revenue decreased $11.0 million in the year ended December 31, 2018, as a result of lower royalties on Bendeka.
License and other revenue for the year ended December 31, 2017, comprised of a $25.0 million milestone under the Cephalon agreement related to Teva reaching $500 million in cumulative net sales of Bendeka and a $12.5 million upfront cash payment earned under the SymBio License Agreement.

Cost of Revenue

	Year Ended December 31,		Increase / (Decrease)
	2018	2017	
	(in thousands)		
Cost of product sales	$42,374	$33,714	$ 8,660
Cost of royalty revenue	19,542	23,472	(3,930)
Total cost of revenue	$61,916	$57,186	$ 4,730

Cost of product sales increased $8.7 million in the year ended December 31, 2018, primarily as a result of increased product sales of Big Bag and Bendeka, offset by decreased product sales of Argatroban, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol.

Cost of royalty revenue decreased $3.9 million in the year ended December 31, 2018 due to the non-recurrence of both the $25.0 million milestone realized under the Cephalon agreement, related to Teva reaching $500 million in

cumulative net sales of Bendeka, and the $12.5 million upfront cash payment earned under the SymBio License Agreement during the year ended December 31, 2017.

Research and Development

	Year Ended December 31,		Increase
	2018	2017	
	(in thousands)		
Research and development	$44,419	$32,607	$11,812

The increase primarily resulted from an increase in project spending for EGL-5385-C-1701 relating to the clinical study, which completed randomization of 600 subjects in the first quarter of 2018.

Selling, General and Administrative

	Year Ended December 31,		
	2018	2017	Decrease
	(in thousands)		
Selling, general and administrative	$60,509	$71,416	$(10,907)

This decrease is principally related to a $14.5 million decrease in sales and marketing spend prior to an expected launch of Ryanodex for exertional heat stroke that did not occur and the non-recurrence of fees related to a co-promotion agreement during 2017 and $0.8 million decrease in professional fees. These decreases were partially offset by a $2.8 million increase in salary and personnel-related expenses, including stock-based compensation expense, as we build out areas to support the needs of the business.

Restructuring Charge

As part of its ongoing organizational review, the Company engaged in a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures included the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection in June 2018 and plans to rationalize research and development operations. Charges consist of inventory and related reserves, certain asset impairment charges related to property, plant and equipment, and personnel related costs. The restructuring costs were $7,911 for the year ended December 31, 2018.

Asset Impairment Charge

On June 30, 2018, we implemented a restructuring initiative resulting in the removal of Non-Alcohol Docetaxel Injection from our product portfolio. Sales for the product ceased entirely at the end of third quarter 2018. We have determined the carrying amount of the asset to no longer be recoverable, resulting in a pre-tax, non-cash asset impairment charge of $2.7 million during the year ended December 31, 2018.

Change in Fair Value of Contingent Consideration

Contingent consideration, which primarily consists of potential milestone payments and royalty obligations, is recorded in our consolidated balance sheets at its estimated fair value at the acquisition date, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in our consolidated statements of income. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting.

Contingent consideration gain of $0.8 million was recorded during the year ended December 31, 2018. This was primarily driven by adjustments to the fair values of the liabilities associated with Non-Alcohol Docetaxel Injection, which was remeasured as a result of the discontinuation of the product and partially offset by accretion for the time value of money.

Other Income and Expense

	Year Ended December 31,		Increase
	2018	2017	
	(in thousands)		
Interest income	$158	$91	$67
Interest expense	(2,736)	(1,136)	(1,600)
Total other income, net	$(2,578)	$(1,045)	$(1,533)

Interest expense increased for the year ended December 31, 2018 related to the amortization of debt issuance costs and interest incurred on long-term debt.

Provision for income taxes

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Provision for income taxes	$(2,135)	$(21,002)
Effective tax rate	6 %	29 %

The provision for income taxes were based on the applicable federal and state tax rates for those periods. The effective tax rate for the year ended December 31, 2018 and 2017 reflects tax benefits related to stock option exercises in the period as well as credits for research and development activity (see Note to Consolidated Financial Statements - Note 8. Income Taxes).

As a result of the Tax Act, the federal statutory tax rate was reduced to 21% from 35% beginning in 2018. In addition, the Company's income tax provision for the year ended December 31, 2017 included a charge for the revaluation of net deferred tax assets due to the Tax Act.

Net Income

Net income for the year ended December 31, 2018 was $31.9 million as compared to a net income of $51.9 million for the year ended December 31, 2017, as a result of the factors discussed above.

Comparison of Years Ended December 31, 2017 and December 31, 2016

Revenues

	Year Ended December 31,		Increase / (Decrease)
	2017	2016	
	(in thousands)		
Product sales	$45,327	$40,646	$ 4,681
Royalty revenue	153,880	99,040	54,840
License and other revenue	37,500	49,796	(12,296)
Total revenue	$236,707	$189,482	$ 47,225

Total revenue increased $47.2 million in the year ended December 31, 2017 to $236.7 million as compared to $189.5 million in the year ended December 31, 2016.
Product sales increased approximately $4.7 million in the year ended December 31, 2017, primarily driven by increases in product sales of Ryanodex of $5.9 million and Non-Alcohol Docetaxel Injection of $1.2 million. These increases were partially offset by decreases of $1.2 million in net product sales of Bendeka and $0.4 million in net product sales of Argatroban. In addition, there was a $0.8 million decrease in net product sales of diclofenac-misoprostol as the Company sold certain intellectual property related to this product in March 2016.
Royalty revenue increased $54.8 million in the year ended December 31, 2017, primarily as a result of increased Bendeka market share on Teva sales amplified by an increase in the Bendeka royalty rate from 20% to 25% upon receipt of the J-code, partially tempered by a decrease in Argatroban royalties.

License and other revenue decreased for the year ended December 31, 2017 as compared to the year ended December 31, 2016. For the year ended December 31, 2017, we realized a $25.0 million milestone under the Cephalon agreement related to Teva reaching $500 million in cumulative net sales of Bendeka and a $12.5 million upfront cash payment earned under the SymBio License Agreement. License and other revenue for the year ended December 31, 2016 was comprised of a $40.0 million milestone related to the receipt of the J-code for Bendeka, $6.0 million recognized from an asset sale in fiscal 2010 (which had previously been deferred), $2.0 million as the Company met certain one-time performance obligations and $1.8 million related to the amendment of the license and supply agreement with Teva, expanding the territories for commercial sale of Bendeka.

Cost of Revenue

	Year Ended December 31,		(Decrease) / Increase
	2017	2016	
	(in thousands)		
Cost of product sales	$33,714	$35,785	$ (2,071)
Cost of royalty revenue	23,472	19,521	3,951
Total cost of revenue	$57,186	$55,306	$ 1,880

Cost of revenue increased $1.9 million in the year ended December 31, 2017 to $57.2 million as compared to $55.3 million in the year ended December 31, 2016.

Cost of product sales decreased $2.1 million in the year ended December 31, 2017, primarily as a result of decreased product sales of Bendeka, Argatroban, and diclofenac-misoprostol, offset by increases in product sales of Ryanodex and Non-Alcohol Docetaxel Injection.

Cost of royalty revenue increased $4.0 million in the year ended December 31, 2017 as a result of an increase in the cost of product royalty for Bendeka, offset by a decrease in the cost of product royalty for Argatroban.

Research and Development

	Year Ended December 31,		Increase
	2017	2016	
	(in thousands)		
Research and development	$32,607	$28,289	$ 4,318

Research and development expenses increased approximately $4.3 million in the year ended December 31, 2017 to $32.6 million as compared to $28.3 million in the year ended December 31, 2016. The increase resulted from an increase in project spending for EGL-5385-C-170, EP-4104, EGL-4104-C-1702, certain other projects and an increase in salary and other personnel-related expenses due to increased headcount. These increases were partially offset by a decrease in project spending for EP-6101 and EP-5101. Additionally, during the year ended December 31, 2016 we received certain cost reimbursements from a commercial partner for $1.6 million and a $2.4 million credit from a supplier related to the resolution of a dispute.

Selling, General and Administrative

	Year Ended December 31,		Increase
	2017	2016	
	(in thousands)		
Selling, general and administrative	$71,416	$53,329	$18,087

Selling, general and administrative expenses increased approximately $18.1 million in the year ended December 31, 2017 to $71.4 million as compared to $53.3 million in the year ended December 31, 2016.
This increase is principally related to a $10.2 million increase in salary and personnel related expenses, including stock-based compensation, as we build out areas to support the growing needs of the business and sales force, $3.0 million increase in sales and marketing spend in preparation for the launch of Ryanodex for exertional heat stroke, $1.7 million increase in professional fees mainly for legal matters, $1.4 million increase in amortization expense related to the Biologics developed technology intangible asset, $0.8 million increase in travel related expenses, and a

$1.0 million increase in miscellaneous expenses.

Gain on sale of asset

On March 29, 2016, we entered into the Diclofenac Asset Purchase Agreement pursuant to which we sold certain intellectual property related to diclofenac-misoprostol in the United States. In consideration of the assets and rights sold under the Diclofenac Asset Purchase Agreement, we received a one-time payment at closing of $1.75 million, which was included in operating expenses.

Asset Impairment Charge

During the year ended December 31, 2017, the Company experienced a decline in customer contracts and saw a drop in market pricing for Non-Alcohol Docetaxel Injection. Accordingly, the Company estimated the fair value of our Non-Alcohol Docetaxel Injection product and determined the carrying amount of the intangible asset was no longer fully recoverable, resulting in a pre-tax, non-cash asset impairment charge of $7.2 million.

Change in Fair Value of Contingent Consideration

Contingent consideration, which primarily consists of potential milestone payments and royalty obligations, is recorded in the Company's consolidated balance sheets at its estimated fair value at the acquisition date, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in the Company's consolidated statements of income. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting.

A change in fair value of contingent consideration was recorded for the year ended December 31, 2017 resulting in income of $7.4 million, net. This includes adjustments to the fair values of the liabilities associated with Non-Alcohol Docetaxel Injection, which was remeasured as a result of changes in forecasted revenues for the product. Also included in the amount was a change in the fair value of contingent consideration liability from the acquisition of Eagle Biologics. In February 2018, the Company amended the Eagle Biologics Stock Purchase Agreement and has paid $15 million for all remaining obligations for milestone payments under that agreement.

Legal Settlement

On February 2, 2016, The Medicines Company (“MDCO”) filed a complaint in the U.S. District Court for the District of New Jersey against the Company, SciDose LLC and TherDose Pharma Pvt. Ltd. (collectively the “Defendants”) relating to the Defendants’ work on a novel ready-to-use bivalirudin injection product (“EP-6101”). MDCO amended that complaint in April of 2016. The complaint cites the May 7, 2008 License and Development Agreement (the “LDA”) between the Defendants and MDCO, which was terminated by the Company on September 17, 2013. In October 2017, the Defendants moved to dismiss the action for lack of subject matter jurisdiction and to stay discovery. In December 2017, while those motions were pending, the parties entered into a settlement agreement pursuant to which Defendants agreed to pay $1.7 million and assign to MDCO all intellectual property rights relating to EP-6101. As a result of the settlement, the parties entered into a stipulation dismissing all claims with prejudice.

Other Income and Expense

	Year Ended December 31,		Increase
	2017	2016	
	(in thousands)		
Interest income	$91	$84	$7
Interest expense	(1,136)	(8)	(1,128)
Total other income, net	$(1,045)	$76	$(1,121)

Interest expense increased for the year ended December 31, 2017 related to the amortization of debt issuance costs and interest incurred on long-term debt.

(Provision for) benefit from income taxes

	Year Ended December 31,	
	2017	2016
	(in thousands)	
(Provision for) benefit from income taxes	$(21,002)	$28,026

Effective tax rate	29	%	(52	)%

We recorded a $21.0 million provision for income taxes for the year ended December 31, 2017 as compared to a $28.0 million benefit for income taxes for the year ended December 31, 2016.

The (provision for) benefit from income taxes were based on the applicable federal and state tax rates for those periods. For periods with a loss before benefit for income taxes, favorable tax items result in an increase in the effective tax rate, while unfavorable

tax items result in a decrease in the effective tax rate. For periods with income before provision for income taxes, favorable tax items result in a decrease in the effective tax rate, while, unfavorable tax items result in an increase in the effective tax rate.

The tax provision for the year ended December 31, 2017 reflects an effective tax rate of 29%. The difference between the notional U.S. statutory federal income tax rate and our effective tax rate includes favorable rate items such as exercise of stock options in the period and credits from research and development activity and unfavorable items such as state tax and a valuation adjustment to our net deferred tax asset as of December 31, 2017 to reflect the new U.S. statutory federal income tax rate from tax reform.

The tax benefit for the year ended December 31, 2016 is due to the release of a previously carried tax valuation allowance on our net deferred tax assets including net operating loss carryforwards and the tax benefit related to the exercises of stock options during 2016. This was partially offset by the tax on 2016 earnings. Our decision to remove the valuation allowance on the Company's net deferred tax assets considered our significant income in 2016 which translated to our becoming a tax payer in 2016 and our outlook on prospective earnings and taxable income driven by Bendeka royalty and milestone revenues.

Net Income

Net income for the year ended December 31, 2017 was $51.9 million as compared to a net income of $81.5 million for the year ended December 31, 2016, as a result of the factors discussed above.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, product development costs, operating expenses as well as strategic business and product acquisitions and repurchases of our common stock. Cash and cash equivalents were $78.8 million, and $114.7 million as of December 31, 2018 and December 31, 2017, respectively.

For the year ended December 31, 2018, we realized net income of $31.9 million. As of December 31, 2018, we had a working capital surplus of $124.2 million. For the year ended December 31, 2017, we realized net income of $51.9 million.

We believe that future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for at least the next twelve months.

We expect to use future loans, if any, under the Credit Facility, for general corporate purposes and any strategic acquisitions.

Operating Activities:

Net cash provided by operating activities for the year ended December 31, 2018 was $52.4 million. Net income for the same period was $31.9 million offset by non-cash adjustments of approximately $28.4 million from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, amortization of debt issuance costs, change in fair value of contingent consideration, asset impairment charge and fair value adjustment related to restructuring. Net changes in working capital decreased cash provided from operating activities by $7.9 million, due to an increase in accounts receivable of $12.7 million, an increase in inventory of $5.6 million, an increase in accrued expenses and other current liabilities of $8.1 million, an increase in other assets of $0.6 million partially offset by a decrease in prepaid expenses and other current assets of $4.8 million, and a decrease in accounts payable of $2.1 million. The total amount of accounts receivable at December 31, 2018 was approximately $66.5 million, which included approximately $25.3 million from product sales, $35.7 million from royalty income, and $5.5 million related to cost reimbursements. Receivables from our product sales have payment terms ranging from 30 to 75 days with select extended terms to wholesalers on initial purchases of product launch quantities. Our receivables from royalty revenue are due 45-days from the end of the quarter.

Net cash provided by operating activities for the year ended December 31, 2017 was $58.9 million. Net income for the same period was $51.9 million offset by non-cash adjustments of approximately $36.5 million principally from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, asset impairment charge, amortization of debt issuance costs, and change in fair value of contingent consideration. Net changes in working capital decreased cash provided from operating activities by $29.6 million, due to an increase in accounts receivable of $11.6 million, an increase in inventory of $2.4 million partially offset by a decrease in prepaid expenses and other current assets of $2.0 million, a decrease in accounts payable of $8.5 million, a decrease in accrued expenses and other current liabilities of $9.1 million. The total amount of accounts receivable at December 31, 2017 was approximately $53.8 million, which included approximately $13.3 million from product sales, $36.4 million from royalty income, and $4.1 million related to cost reimbursements, all with payment terms of 45 days. Royalty income is receivable with terms of 45 days and starts at the end of the quarter to which it relates, the immediately preceding quarter.

Net cash provided by operating activities for the year ended December 31, 2016 was $53.2 million. Net income for the same period was $81.5 million reduced by non-cash adjustments of approximately $19.6 million principally from deferred income taxes, depreciation, amortization of intangible assets and stock-based compensation expense. Net changes in working capital decreased

cash provided from operating activities by $8.6 million, due to an increase in accounts receivable of $15.9 million, an increase in prepaid expenses and other current assets of $9.4 million partially offset by an increase in accounts payable of $10.7 million, a decrease in inventories of $12.3 million and a decrease in deferred revenue of $6.0 million. The total amount of accounts receivable at December 31, 2016 was approximately $42.2 million, which included approximately $10.1 million from product sales and approximately $32.0 million from royalty income, all with payment terms of 45 days. Royalty income is receivable with terms of 45 days and starts at the end of the quarter to which it relates, the immediately preceding quarter.

Investing Activities:

During the years ended December 31, 2018, 2017 and 2016, we invested $0.1 million, $4.4 million, and $1.6 million, respectively, for the purchase of property and equipment.

During the year ended December 31, 2017, we invested $0.8 million related to the purchase of the Ryanodex intangible.

During the year ended December 31, 2016, we purchased Non-Alcohol Docetaxel Injection for $4.9 million, the Ryanodex intangible for $14.3 million and Eagle Biologics for $26.9 million of net cash acquired. We divested diclofenac-misoprostol for proceeds of $1.8 million. We invested $62.0 million in U.S. Treasury securities and redeemed $62.0 million of short-term investments.

Financing Activities:

Net cash used in financing activities for the year ended December 31, 2018 was $88.1 million, primarily resulting from a $15 million payment of contingent consideration in connection with the Arsia Amendment, $73.1 million in cash settlements on repurchases of common stock, $3.7 million payment of debt financing costs and a $4.9 million payment of employee withholding tax for net option exercises. This was offset by the issuance of common stock for stock option exercises of $8.6 million.

Net cash provided by financing activities for the year ended December 31, 2017 was $8.1 million, primarily resulting from $50.0 million in proceeds from debt issuance and the issuance of common stock for stock option exercises of $4.3 million. This was offset by $43.8 million in cash settlements on repurchases of common stock, a $1.2 million payment of debt financing costs, and a $1.3 million payment of debt principal.

Net cash used in financing activities for the year ended December 31, 2016 was $33.7 million primarily resulting from $37.0 million in cash settlements on repurchases of common stock and a $0.3 million payment of contingent consideration partially offset by the issuance of common stock for stock option exercises of $3.6 million.

Contractual Obligations

Our future material contractual obligations include the following (in thousands):

Obligation	Total	2019	2020	2021	2022	2023	Beyond
Operating leases (1)	$3,661	$1,146	$864	$583	$583	$485	$ —
Credit facility	45,000	6,250	38,750	—	—	—	—
Purchase obligations (2)	29,333	29,333	—	—	—	—	—
Total obligations	$77,994	$36,729	$39,614	$583	$583	$485	$ —

(1) The Company leases its office and lab space under lease agreements that expire on June 30, 2020 and October 31, 2023. Rental expense was $571, $664, and $634, for the year ended December 31, 2018, 2017, and 2016, respectively. The remaining future lease payments under the operating leases, exclusive of any renewal option periods, are $3,661 as of December 31, 2018, payable monthly through June 30, 2020 and October 31, 2023.

(2) As of December 31, 2018, the Company has purchase obligations in the amount of $29,333 which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligation under the supply agreement is primarily for finished product, inventory, and research and development.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-02, “Leases (Topic 842)” (ASU 2016-02) to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new guidance, lessees are required to

recognize a lease liability, which represents the discounted obligation to make future minimum lease payments, and a corresponding right-of-use asset on the balance sheet for most leases. In July 2018, the FASB issued ASU No. 2018-10, “Codification Improvements to Topic 842, Leases” (ASU 2018-10), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, “Leases (Topic 842) - Targeted Improvements” (ASU 2018-11), which addresses implementation issues related to the new lease standard. This guidance is effective for the Company as of January 1, 2019 and the Company will adopt this guidance using the modified retrospective approach and will recognize a cumulative-effect adjustment to the opening balance of Retained earnings in that period. This guidance includes a number of optional practical expedients that the Company may elect to apply, including an expedient that permits lease agreements that are twelve months or less to be excluded from the balance sheet. The Company is finalizing the impact that this new guidance will have on its consolidated financial statements, including its disclosures. The primary impact upon adoption will be the recognition, on a discounted basis, of the Company’s minimum commitments under noncancelable operating leases as right of use assets and obligations on the consolidated balance sheets. This will not result in a significant increase in assets and liabilities on the Company’s consolidated balance sheets. In preparation for the adoption of this guidance, the Company is finalizing the process of identifying and validating the Company’s lease information and evaluating the impact that this new guidance will have on its processes and controls.

In January 2017, the FASB issued guidance to simplify the measurement of goodwill. The guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with it's carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The guidance also eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted for interim or annual goodwill impairment tests performed for testing dates after January 1, 2017. The guidance must be adopted on a prospective basis. We do not expect this guidance to have an impact on our consolidated financial statements.

Recent Adopted Accounting Pronouncements

The Company adopted ASC 606, Revenue from Contracts with Customers with a date of initial application of January 1, 2018. As a result, the Company has updated its accounting policy for revenue recognition to reflect the new standard. The adoption of ASC 606 represents a change in accounting principle that will more closely align revenue recognition with the delivery of the Company's services and will provide financial statement readers with enhanced disclosures. The Company applied Topic 606 using the modified retrospective method. The Company has elected to apply this initial application of the standard only to contracts that are not completed at the date of initial application. For contracts which were modified before the adoption date, the Company has not restated the contract for those modifications. Instead, the Company reflected the aggregate effect of all modifications when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price, if necessary. The cumulative effect of initially applying the new revenue standard would be applied as an adjustment to the opening balance of retained earnings. The Company has analyzed this effect and found the adoption of the new guidance did not have a material impact on our consolidated financial statements and our recognition is consistent with our historical accounting policies.

In January 2016, the FASB issued ASU 2016-01, which revises the guidance in ASC 825-10, Recognition and Measurement of Financial Assets and Financial Liabilities, and provides guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. The guidance is effective for reporting periods (interim and annual) beginning after December 15, 2017, for public companies. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In January 2017, the FASB issued guidance clarifying the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities is not a business, provides a framework to assist entities in evaluating whether both an input and substantive process are present, and narrows the definition of the term output. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The guidance must be adopted on a prospective basis. We will consider the guidance for future transactions.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Impact of Inflation

While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we believe the effects of inflation, if any, on our results of operations and financial condition have been immaterial.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a “critical accounting estimate” where:

•the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

•the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in Note 2 to our financial statements included in this Annual Report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are “critical accounting estimates.” We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, accounting for fair value of warrant liabilities and share-based compensation described below are “critical accounting estimates.”

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product revenue - The Company recognizes net revenue on sales to its commercial partners and to end users. In each instance, revenue is generally recognized when the customer obtains control of the Company’s product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract. Revenue on sales to commercial partners relates to Argatroban and Bendeka. Sales to our commercial partners are presented gross because the Company is primarily responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected

value method to which the Company expects to be entitled. As such, revenue on sales to end users for Big Bag, Non-Alcohol Docetaxel Injection, and Ryanodex are recorded net of chargebacks, rebates, returns, prompt pay discounts, wholesaler fees and other deductions. Our products are

contracted with a limited number of oncology distributors and hospital buying groups with narrow differences in ultimate realized contract prices used to estimate our chargeback and rebate reserves. The Company has a product returns policy on some of its products that allows the customer to return pharmaceutical products within a specified period of time both prior to and subsequent to the product's expiration date. The Company's estimate of the provision for returns is analyzed quarterly and is based upon many factors, including historical experience of actual returns and analysis of the level of inventory in the distribution channel, if any. The Company has terms on sales of Ryanodex by which the Company does not accept returns. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration are made using the expected value method and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. The Company believes that the estimates it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

Royalty Revenue — The Company recognizes revenue from license arrangements with its commercial partners' net sales of products. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner's products occurs. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 25 days for Bendeka and 60 days for Argatroban from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter and subsequently determines a true-up when it receives royalty reports from its commercial partners. Historically, these true-up adjustments have been immaterial.

License and other revenue — The Company analyzes each element of its licensing agreements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, the Company determined that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of these future events, the Company will not recognize revenue from the milestone until there is not a high probability of a reversal of revenue, which typically occurs near or upon achievement of the event.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2018.

Collaborative licensing and development revenue — The Company recognizes revenue from reimbursements received in connection with feasibility studies and development work for third parties when its contractual services are performed, provided collectability is reasonably assured. Its principal costs under these agreements include its personnel

conducting research and development, its allocated overhead, as well as the research and development performed by outside contractors or consultants.

Upon termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in its statements of income. The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of its performance obligations under the collaboration agreement.

Stock-Based Compensation

The Company accounts for stock-based compensation using the fair value provisions of ASC 718, Compensation - Stock Compensation that requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based payments including stock options and restricted stock. This topic requires companies to estimate the fair value of the stock-based awards on the date of grant for options issued to employees and directors and record expense over the employees' service periods, which are generally the vesting period of the equity awards. The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. The straight-line method is used to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. The fair value of the Company's stock-based awards to employees and directors is estimated using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate is determined with the implied yield currently available for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options.

Income Taxes

The Company accounts for income taxes using the liability method in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 740 - Income Taxes (“ASC 740”). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is “more likely than not” that all or a portion of deferred tax assets will not be realized. ASC 740 also prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Other Intangible Assets, Net

The Company capitalizes and includes in intangible assets the costs of acquired product licenses and developed technology purchased individually or identified in a business combination. Intangible assets are recorded at fair value at the time of their acquisition and stated net of accumulated amortization. The Company amortizes its definite-lived intangible assets using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. The Company will evaluate the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Events giving rise to impairment are an inherent risk in our industry and many factors cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group and its eventual disposition to the carrying value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of income.

With respect to determining an asset’s fair value and useful life, because this process involves management making certain estimates and these estimates form the basis of the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics acquisition. Goodwill is not amortized, but is evaluated for impairment on an annual basis, in the fourth quarter, or more frequently if events or changes in circumstances indicate that the reporting unit’s goodwill is less than it's carrying amount. The Company did not identify any impairment to goodwill during the periods presented.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. We are exposed to market risk related to changes in interest rates. As of December 31, 2018, we had cash and cash equivalents of $78.8 million held primarily in money market mutual funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, however, due to the short-term duration of our money market mutual funds and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio.

Our exposure to interest rate risk also relates to our variable-rate indebtedness associated with our Amended Credit Agreement. As of December 31, 2018 and 2017, the aggregate principal amount of such variable-rate indebtedness was $44.4 million and $47.8 million, respectively. Borrowings under the Amended Credit Agreement may from time to time bear interest at variable rates, which rates are further described in Note 6. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report. As of December 31, 2018 and 2017, a hypothetical 1% increase in the applicable rate would not have a material effect on the incremental annual interest expense related to our variable-rate debt borrowings.

Item 8. Financial Statements and Supplementary Data
Our Financial Statements and Supplementary Data and Report of Independent Registered Public Accounting Firm appear beginning on page F-1 attached to this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure
Not Applicable.

Item 9A. Controls and Procedures.
Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2018, an evaluation was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based on this evaluation, such officers have concluded that our disclosure controls and procedures were effective as of December 31, 2018. Management has concluded that our consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented therein.

Management’s Annual Report on Internal Control Over Financial Reporting

The management of Eagle Pharmaceuticals, Inc. ("Eagle") has prepared, and is responsible for, Eagle's financial statements and related footnotes. These financial statements have been prepared in conformity with U.S. generally accepted accounting principles. Eagle's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of the Company’s principal executive and principal financial officers and effected by the Company’s board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of Eagle’s assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of Eagle are being made only in accordance with authorizations of management and directors of Eagle; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of Eagle's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Eagle's management conducted an assessment of the Company’s internal control over financial reporting as of December 31, 2018 based upon the criteria established in “Internal Control - Integrated Framework” issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on this assessment, our management has concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

BDO USA, LLP, the independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on the Company’s internal control over financial reporting as of December 31, 2018. This attestation report appears below.

/s/ Scott Tarriff
Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Pete A. Meyers
Chief Financial Officer
(Principal Accounting and Financial Officer)

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company’s internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

Report of Independent Registered Public Accounting Firm
Shareholders and Board of Directors
Eagle Pharmaceuticals, Inc.
Woodbridge, NJ
Opinion on Internal Control over Financial Reporting
We have audited Eagle Pharmaceuticals, Inc. internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.
We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Eagle Pharmaceuticals, Inc. as of December 31, 2018 and 2017, the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes, and our report dated February 28, 2019 expressed an unqualified opinion thereon.
Basis for Opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.
Definition and Limitations of Internal Control over Financial Reporting
A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.
Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.
/s/ BDO USA, LLP
Woodbridge, NJ
February 28, 2019

Item 9B. Other information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report.

The following documents are filed as part of this report:

1. Financial Statements

See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

3. Exhibits

The exhibits listed in the below index to exhibits are filed as part of, or incorporated by reference into, this report.

Exhibit Number	Description
2.1	Stock Purchase Agreement, dated as of November 10, 2016, by and among Eagle Pharmaceuticals, Inc., Arsia Therapeutics, LLC, Arsia Therapeutics, Inc., Amy Schulman, as the Seller Representative, and each person that executed a joinder to the Purchase Agreement (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the

	Commission on November 14, 2016)), as amended by Amendment No. 1 to Stock Purchase Agreement, dated as of February 8, 2018 (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, SEC File No. 001-36306, filed with the Commission on February 14, 2018)
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)

4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
4.2	Third Amended and Restated Investor Rights Agreement, dated April 11, 2013, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.1	Form of Indemnification Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984,

		filed December 20, 2013)
10.2	†	Eagle Pharmaceuticals, Inc. 2007 Incentive Compensation Plan and Form of Stock Option Agreement thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), as amended December 15, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.3	†	Eagle Pharmaceuticals, Inc. 2014 Equity Incentive Plan, as amended and restated, and Form of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder (incorporated by reference to

		Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015), as amended with an additional form of Stock Option Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.4	†	Eagle Pharmaceuticals, Inc. 2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 22, 2014)
10.5	†	Eagle Pharmaceuticals, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on

Form S-1/A, SEC File No. 333-192984, filed January 22, 2014)

10.6	†	Employment Agreement by and between the Registrant and Scott Tarriff dated March 8, 2007, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
10.7	†	Offer Letter by and between the Registrant and Adrian Hepner dated December 11, 2014 (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017) as amended by entry into the Eagle Pharmaceuticals, Inc. Officer Severance Benefit Plan on April 29, 2016 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed

		August 10, 2015)
		Offer Letter by and between the Registrant and Steven L. Krill dated September 7, 2011 (incorporated by reference to
10.8	†	Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
		Lease Agreement between the Registrant and Mack-Cali Chestnut Ridge L.L.C. dated May 28, 2013, as amended on July 1, 2013 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on
10.9	†	Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on March 16, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K , SEC File No. 001-36306, filed March 20, 2015)
10.10	*	Development and License

		Agreement, by and between the Registrant and SciDose, LLC, dated September 24, 2007, as amended March 18, 2008, May 22, 2009 and July 16, 2013 (incorporated by reference to Exhibit 10.11(a) to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.11	*	Development and License Agreement, by and between the Registrant and SciDose, LLC, dated June 12, 2007, as amended March 18, 2008, March 25, 2008, December 3, 2008, May 22, 2009 and July 16, 2013 (incorporated by reference to Exhibit 10.11(b) to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on August 5, 2015 (incorporated by reference to

		Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015)
10.12*		License and Sublicense Agreement, by and between the Registrant and Lyotropic Therapeutics, Inc., dated October 16, 2008 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.13*		License and Development Agreement, by and between the Registrant and The Medicines Company, effective as of September 24, 2009, as amended January 2010 and September 1, 2012 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December

	20, 2013)
10.14*	Supply Agreement, by and between the Registrant and The Medicines Company, dated September 24, 2009 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.15*	Agreement for the Supply of Argatroban and Topotecan, by and between the Registrant and Cipla Limited, dated December 14, 2012, as amended August 30, 2013 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.16*	Supply and Distribution Agreement, by and between the Registrant and Sandoz AG, dated January 28, 2013 (incorporated by

		reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.17*		Development and License Agreement, by and between the Registrant and Robert One, LLC (bendamustine), dated March 18, 2008, as amended November 11, 2009 and July 16, 2013 (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.18*		Development and License Agreement, by and between the Registrant and Robert One, LLC (pemetrexed), dated February 13, 2009, as amended May 22, 2009, December 23, 2010 and July 16, 2013 (incorporated by reference to Exhibit 10.18 to

		the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on August 5, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015)
10.19*		Exclusive License Agreement, by and between the Registrant and Cephalon, Inc., dated February 13, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q/A, SEC File No. 001-36306, filed February 12, 2016)
10.20*		Settlement and License Agreement, by and between the Registrant and Cephalon, Inc., dated February 13, 2015 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report

		on Form 10-Q, SEC File No. 001-36306, filed May 15, 2015)
10.21	†	Eagle Pharmaceuticals, Inc. Officer Severance Benefit Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015)
10.22	†	Form of Letter Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.23	*	License Agreement, by and between the Registrant and Teikoku Pharma USA, Inc., dated October 13, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 29, 2016)
10.24	*	Co-Promotion Agreement, by and between the Registrant and

		Spectrum Pharmaceuticals, Inc., dated November 4, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 29, 2016)
10.25†		Offer Letter by and between the Registrant and David Pernock dated January 2, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 19, 2016)

10.26	Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated January 26, 2017 (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017) as amended and restated by the Amended and Restated Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated August 8, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 9, 2017)
10.27	Amendment to License and Sublicense Agreement, by and between the Registrant and Lyotropic

		Therapeutics, Inc., dated August 3, 2016 (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017)	
10.28	†	Offer Letter between the Registrant and Pete A. Meyers dated May 12, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed May 15, 2017)	
10.29	*	Product Collaboration and License Agreement, by and between the Registrant and SymBio Pharmaceuticals Limited, effective as of September 19, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed November 8, 2017)	

		Separation Agreement by and between the Registrant and David Riggs dated January 24, 2018 (incorporated by
10.30	†	reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed January 30, 2018)
		Form of Restricted Stock Unit Grant Package (2014 Equity Incentive Plan) (incoporated by
10.31	†	reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 26, 2018)
		Form of Performance Stock Unit Grant Package (2014 Equity Incentive Plan) (incoporated by
10.32	†	reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 26, 2018)
10.33	†	Separation Agreement by

		and between the Registrant and Steven L. Krill, dated February 19, 2018 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed May 10, 2018)
21.1	(1)	List of subsidiaries of Eagle Pharmaceuticals, Inc.
23.1	(1)	Consent of BDO USA, LLP, an Independent Registered Public Accounting Firm
24.1		Power of Attorney (incorporated by reference to this signature page of this Annual Report on Form 10-K)
31.1	(1)	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	(1)	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated

		under the Securities Exchange Act of 1934, as amended.
32.1	(1)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document
101.LAB		XBRL Taxonomy Extension Labels Linkbase Document
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document

†Management contract or compensatory plan or arrangement.
*Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

(1) Filed herewith.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on February 28, 2019.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer and Director
(Principal Executive Officer)

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Scott Tarriff and Pete A. Meyers, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/S/ SCOTT TARRIFF Scott Tarriff	Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2019
/S/ PETE A. MEYERS Pete A. Meyers	Chief Financial Officer (Principal Accounting and Financial Officer)	February 28, 2019
/S/ MICHAEL GRAVES Michael Graves	Chairman of the Board of Directors	February 28, 2019
/S/ STEVEN RATOFF Steven Ratoff	Member of the Board of Directors	February 28, 2019
/S/ SANDER FLAUM Sander Flaum	Member of the Board of Directors	February 28, 2019
/S/ DOUGLAS L. BRAUNSTEIN Douglas L. Braunstein	Member of the Board of Directors	February 28, 2019
/S/ ROBERT L. GLENNING Robert L. Glenning	Member of the Board of Directors	February 28, 2019
/S/ RICHARD A. EDLIN Richard A. Edlin	Member of the Board of Directors	February 28, 2019

INDEX TO FINANCIAL STATEMENTS OF
EAGLE PHARMACEUTICALS, INC.

APPENDIX A

Report of Independent Registered Public Accounting Firm
Shareholders and Board of Directors
Eagle Pharmaceuticals, Inc.
Woodcliff Lake, NJ
Opinion on the Consolidated Financial Statements
We have audited the accompanying consolidated balance sheets of Eagle Pharmaceuticals Inc. as of December 31, 2018 and 2017, the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years ended December 31, 2018, and the related notes. In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.
We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated February 28, 2019 expressed an unqualified opinion thereon.
Change in Accounting Principles

On January 1, 2018, the Company adopted Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606). The effects of the adoption are described in Note 2 to the consolidated financial statements.
Basis for Opinion
These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.
Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP
We have served as the Company's auditor since 2007.
Woodbridge, NJ

February 28, 2019

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$78,791	$114,657
Accounts receivable, net	66,486	53,821
Inventories	8,304	5,118
Prepaid expenses and other current assets	10,263	15,101
Total current assets	163,844	188,697
Property and equipment, net	2,397	6,820
Intangible assets, net	18,103	23,322
Goodwill	39,743	39,743
Deferred tax asset, net	13,822	11,354
Other assets	694	124
Total assets	$238,603	$270,060
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$9,917	$11,981
Accrued expenses	23,519	15,391
Current portion of contingent consideration	—	15,055
Current portion of long-term debt	6,250	4,875
Total current liabilities	39,686	47,302
Contingent consideration, less current portion	—	709
Long-term debt, less current portion	38,155	42,905
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of December 31, 2018 and 2017	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,504,283 and 16,089,439 shares issued as of December 31, 2018 and 2017, respectively	17	16
Additional paid in capital	256,458	233,639
Retained earnings	58,187	26,284
Treasury stock, at cost, 2,590,258 and 1,241,695 shares as of December 31, 2018 and 2017, respectively	(153,900)	(80,795)
Total stockholders' equity	160,762	179,144
Total liabilities and stockholders' equity	$238,603	$270,060

See accompanying notes to consolidated financial statements
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EAGLE PHARMACEUTICALS, INC
CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenue:			
Product sales	$70,385	$ 45,327	$ 40,646
Royalty revenue	142,927	153,880	99,040
License and other revenue	—	37,500	49,796
Total revenue	213,312	236,707	189,482
Operating expenses:			
Cost of product sales	42,374	33,714	35,785
Cost of royalty revenue	19,542	23,472	19,521
Research and development	44,419	32,607	28,289
Selling, general and administrative	60,509	71,416	53,329
Restructuring charge	7,911	—	—
Gain on sale of asset	—	—	(1,750)
Asset impairment charge	2,704	7,235	—
Change in fair value of contingent consideration	(763)	(7,377)	957
Legal settlement	—	1,650	—
Total operating expenses	176,696	162,717	136,131
Income from operations	36,616	73,990	53,351
Interest income	158	91	84
Interest expense	(2,736)	(1,136)	(8)
Total other (expense) income, net	(2,578)	(1,045)	76
Income before income tax (provision) benefit	34,038	72,945	53,427
Income tax (provision) benefit	(2,135)	(21,002)	28,026
Net income	$31,903	$ 51,943	$ 81,453
Earnings per share attributable to common stockholders:			
Basic	$2.16	$ 3.44	$ 5.24
Diluted	$2.09	$ 3.27	$ 4.96
Weighted average number of common shares outstanding:			
Basic	14,768,625	15,102,890	15,533,681
Diluted	15,278,651	15,908,211	16,434,104

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock Number of Shares	Amount	Additional Paid-In Capital	Treasury Stock	(Accumulated Deficit) Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2015	15,637	$ 15	$197,440	$—	$ (107,112)	$ 90,343
Stock-based compensation expense	—	—	9,768	—	—	9,768
Issuance of common stock upon exercise of stock option grants	214	1	3,618	—	—	3,619
Common stock repurchases	—	—	—	(37,003)	—	(37,003)
Net income	—	—	—	—	81,453	81,453
Common stock issued for the Eagle Biologics acquisition	40	—	3,046	—	—	3,046
Balance at December 31, 2016	15,891	16	213,872	(37,003)	(25,659)	151,226
Stock-based compensation expense	—	—	15,429	—	—	15,429
Issuance of common stock upon exercise of stock option grants	198	—	4,338	—	—	4,338
Common stock repurchases	—	—	—	(43,792)	—	(43,792)
Net income	—	—	—	—	51,943	51,943
Balance at December 31, 2017	16,089	16	233,639	(80,795)	26,284	179,144
Stock-based compensation expense	—	—	19,082	—	—	19,082
Issuance of common stock upon exercise of stock option grants	415	1	8,614	—	—	8,615
Payments for employee net option exercises	—	—	(4,877)	—	—	(4,877)
Common stock repurchases	—	—	—	(73,105)	—	(73,105)
Net income	—	—	—	—	31,903	31,903
Balance at December 31, 2018	16,504	$ 17	$256,458	$(153,900)	$ 58,187	$ 160,762

See accompanying notes to consolidated financial statements
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EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net income	$31,903	$51,943	$81,453
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred income taxes	(2,468)	17,289	(30,116)
Depreciation expense	1,155	932	641
Amortization expense	2,515	2,815	948
Stock-based compensation	19,082	15,429	9,768
Change in fair value of contingent consideration	(763)	(7,377)	957
Amortization of debt issuance costs	376	222	—
Gain on sale of asset	—	—	(1,750)
Asset impairment charge	2,704	7,235	—
Non-cash restructuring charge	5,769	—	—
Changes in operating assets and liabilities which provided (used) cash:			
Accounts receivable	(12,665)	(11,627)	(15,919)
Inventories	(5,556)	(2,379)	12,303
Prepaid expenses and other current assets	4,838	1,993	(9,430)
Other assets	(570)	—	—
Accounts payable	(2,064)	(8,460)	10,668
Deferred revenue	—	—	(6,000)
Accrued expenses and other liabilities	8,128	(9,096)	(316)
Net cash provided by operating activities	52,384	58,919	53,207
Cash flows from investing activities:			
Purchase of property and equipment	(133)	(4,436)	(1,590)
Purchase of short term investments	—	—	(62,000)
Maturities of short term investments	—	—	62,000
Payment for Docetaxel acquisition	—	—	(4,850)
Payment for Ryanodex intangible asset	—	(750)	(14,250)
Purchase of Eagle Biologics, net of cash acquired	—	—	(26,860)
Proceeds from sale of diclofenac-misoprostol	—	—	1,750
Net cash used in investing activities	(133)	(5,186)	(45,800)
Cash flows from financing activities:			
Repurchases of common stock	(73,105)	(43,792)	(37,003)
Payment of contingent consideration	(15,000)	—	(286)
Proceeds from long-term debt	—	50,000	—
Payment of debt principal	(3,750)	(1,250)	—
Payment of debt financing costs	—	(1,192)	—
Payments for employee net option exercises	(4,877)	—	—
Proceeds from common stock option exercises	8,615	4,338	3,619
Net cash (used in) provided by financing activities	(88,117)	8,104	(33,670)
Net (decrease) increase in cash and cash equivalents	(35,866)	61,837	(26,263)
Cash and cash equivalents at beginning of period	114,657	52,820	79,083

See accompanying notes to consolidated financial statements
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EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash and cash equivalents at end of period	$78,791	$114,657	$52,820
Supplemental disclosures of cash flow information:			
Cash paid during the period for:			
Income taxes	$2,281	$10,542	$2,800
Interest	2,084	651	8
Non-cash investing activities			
Value of common stock issued for the Eagle Biologics acquisition	—	—	3,046
Non-cash financing activities			
Contingent consideration - business acquisitions	—	—	22,470

See accompanying notes to consolidated financial statements
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EAGLE PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except share and per share amounts)

1. Organization and Business

Eagle Pharmaceuticals, Inc. (the "Company") is a specialty pharmaceutical company focused on developing and commercializing injectable products, primarily in the critical care and oncology areas, using the U.S. Food and Drug Administration's ("FDA's") 505(b)(2) New Drug Application ("NDA") regulatory pathway. The Company's business model is to develop proprietary innovations to FDA-approved injectable drugs, referred to as branded reference drugs, that offer favorable attributes to patients and healthcare providers. The Company has two products currently being sold in the United States under various license agreements in place with commercial partners; a ready-to-use formulation of Argatroban and rapidly infused bendamustine RTD 50ml solution (“Bendeka”). In addition, the Company directly sells two products in the United States; Eagle's bendamustine RTD 500ml solution (“Big Bag” or "Belrapzo") and Ryanodex®(dantrolene sodium) ("Ryanodex"). The Company has a number of products currently under development and certain products may be subject to license agreements. We view our operation and manage our business as one reporting segment since the majority of our revenues are from royalties.

On February 13, 2015, the Company submitted a NDA to the FDA for Bendeka, which was approved by the FDA on December 7, 2015. Also, on February 13, 2015, the Company entered into an Exclusive License Agreement (the “Cephalon License”) with Cephalon, Inc. (“Cephalon”), a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. (“Teva”), for U.S. and Canadian rights to Bendeka for treatment of patients with chronic lymphocytic leukemia (“CLL”) and patients with non-Hodgkin’s lymphoma (“NHL”). Subsequently, with the consent of the Company, Cephalon assigned to Teva Pharmaceuticals International GmbH (“TPIG”) all of Cephalon’s rights and obligations under the Cephalon License. Accordingly, all references to “Cephalon” or to the “Cephalon License” and the related supply agreements for Bendeka should be read and construed as references to TPIG and to the license agreement and supply agreements for Bendeka to which the Company and TPIG are now parties. Pursuant to the terms of the Cephalon License, Cephalon will be responsible for all U.S. commercial activities for the product including promotion and distribution, and the Company is responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. In connection with the Cephalon License, the Company has entered into a supply agreement with Cephalon, pursuant to which the Company is responsible for supplying product to Cephalon. During the quarter-ended September 30, 2016, the Company entered into an amendment to the Cephalon License and supply agreements for Bendeka. The amendment expands the geographical scope of the rights granted under the original agreement to include territories outside the U.S. and Canada.

Additionally, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million in February 2015, earned a $15 million milestone payment related to the FDA approval of Bendeka in December 2015, earned $40 million in November 2016 related to the receipt of a unique, product-specific billing code, J-code (J9034), for Bendeka and earned $25 million in March 2017 for an additional sales-based milestone payment. In addition, the Company was entitled to receive royalty payments of 20% of net sales of the product, which increased to 25% on receipt of the J-code.

On August 9, 2016, the Company announced a share repurchase program approved by the Company’s board of directors authorizing the repurchase of up to $75.0 million of the Company’s common stock (the “Share Repurchase Program”). On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company may repurchase up to an additional $100 million of its outstanding common stock (the “New Share Repurchase Program”). Under the Share Repurchase Program and the New Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. The Share Repurchase Programs have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational performance, market conditions, securities law limitations, and

other factors. The repurchases will be made using the Company's cash resources. In any period, cash used in financing activities related to shares repurchased may differ from the comparable change in stockholders' equity, reflecting timing differences between the recognition of share repurchase transactions and their settlement for cash.

On October 30, 2018, the Company announced that its Board of Directors has approved a new share repurchase program providing for the repurchase of up to $150 million of the Company's outstanding common stock, consisting of (i) up to $50 million in repurchases pursuant to an accelerated share repurchase agreement (the “ASR”) with JPMorgan Chase Bank, N.A. (“JPMorgan”), and (ii) up to $100 million in additional repurchases (the “2018 Share Repurchase Program”). In connection with its approval of the 2018 Share Repurchase Program, the Board terminated the Company’s 2016 Share Repurchase Program and 2017 Share Repurchase Program in October 2018. During the fourth quarter of 2018, the Company repurchased 1,000,134 shares of outstanding common stock for $50 million pursuant to the ASR.

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(In thousands, except share and per share amounts)

The Company repurchased 1,348,563 shares of common stock for $73.1 million during the year ended December 31, 2018 and an aggregate of 2,590,258 shares of common stock for $153.9 million through December 31, 2018.

On November 16, 2016 the Company entered into an agreement to acquire Arsia Therapeutics (“Arsia”), an early-stage biotechnology firm with proprietary viscosity-reducing technology and formulation know-how and subsequently renamed the subsidiary Eagle Biologics, Inc. ("Eagle Biologics"). Under the terms of the stock purchase agreement, we paid approximately $27.2 million in cash and 40,200 shares of Eagle common stock worth $3.0 million at closing. We also agreed to pay up to $48 million in additional payments upon the completion of certain milestones, for aggregate potential payments of $78 million.

On February 8, 2018, we entered into an amendment (the “Arsia Amendment”) to the stock purchase agreement dated November 10, 2016 (the “Arsia SPA”), pursuant to which we acquired from Arsia Therapeutics, LLC (the “Seller”) all of the outstanding capital stock of Arsia Therapeutics, Inc. (now Eagle Biologics). Pursuant to the Arsia Amendment, our obligations to make four separate milestone payments pursuant to the Arsia SPA, which could have aggregated to a total of $48 million, were terminated in exchange for a single payment of $15 million to the Seller.

In March 2018, the Company announced that the United States Patent and Trademark Office (“USPTO”) issued a new patent to the Company's Eagle Biologics division. Patent number 9,925,263 will expire in March 2036 and is the third patent issued in the Eagle Biologics family of patents.

On July 26, 2017, the Company received a Complete Response Letter from the FDA regarding its 505(b)(2) NDA for Ryanodex for the treatment of exertional heat stroke ("EHS"), in conjunction with external cooling methods. Based on our meeting with the FDA, the Company conducted an additional clinical trial in August 2018 during the Hajj pilgrimage, similar to the study conducted during the Hajj in 2015. On August 30, 2018, the Company announced the completion of enrollment of the Company’s second clinical study to further evaluate the safety and efficacy of Ryanodex. During the 2018 Hajj, overall emergency room visits were dramatically decreased from previous years due to well-implemented crowd management, lower temperatures, lower humidity and other external factors. As a result, the number of EHS patients available for study enrollment was also significantly less than in previous years, and therefore much lower than anticipated. The preliminary assessment of patients enrolled is consistent with the data from the study conducted in 2015, in which patients dosed with RYANODEX plus Standard of Care (“SOC”) showed an additive benefit compared to patients receiving SOC only. The Company intends to complete the analysis of the data and meet with the U.S. Food and Drug Administration to discuss next steps in 2019.

On August 8, 2017, the Company entered into an Amended and Restated Credit Agreement (the “Amended Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Agent”) and the lenders party thereto, which amended and restated the Company’s existing credit agreement, dated as of January 26, 2017. The Amended Credit Agreement provides for a three-year $50 million revolving credit facility and a three-year $100 million term loan facility (which are collectively referred to as the “Amended Credit Facility”). At closing, which occurred on August 8, 2017, $50 million of the term loan facility was drawn, and none of the revolving credit facility has been drawn. The Company may make one other draw on the term loan facility on or before February 4, 2018. The Company has elected not to draw down further on the term loan facility. The Amended Credit Facility includes a $5 million letter of credit subfacility. Loans under the Amended Credit Facility bear interest, at the Company’s option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 2.25% to 3.00% per annum, based upon the total net

leverage ratio (as defined in the Amended Credit Agreement), or (b) the prime lending rate, plus an applicable margin ranging from 1.25% to 2.00% per annum, based upon the total net leverage ratio. The Company is required to pay a commitment fee on the unused portion of the Amended Credit Facility at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio. The Company is permitted to terminate or reduce the revolving commitments or term commitments of the lenders and to make voluntary prepayments at any time subject to break funding payments. The Company is required to make mandatory prepayments of outstanding indebtedness under the Amended Credit Agreement (a) upon receipt of proceeds from certain sales, transfers or other dispositions, casualty and other condemnation events and the incurrence of certain indebtedness other than indebtedness permitted, subject to customary reinvestment exceptions and (b) in the case that the aggregate amount of all outstanding loans and letters of credit issued under the Amended Credit Facility exceed the aggregate commitment of all lenders under the Amended Credit Facility.

On September 20, 2017, the Company entered into a Product Collaboration and License Agreement, effective as of September 19, 2017, (the “SymBio License Agreement”) with SymBio Pharmaceuticals Limited (“SymBio”) for the rights to develop and commercialize the Company’s bendamustine hydrochloride ready-to-dilute injection product and rapid infusion injection product (collectively, the “Products”) in Japan. Under the License Agreement, SymBio will be responsible for all development of the

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Products in Japan and for obtaining and maintaining all regulatory approvals of the Products in Japan, with a target for regulatory approval of a Product in Japan in 2020. SymBio will bear all costs of development of the Products in Japan except that, if Japanese regulatory authorities require a certain clinical study to be conducted as a condition for approving one of the Products in Japan, Eagle would share 50% of the out-of-pocket costs of that clinical study up to a specified dollar amount as a reduction to future royalty payments. Based on the Company's assessment of the probability of additional costs, we have not deferred revenue on the Symbio License Agreement. SymBio will also be responsible, at its sole cost, for all marketing, promotion, distribution and sales of the Products in Japan and is obligated to launch the Products and meet certain minimum detailing, promotion and marketing commitments in connection with commercialization of the Products in Japan.

SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma (“MCL”), and as a first line treatment of low-grade NHL and MCL. Under the SymBio License Agreement, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Pursuant to the terms of the SymBio License Agreement, the Company and SymBio will enter into a separate supply agreement, under which the Company will be responsible for manufacturing and supplying the Products to SymBio for development and commercialization in Japan. After a period of time following launch of a Product, SymBio will have the right to assume the responsibility for manufacturing of the Products in and for Japan. Under the SymBio License Agreement, the Company will retain the right to control the prosecution, maintenance and enforcement of the Company’s patents covering the Products, both inside and outside of Japan.

Under the SymBio License Agreement, the Company earned an upfront non-refundable cash payment of $12.5 million in the third quarter of 2017, and is eligible to receive a milestone payment upon approval of a Product in Japan and a milestone payment upon achievement of certain cumulative net sales of the Products in Japan, which can aggregate to a total of approximately $10.0 million (subject to currency fluctuations). After regulatory approval of a Product in Japan, the Company will also receive tiered, low double-digit royalties on net sales of the Products in Japan for so long as there are patents covering the Products in Japan or regulatory exclusivity for the Products in Japan.

In March 2018, the FDA approved a second manufacturing site for Bendeka.

On April 16, 2018, the Company announced the FDA's acceptance of the Company's ANDA filing for vasopressin injection, 1ml. This product is the generic version of Endo International plc's original Vasostrict® formulation, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

On May 15, 2018, the FDA granted final approval for Eagle's ready-to-dilute bendamustine hydrochloride solution in a 500ml admixture for the treatment of patients with chronic lymphocytic leukemia (“CLL”) and patients with indolent B-cell non-Hodgkin lymphoma (“NHL”) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

On March 24, 2016 the FDA denied the Company's request for seven years of orphan drug exclusivity in the U.S., for Bendeka. In April 2016, the Company filed a lawsuit against the FDA arguing that Bendeka is entitled to orphan drug exclusivity as a matter of law (see Note 12. Legal Proceedings). On July 2, 2014, the FDA granted the Company orphan drug designations for Bendeka for the treatment of CLL and indolent B-cell NHL. The designations were based on a plausible hypothesis that Bendeka is “clinically superior” to a drug previously approved for the same indications. Generally, an orphan-designated drug is eligible for seven years of marketing exclusivity for the orphan-designated indications upon approval of the drug for those indications. On June 8, 2018, the U.S. District Court for the District of Columbia (the “Court”) issued a decision requiring the FDA to grant seven years of orphan drug exclusivity (“ODE”) in the U.S., for Bendeka, and on July 8, 2018 the FDA granted such ODE through December 2022. In addition, on July 8, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested the Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA’s motion was denied by the Court on August 1, 2018 on the grounds that FDA was seeking an inappropriate advisory opinion. On February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of exclusivity for Bendeka. Pursuant to the decision, no bendamustine product (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka. The Company expects to vigorously pursue the scope of its exclusivity grant.

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In June 2018, as part of an ongoing organizational review, the Company began a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures include the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection and plans to rationalize research and development operations. The Company ceased selling the product by September 30, 2018.

On October 3, 2018, the Company announced that it entered into an agreement with the United States Army Medical Research Institute of Chemical Defense, the nation’s leading science and technology laboratory in the area of medical chemical countermeasures research and development, to conduct a study to evaluate the neuroprotective effects of RYANODEX® (dantrolene sodium).

On October 30, 2018, the Company announced that the Company’s fulvestrant formulation has not met the primary pharmacokinetic endpoint evaluating the bioequivalence of the Company’s formulation compared to Faslodex in its open label, randomized, pharmacokinetic and safety study conducted in 600 healthy female volunteers across multiple U.S. sites.

2. Summary of Significant Accounting Policies

Use of Estimates

These financial statements are presented in U.S. dollars and are prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements including disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period and accompanying notes. The Company's critical accounting policies are those that are both most important to the Company's financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of the uncertainty of factors surrounding the estimates or judgments used in the preparation of the financial statements, actual results may materially vary from these estimates.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation. None of the reclassifications were significant.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. All cash and cash equivalents are held in United States financial institutions. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

The Company, at times, maintains balances with financial institutions in excess of the FDIC limit.

Fair Value Measurements

U.S. GAAP establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. 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 standard describes the following fair value hierarchy based on three levels of inputs, of which the first two are

considered observable and the last unobservable, that may be used to measure fair value:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- 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.

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The fair value of interest-bearing cash, cash equivalents, accounts receivable and accounts payable approximate fair value due to their life being short term in nature, and are classified as Level 1 for all periods presented.
The fair value of debt is classified as Level 2 for the periods presented and approximates its fair value due to the variable interest rate.
The fair value of the contingent consideration/accrued royalty is classified as Level 3 for the period presented.
Intangible Assets
Other Intangible Assets, Net
The Company capitalizes and includes in intangible assets the costs of acquired product licenses and developed technology purchased individually or identified in a business combination. Intangible assets are recorded at fair value at the time of their acquisition and stated net of accumulated amortization. The Company amortizes its definite-lived intangible assets using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. The Company will evaluate the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Events giving rise to impairment are an inherent risk in our industry and many factors cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group and its eventual disposition to the carrying value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of income.
With respect to determining an asset’s fair value and useful life, because this process involves management making certain estimates and these estimates form the basis of the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates.
Goodwill
Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics acquisition. Goodwill is not amortized, but is evaluated for impairment on an annual basis, in the fourth quarter, or more frequently if events or changes in circumstances indicate that the reporting unit’s goodwill is less than it's carrying amount. The Company did not identify any impairment to goodwill during the periods presented.
Acquisition-Related Contingent Consideration
Contingent consideration related to a business combination is recorded on the acquisition date at the estimated fair value of the contingent payments. The acquisition date fair value is measured based on the consideration expected to be transferred using probability-weighted assumptions and discounted back to present value. The discount rate used is determined at the time of the acquisition in accordance with accepted valuation methods. The fair value of the acquisition-related contingent consideration is re-measured at the estimated fair value at each reporting period with the change in fair value recognized as income or expense in the consolidated statements of income.
Concentration of Major Customers and Vendors
The Company is dependent on commercial partners to market and sell Argatroban and Bendeka. The Company's customers for Argatroban and Bendeka are its commercial and licensing partners; therefore, the Company's future revenues are highly dependent on these collaboration and distribution arrangements. The Company earned a $25 million sales-based milestone payment in March 2017 for Bendeka.

Teva markets Bendeka through a license agreement with the Company. Pursuant to that license agreement, Teva pays the Company a royalty based on net sales of the product and also purchases the product from the Company. A disruption in this

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arrangement, caused by among other things, a supply disruption, loss of exclusivity or the launch of a superior product would have a material adverse effect of the Company's financial position, results of operations and cash flows.

The total revenues and accounts receivables broken down by major customers as a percentage of the total are as follows:

	Year Ended December 31,		
	2018	2017	2016
Net revenues			
Cephalon, Inc. (Teva) - See Revenue Recognition	75 %	79 %	79 %
Other	25 %	21 %	21 %
	100%	100%	100%

	December 31,	
	2018	2017
Accounts receivable		
Cephalon, Inc. (Teva) - See Revenue Recognition	61 %	74 %
Other	39 %	26 %
	100%	100%

Currently, for Argatroban, the Company uses one vendor as its sole source supplier, because of the unique equipment and process for manufacturing and transferring manufacturing activities to an alternate supplier is a time consuming and costly endeavor.

Inventories

Inventories are recorded at the lower of cost or net realizable value, with cost determined on a first-in first-out basis. The Company periodically reviews the composition of its inventories in order to identify obsolete, slow-moving or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventories, the Company will record a write-down to net realizable value in the period that the decline in value is first recognized.

Property and Equipment

Property and equipment are stated at cost. Depreciation is recorded over the estimated useful lives of the assets utilizing the straight-line method. Leasehold improvements are being amortized over the shorter of their useful lives or the lease term.

Research and Development Expense

Costs for research and development are charged to expense as incurred and include; employee-related expenses including salaries, benefits, travel and stock-based compensation expense for research and development personnel; expenses incurred under agreements with contract research organizations, contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies; costs associated with preclinical activities and development activities, costs associated with regulatory operations; and depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid expenses or accrued expenses as deemed appropriate. Recoveries of previously

recognized research and development expenses from third parties are recorded as a reduction to research and development expense in the period it becomes realizable.

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were $3,312, $17,770, and $14,784 for the year ended December 31, 2018, 2017, and 2016, respectively.

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Income Taxes

The Company accounts for income taxes using the liability method in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"), Topic 740 - Income Taxes ("ASC 740"). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is "more likely than not" that all or a portion of deferred tax assets will not be realized. ASC 740 also prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product revenue - The Company recognizes net revenue on sales to its commercial partners and to end users. In each instance, revenue is generally recognized when the customer obtains control of the Company's product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract. Revenue on sales to commercial partners relates to Argatroban and Bendeka. Sales to our commercial partners are presented gross because the Company is primarily responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method to which the Company expects to be entitled. As such, revenue on sales to end users for Big Bag, Non-Alcohol Docetaxel Injection, Ryanodex are recorded net of chargebacks, rebates, returns, prompt pay discounts, wholesaler fees and other deductions. Our products are contracted with a limited number of oncology distributors and hospital buying groups with narrow differences in ultimate realized contract prices used to estimate our chargeback and rebate reserves. The Company has a product returns policy on some of its products that allows the customer to return pharmaceutical products within a specified period of time both prior to and subsequent to the product's expiration date. The Company's estimate of the provision for returns is analyzed quarterly and is based upon many

factors, including historical experience of actual returns and analysis of the level of inventory in the distribution channel, if any. The Company has terms on sales of Ryanodex by which the Company does not accept returns. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration are made using the expected value method and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. The Company believes that the estimates it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

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Royalty Revenue — The Company recognizes revenue from license arrangements with its commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 25 days for Bendeka and 15 days for Argatroban from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter and subsequently determines a true-up when it receives royalty reports from its commercial partners. Historically, these true-up adjustments have been immaterial.
License and other revenue — The Company analyzes each element of its licensing agreements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.
If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.
The Company recognizes sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, the Company determined that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of these future events, the Company will not recognize revenue from the milestone until there is not a high probability of a reversal of revenue, which typically occurs near or upon achievement of the event.
As described above, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million, received a milestone payment of $15 million for regulatory approval, received a $40 million milestone upon receipt of the J-Code and received $25 million in an additional sales based milestone payment for reaching $500 million in net product sales of Bendeka. In 2015, $30 million upfront payment was allocated between the license issued to Cephalon and obtaining and maintaining regulatory approvals and conducting post-approval clinical studies using the Company’s best estimate of selling price for each deliverable. The full $30 million was recognized as income in the first quarter of 2015, as the Company substantially completed its requirements for obtaining regulatory approval, which consisted of filing an NDA, on February 13, 2015, and the remaining obligations were estimated to require minimal effort. On December 7, 2015, the FDA approved Bendeka (50 mL bendamustine hydrochloride) marking the achievement of a milestone which entitled the Company to a $15 million payment which was received in January 2016. The Company received a $40 million milestone payment in November 2016 upon receipt of the unique J-Code. Additionally, this event triggered an increase in the royalty rate from 20% to 25% of Bendeka net sales. In March 2017, the Company received a $25 million sales-based milestone payment for reaching $500 million in net product sales. As discussed above, under the SymBio License Agreement, the Company earned an upfront non-refundable cash payment of $12.5 million during the year ended December 31, 2017.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2018.

Collaborative licensing and development revenue — The Company recognizes revenue from reimbursements received in connection with feasibility studies and development work for third parties when its contractual services are performed, provided collectability is reasonably assured. Its principal costs under these agreements include its personnel conducting research and development, its allocated overhead, as well as the research and development performed by outside contractors or consultants.

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Upon termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in its statements of income. The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of its performance obligations under the collaboration agreement.

Stock-Based Compensation

The Company accounts for stock-based compensation using the fair value provisions of ASC 718, Compensation - Stock Compensation that requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based payments including stock options and restricted stock. This topic requires companies to estimate the fair value of the stock-based awards on the date of grant for options issued to employees and directors and record expense over the employees' service periods, which are generally the vesting period of the equity awards. The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. The straight-line method is used to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. The fair value of the Company's stock-based awards to employees and directors is estimated using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate is determined with the implied yield currently available for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options.

Earnings Per Share

Basic earnings per common share is computed using the weighted average number of shares outstanding during the period. Diluted earnings per share is computed in a manner similar to the basic earnings per share, except that the weighted-average number of shares outstanding is increased to include all common shares, including those with the potential to be issued by virtue of warrants, options, convertible debt and other such convertible instruments. Diluted earnings per share contemplate a complete conversion to common shares of all convertible instruments only if they are dilutive in nature with regards to earnings per share.

The anti-dilutive common shares equivalents outstanding at December 31, 2018, 2017, and 2016 were as follows:

	Year Ended December 31,		
	2018	2017	2016
Options	1,824,728	1,592,548	869,957

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The following table sets forth the computation for basic and diluted net income per share for December 31, 2018, 2017, and 2016:

	Year Ended December 31,		
	2018	2017	2016
Numerator			
Numerator for basic and diluted earnings per share-net income	$31,903	51,943	$ 81,453
Denominator			
Basic weighted average common shares outstanding	14,768,625	15,102,890	15,533,681
Dilutive effect of stock options	510,026	805,321	900,423
Diluted weighted average common shares outstanding	15,278,651	15,908,211	16,434,104
Basic net income per share			
Basic net income per share	$2.16	$ 3.44	$ 5.24
Diluted net income per share			
Diluted net income per share	$2.09	$ 3.27	$ 4.96

Recent Accounting Pronouncements
Recent Accounting Pronouncements - Not Yet Adopted
In February 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-02, “Leases (Topic 842)” (ASU 2016-02) to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new guidance, lessees are required to recognize a lease liability, which represents the discounted obligation to make future minimum lease payments, and a corresponding right-of-use asset on the balance sheet for most leases. In July 2018, the FASB issued ASU No. 2018-10, “Codification Improvements to Topic 842, Leases” (ASU 2018-10), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, “Leases (Topic 842) - Targeted Improvements” (ASU 2018-11), which addresses implementation issues related to the new lease standard. This guidance is effective for the Company as of January 1, 2019 and the Company will adopt this guidance using the modified retrospective approach and will recognize a cumulative-effect adjustment to the opening balance of Retained earnings in that period. This guidance includes a number of optional practical expedients that the Company may elect to apply, including an expedient that permits lease agreements that are twelve months or less to be excluded from the balance sheet. The Company is finalizing the impact that this new guidance will have on its consolidated financial statements, including its disclosures. The primary impact upon adoption will be the recognition, on a discounted basis, of the Company’s minimum commitments under noncancelable operating leases as right of use assets and obligations on the consolidated balance sheets, in a range between $3 million to $4 million. In preparation for the adoption of this guidance, the Company is finalizing the process of identifying and validating the Company’s lease information and evaluating the impact that this new guidance will have on its processes and controls.
In January 2017, the FASB issued guidance to simplify the measurement of goodwill. The guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with it's carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The guidance also eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and if

it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted for interim or annual goodwill impairment tests performed for testing dates after

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January 1, 2017. The guidance must be adopted on a prospective basis. We do not expect this guidance to have an impact on our consolidated financial statements.

Recent Adopted Accounting Pronouncements

The Company adopted ASC 606, Revenue from Contracts with Customers with a date of initial application of January 1, 2018. As a result, the Company has updated its accounting policy for revenue recognition to reflect the new standard as detailed above. The adoption of ASC 606 represents a change in accounting principle that will more closely align revenue recognition with the delivery of the Company's services and will provide financial statement readers with enhanced disclosures. The Company applied Topic 606 using the modified retrospective method. The Company has elected to apply this initial application of the standard only to contracts that are not completed at the date of initial application. For contracts which were modified before the adoption date, the Company has not restated the contract for those modifications. Instead, the Company reflected the aggregate effect of all modifications when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price, if necessary. The cumulative effect of initially applying the new revenue standard would be applied as an adjustment to the opening balance of retained earnings. The Company has analyzed this effect and found the adoption of the new guidance did not have a material impact on our consolidated financial statements and our recognition is consistent with our historical accounting policies.

In January 2016, the FASB issued ASU 2016-01, which revises the guidance in ASC 825-10, Recognition and Measurement of Financial Assets and Financial Liabilities, and provides guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. The guidance is effective for reporting periods (interim and annual) beginning after December 15, 2017, for public companies. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In January 2017, the FASB issued guidance clarifying the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities is not a business, provides a framework to assist entities in evaluating whether both an input and substantive process are present, and narrows the definition of the term output. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The guidance must be adopted on a prospective basis. We will consider the guidance for future transactions.

3. Inventories

Inventories consist of the following:

	December 31,	
	2018	2017
Raw materials	$6,303	$2,489
Work in process	1,776	931
Finished products	225	1,698
	$8,304	$5,118

4. Property and Equipment

Property and equipment consists of the following:

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	December 31,		Estimated Useful Life (years)
	2018	2017	
Furniture and equipment	$1,117	$1,187	7
Office equipment	546	513	3
Equipment	2,952	2,962	7
Leasehold improvements	1,129	4,596	2
	5,744	9,258	
Less accumulated depreciation	(3,347)	(2,438)	
Property and equipment, net	$2,397	$6,820	

Depreciation expense amounted to $1,155, $932, and $641, for the year ended December 31, 2018, 2017, and 2016, respectively. During the year ended December 31, 2018, as part of the restructuring initiative, the Company recorded an asset impairment charge related to property and equipment, primarily related to leasehold improvements.

5. Balance Sheet Accounts
Prepaid and Other Current Assets
Prepaid and other current assets consist of the following:

	December 31,	
	2018	2017
Advances to commercial manufacturers	$2,700	$2,389
Prepaid FDA user fee	1,540	1,369
Prepaid insurance	150	116
Prepaid research and development	—	1,069
Prepaid income taxes	5,739	9,597
All other	134	561
Total Prepaid expenses and other current assets	$10,263	$15,101

Accrued Expenses
Accrued expenses consist of the following:

	December 31,	
	2018	2017
Accrued expenses		
Royalties payable to commercial partners	$7,139	$4,310
Accrued research & development	1,245	936
Accrued professional fees	2,408	1,254
Accrued salary and other compensation	5,049	4,811
Accrued product costs	5,869	2,657
All other	1,809	1,423
Total Accrued expenses	$23,519	$15,391

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6. Debt

On January 26, 2017, the Company entered into a Credit Agreement (the "Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative agent ("Agent") and the lenders party thereto. The Credit Agreement provides for a three-year $50 million revolving credit facility (the "Credit Facility"), none of which was drawn at closing. The Credit Facility includes a $5 million letter of credit subfacility.

On August 8, 2017, the Company entered into an Amended and Restated Credit Agreement (the "Amended Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative agent (the "Agent") and the lenders party thereto, which amended and restated the Company's existing credit agreement, dated as of January 26, 2017. The Amended Credit Agreement provides for a three-year $50 million revolving credit facility and a three-year $100 million term loan facility (which are collectively referred to as the "Amended Credit Facility"). The Company recorded $0.3 million of debt extinguishment costs related to the amendment included in selling, general and administrative expenses during the year ended December 31, 2017. As of December 31, 2018, the Company has $0.6 million of unamortized deferred debt issuance costs as part of long-term debt in our consolidated balance sheets.

At closing, $50 million of the term loan facility was drawn, and none of the revolving credit facility has been drawn. The Company was permitted to make one other draw on the term loan facility on or before February 4, 2018. The Company has elected not to draw down further on the term loan facility. The Amended Credit Facility includes a $5 million letter of credit subfacility. Loans under the Amended Credit Facility bear interest, at the Company's option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 2.25% to 3.00% per annum, based upon the total net leverage ratio (as defined in the Amended Credit Agreement), or (b) the prime lending rate, plus an applicable margin ranging from 1.25% to 2.00% per annum, based upon the total net leverage ratio. The Company is required to pay a commitment fee on the unused portion of the Amended Credit Facility at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio. The Company is permitted to terminate or reduce the revolving commitments or term commitments of the lenders and to make voluntary prepayments at any time subject to break funding payments. The Company is required to make mandatory prepayments of outstanding indebtedness under the Amended Credit Agreement (a) upon receipt of proceeds from certain sales, transfers or other dispositions, casualty and other condemnation events and the incurrence of certain indebtedness other than indebtedness permitted, subject to customary reinvestment exceptions and (b) in the case that the aggregate amount of all outstanding loans and letters of credit issued under the Amended Credit Facility exceed the aggregate commitment of all lenders under the Amended Credit Facility. The Company is obligated to repay the term loan facility on the last day of each March, June, September and December in an aggregate principal amount equal to 2.5% during the term of the loan.

Debt Maturities	as of December 31, 2018
2019	6,250
2020	38,750
Total debt	$ 45,000

7. Common Stock and Stock-Based Compensation

Common Stock

On October 30, 2018, the Company announced a new repurchase program approved by the Board pursuant to which the Company may repurchase of up to $150 million of the its outstanding common stock, consisting of (i) up to $50 million in repurchases pursuant to an accelerated share repurchase agreement (the "ASR"), with JPMorgan Chase Bank, N.A. ("JPMorgan"), and (ii) up to $100 million in additional repurchases (collectively, the "2018 Share Repurchase Program"). In connection with its approval of the 2018 Share Repurchase Program, the Board terminated the Company's 2016 Share Repurchase Program and 2017 Share Repurchase Program in October 2018. Under the 2018 Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions, accelerated share repurchases or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. Under the 2018 Share Repurchase Program, the additional repurchases have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other

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financial and operational performance, market conditions, securities law limitations, and other factors. The repurchases will be made using the Company’s cash resources.

In connection with the 2018 Share Repurchase Program, on October 30, 2018, the Company entered into the ASR with JPMorgan to repurchase an aggregate of $50 million of the Company’s common stock. Under the terms of the ASR, the Company paid $50 million to JP Morgan on November 1, 2018, and received 702,988 shares, representing approximately 80% of the notional amount of the ASR, based on the closing price of $56.90 on October 29, 2018. Upon settlement of the ASR, the final number of shares repurchased were trued up based on the average of the daily volume weighted average share prices of the Company’s common stock, less a discount, during the term of the ASR. The Company received 297,146 shares on December 6, 2018, the termination date.
On August 9, 2016, the Company announced a share repurchase program approved by the Company’s board of directors authorizing the repurchase of up to $75.0 million of the Company’s common stock (the “Share Repurchase Program”). On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company may repurchase up to an additional $100 million of its outstanding common stock (the “New Share Repurchase Program”). Under the Share Repurchase Program and the New Share Repurchase Program, the Company was authorized to repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. These Share Repurchase Programs were terminated as noted above.
We repurchased the following shares of common stock with cash resources:

	Year Ended December 31,	
	2018	2017
Shares of common stock repurchased	1,348,563	674,857
Value of common stock repurchased	$73,105	$43,792

Stock-Based Compensation
In December 2007, the Company's board of directors approved the 2007 Incentive Compensation Plan (the "2007 Plan") enabling the Company to grant multiple stock-based awards to employees, directors and consultants, the most common being stock options and restricted stock awards. In November 2013, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. The 2007 Plan was terminated upon the effectiveness of the 2014 Plan and all shares available for issuance under the 2007 Plan were made available under the 2014 Plan. The 2014 Plan provides for the awards of incentive stock options, non-qualified stock options, restricted stock, restricted stock units and other stock-based awards. Awards generally vest equally over a period of four years from grant date. Vesting is accelerated under a change in control of the Company or in the event of death or disability to the recipient. In the event of termination, any unvested shares or options are forfeited. At the Company's annual meeting of stockholders held on August 4, 2015, the stockholders approved an amendment to the 2014 Plan to, among other things, increase the number of shares of common stock authorized for issuance thereunder by 500,000 shares. After accounting for such increase, and as of such amendment, the Company has reserved and made available 1,748,878 shares of common stock for issuance under the 2014 Plan.
During the year ended December 31, 2018, the Company introduced a new long-term incentive program with the objective to better align the share-based awards granted to management with the Company's focus on improving total shareholder return over the long-term. The share-based awards granted under this long-term incentive program consist of time-based stock options, time-based restricted stock units ("RSUs") and performance-based stock units ("PSUs").

PSUs are comprised of awards that vest upon achievement of certain share price appreciation conditions.
Stock Options

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The fair value of stock options granted to employees, directors, and consultants is estimated using the following assumptions:

	Year Ended December 31,		
	2018	2017	2016
Risk-free interest rate	2.30% - 3.07%	1.70% - 2.42%	0.94% - 2.34%
Volatility	43.76%	28.56% - 37.63%	30.95% - 32.36%
Expected term (in years)	5.50 - 6.08 years	5.50 - 7.0 years	5.04 - 7.0 years
Expected dividend yield	0.0%	0.0%	0.0%

The following table summarizes information about stock option activity related to the 2014 Plan:

	Number of Stock Option Shares	Weighted Average Exercise Price (Per Share)	Non-Exercisable	Exercisable
Outstanding at December 31, 2016	2,324,918	$ 44.53	1,281,208	1,043,710
Granted	925,329	83.94		
Exercised	(197,895)	21.78		
Forfeited or expired	(265,784)			
Outstanding at December 31, 2017	2,786,568	$ 57.13	1,349,339	1,437,229
Granted	672,092	59.17		
Exercised	(502,322)	17.19		
Forfeited or expired	(399,973)			
Outstanding at December 31, 2018	2,556,365	$ 62.78	1,074,456	1,481,909

The weighted-average grant-date fair value of options granted during the year ended December 31, 2018, 2017, and 2016 was $26.73, $32.83, and $27.79, respectively. As of December 31, 2018, there was $20,148 of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2 years. The total intrinsic value of options exercised during the year ended December 31, 2018 was $24,418.

The weighted average contractual terms of options outstanding as of December 31, 2018, 2017, and 2016 was 7.3, 7.0, and 7.0 years, respectively.

The aggregate pre-tax intrinsic value of options outstanding as of December 31, 2018, 2017, and 2016 was $10.7 million, $33.7 million, and $59.2 million, respectively.

RSUs
Each vested time-based RSU represents the right of a holder to receive one of the Company’s common shares. The fair value of each RSU granted was estimated based on the trading price of the Company’s common shares on the date of grant.

The following table summarizes information about RSU activity related to the 2014 Plan:

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	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value (Per Share)
Non-vested at December 31, 2017	—	$ —
Granted	64,080	59.04
Vested	—	—
Forfeited	(9,861)	$ 59.14
Non-vested at December 31, 2018	54,219	$ 59.02

As of December 31, 2018, there was $1,658 of unrecognized stock-based compensation expense related to non-vested RSUs that is expected to be recognized over a weighted average period of 3 years.

PSUs
The fair value of PSUs granted to employees was estimated using a monte carlo simulation model. Inputs used in the calculation include a risk-free interest rate of 2.06%, an expected volatility of 47%, contractual term of 3 years, and no expected dividend yield.

The following table summarizes information about PSU activity related to the 2014 Plan:

	Number of Performance Stock Units	Weighted Average Grant Date Fair Value (Per Share)
Non-vested at December 31, 2017	—	$ —
Granted	127,080	90.19
Vested	—	—
Forfeited	(9,861)	$ 90.19
Non-vested at December 31, 2018	117,219	$ 90.19

As of December 31, 2018, there was $6,242 of unrecognized stock-based compensation expense related to non-vested PSUs that is expected to be recognized over a weighted average period of 2 years.

The Company recognized stock-based compensation in its consolidated statements of income for the year ended December 31, 2018, 2017, and 2016 as follows:

	Year Ended December 31,		
	2018	2017	2016

Stock options	$15,333	$15,429	$9,768
PSUs	3,059	—	—
RSUs	690	—	—
Stock-based compensation expense	$19,082	$15,429	$9,768

Selling, general and administrative	$15,068	$11,486	$7,073
Research and development	4,014	3,943	2,695
Stock-based compensation expense	$19,082	$15,429	$9,768

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8. Income Taxes

The components of our (provision for) benefit from income taxes is as follows:

	Year Ended December 31,		
	2018	2017	2016
Current:			
Federal	$(4,137)	$(1,304)	$(1,175)
State	(466)	(2,409)	(919)
	$(4,603)	$(3,713)	$(2,094)
Deferred:			
Federal	2,565	(18,045)	29,553
State	(97)	756	567
	$2,468	$(17,289)	$30,120
(Provision for) benefit from income taxes	$(2,135)	$(21,002)	$28,026

The reconciliation of the statutory U.S. Federal income tax rate to the Company's effective income tax rate is as follows;

	Year Ended December 31,		
	2018	2017	2016
Federal statutory tax rate	21 %	35 %	35 %
State income taxes, net of federal benefit	1 %	3 %	3 %
Tax benefit on stock option exercises, net of forfeitures	(11)%	(4)%	(7)%
R&D tax credits and Orphan Drug credits	(7)%	(10)%	(3)%
Limitation on executive compensation	3 %	N/A	N/A
Revaluation of net deferred tax assets due to U.S. tax reform	— %	5 %	N/A
Change in valuation allowance	— %	— %	(79)%
Other	(1)%	— %	(1)%
Effective tax rate	6 %	29 %	(52)%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets were as follows:

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	December 31,	
	2018	2017
Deferred tax assets		
Net operating loss carryforward	$—	$151
Stock based compensation	7,934	6,454
Research and development and other tax credit carryforwards	3,251	5,190
Inventories	1,767	764
Employee-related expenses	732	240
Prepaid R&D expenses	761	964
Other	64	641
Total deferred tax assets	14,509	14,404
Deferred tax liabilities		
Intangible assets	280	1,655
Prepaid expenses	34	28
Fixed assets	282	1,172
Other	91	195
Total deferred tax liabilities	687	3,050
Valuation allowance	—	—
Net deferred tax assets	$13,822	$11,354

The Tax Cuts and Jobs Act (the “Tax Act”) significantly revised U.S. corporate income tax law by, among other things, reducing the corporate income tax rate to 21% and implementing a modified territorial tax system. In response to the Tax Act, the SEC issued SAB 118 which allows issuers to recognize provisional estimates of the impact of the Tax Act in their financial statements and adjust in the period in which the estimate becomes finalized, or in circumstances where estimates cannot be made, to disclose and recognize within a one year measurement period.
Implementation of the Tax Act resulted in an approximate $3.4 million charge for the revaluation of the Company’s net deferred tax assets during the year ended December 31, 2017. In reaching these estimates, the Company utilized all available guidance and notices issued by the U.S. Department of the Treasury. During 2018, the Company finalized the impact of the Tax Act. An immaterial adjustment was recorded in the year ended December 31, 2018.
As a result of recently attaining profitability and the expectation that substantially all net operating loss carryforwards would be utilized in 2017, the Company performed a formal tax evaluation to determine maximum research and development credits that are available based on current law. As a result of the evaluation of historical records and data, our tax filings, and various tax law interpretations related to the R&D credit availability, additional tax credits were identified. The Company recorded an adjustment of such tax credits of $5.5 million resulting in a reduction of income tax expense in 2017.

In the year ended December 31, 2016, we released a previously carried tax valuation allowance on our net deferred tax assets including net operating loss carryforwards and the tax benefit related to the exercises of stock options. Our decision to remove the valuation allowance on the Company's net deferred tax assets considered our significant income in 2016 which translated to our becoming a tax payer in 2016 and our outlook on prospective earnings and taxable income driven by Bendeka royalty and milestone revenues.
As of December 31, 2018, the Company had no federal and state net operating loss carryforwards. The Company also had a federal research and development tax credit carryforward of approximately $3.2 million. The net operating loss

and tax credit carryforwards will expire at various times through 2036.

In July 2006, the Financial Accounting Standards Board ("FASB") issued ASC 740-10, Uncertainty in Income Taxes, which defines the threshold for recognizing the benefits of tax-return positions in the financial statements as "more-likely-than-not" to be sustained by the taxing authorities. This statement also requires explicit disclosure requirements about a Company's uncertainties related to their income tax position, including a detailed roll forward of tax benefits taken that do not qualify for financial statement recognition.

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The Company files income tax returns in the U.S. federal jurisdiction and several states. Given that the company has incurred tax losses in most years since its inception, all of the Company's tax years are effectively open to examination. The Company has no amount recorded for any unrecognized tax benefits as of December 31, 2018. The Company regularly evaluates its tax positions for additional unrecognized tax benefits and associated interest and penalties, if applicable. There are many factors that are considered when evaluating these tax positions including: interpretation of tax laws, recent tax litigation on a position, past audit or examination history, and subjective estimates and assumptions.

9. License Agreements of Development and Commercialization Rights

Development

On February 13, 2015, the Company submitted a New Drug Application or NDA to the FDA for Bendeka, which was approved by the FDA on December 7, 2015. Also, on February 13, 2015, the Company entered into the Cephalon License for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Pursuant to the terms of the Cephalon License, Cephalon will be responsible for all U.S. commercial activities for the product including promotion and distribution, and the Company is responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. Additionally, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million, in January 2016, received a $15 million milestone payment related to the FDA approval of Bendeka in December 2015, received $40 million related to the receipt of the J-code for Bendeka and is currently eligible to receive up to $25 million in an additional sales-based milestone payment. In addition, the Company was entitled to receive royalty payments of 20% of net sales of the product which increased to 25% on receipt of the J-code in November 2016. In connection with the Cephalon License, the Company has entered into a supply agreement with Cephalon, pursuant to which the Company is responsible for supplying product to Cephalon.

On September 20, 2017, the Company entered into a Product Collaboration and License Agreement, effective as of September 19, 2017, (the "SymBio License Agreement") with SymBio Pharmaceuticals Limited ("SymBio") for the rights to develop and commercialize the Company's bendamustine hydrochloride ready-to-dilute injection product and rapid infusion injection product (collectively, the "Products") in Japan. Under the License Agreement, SymBio will be responsible for all development of the Products in Japan and for obtaining and maintaining all regulatory approvals of the Products in Japan, with a target for regulatory approval of a Product in Japan in 2020. SymBio will bear all costs of development of the Products in Japan except that, if Japanese regulatory authorities require a certain clinical study to be conducted as a condition for approving one of the Products in Japan, Eagle would share 50% of the out-of-pocket costs of that clinical study up to a specified dollar amount as a reduction to future royalty payments. Based on the Company's assessment of the probability of additional costs, we have not deferred revenue on the SymBio License Agreement. SymBio will also be responsible, at its sole cost, for all marketing, promotion, distribution and sales of the Products in Japan and is obligated to launch the Products and meet certain minimum detailing, promotion and marketing commitments in connection with commercialization of the Products in Japan.

SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma ("MCL"), and as a first line treatment of low-grade NHL and MCL. Under the SymBio License Agreement, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Pursuant to the terms of the SymBio License Agreement, the Company and SymBio will enter into a separate supply agreement, under which the Company will be responsible for manufacturing and supplying the Products to SymBio for development and commercialization in Japan. After a period of time following launch of a Product, SymBio will have the right to assume the responsibility for manufacturing of the Products in and for Japan. Under the SymBio License Agreement, the Company will retain the right to control the prosecution, maintenance and enforcement of the Company's patents covering the Products, both inside and outside of Japan.

Under the SymBio License Agreement, the Company earned an upfront non-refundable cash payment of $12.5 million in the third quarter of 2017, and is eligible to receive a milestone payment upon approval of a Product in Japan and a milestone payment upon achievement of certain cumulative net sales of the Products in Japan. After regulatory approval of a Product in Japan, the Company will also receive tiered, low double-digit royalties on net sales of the Products in Japan for so long as there are patents covering the Products in Japan or regulatory exclusivity for the Products in Japan.

The Company has entered into several product development agreements with development partners whereby the Company acquired the exclusive rights in the United States and, in most cases, worldwide rights to a total of thirty-three products for ten years following

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first commercial sale of each product. The Company will share varying percentages of the profits after, in most cases, recapturing development, legal and certain operating costs, from the sales of the products with the development partners if the products are commercialized. The Company expenses these costs as incurred.

10. Asset Sales

During fiscal year 2010 and 2011, the Company divested a non-core product and received proceeds of $6,500, comprised of $5,500 as a signing milestone which is recorded in deferred revenues and $500 for the initiation of technology transfer of which $250 remains in deferred revenues and a second payment of $500 for the completion of the technology transfer of which $250 remains in deferred revenues. Under the terms of this agreement, the licensor must obtain all of the following milestones in order for the Company to earn the revenues. These milestones are a) the receipt of an approval letter from the FDA, b) acknowledgment from the FDA that no further clinical studies will be needed and c) an approval letter from the FDA.

The Company, through various requests for information, was informed by the licensor in 2016 that it had voluntarily withdrawn the filing of the product application from the FDA in a prior year. Under the terms of the agreement, the milestones required to earn the $6,000 previously included in deferred revenue all related to the filing. The voluntary withdrawal of the filing by the licensor relieved the Company of further obligation with regard to performance under the milestones. Accordingly, during the year ended December 31, 2016, the Company recognized $6,000 as license and other income.

In 2016, the Company entered into the Diclofenac Asset Purchase Agreement pursuant to which the Company sold certain intellectual property related to diclofenac-misoprostol in the United States. In consideration of the assets and rights sold under the Diclofenac Asset Purchase Agreement, the Company received a one-time payment at closing of $1,750, which was recognized as a gain in 2016. In consideration of the rights granted under the Diclofenac Asset Purchase Agreement, the purchaser will pay the Company a 25% royalty on net profits of diclofenac-misoprostol in the territory for five years from the date of sale.

11. Commitments

Our future material contractual obligations include the following:

Obligation	Total	2019	2020	2021	2022	2023	Beyond
Operating leases (1)	$3,661	$1,146	$864	$583	$583	$485	$ —
Credit facility	45,000	6,250	38,750	—	—	—	—
Purchase obligations (2)	29,333	29,333	—	—	—	—	—
Total obligations	$77,994	$36,729	$39,614	$583	$583	$485	$ —

(1) The Company leases its office and lab space under lease agreements that expire on June 30, 2020 and October 31, 2023. Rental expense was $571, $664, and $634, for the year ended December 31, 2018, 2017, and 2016, respectively. The remaining future lease payments under the operating leases, exclusive of any renewal option periods, are $3,661 as of December 31, 2018, payable monthly through June 30, 2020 and October 31, 2023.

(2) As of December 31, 2018, the Company has purchase obligations in the amount of $29,333 which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligation under the supply agreement is primarily for finished product, inventory, and research and development.

12. Acquisitions

Acquisition of Docetaxel-Injection, Non-Alcohol Formula

On October 13, 2015, the Company entered into the Teikoku Agreement with Teikoku to market, sell and distribute Non-Alcohol Docetaxel Injection, an investigational product intended for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer. The NDA for Non-Alcohol

Docetaxel Injection for these indications was approved by the FDA on December 22, 2015. Under the terms of the agreement, the Company paid $4,850 upon FDA approval and NDA transfer to the Company, which occurred on January 12, 2016. The Company also paid 25% royalties on gross profits to Teikoku. The Company accounted for the transaction as a purchase of a business in 2016, in accordance with ASC 805 Business Combinations.

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The Company has measured the fair value of the future royalty payment using its own assumptions of future profitability of Non-Alcohol Docetaxel Injection. Acquisition contingent consideration is measured at fair value on a recurring basis using unobservable inputs; which accordingly represents a Level 3 measurement within the fair value hierarchy. Any change in fair value of the contingent consideration subsequent to the acquisition date is recognized in operating income within the statement of operations.

During the year ended December 31, 2017, the Company recorded a change in the fair value of contingent consideration of $6.2 million. This was primarily driven by adjustments to the fair values of the liabilities associated with Non-Alcohol Docetaxel Injection, which was remeasured due to the loss of a customer and other market conditions identified during the third quarter of 2017 for the product and partially offset by accretion for the time value of money.

During the year ended December 31, 2018, the Company recorded an adjustment to the remaining contingent consideration to reflect the Company's decision to discontinue sales of Non-Alcohol Docetaxel Injection.

The following table represents a reconciliation of the change in the fair value measurement of the contingent consideration liability, which was recorded in the Company's consolidated statements of income:

Closing Balance December 31, 2016	Changes in fair value	Payment of contingent consideration	Closing Balance December 31, 2017	Changes in fair value	Payment of contingent consideration	Closing Balance December 31, 2018
$6,940	$(6,176)	$ —	$ 764	$ (763)	$ (1)	$ —

Total consideration of $11,220, which is comprised of the $4,850 cash paid on FDA approval and NDA transfer to the Company and the fair value of contingent consideration has been attributed to the intangible asset for Non-Alcohol Docetaxel Injection product rights.

Eagle Biologics Acquisition
On November 16, 2016, the Company entered into a stock purchase agreement (“Arsia SPA”) to acquire Arsia Therapeutics (“Arsia” “Seller”), an early-stage biotechnology firm with proprietary viscosity-reducing technology and formulation know-how and subsequently renamed the subsidiary Eagle Biologics, Inc. ("Eagle Biologics"). Under the terms of the stock purchase agreement, we paid approximately $27.2 million in cash and 40,200 shares of Eagle common stock worth $3.0 million at closing. We also agreed to pay up to $48 million in additional payments upon the completion of certain milestones, for aggregate potential payments of $78 million.

On February 8, 2018, the Company entered into an amendment (the “Arsia Amendment”) to the Arsia SPA. Pursuant to the Arsia Amendment, the Company's obligation to make four separate milestone payments pursuant to the Arsia SPA, which could have aggregated to a total of $48 million, were terminated in exchange for a single payment of $15 million to the Seller.

The acquisition was accounted for as a business combination in accordance with ASC 805, which requires the assets acquired and liabilities assumed from Eagle Biologics to be recorded on the acquisition date at their respective fair values. Eagle Biologics' results of operations are included in the financial statements from the date of acquisition.

Eagle Biologics' platform technology enables subcutaneous administration of high-dose biologics through improved formulation. Eagle Biologics has developed early-stage partnerships with major pharmaceutical companies to apply its technology to their biosimilar molecules, create subcutaneous versions of currently-marketed IV products and produce high-concentration formulations of clinical candidates. In addition to acquiring the technology platform, the Company plans to establish a Biologics Innovation Center in Kendall Square in Cambridge, Massachusetts.

The following table summarizes the consideration transferred to acquire Eagle Biologics at the date of acquisition:

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The aggregate consideration consisted of:	Preliminary fair value
Cash consideration paid	$ 27,209
Common stock issued (i)	3,046
Fair value of contingent consideration payable to seller (long term) (ii)	16,100
Total consideration	$ 46,355

(i) Under the stock purchase agreement, the number of common shares to be issued to the seller is equal to $2.7 million divided by the average of the closing day price per share for the thirty (30) trading days prior to the Closing Date. The average price of the common stock of 30 days prior to closing was $68.18. Accordingly, the number of common stock to be issued to the seller was determined at 40,200 shares ($2.7 million/$68.18 per share). The fair value of the common stock issued was determined based on the closing price of Eagle’s common stock on November 16, 2016.

(ii) Under the Arsia SPA, the contingent consideration includes four separate milestone payments which could aggregate to a total of $48 million payable to the Seller upon achievement of certain clinical, regulatory and development milestones. These milestone payments are also subject to acceleration under certain circumstances described in the Arsia SPA. In accordance with the provisions of ASC 805-30-25-5, each unit of contingent consideration is recognized at the acquisition date fair value. The acquisition date fair value of the contingent consideration is $16.1 million and has been classified as other liabilities within non-current liabilities. Such fair values are determined based on a probabilistic model with weights assigned on the likelihood of the Company achieving the clinical, regulatory and development milestones as well as an acceleration event in the future. Each unit of contingent consideration is classified as a liability in the balance sheet and would be subsequently measured at fair value on each reporting date. Any future change in fair value would be recognized in the statement of operations. As described above, on February 8, 2018, the Company entered into the Arsia Amendment, pursuant to which the Company’s obligations to make four separate milestone payments under the Arsia SPA were terminated in exchange for a single payment of $15 million to the Seller.

During the year ended December 31, 2017, the Company recorded a change in the fair value of contingent consideration of $1.2 million related to the Arsia Amendment.

The following table represents a reconciliation of the change in the fair value measurement of the contingent consideration liability, which was recorded in the Company's consolidated statements of income:

Closing Balance December 31, 2016	Changes in fair value	Payment of contingent consideration	Closing Balance December 31, 2017	Changes in fair value	Payment of contingent consideration	Closing Balance December 31, 2018
$16,201	$(1,201)	$ —	$ 15,000	$ —	$ (15,000)	$ —

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
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13. Intangible Assets, Net

The gross carrying amounts and net book value of our intangible assets are as follows:

		December 31, 2018			
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment Charges	Net Book Value
Docetaxel product rights	10	$11,220	$ (1,281)	$ (9,939)	$—
Ryanodex intangible	20	15,000	(1,554)	—	13,446
Developed technology	5	8,100	(3,443)	—	4,657
Total		$34,320	$ (6,278)	$ (9,939)	$18,103

		December 31, 2017			
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment Charge	Net Book Value
Docetaxel product rights	10	$11,220	$ (1,164)	$ (7,235)	$2,821
Ryanodex intangible	20	15,000	(777)	—	14,223
Developed technology	5	8,100	(1,822)	—	6,278
Total		$34,320	$ (3,763)	$ (7,235)	$23,322

Amortization expense amounted to $2,515, $2,815, and $948, for the year ended December 31, 2018, 2017, and 2016, respectively.

Intangible Asset Impairment

During the year ended December 31, 2017, the Company experienced a decline in customer contracts and saw a drop in market pricing for Non-Alcohol Docetaxel Injection. Accordingly, the Company estimated the fair value of our Non-Alcohol Docetaxel Injection product and determined the carrying amount of the intangible asset was no longer fully recoverable, resulting in a pre-tax, non-cash asset impairment charge of $7.2 million during the year ended December 31, 2017.

On June 30, 2018, the Company implemented a restructuring initiative based on its assessment of the current product portfolio and made a decision to discontinue manufacture and distribution of Non-Alcohol Docetaxel Injection. The Company ceased selling the product by September 30, 2018. As a result, the Company recognized a pre-tax, non-cash asset impairment charge of $2.7 million during the year ended December 31, 2018.

Estimated Amortization Expense for Intangible Assets

Based on definite-lived intangible assets recorded as of December 31, 2018, and assuming that the underlying assets will not be impaired and that the Company will not change the expected lives of the assets, future amortization expenses are estimated as follows:

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
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	Estimated Amortization Expense
Year Ending December 31,	
2019	$ 2,520
2020	2,666
2021	2,623
2022	1,369
2023	1,570
All other	7,355
Total estimated amortization expense	$ 18,103

14. Legal Proceedings

In addition to the below legal proceedings, from time to time, we may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Commercial Litigation

In Re: Taxotere (Docetaxel)

On February 1, 2017, the Company was named as a defendant, among various other manufacturers, in several product liability suits that are consolidated in the U.S. District Court for the Eastern District of Louisiana as part of MDL 2740 (Civil Action No 2:16 md-2740). The claims are for personal injuries allegedly arising out of the use of docetaxel.

In March 2017, the Company reached agreements in principle with the Plaintiffs' Steering Committee in this matter to voluntarily dismiss the Company from all of the lawsuits in which it was named and from the master complaint. The Company is in the process of working with the other parties in this matter to have it removed from the Multidistrict litigation entirely. As part of the agreement, in the event a case is brought in the future with facts that justify the Company's inclusion, the plaintiffs reserved the right to include the Company in such matter. The plaintiffs have filed several additional lawsuits since the parties' agreement in principle to dismiss, and the Company is in the process of working with plaintiffs to explore the possibility of dismissing those lawsuits.

Eagle v. Burwell

On April 27, 2016, the Company filed an action in the U.S. District Court for the District of Columbia against the FDA and other federal defendants seeking an order requiring the FDA to recognize orphan drug exclusivity for Bendeka for the treatment of CLL and indolent B-cell NHL. On June 8, 2018, the Court issued a decision requiring the FDA to recognize seven years of orphan drug exclusivity in the U.S. for Bendeka, and on July 6, 2018 the FDA recognized such ODE until December 7, 2022. In addition, on July 6, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested that the Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA's motion was denied by the Court on August 1, 2018 on the grounds that the FDA had not satisfied the standard for altering or

amending the judgment. The FDA and two intervenors have appealed the Court’s final judgment to the U.S. Court of Appeals for the District of Columbia Circuit. The briefing schedule issued by the Court of Appeals provides for briefing in those appeals to be completed by June 24, 2019. On February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of exclusivity for Bendeka. Pursuant to the decision and provided that the Court's decision is not reversed upon appeal, no bendamustine product used to treat the same indications (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka. The Company expects to vigorously pursue the scope of its exclusivity grant.

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Eagle v. Eli Lilly

On August 24, 2017, the Company filed an antitrust complaint in the United States District Court for the District of New Jersey ("New Jersey District Court") against Eli Lilly and Company ("Lilly"). The complaint alleges that Lilly engaged in anticompetitive conduct which restrained competition by delaying and blocking the Company's launch of a competing pemetrexed injection product (to compete with Lilly's Alimta). Lilly accepted service and answered the complaint on October 27, 2017. Lilly also filed a motion to transfer this case to Delaware on October 27, 2017. The Company filed a motion to oppose such transfer on November 6, 2017. On July 20, 2018, the New Jersey District Court transferred the case to Delaware. On November 27, 2018, the Delaware Court stayed the case at least until conclusion of the PEMFEXY™ patent trial described below.

Patent Litigation

Eli Lilly and Company. v. Eagle Pharmaceuticals, Inc. (PEMFEXY™ (Pemetrexed))

On August 14, 2017, Lilly filed suit against the Company in the United States District Court for the Southern District of Indiana (the "Indiana Suit"). Lilly alleged patent infringement based on the filing of the Company's 505(b)(2) NDA seeking approval to manufacture and sell the Company's EP-5101. EP-5101, if finally approved by FDA, will be a branded alternative to Alimta®, which is indicated (in combination with cisplatin) (a) for the treatment of patients with malignant pleural mesothelioma, or (b) for the initial treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer. Alimta® also is indicated as a single-agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy. Alimta® also is indicated for maintenance treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

On September 8, 2017, Eagle moved to dismiss the Indiana Suit for improper venue. On September 11, 2017, Lilly voluntarily dismissed the Indiana Suit. It then filed a complaint in the United States District Court for the District of Delaware, alleging similar patent infringement claims (the "Delaware Suit"). Eagle answered and filed various counterclaims in the Delaware Suit on October 3, 2017. Lilly answered Eagle's counterclaims on October 24, 2017. The Court held a scheduling conference on December 11, 2017 and set trial in the Delaware Suit to begin on September 9, 2019. On May 31, 2018, Eagle filed a Motion for Judgment on the Pleadings, which the Court denied on October 26, 2018. On January 23, 2019, the Court held a Markman hearing. Trial is scheduled to begin on September 9, 2019. The Delaware Suit is pending.

Eagle Pharmaceuticals, Inc., et al. v. Slayback Pharma Limited Liability Company; Eagle Pharmaceuticals, Inc., et al. v. Apotex Inc. and Apotex Corp.; Eagle Pharmaceuticals, Inc., et al. v. Fresenius Kabi USA, LLC; Eagle Pharmaceuticals, Inc., et al. v. Mylan Laboratories Limited; Eagle Pharmaceuticals, Inc. et al. v. Hospira, Inc. - (BENDEKA®)

BENDEKA®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin's lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Four companies - Slayback Pharma Limited Liability Company ("Slayback"), Apotex Inc. and Apotex Corp. ("Apotex"), Fresenius Kabi USA, LLC ("Fresenius"), and Mylan Laboratories Limited ("Mylan") - have filed Abbreviated New Drug Applications ("ANDA's") referencing BENDEKA® that include challenges to one or more of the BENDEKA® Orange Book-listed patents. Hospira, Inc. ("Hospira") a 505(b)(2) NDA.

The Company, Cephalon, Inc. and/or Teva Pharmaceuticals International GMBH (together the “Patentees”), filed separate suits against Slayback, Apotex, Fresenius, Mylan and Hospira in the United States District Court for the District of Delaware on August 16, 2017 (Slayback (“Slayback I”)), August 18, 2017 (Apotex), August 24, 2017 (Fresenius), December 12, 2017 (Mylan), January 19, 2018 (Slayback (“Slayback II”)), and July 19, 2018 (Hospira). In these Complaints, the Patentees allege infringement of the challenged patents, namely U.S. Patent Nos. 8,791,270 and 9,572,887 against Slayback (Slayback I and Slayback II), and of U.S. Patent Nos. 8,609,707, 8,791,270, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399 against Fresenius, Apotex, and Mylan, and of U.S. Patent Nos. 9,572,887, 10,010,533, 9,034,908, 9,144,568, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384 against Hospira. The parties stipulated to dismiss without prejudice U.S. Patent No. 8,791,270 as to Apotex, Fresenius and Mylan on July 24, 2018, August 2, 2018, and August 3, 2018,

respectively. Slayback, Apotex, Fresenius, and Mylan answered their Complaints and some filed various counterclaims on September 29, 2017 (Slayback I), February 12, 2018 (Slayback II), November 27, 2017, September 15, 2017, and February 14, 2018, respectively. The Patentees answered the Slayback I, Slayback II, Fresenius, and Apotex counterclaims on October 20, 2017, March 5, 2018, October 6, 2017, and December 18, 2017, respectively. The Slayback I, Slayback II, Apotex, Fresenius and Mylan cases have been consolidated for all purposes, with Trial scheduled to begin September 3, 2019. On October 15, 2018, the Patentees filed a suit against Fresenius and Mylan in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 10,010,533 and 10,052,385. Hospira filed a motion to dismiss the case, which was fully briefed on November 16, 2018. All seven cases are pending.

The FDA is stayed from approving Apotex's, Fresenius', Mylan's ANDA's, and Hospira's 505(b)(2) application until the earlier of (1) January 7, 2020, January 14, 2020, April 30, 2020, and December 20, 2020 respectively (the "30-month stay dates"); and (2) a court decision that each of the challenged patents is not infringed, invalid or unenforceable. The 30-month stay dates may be shortened or lengthened if either party to the action fails to reasonably cooperate in expediting the action. The FDA cannot approve Slayback's ANDA until March 2033.

Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company
Slayback Pharma Limited Liability Company ("Slayback") filed an ANDA referencing Eagle's Big Bag. Slayback's ANDA includes challenges to one or more of the Big Bag Orange Book-listed patents. On September 20, 2018, the Company filed a suit against Slayback in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797 and 10,010,533. On October 10, 2018, Slayback answered the Complaint and filed various counterclaims. On October 31, 2018, the Company answered Slayback's counterclaims. This case is currently stayed.

Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company
Slayback filed a 505(b)(2) NDA referencing Eagle's Big Bag. Slayback's NDA includes challenges to one or more of the Big Bag Orange Book-listed patents. On December 11, 2018, the Company filed a suit against Slayback in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 9,265,831, 9,572,796, 9,572,797 and 10,010,533. On December 13, 2018, Slayback answered the Complaint and filed various counterclaims. This case is pending.

Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals, Inc. (Vasopressin)
On May 31, 2018, Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (together "Par") filed suit against the Company in the United States District Court for the District of Delaware. Par alleged patent infringement based on the filing of the Company's Abbreviated New Drug Application ("ANDA") seeking approval to manufacture and sell the Company's vasopressin product. The Company's vasopressin product, if approved by FDA, will be an alternative to Vasostrict, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. The Company answered the complaint on August 6, 2018. Trial is scheduled to begin May 18, 2020. This suit is pending.

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15. Selected Quarterly Financial Data - Unaudited

A summary of quarterly financial information for the year ended December 31, 2018 and 2017 is as follows:

	For the Quarter Ended				
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018	Total Fiscal Year 2018
	(in thousands except share and per share amounts)				
Revenue	$46,626	$59,296	$ 51,337	$ 56,053	$213,312
Income from operations	$2,305	$183	$ 18,402	$ 15,726	$36,616
Net income attributable to common stockholders	$2,616	$2,659	$ 1,404	$ 25,224	$31,903
Income per share attributable to common stockholders- basic	$0.18	$0.18	$ 0.94	$ 0.86	$2.16
Income per share attributable to common stockholders- diluted	$0.17	$0.17	$ 0.91	$ 0.84	$2.09

	For the Quarter Ended				
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017	Total Fiscal Year 2017
	(in thousands except share and per share amounts)				
Revenue	$76,793	$50,108	$ 63,021	$ 46,785	$236,707
Income from operations	$32,696	$5,902	$ 24,950	$ 10,442	$73,990
Net income attributable to common stockholders	$22,924	$4,503	$ 15,431	$ 9,085	$51,943
Income per share attributable to common stockholders- basic	$1.50	$0.30	$ 1.03	$ 0.61	$3.44
Income per share attributable to common stockholders- diluted	$1.42	$0.28	$ 0.98	$ 0.58	$3.27

16. Restructuring

As part of its ongoing organizational review, the Company engaged in a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures included the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection in June 2018 and plans to rationalize research and development operations. Charges consist of inventory and related reserves, certain asset impairment charges related to property and equipment, and personnel related costs. The restructuring costs of $7,911 for the year ended December 31, 2018 has been recorded to Restructuring charge on the Consolidated Statements of Income. The Company also recorded an asset impairment charge for the remaining Intangible asset for Non-Alcohol Docetaxel Injection of $2,704 as well as an adjustment to remove the contingent consideration of $790 on the related line items in the Statements of Income for the year ended December 31, 2018. The Company does not expect to incur additional expenses related to this restructuring initiative. There is no liability remaining for the restructuring as of December 31, 2018.

17. Related Party Transaction

During the year ended December 31, 2018, the Company obtained legal services from Greenberg Traurig, LLP in exchange for $0.2 million. Richard A. Edlin, a member of the Company's Board, is an attorney and shareholder of Greenberg Traurig, LLP.