EAGLE PHARMACEUTICALS, INC.
Form 10-K
December 22, 2014

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 September 30, 2014

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)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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 or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting 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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant on was approximately $101,476,651 computed by reference to the last reported sale price of $12.75 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, March 31, 2014. 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 as of December 17, 2014 was 14,032,167 shares.

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EAGLE PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
For the fiscal year ended September 30, 2014

Eagle Pharmaceuticals, Inc.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

Eagle Pharmaceuticals, Inc. name and logo and Ryanodex®, are either registered trademarks or trademarks of Eagle Pharmaceuticals in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this annual report on Form 10-K are the property of their respective owners. References to the "Company," "we," "us" or "our" mean Eagle Pharmaceuticals, Inc., a Delaware corporation.

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 product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- 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 expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 ("JOBS Act");
- our use of the proceeds from our initial public 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.

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. 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. These important factors include our "critical accounting estimates" described in Item 7 in Part II of this annual report and the factors set forth under the caption "Risk Factors" in Item 1A in Part I of this annual report. 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, 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.

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PART I
Item 1. Business

Overview

We are a specialty pharmaceutical company focused on developing and commercializing injectable products, 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. Our business model is to develop proprietary innovations to FDA-approved, injectable drugs, which we refer to as branded reference drugs, that offer longer commercial duration at attractive prices compared to generic competitors. We intend to enter the market no later than the first generic drug and substantially convert 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 the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as applicable. 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 regulatory and commercial strategy is to introduce our products no later than the first generic competitor of the branded reference product, which provides us with the potential for superior pricing and helps diminish competition from impending generic products to the branded reference drug. Our model has been validated by the approval and successful launches of our novel formulations of EP-1101 (argatroban) and, most recently Ryanodex® (dantrolene sodium) for injectable suspension indicated for the treatment of malignant hyperthermia ("MH"), which we launched on August 29, 2014.

Our product portfolio now includes three approved products: argatroban, Ryanodex® and diclofenac-misoprostol. Of these, argatroban and Ryanodex® are commercialized. We are planning the launch of diclofenac-misoprostol, a legacy product.
We currently have five product candidates in advanced stages of development. Our lead product candidate is a patented bendamustine hydrochloride injection, ready to dilute (“RTD”) concentrate solution. Our bendamustine candidate is a proprietary intravenous version of the chemotherapeutic agent that is indicated for the treatment of chronic lymphocytic leukemia (“CLL”) and indolent B-cell non-Hodgkin’s lymphoma (“NHL”), and marketed by Teva Pharmaceutical Industries Ltd. ("Teva") under the brand name Treanda®. When administered in a 500 mL admixture EP-3101 Bendamustine RTD, our product candidate has the same 30 or 60 minute infusion time as Treanda®.

On July 2, 2014, we were granted tentative approval for EP-3101 Bendamustine RTD. Also in July 2014, Eagle was granted orphan drug designation for EP-3102 for the treatment of CLL and indolent B-cell NHL by the FDA.

In November 2014 we received positive results from our clinical trial of EP-3102 Bendamustine RTD, in which the same formulation of EP-3101 was delivered in a 50mL admixture in ten minutes versus the 500mL admixture delivered in a 60-minute infusion required for Treanda®. In this study, EP-3102 was found to be bioequivalent to Treanda®, which was the primary endpoint of the study. The incidence and profile of adverse events, both infusion-related and general, for EP-3102 was comparable to Treanda®. This is particularly important because EP-3102 delivers the same amount of active ingredient as Treanda® but with a lower admixture volume, which enables our product to be administered more quickly.

Due to orphan drug exclusivity for Treanda®, the earliest that the tentative approval we received on July 2, 2014 may convert to final approval is September 2015, if we are able to demonstrate at an earlier date that our bendamustine product which has orphan drug designation in the U.S., is clinically superior to Teva’s currently-marketed formulation.

We believe that bendamustine represents a domestic market opportunity of over $700 million.

Our product portfolio consists of:

Product	U.S. Brand Reference Drug	Description	Indication	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 designation received for MH (U.S.)
EP-1101 (argatroban)	Argatroban	Anti-coagulant; thrombin inhibitor	Heparin-induced thrombocytopenia	$99[2]	Approved (US); marketed by The Medicines Company and Sandoz
EP-3101 (bendamustine RTD)	Treanda®	Chemotherapeutic agent	Chronic lymphocytic leukemia (CLL); Indolent non-Hodgkin's lymphoma (NHL)	over $700[1]	Tentative approval for NHL July 2014
EP-3102 (rapidly infused bendamustine RTD)	Treanda®	Chemotherapeutic agent	CLL; Indolent NHL	over $700[1]	Label expansion of EP-3101. Orphan drug designation for CLL and NHL (U.S.); Clinica trial completed with positive results announc November 2014.
EP-4104 (dantrolene sodium)	No drug currently approved	Muscle relaxant	Exertional heat stroke	$150[2]	Orphan drug designation received for heat stroke (U.S.); IND submission 2015
EP-6101 (bivalirudin)	Angiomax	Anti-Coagulant; thrombin inhibitor	Percutaneous transluminal angioplasty	$609[1]	Registrati batches to support U.S. NDA filing manufactured in 2Q2014
EP-5101 (pemetrexed)	Alimta	Chemotherapeutic agent	Lung cancer and mesothelioma	$1,210[1]	Formulation work complete. NDA targeted fo 2016

[1]Based on publicly filed reports with the SEC.

[2]Based on independent market research and management's estimates extrapolated therefrom.

The global generics injectables market is estimated at $12.0 billion, with the United States accounting for approximately $7.6 billion of this. Based on industry data, we believe that the U.S. generic injectable market will continue to grow at a compound annual growth rate of 16.3% from 2012-2017 due to several factors, including (i) label expansion for approved products increasing the patient pool for such products, (ii) a pipeline of injectable medications at various stages of clinical development, and (iii) the increasing incidence of certain diseases that necessarily utilize injectable medications such as cancer and autoimmune disorders. Further, we estimate that the current worldwide market for the branded reference drugs addressed by our disclosed product portfolio is approximately $4.0 billion. Our recently contracted specialty sales force focuses on domestic GPOs (Group Purchasing Organizations), hospital groups and key stakeholders in acute care settings. Outside of the United States, we intend to utilize partners for the commercialization of our products.

In general, our goal is to launch our proprietary products no later than the first generic to the branded reference drug. This allows us to take advantage of the market opportunity during its most profitable cycle where price is higher and fewer, if any, generic competitors exist. In addition, we benefit from meaningful barriers to entry that are not inherent to generic drugs under the Abbreviated New Drug Application ("ANDA") regulatory pathway, including a robust

patent portfolio and the potential for three years of marketing exclusivity for our future product candidates as a result of the 505(b)(2) regulatory pathway of the Hatch-Waxman Act.

A generic drug company must either (i) wait for the innovator's patents to expire or to be proven invalid to gain market entry or (ii) choose to enter the market at risk of patent infringement. Patent invalidity challenges are time consuming and complex, and outcomes are uncertain. Compared to the ANDA regulatory pathway, which is only available for generic drugs that are the same as, and bioequivalent to, the branded reference drug, the 505(b)(2) regulatory pathway enables us to more broadly modify our drugs while still relying on the safety and efficacy data supporting approval of the branded reference drug. We are therefore able to design our products in an effort to avoid infringing existing patents covering the branded reference drug, which, we believe, in many cases will allow us to enter the existing market earlier than applicable generic drugs. In addition, our drugs that we expect to be approved under the 505(b)(2) regulatory pathway are not precluded from marketing during the 180-day exclusivity period that the first ANDA holder(s) may enjoy under the Hatch-Waxman Act.

Industry Background

Injection is a common drug delivery route for biopharmaceuticals due to the lower bioavailability of alternative administration routes. Based on market data provided by Markets and Markets, the global market for injectable products was estimated to be approximately $12.0 billion. The data project that the United States generic injectable market will continue to grow at a compound annual growth rate of 16.3% due to several factors, including (i) label expansion for approved products increasing the patient pool for such products, (ii) a pipeline of injectable medications at various stages of clinical development, and (iii) the increasing incidence of certain diseases that necessarily utilize injectable medications such as cancer and autoimmune disorders.

Limitations of Existing Drug Products and Generics

We believe that many currently available critical care and oncology injectable products 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 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.

Market Opportunity

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. Such improvements could also reduce infusion times, reduce dosing errors, remove unnecessary exposure to toxic materials and potentially improve the safety of the product.

Hatch-Waxman Act. Section 505 of the Federal Food, Drug and Cosmetic Act ("FDCA") describes three types of NDAs that may be submitted to request marketing authorization for a new drug. A 505(b)(1) NDA is an application that contains full reports of investigations of safety and effectiveness. The Hatch-Waxman Act created two additional marketing pathways under Sections 505(j) and 505(b)(2) of the FDCA. Section 505(j) establishes an abbreviated approval process for generic versions of approved drug products through the submission of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. ANDA applicants are required to conduct bioequivalence testing to confirm chemical and therapeutic equivalence to the branded reference drug. Generic versions of drugs can often be substituted by pharmacists under prescriptions written for the branded reference drug.

A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant. This alternate regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant 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. If the paragraph IV certification is challenged by an NDA holder or patent owner(s) asserts a patent challenge to the paragraph IV certification, the

FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept for filing) an ANDA or 505(b)(2) NDA application that relies on the branded reference drug. For example, the holder of an NDA may obtain five years of exclusivity upon approval of a new drug containing a new chemical entity ("NCE"), that has not been previously approved by the FDA. The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) 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) were essential to the approval of the application and were conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDA for drugs that include the innovation that required the new clinical data.

Orphan Drug Act. In addition, 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. 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 the treatment of that disease or condition for which it has such designation, the product may be entitled to orphan drug exclusivity, which for seven years would prohibit the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances such as when a subsequent product demonstrates clinical superiority.

The following table provides a description of general similarities and differences between the various regulatory pathways:

	ANDA	505(b)(2) NDA	Traditional NDA
Clinical Trials/Testing Required	Only to show bioequivalence	Yes, to address potential differences between the branded reference product and the 505(b)(2) product.	Yes
Results in Orange Book Listed Patents	No	Yes, for novel formulations, other enhancements and new indications	Yes
Exclusivity	Potential for 180 days against other generic filers if first generic to file	Potential for three years for new clinical investigations (other than bioavailability and bioequivalence studies) that are essential to approval of the application. Potential for 30-month stay for Orange Book-listed patents	Potential for five years for a new chemical entity, or three years for new clinical investigations
	Yes	Yes	No

Paragraph IV Certification Required			
Potential Orphan Drug Status	No	Yes	Yes

Our Competitive Strengths

We believe that our management's unique knowledge of the industry, including its ability to identify products for enhancement, its experience with the 505(b)(2) regulatory pathway, and its ability to navigate paragraph IV challenges, combined with our portfolio of attractive assets, enables us to compete effectively in the market for injectable therapeutics.

Attractive portfolio of injectable assets that address a large market opportunity. Our product portfolio is focused on oncology,

critical care, and orphan diseases and includes three approved products, one tentative approval, and five distinct product candidates in advanced development. 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.

Validated business model. We believe that our differentiated business model as compared to generic and branded specialty pharmaceutical drug companies was validated with our first approval and commercial launch in the United States of a novel version of argatroban, for which we received approval of a 505(b)(2) NDA in June 2011. Our version of argatroban was formulated in a manner designed to avoid the infringement of related Orange Book patents for the branded reference product, and we were successful in doing so without triggering a patent infringement suit by the innovator of the branded reference drug. We therefore entered the market prior to the first generic version of argatroban and our version of the drug has reached a market share of 36% of the total argatroban market. Our competitors' undifferentiated ANDAs referencing the branded drug remain tentatively approved by FDA and, because they were not able to prove invalidity or non-infringement of the applicable patents, had to wait for approximately three years for patent expiration in June 2014 before full approval and commercialization. On June 30, 2014, two generic argatroban products were approved.

Unique insight into limitations of existing products. We believe that many injectable products for use in acute care settings 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. Because generic drugs are essentially copies of the branded reference drugs, these suboptimal characteristics are shared by the generic versions. We have and continue to engage physicians, nurses, pharmacists and key opinion leaders "(KOL's"), 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 in branded and generic pharmaceuticals, including significant experience with injectable pharmaceuticals, and a track record of success in product development, regulatory relations, and quality assurance to develop improved products.

Barriers to entry and intellectual property. 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 delaying 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 eleven owned or exclusively-licensed U.S. issued patents and ten filed U.S. patent applications, as well as several patent applications that have been filed in various worldwide territories, that protect or will protect, as applicable the market value of our current portfolio products. We believe that

other potential barriers to entry consist of one or more of the following:

- our own patents, which could prevent competition from generic versions of our products. In addition, we expect to be able to list our patents in the Orange Book, which will offer us the potential to trigger our own 30-month stay under the Hatch-Waxman Act against future 505(b)(2) and ANDA filers that reference our drugs;

- 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 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. 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 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. We believe that we can cost-effectively commercialize our products in the United States, and thereby retain full 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. Because we focus on proprietary versions of already well established branded products, we generally believe we will not need to focus our commercial resources on marketing our products directly to physicians, thereby substantially limiting our commercial expense. Outside of the United States, we intend to 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 eleven owned or exclusively-licensed U.S. issued patents and ten 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. These patents consist primarily of formulation and method-of-use patents. 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

EP-3101 (bendamustine RTD) and EP-3102 (bendamustine rapid infusion) for Chronic Lymphocytic Leukemia and Non-Hodgkin's Lymphoma

Overview

Bendamustine is an alkylating agent approved for use in chronic lymphocytic leukemia, or CLL, and indolent B-cell non-Hodgkin's lymphoma, or 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). We have developed a ready to dilute, or RTD, liquid formulation of bendamustine. We expect to commercialize :

EP-3101 (bendamustine RTD), is an RTD, multi-dose liquid with extended drug stability for use with a 500mL intravenous, or IV, infusion bag, for which we were granted tentative approval for patented bendamustine RTD. Due to orphan drug exclusivity on Treanda®, the earliest that the tentative approval we received on July 2, 2014 may convert to final approval is September 2015, if we are able to demonstrate that EP-3101 is clinically superior to Treanda®.

In September 2014, Cephalon, a subsidiary of Teva, had moved to dismiss with prejudice its first lawsuit alleging that Eagle's tentatively approved bendamustine hydrochloride injection infusion product infringes one of its patents, U.S. Patent No. 8,445,524. The case was filed in the United States District Court for the District of Delaware in October, 2013.

Cephalon recently filed a second lawsuit in the District of Delaware alleging that Eagle's bendamustine product infringes Cephalon's newly-issued U.S. Patent No. 8,791,270. That case remains pending.

EP-3102 (bendamustine rapid infusion), is the same RTD, multi-dose liquid formulation as EP-3101 with extended drug stability but for use with a 50 mL intravenous 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 EP-3101. We received Orphan drug designation for EP-3102 for CLL and NHL in July 2014. In November 2014 we announced positive results from the EP-3102 clinical trial, in which the dose was delivered in a 50mL admixture in ten minutes versus a 500mL admixture in the 60-minute infusion required for Treanda® (bendamustine HCl). In this study, EP-3102 was found to be bioequivalent to Treanda®, which was the primary endpoint of the study. The incidence and profile of adverse events, both infusion-related and general, for EP-3102 was comparable to Treanda®. This is particularly important because EP-3102 delivers the same amount of active ingredient as Treanda® but with a lower admixture volume, which enables our product to be administered more quickly.

Depending on the outcome of regulatory and legal hurdles, we would commercialize either EP-3101 (bendamustine RTD) or EP-3102 (bendamustine rapid infusion), both of which would treat the same indications as the branded form of bendamustine, but will not require reconstitution prior to administration, which we believe is a significant advantage.

Currently-U.S. Marketed Bendamustine Products

Teva currently markets its bendamustine product under the trade name Treanda®. The lyophilized product is available in 25 mg and 100 mg single use vials. Treanda® liquid formulation is available in .5mL and 2 mL single use vials.

Limitations of Treanda®

Treanda® Lyophilized
There are currently several drawbacks with reconstituting a lyophilized oncology drug, such as Treanda®. When mixing the Treanda® lyophilized powder with the diluent, there is also the potential for exposure of the healthcare professional to cytotoxic vapors. Many oncologists do not allow pregnant nurses to mix oncology drugs because of concern for fetal exposure to cytotoxic drugs. The Joint Commission on Accreditation of Healthcare Organizations, ("the Joint Commission"), the premier, independent, non-profit organization that accredits hospitals in the United States, encourages the use of RTU and RTD presentations over products that require reconstitution. Further, Treanda® has limited vial stability of 30 minutes at room temperature after the vial stopper has been punctured, potentially resulting in significant waste if the product is not used within that period of time.

Treanda® Liquid
Treanda® liquid RTD formulation also has drawbacks associated with its presentation. Once the liquid product is diluted in the IV bag, the product is only stable for two hours versus three hours with Treanda’s lyophilized powder presentation. Additionally, the product vial shelf life for Treanda liquid is one year. Additionally the liquid presentation has a new concentration of 90mg/mL versus 5mg/mL for Treanda® powder. Feedback from market stakeholders to this new concentration has been that it is more difficult to make patient dose calculations as 90mg/mL is not a typical concentration and having a product in a 25mg/mL or 50mg/mL concentration would be preferred. The Treanda® liquid formulation is also only available in a single use vial creating the potential for drug waste to occur.

Eagle's Solution: EP-3101 (bendamustine RTD) and EP-3102 (bendamustine rapid infusion)

The EP-3101 and EP-3102 liquid formulation eliminates 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. The EP-3101 (bendamustine RTD) and EP-3102 (bendamustine rapid infusion) is an RTD formulation, like Treanda® liquid as preferred by the Joint Commission. Also, because the EP-3101 (bendamustine RTD) and EP-3102

(bendamustine rapid infusion) product will be available in a multi-dose vial with extended vial stability of 28 days, this will reduce the amount of drug waste that typically occurs with single-use vials (such as Treanda®) in oncology settings.

The following chart illustrates certain potential benefits of our product candidates, EP-3101 (bendamustine RTD) and EP-3102 (bendamustine rapid infusion), both of which share the same formulation, over the currently marketed versions of Treanda®:

Key Product Characteristics	Treanda® Treanda® Lyophilized	Treanda® Liquid(1)	Eagle EP-3101	EP-3102 rapid infusion	EP-3101/EP-3102 Potential Benefits
Product description	Lyophilized powder for reconstitution (5 mg/mL)	Ready-to- dilute (90 mg/mL)	Ready-to-dilute liquid (25 mg/mL)		Relative to lyophilized Treanda®, reduced risk of dosing errors, less exposure to cytotoxic powders and time savings; Joint Commission-preferred
Shelf-life	24 months	12 months	24 months		Increased stability over Treanda® liquid
Multi-use vial	No, product must be diluted 30 minutes after reconstitution	No	Yes, must be used within 28 days if stored at 2-8° C and protected from light		Reduced potential for waste over both Treanda® products
Admixture stability (all must be refrigerated 24 hrs.)	Room Temp: 3 hrs.	Room Temp: 3 hrs.	Room Temp: 3 hrs.	Room Temp: 6 hrs. 5% dextrose water (D5W) 4 hrs.	Improved admixture stability over both Treanda® products. Additional admixture vehicle avoiding sodium for renally impaired patients
Infusion time	30-60 minutes	30-60 minutes	30-60 minutes	10 minutes	Less time in infusion chair for EP-3102 patient; greater office efficiencies due to less nursing time with each patient
Admixture fluid volume	500 mL	500 mL	500 mL	50 mL	Less potential for EP-3102 patient fluid load and edema

(1) Treanda® liquid is commercially available as of November 2014

EP-3101 (bendamustine RTD) and EP-3102 (bendamustine rapid infusion) Clinical Development and Regulatory Status

We submitted a 505(b)(2) NDA for our bendamustine product, EP-3101 (bendamustine RTD), and received tentative approval from the FDA on July 2, 2014. We had notified Teva of our 505(b)(2) filing and paragraph IV certification, and Teva filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware on October 21, 2013. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of our bendamustine product, which will delay the FDA from approving EP-3101 bendamustine RTD until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in our favor or otherwise acts to shorten the stay. Moreover, Teva has received orphan drug and related pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications, respectively. When a drug, such as Treanda®, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If we cannot demonstrate that EP-3101 is clinically superior to Treanda®, or qualify under certain other limited exceptions, we will not be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

After numerous discussions with the FDA, we have developed a regulatory strategy for EP-3102 (bendamustine rapid infusion). In November 2014 we received positive results from the EP-3102 clinical trial, in which the our EP3101

formulation was delivered in a 50mL admixture in ten minutes versus a 500mL admixture in the 60-minute infusion required for Treanda® (bendamustine HCl). In this study, EP-3102 was found to be bioequivalent to Treanda®, which was the primary endpoint of the study. The incidence and profile of adverse events, both infusion-related and general, for EP-3102 was comparable to Treanda®. This is particularly important because EP-3102 delivers the same amount of active ingredient as Treanda® but with a lower admixture volume, which enables our product to be administered more quickly.

Our bendamustine product candidates, if approved, could be reimbursed using a "J-code" assigned for injectable drugs. If we can demonstrate that EP-3102 (bendamustine rapid infusion) for administration in a smaller infusion volume is clinically significantly different than the other drugs that share the J-code, such as Treanda®, the Center for Medicare & Medicaid Services ("CMS"), may assign a unique J-code allowing more pricing flexibility.

Ryanodex® (dantrolene) 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 requires that all hospitals stock vials of this product at all times, generally in the operating room area. In July, 2014 we received FDA approval for Ryanodex® (dantrolene sodium).

Currently-Preexisitng Dantrolene Products for MH

The two preexisting 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-$80 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® (dantrolene sodium)

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 and 2ml 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 one 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. Additionally, fluid volume to the patient is also be reduced from up to 720mL or more with Dantrium® and Revonto® to only 5mL with Ryanodex®, potentially further

reducing secondary physiological complications for the patient.

We engaged Phoenix Marketing International, Healogix and BAL Consulting to conduct three independent market research studies with approximately 30 anesthesiologists and other doctors, hospital pharmacists and payors to assess the value of our Ryanodex® product. All of these groups of healthcare professionals agreed that rapid administration of dantrolene is critical in averting a serious negative outcome in MH. Anesthesiologists also stated that the greatest drawback to the existing dantrolene products is the time required to administer this drug in a life or death situation. Many of these physicians also noted their substantial concern over encountering a patient with MH because of the risks of mortality, the challenges in diagnosing its onset, and their lack of experience in treating this rare disease. They confirmed that time to administration is the greatest concern when they encounter an MH crisis. When asked to rate the value of Ryanodex® on a scale of 1 to 10 (10 being the best), anesthesiologists and pharmacists rated Ryanodex® a 9 on average and stated that they would use this product as their drug of choice. The most-mentioned reason

for this very high rating is the faster time to mix Ryanodex® and administer it to their patients.

Sales and Marketing

We contracted a third party logistics partner who stores our inventory of Ryanodex®, fulfills sales orders and provides detailed real time reporting. Additionally, we contracted with a third party sales force comprised of 20 representatives who are focusing their promotional activities of Ryanodex® on important stakeholders within the hospital setting. To compliment these efforts, we have also engaged group purchasing organizations and wholesalers in contracting discussions.

EP-4104 (dantrolene) for Exertional Heat Stroke

Exertional heat stroke ("EHS") is a rare, emergency and serious medical condition that is potentially life-threatening. Its symptoms and effects are closely correlated to MH and our research and development efforts have suggested dantrolene's efficacy for treating EHS. Based on the clinical relationship that exists between MH and EHS, we also are developing a dantrolene formulation for EHS.

EHS is one of the causes of sudden death in athletes and, we believe, most likely is the leading cause of death during the months of July and August in this group. We believe it 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 at the same rate. EHS typically affects young, 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. Although well-known, 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. There is also a genetic component related to those who suffer from MH. The pathogenesis of EHS is multifactorial and complex and not completely understood, but it is believed that a defect in the calcium transport in skeletal muscle sarcoplasmic reticulum is a key component of both EHS and MH. This link suggests that the genetic variant which predisposes patients to MH also puts those patients at an increased susceptibility to EHS.

Currently Marketed Products for EHS

There are currently no FDA-approved products that treat EHS, and patients continue to die or suffer significant morbidity from the condition. Independent market research commissioned by us suggests that the worldwide peak revenue for EHS could exceed $150 million.

Limitations of Current EHS Therapies

The current treatment regimen for EHS is not directed at the underlying cause of the disease, but is essentially symptomatic therapy, which in some cases results in mortality or permanent organ damage. Currently, to treat EHS, the standard treatment includes immediate surface cooling with ice and support of organ system function with a goal of accelerating the transfer of heat from the skin to the environment without compromising the flow of blood to the skin. 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 (dantrolene) for EHS

EP-4104's (dantrolene for EHS) presentation will be initially similar to Eagle's presentation of Ryanodex® (dantrolene for MH) - a 5mL vial containing 250mg of dantrolene in lyophilized powder form requiring reconstitution. Like Ryanodex®, only one 5mL injection of EP-4104 (dantrolene for EHS) will be required to initially treat EHS, avoiding

the potential need to reconstitute up to 12 or more vials of drug in a short time, as is the current treatment for the related condition of MH. Additionally, because our formulation of EP-4104 (dantrolene for EHS) could be carried by emergency responders (currently impractical with marketed dantrolene products due to the IV volume of up to 720 mL or more required under current dosing guidelines), we believe that administering EP-4104 (dantrolene for EHS) in the field, prior to arriving at the hospital, would be possible. Given that immediate treatment for EHS is crucial for improving outcomes, we believe that our formulation will provide significant benefits over the current standard of care.

EP-4104 Clinical Development and Regulatory Status

EP-4104 has completed a Phase 1 clinical study in human volunteers and we are currently designing a pivotal clinical study to support our NDA submission. Our clinical development plan will be discussed with FDA at a Type C meeting in the first quarter

of 2015, and we expect to make an IND submission shortly thereafter. Additionally, we were granted Orphan Drug designation for (dantrolene sodium for heat stroke) in September 2012.

EP-5101 (pemetrexed) for Lung Cancer

Pemetrexed is an IV-administered cancer agent indicated for locally advanced or metastatic non-small cell lung cancer and mesothelioma. We are developing EP-5101 (pemetrexed) as an RTD liquid form of pemetrexed that will be available in a 500mg multi-dose vial with extended stability. We are currently performing pre-clinical formulation and toxicology studies on EP-5101 (pemetrexed). Because our product 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 pemetrexed is marketed by Lilly Pharmaceuticals as Alimta. Alimta is approved for use to treat non-small cell lung cancer and mesothelioma. 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 year ended December 31, 2013 were approximately $2.7 billion.

Limitations of Alimta

Alimta requires reconstitution, which adds significant 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. Additionally, 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, this lyophilized formulation is less preferred by the Joint Commission as compared to an RTD product.

Eagle's Solution: EP-5101 (Pemetrexed)

EP-5101 (pemetrexed) is an RTD liquid formulation of pemetrexed that we are designing as a 500mg multi-dose vial with extended stability. As an RTD liquid formulation, EP-5101 (pemetrexed) will not require additional time for reconstitution and will avoid certain safety concerns to healthcare professionals and potential dosing errors during mixing. This allows for a more efficient work flow within the infusion clinic, may result in more patients being seen each day and reduces exposure to the drug's cytotoxic vapors during reconstitution by healthcare providers.

We engaged Phoenix Marketing International to conduct independent market research with pharmacists and oncology nurses to study our proposed formulation of EP-5101 (pemetrexed). When subjects were asked to describe the ideal product profile for Alimta, many respondents indicated a desire for an RTD liquid formulation in a multi-dose vial. Extended stability was also described as an improvement to the existing drug.

The benefits of our proposed formulation identified by our research included a reduction in dosing errors as no reconstitution is required, as well as more flexibility in patient scheduling, possibly allowing a greater number of patients to be seen each day. Also mentioned was a possible opportunity to reduce office staff due to a more efficient work flow within the infusion clinic.

EP-5101 (pemetrexed) Development and Regulatory Status

We plan to seek U.S. approval of EP-5101 (pemetrexed) for use in non-small cell lung cancer and mesothelioma. We are anticipating a 505(b)(2) NDA filing in 2016 in the United States.

EP-6101 (bivalirudin) for Percutaneous Transluminal Angioplasty

Bivalirudin is a direct thrombin inhibitor, administered as an IV infusion and indicated for use as an anticoagulant during coronary surgical procedures. We are developing EP-6101 (bivalirudin) as a ready-to-use, or, RTU, liquid formulation of bivalirudin in a 250mL vial that can be administered to patients without having to reconstitute the drug. As a result, EP-6101 (bivalirudin) will be Joint Commission-preferred.

Currently-Marketed Bivalirudin Product

Bivalirudin is marketed by The Medicines Company in the United States under the brand name Angiomax. The approved product's presentation is a vial containing 250mg of lyophilized powder which requires reconstitution. Domestic net sales of Angiomax were approximately $609 million in 2013.

Limitations of Angiomax

The powder form of Angiomax must be reconstituted before administration at the beginning of a catheter laboratory ("cath lab") procedure, then further diluted into an IV bag. As with any drug requiring reconstitution, mixing can result in dosing errors if, for example, the wrong diluent or incorrect amount of diluent is added to the product. Additionally, reconstitution takes time, which results in slower work flows. Finally, Angiomax is limited in that the Joint Commission guidelines encourage the use of RTU presentations over products that require reconstitution. Additionally, U.S. Pharmacopoeia, the scientific nonprofit organization that sets standards for medicines manufactured, distributed and consumed worldwide and whose drug standards are enforceable in the United States by the FDA, has issued USP 797, a far-reaching regulation that governs any pharmacy that prepares compounded sterile preparations and, among other things, requires that drug compounding be done in a clean room environment by a licensed pharmacist. In many situations where no licensed pharmacist is available (for example, during late-night shifts), nurses and other healthcare providers are required to mix the drug themselves.

Eagle's Solution: EP-6101 RTU Bivalirudin

We are developing EP-6101, a bivalirudin RTU liquid formulation to resolve each of the current limitations of Angiomax. If approved, our product formulation would be available for immediate patient administration with no reconstitution required. This would save time and reduce risks of dosing errors during reconstitution. Additionally, because no mixing of our drug is required, compliance with regulations such as USP 797 can be achieved regardless of the situation in which our drug is required to be administered. As a multi-use vial, drug waste is minimized over the brand product and requires only one presentation

We engaged Phoenix Marketing International to perform market research on our behalf for EP-6101 (bivalirudin) to determine how receptive hospital stakeholders would be to this new formulation. Phoenix worked with both hospital pharmacists and cath lab nurses in conducting this research. We believe these two groups of clinicians are the most important within an institution in terms of evaluating the opportunity for an RTU formulation of Angiomax, as they have extensive experience with the existing lyophilized powder product. Hospital nurses and pharmacists provided feedback regarding EP-6101 (bivalirudin) stating that they believe this product will offer several benefits to both the staff and the patient, including more efficient work flows and the ability to more quickly and flexibly administer the drug in a variety of settings.

EP-6101 (bivalirudin) Development and Regulatory Status

We completed a Type C meeting with the FDA in November 2013 at which we discussed the expected product attributes of EP-6101. Registration batches to support our U.S. filing were manufactured in the second quarter of 2014. We anticipate submitting 505(b)(2) NDA for this candidate in the first half of 2015.

Argatroban for Heparin-Induced Thrombocytopenia

Argatroban is an anti-coagulant originally developed for the treatment of heparin-induced thrombocytopenia ("HIT"). Our formulation of argatroban, EP-1101, is our first product approved by the FDA, and marketed by The Medicines Company and Sandoz under agreements with us. Through our agreement with The Medicines Company, we granted

The Medicines Company exclusive rights to commercialize argatroban in the United States and Canada and a right of first negotiation to commercialize argatroban in other countries (except China). Through our settlement agreement and related supply and distribution agreement with Sandoz, we granted Sandoz the right to distribute an unbranded (generic) version of argatroban in 50mg/50mL vials in the United States. Through our contract manufacturer we supply The Medicines Company with argatroban in 50mg/50mL vials and we supply Sandoz with an unbranded (generic) version of argatroban in 50mg/50mL vials. Sandoz also markets argatroban in 125mg/125mL vials and pursuant to our agreements with Sandoz, Sandoz is obligated to pay us a majority of the net profits Sandoz receives for sales of such product in the United States. For more information regarding these agreements, see below under "- License Agreements."

Currently-Marketed Argatroban Products

Argatroban is currently sold by GSK, West-ward, The Medicines Company and Sandoz. It is sold in 250mL (GSK and West-ward), 125mL (Sandoz) and 50mL (The Medicines Company and Sandoz) presentations. According to IMS Health, argatroban had U.S. annual sales of $99 million in 2012. In June 2014, there were two new ANDA approvals granted to competitors, Par Sterile Products, LLC and Mylan Institutional LLC, increasing competition.

Limitations of Argatroban

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. EP-1101 (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.

We believe that the development, approval and commercialization of EP-1101 (argatroban) provides validation of our business model and strategy because it has resulted in a product that improves upon the formulation of the branded reference product in terms of ease of use, reduced waste and lower overall cost of treatment. Our argatroban product is currently demonstrating a strong pricing position relative to the branded price, and according to recent monthly IMS Health data, has a market share of 36%.

Additional Products in our Portfolio

In addition to our disclosed products pipeline, we are pursuing a number of potential products that address broad indications such as oncology, 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.

Sales and Marketing

Historically, we have chosen to out-license the commercial rights for products we have developed, such as argatroban which launched in the United States in 2011 and is sold by The Medicines Company as argatroban in the United States and Canada under an exclusive license from us. This arrangement allowed our management to focus our financial resources on research and development of other products in our portfolio. Additionally, in 2013 our management decided to also license certain rights to commercialize argatroban in the United States to Sandoz as part of a settlement of a paragraph IV dispute between the parties. Sandoz has developed strong relationships with the pharmaceutical group purchasing organizations and wholesalers, providing stronger commercial terms for argatroban with these important customers. For more information regarding this arrangement, see below under "- License Agreements."

Other than with respect to the arrangement with Sandoz and The Medicines Company described below, we will commercialize our product portfolio in the United States on our own while out-licensing commercialization rights for other territories. Our goal is to retain significant control over the development process and commercial execution for our product portfolio, while participating in a meaningful way in the global economics of all drugs that we bring to the market. Our first example of this strategy was the product launch of Ryanodex® (dantrolene sodium) which was FDA approved on July 22, 2014. Eagle Pharmaceuticals launched this product on its own in August, 2014 with a

contracted, focused specialty sales force consisting of key account managers, clinical liaisons and telesales representatives. Their target audience is comprised of medium and large healthcare systems that operate multiple hospitals and purchase through group purchasing organizations, as well as hospital based physicians and hospital pharmacists. These contained detailing points allow the sales team to be more efficient than traditional pharmaceutical sales forces, as the important clinical customers are located in a smaller number of key locations as opposed to the need to call on multiple physicians across a broad sales territory.

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 one 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 four issued U.S. patents, and one pending U.S. patent application, along with foreign counterparts that include both issued patents and pending applications. The issued U.S. patents (US 8,110,225, US 7,758,890 and US 8,604,072, US 8,685,460) 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, and the applications, if issued, will expire no later than June 13, 2022.

We are the sole owner of one issued and seven pending U.S. patent applications, and four 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 no later than March 15, 2033.

We are the co-owner, with The Medicines Company, of two issued U.S. patents (US 7,713,928 and US 7,803,762) that cover ready to use formulations and methods of treatment of bivalirudin, and there are is one pending application

or foreign filings. We expect that our issued patents will expire no later than August 20, 2029.

We are the sole owner of a portfolio of issued U.S. patents and pending applications (including U.S. patents US 7,589,106 and US 7,687,516), 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.

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., or 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.

Under the terms of this license agreement with Lyotropic, we are responsible for the prosecution and maintenance of all of the licensed patents that solely or predominantly cover the dantrolene product. We are also required to use commercially reasonable efforts to progress the development of our dantrolene product in the United States, and after completion of required clinical trials, to file a 505(b)(2) application in the United States for such product. We are also required to use commercially reasonable efforts to obtain regulatory approval and make commercial sales of our dantrolene product in at least two countries in Europe, in Japan and in at least one of Korea, Australia, Canada or Brazil within certain specified time periods, or to enter into a bona fide sublicense agreement under which a third party would progress commercialization of the product in such country or countries. These time periods may be extended if additional clinical trials are required in any such country in order to obtain regulatory approval in such country. Each of Europe, Japan and the rest of the countries in the world, including Korea, Australia, Canada or Brazil are considered to be separate Ex-U.S. Regions for the purpose of our license with Lyotropic. If we fail to comply with these commercial and regulatory diligence obligations in, each of the Ex-U.S. Regions, our license in the applicable Ex-U.S. Region will be revoked, and we will be required to discontinue operations in relation to the product in the applicable countries, and to transfer to Lyotropic all materials and information developed by us in relation to our dantrolene product in the Ex-U.S. Regions.

Under our license agreement with Lyotropic, we are not required to make any milestone payments but we are required to pay royalties on a country-by-country basis at a percentage in the mid-teens on net sales of our dantrolene product until the earlier of (i) the later of ten years from the date of first commercial sale of our dantrolene product in such country and expiration of the last valid claim covering such product in such country and (ii) with respect to any country in which we or our affiliates (but not our sublicensees) are selling the dantrolene product, as of the beginning

of the first fiscal quarter following the date of the first commercial sale of a generic version of our dantrolene product that results in a decrease in our net profits in such country by a specified percentage based on our average quarterly net profits for sales of our dantrolene product in such country over the 18 months immediately preceding the launch of such generic product.

Our agreement with Lyotropic will continue in force until terminated. The agreement may be terminated by either party for the other party's insolvency or material uncured breach, and we have the right to terminate the agreement upon 90 days written notice if, in our sole discretion, commercial development of the dantrolene product is no longer commercially reasonable.

License and Development Agreement with The Medicines Company

In September 2009, we entered into a license and development agreement with The Medicines Company under which we granted The Medicines Company 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 are responsible for development and obtaining regulatory approvals for argatroban in the United States, at our cost, and are required to use commercially reasonable efforts with respect to such activities. The Medicines Company is required to use commercially reasonable efforts to commercialize such argatroban products. We are also responsible, at our cost, for prosecution and maintenance of the licensed patents that cover the argatroban products, although The Medicines Company is required to reimburse us for half of our costs.

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

Our agreement with The Medicines Company will continue in force until terminated. The agreement may be terminated by either party for the other party's material uncured breach, and The Medicines Company has the right to terminate the agreement in its entirety or on a product-by-product basis upon 60 days written notice to us. In November 2011, we initiated a voluntary product recall of the argatroban product which was reintroduced on the market in May 2012. Under a 2012 amendment to this agreement we agreed to and received net payment of $471,077 from The Medicines Company. In 2009, we and The Medicines Company also entered into a related supply agreement under which we are the exclusive supplier of argatroban product to The Medicines Company for sales in the United States and Canada. This agreement will remain in force for a period of ten years, unless our license to The Medicines Company is terminated, in which case the supply agreement will automatically terminate. Either we or The Medicines Company may also terminate this supply agreement for uncured material breach.

Settlement Agreement and Related Supply and Distribution Agreement with Sandoz

In January 2013, we entered into a settlement agreement with Sandoz Inc., ("Sandoz") to resolve the suit 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.

Sandoz was authorized to begin commercial sales of our argatroban 50mg/50mL product in the United States upon execution of this agreement and the agreement will continue in force for three years from the date of signing. The agreement will automatically renew for additional one year periods unless either party gives notice to the other of non-renewal at least six months prior to each renewal date. Either we or Sandoz may terminate this agreement earlier for the other party's uncured material breach, insolvency or force majeure. In addition, either we or Sandoz may terminate the agreement earlier if the agreement violates or could violate applicable laws, or if a party is subjected to increased risk due to a change in laws or regulations after the effective date of the agreement, in each case based on the opinion of governmental agencies and/or the advice of legal counsel, or if it is no longer commercially viable to

continue sales of argatroban in the 50mg/50mL preparation in the United States, which is defined as the point at which net sales fall below a specified percentage of the cost argatroban product is sold to Sandoz under the agreement.

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).

Our collaboration with SciDose is guided by a joint development committee. SciDose is responsible, at its cost, for prosecuting and maintaining the licensed patents that cover the SciDose Subject Products. We are required to use commercially reasonable efforts to develop, obtain marketing authorization for and commercialize the SciDose Subject Products under this agreement.

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 50 percent for 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), and (ii) at a percentage in the range of 20 to 30 percent with respect to SciDose Subject 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 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. In the event we grant a license to any third party under the patents assigned to us or the intellectual property rights licensed to us with respect to any SciDose Subject Product, we are required to pay to SciDose 100% of all milestone payments we receive with respect to commercialization of any such SciDose Subject Products outside the United States, and a percentage in the range of 45 to 55 percent of any milestone payments we receive with respect to commercialization of any such SciDose Subject Products in the United States.

This agreement expires upon the expiration of our royalty obligations. The agreement may be terminated earlier by either us or SciDose, for the other party's material uncured breach and we may terminate this agreement on a product-by-product basis if the costs and expenses related to clinical trials for a SciDose Subject Product exceed a specified threshold.

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.

Our collaboration with Robert One is guided by a joint development committee. If the joint development committee is not able to make a decision by consensus then the dispute will be escalated to specified senior executive officers of the parties. Robert One is responsible, at its cost, for prosecuting and maintaining the licensed patents that cover the Robert One (bendamustine) Subject Products. We are required to use commercially reasonable efforts to develop the Robert One (bendamustine) Subject Products and obtain marketing authorization for the Robert One (bendamustine) Subject Products in the Territory and, upon receipt of marketing authorization, commercialize the Robert One (bendamustine) Subject Products under this agreement.

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 a percentage in the range of 5 to 15 percent for bendamustine products and (ii) at a percentage in the range of 45 to 55 percent 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 a percentage in the range of 20 to 30 percent 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. In the event we grant a license to any third party under the patents assigned to us or the intellectual property rights licensed to us with respect to any Robert One (bendamustine) Subject Product, we are required to pay to Robert One 100% of all milestone payments we receive with respect to commercialization of any such Robert One (bendamustine) Subject Products outside the United States, and a percentage in the range of 45 to 55 percent of any milestone payments we receive with respect to commercialization of any such Robert One (bendamustine) Subject Products commercialized in the United States.

This agreement expires upon the expiration of our royalty obligations. The agreement may be terminated earlier by either us or Robert One, for the other party's material uncured breach and we may terminate this agreement on a product-by-product basis if

the costs and expenses related to clinical trials for a Robert One (bendamustine) Subject Product exceed a specified threshold and either party may terminate the agreement if the ANDA or 505(b)(2) applications, as applicable, for the formulation of the Robert One (bendamustine) Subject Product has not been accepted by the FDA or if the ANDA or 505(b)(2), as applicable, is not approved by the FDA.

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 (pemetrexed) Subject Product)" and granted us an exclusive, sub-licensable, license under Robert One's intellectual property rights to develop make, use, sell and import Robert One (pemetrexed) 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.

Our collaboration with Robert One is guided by a joint development committee. If the joint development committee is not able to make a decision by consensus then the dispute will be escalated to specified senior executive officers of the parties. Robert One is responsible, at its cost, for prosecuting and maintaining the licensed patents that cover the Robert One (pemetrexed) Subject Products. We are required to use commercially reasonable efforts to develop the Robert One (pemetrexed) Subject Products and obtain marketing authorization for the Robert One (pemetrexed) Subject Products in the United States and, upon receipt of marketing authorization, commercialize the Robert One (pemetrexed) Subject Products under this agreement.

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 (pemetrexed) Subject Product by us and our affiliates in the Territory (i) at a percentage in the range of 45 to 55 percent for Robert One (pemetrexed) 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), and (ii) at a percentage in the range of 20 to 30 percent with respect to Robert One (pemetrexed) Subject 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 (pemetrexed) Subject Product and the expiration of the last valid claim covering such Robert One (pemetrexed) 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 (pemetrexed) Subject Product in a country in the territory. In the event we grant a license to any third party under the patents assigned to us or the intellectual property rights licensed to us with respect to any Robert One (pemetrexed) Subject Product, we are required to pay to Robert One 100% of all milestone payments we receive with respect to commercialization of any such Robert One (pemetrexed) Subject Products outside the United States and a percentage in the range of 45 to 55 percent of any milestone payments we receive with respect to commercialization of any such Robert One (pemetrexed) Subject Products commercialized in the United States. This agreement expires upon the expiration of our royalty obligations. The agreement may be terminated earlier by either us or Robert One, for the other party's material uncured breach and we may terminate this agreement on a product-by-product basis if the costs and expenses related to clinical trials for a Robert One (pemetrexed) Subject Product exceed a specified threshold and either party may terminate this agreement if the ANDA or 505(b)(2) applications, as applicable, for the formulation of the Robert One (pemetrexed) Subject Product has not been accepted by the FDA in each case if the ANDA or 505(b)(2), as applicable, is not approved by the FDA and the joint development committee has not selected a replacement product within the specified timeframe.

Supply Agreement with Cipla Limited

In December of 2012 we entered into a non-exclusive supply agreement with Cipla Limited ("Cipla") pursuant to which Cipla agreed to supply argatroban product to us for sale in the United States and topotecan product to us for sale in the European Union. Under the terms of this agreement we are obligated to use commercially reasonable efforts to affect a transfer of the manufacture of argatroban to an alternate manufacturer by a specified date.

This agreement expires with respect to argatroban upon the later of (i) receipt by us of approval from the FDA for manufacture of argatroban for sale in the United States at a third party manufacturing site or (ii) December 31, 2014. This agreement expires with respect to topotecan upon the earlier of (i) receipt by us of approval for the manufacture of topotecan product for sale in the European Union at a third party manufacturing site or (ii) December 31, 2014, unless the parties agree in writing to extend this agreement beyond such date. The agreement may be terminated earlier by either us or Cipla, for the other party's uncured failure to pay an amount due under the agreement, for the other party's material uncured breach of the agreement, or if the other party becomes subject to specified bankruptcy, insolvency or similar circumstances.

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 payers. 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

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDCA 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 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;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA.

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 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 NDA 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 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 NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees.

The FDA has 60 days from its receipt of an NDA 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 NDA for filing. In this event, the NDA 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 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, 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 NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA 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 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 NDA, 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 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 or NDA 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 NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Once an NDA 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. 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 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.

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.

The Animal Rule

In the case of product candidates that are intended to treat certain rare life-threatening diseases, conducting controlled clinical trials to determine efficacy may be unethical or unfeasible. Under regulations issued by the FDA in 2002, often referred to as the "Animal Rule," the approval of such products can be based on clinical data from trials in healthy human subjects that demonstrate adequate safety and efficacy data from adequate and well-controlled animal studies. Among other requirements, the animal studies must establish that the drug or biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, seeking approval under the Animal Rule may add significant time, complexity and uncertainty to the testing and approval process. In addition, products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

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.

In the European Union ("EU"), we may seek marketing authorization under either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The European Medicines Agency ("EMA") implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization issued by the European Commission following a favorable opinion by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: the decentralized procedure and the mutual recognition procedure. Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country for medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following a national authorization, the applicant may seek further marketing authorizations from other EU countries under a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, medicinal products designated as orphan products benefit from financial incentives such as reductions in marketing authorization application fees or fee waivers and 10 years of marketing exclusivity following medicinal product approval. For a medicinal product to qualify as orphan: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than five in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

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, HHS and its various enforcement divisions, such as 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.

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 in return for 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 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 Affordable Care Act ("ACA"), among other things, amended the intent standard under the federal Anti-Kickback Statute to a stricter standard 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.

The federal civil False Claims Act prohibits, 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 False Claims Act allow a private individual to bring civil actions 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 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 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 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. Additionally, the civil monetary penalties statute, which, among other things, imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

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.

Also, HIPAA created several new federal crimes, including 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 Anti-Kickback Statute, ACA amended certain of these federal criminal statutes to a stricter standard 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 healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, 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 HITECH as an expansion 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 Affordable Care Act and its implementing regulations require that certain manufacturers of drugs 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, the physicians and teaching hospitals. Additionally, applicable manufacturers and applicable group purchasing organizations are required to report annually to the CMS certain ownership and investment interests held by physicians (as defined above) and their immediate family members, with data collection required beginning August 1, 2013, and reporting to CMS was required by March 31, 2014 (and by the 90th day of each subsequent calendar year). Disclosure of such information was made on a publicly available CMS website beginning in September 2014.

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. For example, several states have 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 prescriber-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 criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, 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. To the extent that any of our products are sold in a foreign country, we 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 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 and 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. In March 2010, the ACA was passed, which includes measures that have the potential to significantly change health care financing by both governmental and private insurers. The provisions of the Affordable Care Act of importance to the pharmaceutical and biotechnology industry are, 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 agree to offer 50% 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 beginning in 2014, 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 False Claims Act and the 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 Payment Sunshine Act for drug 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.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. 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 will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other

things, further reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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 recently enacted Drug Supply Chain Security Act imposes on manufacturers of certain pharmaceutical products new obligations related to product tracking and tracing, among others, which will be phased in over several years beginning in 2015. 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, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product portfolio or additional pricing pressures.

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 September 30, 2014, we had a total of 28 full-time employees in the United States, two part time employees in the United States, and one full time consultant in India. Of these, thirteen were in research and development, five were in regulatory affairs and quality control compliance, two in sales and marketing, three were in administration and seven in finance. 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.

Segments and Geographic Information

We have one reporting segment. For information regarding revenue and other information regarding our results of operations for each of our last three fiscal years, please refer to our financial statements included in this annual report on Form 10-K, and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 of this annual report.

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 are not a part of this annual report on Form 10-K, and the inclusion of our website address in this annual report 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.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700 million as of the prior March 31st, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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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. 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 incurred significant losses since our inception and we will continue to incur significant losses for the foreseeable future and may never be profitable.

We have a limited operating history. To date, we have focused primarily on developing a broad product portfolio and have obtained regulatory approval for three 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. We may not generate significant revenue from sales of our product candidates in the near-term, if ever. We have incurred significant net losses of $(18.0) million, $(6.0) million and $(19.4) million for the years ended September 30, 2014, 2013 and 2012, respectively. As of September 30, 2014, we had an accumulated deficit of $(104.2) million.

We have devoted most of our financial resources to product development. To date, we have financed our operations primarily through the sale of equity and debt securities. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, only argatroban and Ryanodex® have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenue is also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success in those jurisdictions.

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 expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods. We believe that our existing cash and cash equivalents, together with interest thereon, may only be sufficient to fund our operations for a minimum of twelve months.

If we fail to obtain additional financing, we would 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.

The net proceeds from our initial public offering were approximately $46.1 million. Regardless of our expectations as to how long our net proceeds from our initial public offering will fund our operations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our product 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 of our 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 our 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 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 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 would result in increased fixed payment obligations and could also 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.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in and have only been conducting operations since 2007. Our operations to date have been limited to developing and bringing to market a limited number of products and developing our other product candidates. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing a significant number of pharmaceutical products.

Risks Related to Regulatory Approval

We are heavily dependent on the success of our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine rapid infusion), EP-6101 (bivalirudin) and EP-4104 (dantrolene for EHS). We cannot give any assurance that we will receive regulatory approval for such 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 lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine rapid infusion), and EP-4104 (dantrolene for EHS). Any delay or setback in the development of any of these product candidates could adversely affect our business. Our planned development, approval and commercialization of these product candidates may fail to be completed in a timely manner or at all. Our other product candidates, EP-6101 (bivalirudin) and EP-5101 (pemetrexed), are at an earlier development stage and it will require additional time and resources to develop and seek regulatory approval for such product candidates and, if we are successful, to proceed with commercialization. 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. For example, in August 2009, we submitted our product EP-2101 (topotecan) for approval in the United States under the 505(b)(2) regulatory pathway, referencing the brand product, Hycamtin. Ultimately, the FDA determined that it could not approve the application as submitted due to the amount of active drug per vial in our product and the potential for unintentional overdose. Based on the FDA's feedback and our determination that the market for topotecan had become overly competitive with multiple players, we decided not to continue to pursue product approval and we do not currently have plans to commercialize EP-2101 (topotecan). Additionally as of September 30, 2014 we have decided not to commercialize EP-2101.

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) 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 each of our product candidates described in this Annual Report on Form 10-K. 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 Federal Food, Drug and Cosmetic Act ("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.

If the FDA does not allow us to pursue the 505(b)(2) 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 the 505(b)(2) 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 the 505(b)(2) 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 that we submit under Section 505(b)(2).

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, 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. 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;

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- 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 the nature of our products or product candidates as containing active ingredients that have already been approved means that the side effects arising from the use of the active ingredient or class of drug in our products or product candidates is 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 two products, and tentative approval for a third product in the United States and one product in Europe, but 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 meet the criteria for the 505(b)(2) 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

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- 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 not approve the price we intend to charge for our products, 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 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, we obtained FDA approval for our product argatroban using the 505(b)(2) regulatory pathway, but, after discussions with the FDA, we decided not to continue pursuing FDA approval of our product EP-2101 (topotecan). The FDA determined that it could not approve the application as submitted due to the amount of active drug per vial in our product and the potential for unintentional overdose. Based on the FDA's feedback and our determination that the market for topotecan had become overly competitive with multiple players, we decided not to continue to pursue product approval and we do not currently have plans to commercialize EP-2101 (topotecan). 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 candidate.

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. We filed a 505(b)(2) NDA with the FDA for our EP-3101 (bendamustine RTD) product candidate on September 6, 2013, referencing Teva's Treanda® product, including a

paragraph IV certification stating our belief that our bendamustine product will not infringe Teva's patents on Treanda®. We notified Teva of our 505(b)(2) filing and paragraph IV certification, and Teva filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware on October 21, 2013. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of our bendamustine product, which will delay the FDA from granting final approval for EP-3101 (bendamustine RTD) until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in our favor or otherwise acts to shorten the stay. Moreover, regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from approving our 505(b)(2) NDA due to Teva's unexpired orphan drug and related pediatric exclusivities for Treanda®. Specifically, Teva has received orphan drug and pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications (as defined in "Business—Our Products and Product Portfolio"), respectively. When a drug, such as Treanda®, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If we cannot demonstrate that EP-3101 is clinically superior to Treanda®, or qualify under certain other limited exceptions, we will not be able to enter the market for the CLL indication until earliest, September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

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. 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/or 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 will 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 is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA 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 NDA. 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 NDA or supplements to an NDA 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 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, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, 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 are and will continue to be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims 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, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, 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 False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as 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. The 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;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit and impose penalties for, among other things, individuals or entities from 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 new federal 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 covered health care providers, health plans and health care clearinghouses as well as their respective business associates 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, ACA, and its implementing regulations 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, or HHS, 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, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services was required by March 31, 2014 and by the 90th day of each subsequent calendar year;
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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 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.

The ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. 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 civil False Claims Act.

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, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, 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 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 and pricing 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 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 enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although we intend to establish a small, focused, specialty sales and marketing organization to promote any approved products in the United States, we currently have no such organization or capabilities, 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. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We also intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to

generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded

marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market these products, as well as argatroban, 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;
- 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.

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

Our strategy is to have our drugs enter the market no later than the first generic 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 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 product candidates against other drugs, the opportunity for our 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 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 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 product candidate 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 product candidate. 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 product candidates would materially adversely impact our ability to successfully commercialize our product candidates.

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. We expect to have competitors both in the United States and internationally, including 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, and bendamustine is marketed in the United States by Teva Pharmaceuticals under the brand name Treanda®. Further, makers of branded reference drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. Teva has

obtained approval for a ready to dilute, or RTD, version of Treanda® which will compete with our EP-3101 (bendamustine RTD) product. We submitted for our 505(b)(2) NDA for EP-3101 to the FDA on September 6, 2013, including a paragraph IV certification of non-infringement of Teva's patents covering its Treanda® product and received tentative approval on July 2, 2014. We notified Teva of our 505(b)(2) filing and paragraph IV certification, and Teva filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware on October 21, 2013. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of our bendamustine product, which could have delayed the FDA from approving EP-3101 (bendamustine RTD) until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in our favor or otherwise acts to shorten the stay. In September 2014, Teva’s subsidiary Cephalon moved to dismiss with prejudice this lawsuit and the 30-month stay was removed; however regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from granting final product approval of our 505(b)(2) NDA due to Teva's unexpired orphan drug and related pediatric exclusivities for Treanda®. Specifically, Teva has received orphan drug and pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications (as defined in "Business—Our Products and Product Portfolio"), respectively. When a drug, such as Treanda®, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If we cannot demonstrate that EP-3101 is clinically superior to Treanda®, or qualify under certain other limited exceptions, we will not be able to enter the market for the CLL indication until earliest, September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

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 argatroban 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 NDA that we submit under Section 505(b)(2).

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 product candidates, if any, or that reach the market sooner than our product candidates, if any, 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 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. 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 argatroban 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 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.

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

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.

In March 2010, the ACA was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical industry are the following:

- an annual, non-deductible 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 health care programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- 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 extensions;
- changes to the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% 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;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing 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 beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- requirements under the federal Physician Payments Sunshine Act for reporting by manufacturers of drugs, devices, biologicals and medical supplies of information related to payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as certain investment interests;
- the requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners or to pharmacies of hospitals or other health care entities;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute changes, new government investigative powers and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs.

While the United States Supreme Court upheld the constitutionality of most elements of the ACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the ACA. At this time, it remains unclear whether there will be any changes made to the ACA, whether to certain provisions or its entirety. We cannot assure you that the ACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and 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 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 will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the

government to recover overpayments to providers from three to five years. Further, under the recently enacted Drug Supply Chain Security Act, 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. The full impact of these new laws, as well as laws and other 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 laws and regulations 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 Conference on 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.

We rely on third parties to manufacture commercial supplies of argatroban 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 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 argatroban or commercialize any of our other 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 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 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 product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of argatroban, 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 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 argatroban and for our product candidates, and any disruption in the chain of supply may impact production and sales of argatroban 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 product candidates and for our commercial supply of argatroban. These include development relationships with Zydus BSV Pharma Pvt. Ltd. for our EP-3101 (bendamustine RTD) product and AAIPharma Services Corp. for our dantrolene product and a supply agreement with Cipla Limited for supply of argatroban product to The Medicines Company and Sandoz under their agreements with us for commercialization of argatroban. Because of the unique equipment and process for manufacturing argatroban, transferring manufacturing activities for argatroban 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. For example, we are exploring selective partnerships with third parties for development and commercialization of our product candidates outside of the United States. We may, however, be unable to advance the development of our product candidates in territories outside of the United States, which may limit the market potential for this product candidate.

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. If we are unable to enter into any 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.

Even if we are able to establish collaboration arrangements, any such collaboration 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 candidate, we can expect to relinquish some or all of the control over the future success of that 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 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.

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 includes Scott Tarriff, our Chief Executive Officer, David E. Riggs, our Chief Financial Officer, Paul Bruinenberg, M.D., our Chief Medical Officer and Steven Krill, Ph.D., our Chief Scientific 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 September 30, 2014 we had a total of 28 full-time and two part time employees in the United States and one full time consultant 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. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, 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 argatroban and commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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 argatroban 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 argatroban, 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 argatroban 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. The loss 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 argatroban, Ryanodex® and any other 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.

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 argatroban 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 argatroban 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 argatroban 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 ingredient in argatroban has expired, and there is therefore no composition of matter patent protection available for the active ingredient in argatroban. 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 argatroban 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 will be able to commercialize products with the same active ingredients as argatroban and such other 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 argatroban 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 argatroban and our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of argatroban and our product candidates that are different from ours and do not infringe our issued patents covering our products.

Ryanodex® (dantrolene sodium) and argatroban 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® (dantrolene sodium) and argatroban 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 in court or the US PTO, 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 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 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 product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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 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. 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 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.

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

We expect that our stock price may 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 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 argatroban 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 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 argatroban or any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies 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; and
- trading volume of our common stock.

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 on our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- 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 inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;
- 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. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

An active trading market for our common stock may not develop.

There has been a public market for our common stock for only a short period of time. If an active market for our common stock does not develop, you may not be able to sell your shares quickly or at an acceptable price.

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 September 30, 2014, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own approximately 64% 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 are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the initial public offering, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior March 31st, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our condensed financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will incur 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 December 17, 2014 we had 14,032,167 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 4% of all shares of our capital stock outstanding as of September 30 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 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. If we face such litigation, it could result in substantial costs 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 may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our recently completed initial public offering. Because of the number and variability of factors that will determine our use of the net proceeds from our initial public offering, 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 invest the net proceeds from our initial public offering 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. We believe that, with our initial public offering, our most recent private placement and other transactions that have occurred over the past three years, we may have triggered an "ownership change" limitation. 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 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 return to stockholders will therefore be limited to the appreciation of their stock.

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of September 30, 2014 we conducted all of our non-outsourced operations at its 9,906 square foot leased office space located at 50 Tice Boulevard, Woodcliff Lake, NJ 07677. The term of the lease is for 24 months, expiring on May 30, 2015. Prior to May 31, 2013 we were located at 470 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 since September 2007.

Item 3. Legal Proceedings

Hikma

On March 28, 2012, we entered into an Asset Purchase Agreement (“APA”) with Hikma Pharmaceutical Co. LTD, or Hikma. Under the terms of the agreement, Hikma acquired exclusive U.S. rights to market diclofenac-misoprostol following regulatory approval. We received $3.5 million upon signing the APA. In addition, we were entitled to receive another $1.0 million upon regulatory approval, validation batch manufacturing with inventory released for launch, and sufficient launch inventory. Before approval, this approval milestone was to be reduced for each generic competitor that received regulatory approval (excluding an "authorized generic" version of the Brand Product); however, the milestone was not to be reduced to an amount less than $0.5 million.

On June 24, 2013, Hikma filed a lawsuit against us in the United States District Court for the Southern District of New York alleging that we (a) breached the Hikma APA by failing to refund the purchase price following Hikma's purported termination of the Hikma APA as a result of us failing to receive timely ANDA approval, and (b) intentionally failed to disclose alleged manufacturing product defects to Hikma. We believed that we did not fail to receive timely ANDA approval and therefore Hikma was not entitled to (a) terminate the Hikma APA or (b) receive a refund of the purchase price. We also believed that we did not intentionally fail to disclose alleged manufacturing product defects to Hikma.

On March 14, 2014, we received FDA approval of our Abbreviated New Drug Application for diclofenac-misoprostol tablets. In May 2014, under a CBE-30 supplement, we submitted additional data to the FDA with respect to manufacturing procedures of the product and achieved final approval in June 2014.

On August 8, 2014, we settled the lawsuit with Hikma related to the APA. Pursuant to the terms of the settlement we retained ownership of diclofenac-misoprostol including the rights to launch and commercialize the product, and we will pay to Hikma a percentage of net profits after recovery of certain of our expenses.

Cephalon (U.S. Patent No. 8,445,524)

On October 21, 2013, Cephalon, a subsidiary of Teva, filed a lawsuit in the United States District Court for the District of Delaware alleging that our tentatively approved bendamustine hydrochloride injection infusion product infringes one of its patents, U.S. Patent No. 8,445,524. On November 15, 2013, we filed an Answer and Counterclaims seeking Declaration of Non-infringement. On December 9, 2013, Cephalon filed an Answer to our counterclaims. At Cephalon’s request, the court dismissed this suit with prejudice on November 10, 2014.

Cephalon (U.S. Patent No. 8,791,270)

On July 29, 2014, Patent No. 8,791,270 was issued to Cephalon, and was subsequently listed in the FDA's Orange Book for the referenced listed drug Treanda®. On August 12, 2014, Cephalon filed a lawsuit against us in the United Stated District Court for the District of Delaware alleging infringement by our NDA filing of U.S. Patent No. 8,791,270. On September 3, 2014, we filed an Answer and Counterclaims seeking a Declaration of Non-infringement and/or Invalidity. On September 15, 2014, Cephalon filed an Answer to our counterclaims. On October 31, 2014, our lawsuit was consolidated with twenty-five other lawsuits Cephalon

had filed against sixteen defendants who seek to manufacture generic Treanda®. A claim construction hearing is scheduled for March 4, 2015, and trial is set for November 30, 2015. We intend to defend this action vigorously and to pursue any available counterclaims against Cephalon; however, we cannot predict the timing or outcome of this matter.

Other

From time to time we are party to legal proceedings in the course of our business in addition to those described above. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

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 and Holders of Record

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. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market:

	High	Low
Year Ended September 30, 2014		
Fourth Quarter	$14.75	$10.06
Third Quarter	$14.50	$9.16
Second Quarter (from February 12, 2014)	$16.44	$11.41

As of December 17, 2014, we had 12 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 of our common stock on December 17, 2014 was $12.98.

Dividends

We have never declared or paid a cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in 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, general business conditions, and any other factors that our board of directors may deem relevant. In addition, the terms of our credit facility currently prohibit us from paying cash dividends on our capital stock.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Eagle Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph shows a comparison from February 12, 2014 (the date our common stock commenced trading on the Nasdaq Global Market) through September 30, 2014 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	02/12/14	03/31/14	06/30/14	09/30/14
Eagle Pharmaceuticals, Inc	$100	$99.38	$111.69	$98.60
NASDAQ Composite	100	99.93	104.93	106.95
NASDAQ Biotechnology	100	92.23	99.70	106.84

Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities

(a) Sales of Unregistered Securities

None

(b) Use of Proceeds

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 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.

We invested the net proceeds received from the offering 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).

(c) Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data

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

The statement of operations data for the years ended September 30, 2014, 2013 and 2012, and the balance sheet data as of September 30, 2014 and 2013, are derived from our audited financial statements included elsewhere in this Annual Report. 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 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 September 30,		
Statement of Operations Data:	2014	2013	2012
	(in thousands except share and per share amounts)		
Total revenues	$19,099	$13,679	$2,539
Cost of Revenue	11,714	7,381	3,166
Research and Development	16,816	9,795	12,805
Selling, General and administrative	9,326	4,958	6,399
Loss from Operations	(18,757)	(8,455)	(19,831)
Net loss attributable to common stockholders	(19,643)	(9,885)	(23,316)
Loss per share attributable to common stockholders basic and diluted	$(1.97)	$(3.25)	$(14.11)
Weighted average common shares outstanding basic and diluted	9,955,937	3,044,308	1,652,904

	September 30,		
Balance Sheet Data:	2014	2013	2012
	(in thousands)		
Cash and cash equivalents	$22,722	$10,456	$5,067
Investments	19,999	—	1,500
Accounts receivable	7,296	5,124	1,581
Inventories	1,294	—	87
Total assets	53,411	18,103	9,438
Accounts Payable	4,059	1,192	1,444
Accrued expenses	9,671	3,130	1,340
Deferred revenue	6,585	10,020	9,500
Total stockholders' equity (deficit)	$33,096	$(87,929)	$(93,434)

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

We are a specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the FDA's 505(b)(2) regulatory pathway. Our business model is to develop proprietary innovations to FDA-approved, injectable drugs that offer longer commercial duration at attractive prices. For each of our products, we intend to enter the market no later than the first

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generic drug, allowing us to substantially convert the market to our product 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 regulatory exclusivity as provided under the Hatch-Waxman Act, as applicable.

Our product portfolio now includes three approved products, argatroban, Ryanodex® (dantrolene sodium) and diclofenac-misoprostol. We were granted tentative approval for EP-3101 (patented Bendamustine Hydrochloride Injection, ready-to-dilute concentrate solution), ("bendamustine RTD") and orphan drug designation on EP-3102 Bendamustine RTD currently under development as a rapid infusion product. Orphan drug designation was granted for the treatment of chronic lymphocytic leukemia ("CLL") and indolent B-cell non-Hodgkin's lymphoma ("NHL"). We currently have five advanced product candidates and two commercialized products, argatroban and Ryanodex® (dantrolene sodium).

We have two commercial partners, The Medicines Company and Sandoz Inc., who pursuant to separate agreements market argatroban. As a result of our commercialization strategy, we have been able to minimize certain expenses, but also are required to share revenues from argatroban with our commercial partners.

We intend to commercialize our future products independently in the United States; while outside of the United States, we intend to utilize partners for the commercialization of our products. As part of this strategy, we have contracted a specialty sales force who is targeting group purchasing organizations, hospital groups and key stakeholders in acute care settings and primary hospitals. We expect the impact on our results of operations of this commercialization strategy will be that we will receive revenue from direct sales and royalty income will be a less significant part of our revenues. This commercialization strategy will also result in higher infrastructure and selling expenses, along with greater working capital requirements to support this strategy.

Recent Developments

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 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 from the offering were approximately $46.1 million.

On March 14, 2014, we received FDA approval of our Abbreviated New Drug Application for diclofenac-misoprostol tablets. In May 2014, we submitted additional data to the FDA with respect to manufacturing procedures of the product and final approval was achieved in June 2014.

On July 2, 2014, we were granted tentative approval for EP-3101 patented bendamustine RTD. Due to orphan drug exclusivity held by Cephalon, the tentative approval received in July 2014 will not convert to final approval until September 2015, unless, we are able to demonstrate at an earlier date that our bendamustine product, which has been granted orphan drug designation by the FDA, is clinically superior to Cephalon's currently-marketed formulation. We believe that bendamustine represents a domestic market opportunity of over $700 million. The EP-3101 NDA was filed with the FDA on September 6, 2013. This NDA is subject to on-going litigation with the application holder (Teva/Cephalon) and we expect to continue to incur legal expenses associated with defending our position.

On July 22, 2014 we received FDA approval for Ryanodex® (dantrolene sodium) for injectable suspension indicated for the treatment of malignant hyperthermia ("MH"), for which an NDA was filed with the FDA on January 17, 2014. We launched in August 2014 and incurred expenses associated with marketing and other launch efforts.

On August 8, 2014, we settled the lawsuit with Hikma related to the APA (See Note 10 "Asset Sales"). Pursuant to the terms of the settlement we will retain ownership of diclofenac-misoprostol including the rights to launch and commercialize the product and we will pay to Hikma a percentage of Net Profits after recovery of certain expenses.

On August 29, 2014, we successfully executed the product launch of Ryanodex®. We contracted a third party logistics partner who stores our inventory, fulfills sales orders and provides detailed real time reporting. Additionally, we contracted with a third party sales force comprised of 20 representatives who are focusing their promotional activities on important stakeholders within the hospital setting. To compliment these efforts, we have also engaged group purchasing organizations and wholesalers in contracting discussions.

In November 2014 we received positive results from the clinical trial, in which the dose was delivered in a 50mL admixture in ten minutes (the “rapidly infused product”) versus a 500mL admixture in the 60-minute infusion required for Treanda® (bendamustine HCl). In this study, our rapidly infused product was found to be bioequivalent to Treanda®, which was the primary endpoint of the study. The incidence and profile of adverse events, both infusion-related and general, for the rapidly infused product was comparable to Treanda®. This is particularly important because the rapidly infused product delivers the same amount of active ingredient as Treanda® but with a lower admixture volume, which enables our product to be administered more quickly.

Financial Operations Overview

Revenue

Revenue includes product sales, royalty income and revenue from collaborative arrangements. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause operating results to vary significantly from quarter to quarter and year to year.

Product Sales. We recognize revenues from product sales of Ryanodex® and argatroban. Ryanodex®, launched in August 2014, is sold directly to wholesalers, hospitals and surgery centers through a third party logistics partner and argatroban revenues are through sales to our commercial partners. Sales to our commercial partners are typically made at little or no profit for resale.

Royalty Income. We recognize revenue from royalties based on our commercial partners' net sales of products, typically calculated as a percentage of the net selling price, which is net of discounts, returns and allowances incurred by our commercial partners. Royalty Income is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured.

Collaborative Arrangements. We recognize revenue from reimbursement received in connection with feasibility studies and development work for third parties. Our principal costs under these arrangements include our personnel conducting research and development, and our allocated overhead, as well as research and development performed by outside contractors or consultants.

Our revenues from collaborative arrangements 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.

Currently, our product sales are from argatroban and Ryanodex® and royalty income are derived from the sale of argatroban to, and the resale by, two commercial partners, Sandoz Inc., or Sandoz, and The Medicines Company. The primary factors that determine our revenues derived from argatroban are:

- the level of orders submitted by our commercial partners — Sandoz and The Medicines Company;
- the level of institutional demand for argatroban;
- unit sales prices; and
- the amount of gross-to-net sales adjustments realized by our marketing partners.

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

- the effectiveness of our contracted sales force;
- the level of orders submitted by wholesalers, hospitals and surgery centers;
- the level of institutional demand for Ryanodex®;
- unit sales prices; and
- the amount of gross-to-net sales and chargebacks.

Chargebacks. We typically enter into agreements with group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of products. Based on these agreements, most of our hospital customers have the right to receive a discounted price for products and volume-based rebates on product purchases. In the case of discounted pricing, we typically receive a chargeback, representing the difference between the contract acquisition list price and the discounted price.

We also have generated collaborative licensing and development revenue from our collaboration arrangements with third parties. Revenues have been generated from the achievement of milestones pursuant to, or other payments made under, arrangements related to the divestiture of non-core assets, namely diclofenac-misoprostol tablets, a generic product candidate sold to Hikma, and EP-2101 (topotecan), which was licensed to Pfizer.

Cost of Revenue

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 argatroban paid to a contract manufacturing organization coupled with shipping and customs charges, as well as royalty expense. Cost of revenue may also include the effects of product recalls, if applicable.

Research and Development

Our research and development expenses consist of expenses incurred in developing, testing, manufacturing and seeking regulatory approval of our product candidates, including: expenses associated with regulatory submissions, clinical trials and manufacturing, including additional expenses in preparing for the commercial manufacture of products including Ryanodex®, launched in August

2014, (bendamustine RTD), (bendamustine rapid infusion), EP-6101 (bivalirudin) and our other product candidates; payments made to third-party clinical research organizations, contract laboratories and independent contractors; payments made to consultants who perform research and development on our behalf and assist us in the preparation of regulatory filings; payments made to third-party investigators who perform research and development on our behalf and clinical sites where such research and development is conducted; expenses incurred to maintain technology licenses; and facility, maintenance, allocated rent, utilities, depreciation and amortization and other related expenses. Additionally, costs include salaries, benefits and other related costs, including stock-based compensation for research and development personnel.

Clinical trial expenses for our product candidates are and will be a significant component of our research and development expenses. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

We expect to incur additional research and development expenses as we accelerate the development of our product portfolio. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

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, selling and operations personnel. Included in selling costs are expenses related to our contracted sales organization and marketing related to the product launch of Ryanodex® in August 2014. General and administrative expenses include facility and related costs, professional fees for legal, consulting, tax and accounting services, insurance, selling, market research, advisory board and key opinion leaders, depreciation and general corporate expenses. We expect that our selling, general and administrative expenses will increase with the continued development and potential commercialization of our product candidates particularly as we begin to commercialize our own products in the United States, as well as increased expenses associated with being a public company.

Other Income and Expense

Other income (expense) consists primarily of interest income, interest expense and changes in value of our warrant liability. Interest income consists of interest earned on our cash and cash equivalents. Interest expense consists primarily of cash and non-cash interest costs related to our issuance of convertible notes, including the amortization of debt discounts and deferred financing costs.

Income Tax Benefit

Income tax benefit primarily consists of proceeds from the sale of our New Jersey state net operating losses which is net of any minimum state taxes paid.

Results of Operations

Comparison of Years Ended September 30, 2014 and 2013

Revenues

	Year Ended September 30,		
	2014	2013	Increase/(Decrease)
	(in thousands)		
Product sales	$4,626	$5,315	$(689)
Royalty income	10,708	8,364	2,344
Other income	3,765	—	3,765
Total revenue	$19,099	$13,679	$5,420

Total revenue increased $5.4 million in the year ended September 30, 2014 to $19.1 million as compared to $13.7 million in the year ended September 30, 2013.

The net increase in total revenue was offset by a decrease in product sales of $(0.7) million in the year ended September 30, 2014 to $4.6 million as compared to $5.3 million in the year ended September 30, 2013. This net decrease in product sales was due to longer lead times in procuring materials for manufacturing argatroban, partially offset by the August 2014 launch of Ryanodex® which resulted in net product sales of $0.2 million.

Royalty income increased $2.3 million in the year ended September 30, 2014 to $10.7 million as compared to $8.4 million in the year ended September 30, 2013 as a result of increased end use sales of argatroban by our commercial partners earlier in the period offset by decreased end-use sales of argatroban that may be related to market competition.

Other income increased by $3.8 million primarily as a result of the FDA approval of diclofenac-misoprostol related to the asset sale agreement with Hikma Pharmaceutical for $3.5 million. Additionally we recognized a final milestone of $0.3 million. There were no revenues from collaborative arrangements in the periods presented.

Cost of Revenue

	Year Ended September 30,		
	2014	2013	Increase
	(in thousands)		
Cost of revenue	$11,714	$7,381	$4,333

Cost of revenue increased $4.3 million in the year ended September 30, 2014 to $11.7 million as compared to $7.4 million in the year ended September 30, 2013 mainly as a result of the increase in royalty expense associated with argatroban and our commercial marketing partners. Royalty related to argatroban increased by $4.1 million due to an increase in royalty expense to both SciDose and the Medicines Company. Under the terms of our revenue sharing arrangement with SciDose, we retain all revenue from the sale of a product commercialized under a 505(b)(2) application until we have recouped our expenses related to the development of that product. Once our expenses are recouped, we are required to split the net proceeds from royalty income received equally with SciDose. Expenses related to the development of argatroban were recouped during the quarter ended September 30, 2013. As a result, we recognized an increase of $3.4 million in royalty expense in the year ended September 30, 2014 that was not recognized in the year ended September 30, 2013. Additionally as a result of the Hikma settlement we incurred $0.3 million related to a one-time royalty due to diclofenac-misoprostol expenses. Royalty expense related to Ryanodex®, launched in August 2014, was approximately $35 thousand.

With respect to argatroban product sales we experienced a net decrease in the cost of revenue of approximately $(0.2) million in the year ended September 30, 2014 over the year ended September 30, 2013. This net decrease is comprised of a $0.6 million increase in testing costs offset by an $(0.9) million decrease in product costs. The volume of product shipped in year ended September 30, 2014, excluding the product recall was approximately 18% less than product shipped in the year ended September 30, 2013. This decrease also correlates to the decrease in product revenue. We experienced a product recall in the October through December 2012 period and experienced fewer shipments in the April through September 2014 period due to longer lead times in procuring materials for manufacturing. Cost of revenue related to Ryanodex® was approximately $0.2 million, of which $20 thousand was related to product sales and $0.1 million for other expenses incurred including predominantly certain regulatory and other expenses to our third party logistics partner.

We would expect our cost of revenues as a percentage of product sales and royalty income to remain consistent with the year ended September 30, 2014.

Research and Development

	Year Ended September 30,		
	2014	2013	Increase/(Decrease)
	(in thousands)		
EP-6101 (bivalirudin)	$2,366	$—	$ 2,366
EP-3102 (bendamustine rapid infusion)	4,526	—	4,526

Ryanodex® (dantrolene for MH)	1,474	1,682	(208)
EP-3101 (bendamustine RTD)	2,801	1,090	1,711
diclofenac-misoprostol	978	—	978
EP-4104 (dantrolene for EHS)	199	162	37
All other projects	648	3,553	(2,905)
Salary and other personnel related expenses	3,824	3,308	516
Total research and development	$16,816	$9,795	$ 7,021

Research and development expenses increased $7.0 million in the year ended September 30, 2014 to $16.8 million as compared to $9.8 million in the year ended September 30, 2013.

Research and development expenses incurred in the year ended September 30, 2014 were higher than in the year ended September 30, 2013 as a result of increased project spending for EP-6101 (bivalirudin) related to registration batches, and technical transfer and manufacturing services, EP-3102 (bendamustine rapid infusion) related to spending on the PK (pharmacokinetic) study related to support of product approval and certain legal and professional expenses. Spending increase on diclofenac-misoprostol was related to legal costs and development costs to support product approval. These increases were offset by a reduction in spending on other projects that have been delayed or will no longer be pursued. Salary and other personnel related expenses increased due to increased staffing and higher overall compensation costs.

Selling, General and Administrative

Selling, general and administrative expenses increased approximately $4.4 million in the year ended September 30, 2014 to $9.3 million as compared to $5.0 million in the year ended September 30, 2013.

This increase is related to a $2.4 million increase in marketing related to the August 2014 launch of Ryanodex® (dantrolene sodium). As a result of our public offering in February 2014 and operating as a publicly traded company, overall compensation related expense increased by $1.4 million and we experienced an increase of $0.5 million of insurance and professional fees. We experienced a $0.1 million net increase in various other expenses without material concentrations.

Other Income and Expense

	Year Ended September 30,		
	2014	2013	Increase/(Decrease)
	(in thousands)		
Interest income	$31	$3	$28
Net proceeds from MDCO Arbitration	—	4,050	(4,050)
Interest expense	(8)	(309)	301
Deferred financing costs	—	(96)	96
Amortization of debt discount	—	(1,091)	1,091
Change in value of warrant liability	(573)	(1,052)	479
Other income, net	35	3	32
Total other income/(expense), net	$(515)	$1,508	$(2,023)

Other income and (expense) decreased to $(0.5) million for the year ended September 30, 2014 from income of $1.5 million for year ended September 30, 2013. The fiscal 2014 amount consists primarily of the recognition of the change in value of the warrant liability. The fiscal 2013 other income and expense primarily includes interest expense and the amortization of deferred financing costs and debt discount related to the convertible notes that were issued in the fourth quarter of fiscal 2012, the recognition of the change in value of the warrant liability and the settlement related to the MDCO arbitration.

State Income Tax Benefit

In the years ended September 30, 2014 and 2013 we realized proceeds from the sale of our New Jersey state net operating losses of $1.3 million and $0.9 million, respectively.

Net Loss

Net loss for years ended September 30, 2014 and 2013 was $(18.0) million and $(6.0) million, respectively , as a result of the factors described above.

Comparison of Years Ended September 30, 2013 and 2012

Revenues

	Year Ended September 30,		
	2013	2012	Increase
	(in thousands)		
Product sales	$5,315	$1,155	$4,160
Royalty income	8,364	1,384	6,980
Total revenue	$13,679	$2,539	$11,140

Total revenue increased approximately $11.1 million in the 2013 fiscal year to $13.7 million as compared to $2.5 million in fiscal 2012.

In fiscal 2013, total product sales increased approximately $4.1 million to $5.3 million as compared to $1.1 million in fiscal 2012 due to the longer period of time during which argatroban was marketed in fiscal 2013 as compared to fiscal 2012 as well as greater market penetration by our marketing partners.

Royalty income increased $7.0 million in fiscal 2013 to $8.4 million as compared to $1.4 million in fiscal 2012, as a result of the longer period of time during which argatroban was marketed in fiscal 2013 as well as greater market penetration by our marketing partners, which resulted in higher royalty revenues from the end use sales of argatroban by our commercial partners.

There were no revenues from collaborative arrangements in 2013 or 2012.

Cost of Revenue

	Year Ended September 30,		
	2013	2012	Increase
	(in thousands)		
Cost of revenue	$7,381	$3,166	$4,215

Cost of revenue increased $4.2 million in fiscal 2013 to $7.4 million as compared to $3.2 million in fiscal 2012 as a result of the increased product sales from the full launch of argatroban. Included in fiscal 2012 are approximately $1.6 million in costs associated with an argatroban product recall and related inventory write-offs.

Research and Development

	Year Ended September 30,		
	2013	2012	Increase/(Decrease)
	(in thousands)		
Ryanodex® (dantrolene for MH)	$1,682	$2,932	$(1,250)
EP-3101 (bendamustine RTD)	1,090	1,623	(533)
EP-4104 (dantrolene for EHS)	162	1,205	(1,043)
All other projects	3,553	2,974	579
Salary and other personnel related expenses	3,308	4,071	(763)
Total research and development	$9,795	$12,805	$(3,010)

Research and development expenses decreased $3.0 million in fiscal 2013 to $9.8 million as compared to $12.8 million in fiscal 2012. Expenses in fiscal 2013 were lower than in fiscal 2012 as a result of decreased project spending specifically for the Ryanodex®, EP-4104 (dantrolene for EHS) and bendamustine RTD projects and lower personnel and related expenses, partially offset by higher spending in other completed projects.

Selling, General and Administrative

Selling general and administrative expenses decreased $1.4 million in fiscal 2013 to $5.0 million from $6.4 million in fiscal 2012. The decreased costs in fiscal 2013 over fiscal 2012 are primarily due to approximately $0.9 million in costs related to The Medicines Company arbitration described elsewhere in this annual report on Form 10-K, $0.2 million in market research activities and $0.3 million in miscellaneous expenses.

Other Income and Expense

	Year Ended September 30,		
	2013	2012	Increase/(Decrease)
	(in thousands)		
Interest income	$3	$34	$(31)
Net proceeds from MDCO Arbitration	4,050	—	4,050
Interest expense	(309)	(91)	(218)
Deferred financing costs	(96)	(19)	(77)
Amortization of debt discount	(1,091)	(218)	(873)
Change in value of warrant liability	(1,052)	—	(1,052)
Loss on subscription loan settlement	—	(51)	51
Other income, net	3	12	(9)
Total other income/(expense), net	$1,508	$(333)	$1,841

Other income and expense increased $1.8 million in fiscal 2013 to income of $1.5 million as compared to net other expense of $0.3 million in fiscal 2012. The fiscal 2013 other income and expense primarily includes interest expense and the amortization of deferred financing costs and debt discount related to the convertible notes that were issued in the fourth quarter of fiscal 2012, the recognition of the change in value of the warrant liability and the settlement related to the MDCO arbitration. The fiscal 2012 other income and expense primarily includes interest expense and the amortization of deferred financing costs and debt discount related to the convertible notes that were issued in the fourth quarter of fiscal 2012.

State Income Tax Benefit

In the fiscal years ended 2013 and 2012, we realized proceeds from the sale of our New Jersey state net operating losses of $0.9 million and $0.8 million, respectively.

Net Loss

Net loss for fiscal 2013 was $6.0 million as compared to net loss of $19.4 million in fiscal 2012, as a result of the factors described above.

Liquidity and Capital Resources

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 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 from the offering were approximately $46.1 million.

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Historically, we have funded our operations primarily through private placements of preferred stock and convertible notes and out-licensing product rights. Cash and cash equivalents were $22.7 million and $10.5 million as of September 30, 2014 and September 30, 2013, respectively. In addition we have short term investments in U.S. Treasury Bills of $20.0 million at September 30, 2014.

For the year ended September 30, 2014, we incurred a net loss of $(18.0) million. As of September 30, 2014, we had a working capital surplus of $32.7 million. For the year ended September 30, 2013, we incurred a net loss of $(6.0) million. We have sustained significant losses since our inception on January 2, 2007 and had accumulated a deficit of $(104.2) million as of September 30, 2014.

We believe that future cash flows from operations, together with proceeds from the initial public offering will be sufficient to fund our currently anticipated working capital requirements for a minimum of twelve months. No

assurance can be given that operating results will improve, out-licensing of products will be successful or that additional financing could be obtained on terms acceptable to us.

Operating Activities:

Net cash used in operating activities for the year ended September 30, 2014 was $(13.8) million. Net loss for the period was $(18.0) million offset by non-cash adjustments of approximately $1.3 million from the change in the value of the warrant liability, depreciation and stock-based compensation expense. Net changes in working capital increased cash from operating

activities by approximately $2.9 million, due to a decrease prepaid expenses of $0.2 million related to prepaid insurance, and a decrease in deferred revenue of $(3.4) million. We experienced an increase in accounts receivable of $(2.2) million, an increase of $(1.3) million in inventory and an increase in accounts payable and accrued expenses of $9.6 million. Accounts payable and accrued expenses increased primarily due to accrued royalties. The total amount of accounts receivable at September 30, 2014 was approximately $7.3 million, which included approximately $0.7 million of product sales and approximately $6.2 million of royalty income, all with payment terms of 45 days and approximately $0.4 million of other receivables. For royalty income, the 45-day period starts at the end of the quarter upon receipt of the royalty statement detailing the amount of sales in the prior completed quarter, and, for product sales, the period starts upon delivery of product.

At September 30, 2014, our cumulative receivables related to royalty income consist of approximately $5.3 million in receivables from The Medicines Company and $0.8 million in receivables from Sandoz.

Based on our agreement with The Medicines Company, our cumulative receivables related to that agreement will continue to aggregate in future periods. Our agreement with The Medicines Company does not contemplate the ability for the parties to net settle amounts receivable or payable. Notwithstanding this, we have periodically collected from The Medicines Company amounts that would be equal to the net amount of receivables due from The Medicines Company, but, because it is unclear whether such cash receipt is intended to be settlement of the net receivable or only a partial payment towards the gross receivable, we have presented these receivables and payables in gross amounts on its financial statements. As a result, the cumulative receivable from The Medicines Company, as reduced by the cash received from The Medicines Company, aggregates from period-to-period and has never been fully offset by those actual cash payments. At September 30, 2014, we recorded a receivable of approximately $5.3 million and a payable of $4.7 million to The Medicines Company (based upon a 50% revenue split on Sandoz sales). The net receivable due from The Medicines Company as of September 30, 2014 therefore is $0.6 million. The receivable of $0.6 million from The Medicines Company as of September 30, 2014 therefore represents our net cumulative receivable.

We believe that our accounts receivable as of September 30, 2014, after taking into account netting of receivables and payables related to The Medicines Company, are reasonably collectible, and given the payment terms, will be collected in approximately 90 days, and thus would not have a material effect on our liquidity.

Net cash used in operating activities for the year ended September 30, 2013 was $(5.9) million and resulted primarily from $(6.0) million of net loss for the period. Non-cash adjustments amounted to $3.0 million in depreciation, amortization, interest, stock-based compensation expense and the change in value of warrant liability. Net changes in working capital decreased cash from operating activities by approximately $(2.8) million, primarily due to an increase in accounts receivable of $(3.5) million from the higher product revenues of argatroban, an increase in prepaid expenses of $(1.4) million ($0.7 million for prepaid product costs and $0.8 million for FDA user fees, offset by decreases of $0.1 million in other prepaid expenses) and a decrease in accounts payable of $(0.3) million offset by an increase of $1.7 million in accrued expenses ($2.2 million in royalties due to The Medicines Company and SciDose offset by $0.5 million of reductions in other accrued expenses) and an increase in deferred revenue of $0.5 million.

Net cash used in operating activities for the year ended September 30, 2012 was $(15.5) million and resulted primarily from $(19.4) million of net loss for the period. Non-cash adjustments amounted to approximately $1.0 million in depreciation and amortization and stock-based compensation expense. Net changes in working capital increased cash from operating activities by approximately $2.8 million, primarily due to an increase in accounts receivable of $1.3 million from the higher product revenues of argatroban, a decrease in inventories of $1.0 million, an increase in deferred revenue of $3.5 million related to the divestiture of diclofenac-misoprostol tablets and related assets to Hikma and a decrease in accounts payable and accrued expenses of approximately of $0.6 million.

Investing Activities:

In the year ended September 30, 2014, 2013, and 2012 we invested $46, $41 and $33 thousand, respectively, for the purchase of property and equipment.

In the year ended September 30, 2014 we invested $20.0 million in U.S. Treasury securities and in 2013 and 2012, we redeemed $1.5 million and $3.0 million, respectively, of short term investments.

Financing Activities:

Net cash provided by financing activities for the year ended September 30, 2014 was $46.2 million primarily resulting from the issuance of Common Stock from the initial public offering and the exercise of warrants of $21 thousand and proceeds from stock options exercised of $65 thousand.

Net cash provided by financing activities in fiscal 2013 and 2012 was $9.8 million and $9.5 million resulting from the issuance of Series C Preferred Stock in fiscal 2013 and the issuance of convertible notes and warrants in fiscal 2012.

Contractual Obligations

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

	Total	2015	2016	2017	2018	2019	Beyond
Operating lease obligations	$182	182	—	—	—	—	—

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our financial statements and have not yet determined the method by which we will adopt the standard in 2017.

No accounting standards or interpretations issued recently are expected to have a material impact on our financial position, operation or cash flow.

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

The 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 recognition determines the timing of certain expenses, such as commissions and royalties. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause operating results to vary significantly from

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quarter to quarter and year to year. Royalty revenues, based on net sales by licensees, are recorded as revenue for the period in which those sales are made by the licensees. License fees are recorded over the life of the license. Deferred revenue is recognized upon the achievement of milestones. Other deferred revenue is amortized over the life of the underlying agreement.

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition, and Statement of Financial Accounting Standards, or ASC 605, Revenue Recognition.

Product sales. We recognize net revenues from products manufactured and supplied to our commercial partners, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to the shipment of our manufactured products, we conduct initial product release and stability testing in accordance with current good manufacturing practices, or cGMP. Our commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. We estimate our return reserves based on our experience with historical return rates. Historically, our product returns have not been material.

Royalty income. We recognize revenue from royalties based on our 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. Our commercial partners are obligated to report their net product sales and the resulting royalty due to us within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, we accrue royalty revenue each quarter and subsequently true-up when we receive royalty reports from our commercial partners.

Collaborative arrangements. We recognize revenue from reimbursements received in connection with feasibility studies and development work for third parties when our contractual services are performed, provided collectability is reasonably assured. Our principal costs under these arrangements include our personnel conducting research and development, and our allocated overhead, as well as research and development performed by outside contractors or consultants.

We recognize revenues from non-refundable up-front license fees received under collaboration arrangements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development arrangements, and contract period or longest patent life in the case of supply and distribution arrangements). If the estimated performance period is subsequently modified, we will modify the period over which the up-front license fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable license fees received by us, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in our statements of operations. We recognize revenue from milestone payments received under collaboration arrangements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, we have no further performance obligations relating to the event and collectability is reasonably assured. If these criteria are not met, we recognize milestone payments ratably over the remaining period of our performance obligations under the collaboration agreement.

Accounting for Fair Value for Warrant Liabilities. The estimated fair value of the preferred stock warrant liability is determined by using the Black-Scholes option pricing model which is based on our stock price at measurement date, exercise price of this warrant, risk-free rate and historical volatility and are classified as a Level 3 measurement.

The guidance in ASC 815 requires that we mark the value of the warrant liability to market and recognize the change in valuation in its statement of operations each reporting period. These mark-to-market adjustments each reporting

period could materially affect our future operating results. Determining the warrant liability to be recorded requires us to develop estimates to be used in calculating the fair value of the warrant.

Since these preferred stock warrants do not trade in an active securities market, we recognize a warrant liability and estimate the fair value of these warrants using a Probability-Weighted Expected Returns valuation model. Therefore, the warrant liability is considered a Level 3 measurement.

Stock-based compensation. We account for stock-based compensation under ASC, 718 "Accounting for Stock Based Compensation." All stock-based awards granted to nonemployees are accounted for at their fair value in accordance with ASC 718, and ASC 505, " Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services ," under which compensation expense is generally recognized over the vesting period of the award. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of fair values of stock options as of the grant date.

We account 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. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees and directors 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 and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was 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.

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 September 30, 2014, we had cash and cash equivalents of $22.7 million held primarily in money market mutual funds and U.S. Treasury Bills consisting of U.S. government-backed securities, and an investment of $20.0 million held in U.S. Treasury Bills with an original maturity of approximately 6 months. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio 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.

Item 8. Financial Statements and Supplementary Data

Our Financial Statements 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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2014, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Controls Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting occurred during the quarter ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and will be included in an amendment to this Annual Report on Form 10-K filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be set forth in an amendment to this Annual Report on Form 10-K filed 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 will be set forth in an amendment to this Annual Report on Form 10-K filed 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 will be set forth in an amendment to this Annual Report on Form 10-K filed 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 will be set forth in an amendment to this Annual Report on Form 10-K filed 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 will be set forth in an amendment to this Annual Report on Form 10-K filed 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 accompanying index to exhibits are filed as part of, or incorporated by reference into, this report.

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 December 22, 2014.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Scott Tarriff
President and Chief 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.

Signature	Title	Date
/S/ SCOTT TARRIFF Scott Tarriff	Chief Executive Officer and President and Chief Executive Officer (Principal Executive Officer)	December 22, 2014
/S/ DAVID E. RIGGS David E. Riggs	Chief Financial Officer (Principal Accounting and Financial Officer)	December 22, 2014
/S/ JAY MOORIN Jay Moorin	Chairman of the Board of Directors	December 22, 2014
/S/ STEVEN RATOFF Steven Ratoff	Member of the Board of Directors	December 22, 2014
/S/ SANDER FLAUM Sander Flaum	Member of the Board of Directors	December 22, 2014
/S/ MICHAEL GRAVES Michael Graves	Member of the Board of Directors	December 22, 2014
/S/ ALAIN SCHREIBER, M.D. Alain Schreiber, M.D.	Member of the Board of Directors	December 22, 2014

EXHIBIT INDEX

Exhibit Number		Description of Exhibit
3.1	(1)	Amended and Restated Certificate of Incorporation
3.3	(1)	Amended and Restated Bylaws
4.1	(1)	Form of Common Stock Certificate of the Registrant
4.2	(1)	Third Amended and Restated Investor Rights Agreement, dated April 11, 2013, by and among the Registrant and certain of its stockholders
10.1	(1)	Form of Indemnity Agreement by and between the Registrant and its directors and officers
10.2	†(1)	Eagle Pharmaceuticals, Inc. 2007 Incentive Compensation Plan and Form of Stock Option Agreement thereunder
10.3	†(1)	Eagle Pharmaceuticals, Inc. 2014 Equity Incentive Plan and Form of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder
10.4	†(1)	Eagle Pharmaceuticals, Inc. 2014 Employee Stock Purchase Plan
10.5	†(1)	Eagle Pharmaceuticals, Inc. Non-Employee Director Compensation Policy
10.6	†(1)	Employment Agreement by and between the Registrant and Scott Tarriff dated March 8, 2007, as amended
10.7	†(1)	Offer Letter by and between the Registrant and Paul Bruinenberg dated September 7, 2011
10.8	†(1)	Offer Letter by and between the Registrant and Steven Krill dated September 7, 2011
10.9	†(1)	Offer Letter by and between the Registrant and David Riggs dated November 7, 2013
10.10	(1)	Lease Agreement between the Registrant and Mack-Cali Chestnut Ridge L.L.C. dated May 28, 2013, as amended on July 1, 2013
10.11	(a)* (1)	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
10.11	(b)* (1)	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
10.12	*(1)	License and Sublicense Agreement, by and between the Registrant and Lyotropic Therapeutics, Inc., dated October 16, 2008
10.13	*(1)	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
10.14	*(1)	Supply Agreement, by and between the Registrant and The Medicines Company, dated September 24, 2009
10.15	*(1)	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
10.16	*(1)	Supply and Distribution Agreement, by and between the Registrant and Sandoz AG, dated January 28, 2013
10.17	*(1)	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
10.18	*(1)	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
23.1		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)