EAGLE PHARMACEUTICALS, INC.
Form 424B4
February 13, 2014

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Filed Pursuant to Rule 424(b)(4)
Registration Statement No. 333-192984

3,350,000 Shares
EAGLE PHARMACEUTICALS, INC.
Common Stock

$15.00 per share

Eagle Pharmaceuticals, Inc. is offering 3,350,000 shares.

The initial public offering price is $15.00 per share.

This is our initial public offering and no public market exists for our shares.

Trading symbol: EGRX

This investment involves risk. See "Risk Factors" beginning on page 10.

We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per Share	Total
Public offering price	$ 15.00	$ 50,250,000
Underwriting discount[(1)]	$ 1.05	$ 3,517,500

Proceeds, before expenses, to Eagle Pharmaceuticals, Inc.	$ 13.95	$ 46,732,500

(1) We refer you to "Underwriting" beginning on page 164 of this prospectus for additional information regarding underwriting compensation.

The underwriters have a 30-day option to purchase up to 502,500 additional shares of common stock from us.

Certain of our existing principal stockholders and their affiliated entities have agreed to purchase an aggregate of approximately $6.5 million in shares of our common stock in this offering at the initial public offering price.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone's investment in these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Piper Jaffray **William Blair**

Cantor Fitzgerald & Co.

The date of this prospectus is February 11, 2014.

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We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

Dealer Prospectus Delivery Obligation

Through and including March 9, 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially "Risk Factors" and our financial statements and the related notes, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to "Eagle," "Eagle Pharmaceuticals," "we," "us" and "our" refer to Eagle Pharmaceuticals, Inc.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the FDA's 505(b)(2) regulatory pathway. We develop products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Our currently disclosed product portfolio includes two approved products and six advanced product candidates that together account for approximately $4 billion in peak U.S. branded reference drug sales. For each of our products, we intend to enter the market no later than the first generic drug, allowing us to substantially convert the market to our product while maintaining attractive pricing. We believe we can further extend the commercial duration of our products 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. We believe our strategy has been validated with the approval of our first product, EP-1101, a proprietary version of argatroban, which was approved by the FDA in June 2011. EP-1101 entered the market prior to the first generic version of argatroban and has captured a 28%, and growing, share of the overall argatroban market while maintaining attractive pricing.

Two of our most advanced product candidates are proprietary presentations of bendamustine, which is currently marketed by Teva Pharmaceuticals, or Teva, under the brand name Treanda and indicated for the treatment of certain hematologic cancers. Bendamustine had 2012 U.S. branded sales of over $600 million, and based on recent market research we anticipate sales to continue to grow substantially in 2013 and 2014, and we estimate that sales could reach $800 million in 2015. We believe our proprietary bendamustine products, EP-3101 and EP-3102, are improved products compared to Teva's Treanda because they are ready to dilute, or RTD, liquids with longer stability and also offer the potential for shorter infusion time. These attributes result in added benefits to nurses, patients and pharmacists, and improved economics to physicians and other stakeholders. Our NDA for EP-3101 was filed with the FDA on September 6, 2013 and we believe EP-3101 will enter the market prior to generic competition and will capture a significant portion of the bendamustine market, as has been the case for our argatroban product.

Our currently disclosed product portfolio also includes proprietary innovations of Alimta, Angiomax, and Dantrium (dantrolene), which together represent $3.4 billion in U.S. peak branded drug sales. Our orphan drug designated version of dantrolene (Ryanodex) is formulated to require substantially less volume and shorter reconstitution time when treating malignant hyperthermia, a hyperacute situation where time to treatment is of critical importance. We believe these formulation characteristics afford us

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the unique ability to treat exertional heat stroke, for which there are no currently approved drugs, and therefore represents a major unmet market opportunity.

Product	U.S. Branded Reference Drug	2012 U.S. Branded Sales[1]	Status
EP-3101 (bendamustine RTD)	Treanda	$608 million	NDA submitted
EP-3102 (bendamustine short infusion time)	Treanda	$608 million	In pivotal clinical trials
Ryanodex (dantrolene)	Dantrium/ Revonto	$20 million	NDA submitted in January 2014; orphan drug designation received
EP-4104 (dantrolene)	No drug currently approved	N/A	Orphan drug designation received for heat stroke
EP-6101 (bivalirudin)	Angiomax	$502 million	Type C meeting with the FDA completed in the fourth quarter of 2013
EP-5101 (pemetrexed)	Alimta	$1,122 million	Formulation work complete
EP-1101 (argatroban)	Argatroban	$99 million	Approved (US); marketed by The Medicines Company and Sandoz
EP-2101 (topotecan)	Hycamtin	$25 million	Approved (EU); not marketed; no current plans to commercialize in the U.S.

(1) Based on publicly filed reports with the SEC, independent market research and management's estimates extrapolated therefrom.

Our Strengths

We believe our competitive strengths include our:

currently disclosed portfolio which includes two approved products and six distinct product candidates in development that target an overall U.S. market of approximately $4 billion in peak annual branded reference drug revenue;

knowledge of the industry, including our ability to optimize products' ease and safety of use for healthcare providers, produce less drug waste and lower cost to stakeholders; and our experience with the 505(b)(2) regulatory pathway, and our ability to navigate paragraph IV challenges;

differentiated business model as compared to generic and branded specialty pharmaceutical drug companies, which we believe has been validated by our first approval and commercial launch in the United States of our novel formulation of argatroban, EP-1101, utilizing the 505(b)(2) pathway;

patent estate of ten owned or exclusively licensed U.S. issued patents and twelve 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 of products;

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ability to leverage our formulation and development expertise to avoid infringing existing patents; and

senior management team, which has over 100 years of combined experience in building and running leading pharmaceutical companies including our President and Chief Executive Officer, Scott Tarriff, who spearheaded the most successful product introductions in Par Pharmaceuticals' history.

Our Strategy

Take advantage of the 505(b)(2) regulatory pathway in order to 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 in terms of potential for longer stability, shorter infusion time, less waste and/or ease and safety of use for healthcare professionals, 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 plan to establish a small, specialty sales force that will focus on group purchasing organizations, hospital systems and key stakeholders in acute care settings, primarily hospitals and infusion centers.

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 our robust intellectual property portfolio. We are the owner or exclusive licensee of a patent estate consisting 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 product candidates that will not infringe patents that cover the branded reference drugs. We expect these patents will, if issued, allow us to list our own 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, if approved.

Our Market Opportunity

We believe there is a large and unmet market need for improved injectable drugs that address the specific needs of patients, physicians, nurses, and pharmacists to simplify their use, reduce waste, increase shelf life and lower healthcare costs.

Based on market data, we estimate that the U.S. generic injectable industry reported approximately $7.0 billion in sales in 2012 and grew at a compound annual growth rate of 17% over the last five

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years. Based on industry data, we believe that the U.S. generic injectable market will continue to grow at a compound annual growth rate of 11.6% 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.

Selected Risk Factors

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy.

These risks include, but are not limited to, the following:

- we have incurred significant losses in the past and may not be able to achieve or sustain profitability in the future;
- our independent registered public accounting firms have expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing;
- we are heavily dependent on the success of our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time), Ryanodex (dantrolene for malignant hyperthermia, or MH) and EP-4104 (dantrolene for exertional heat stroke, or EHS);
- if the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in any case may not be successful;
- 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;
- 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;
- a competitor may obtain, or may have obtained as in the case of bendamustine, orphan drug exclusivity, thereby precluding us from commercializing our product for the same indication for up to seven years, plus an additional six months for pediatric exclusivity, as applicable, unless we show superior safety or efficacy, or qualify under certain other limited exceptions;
- 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;

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we rely on third parties to conduct preclinical studies and manufacture commercial supplies and any disruptions in those relationships could have a material adverse effect on our business;

we operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow;

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;

if we or our sales representatives fail to comply with U.S. federal and state fraud and abuse laws, we could be subject to civil and criminal penalties, which could adversely impact our reputation and business operations; and

if we are unable to protect our intellectual property rights, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

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. Our corporate website address is www.eagleus.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

This prospectus contains references to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or 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 $700.0 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. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the "JOBS Act" and references herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

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THE OFFERING

Shares of common stock offered by us	3,350,000 shares
Shares of common stock to be outstanding after this offering	13,918,742 shares (of which 34.0% will be held by non-affiliates)
Option to purchase additional shares	502,500 shares
Use of proceeds	We intend to use the net proceeds from this offering for research and development expenses, to expand U.S. and international sales and marketing efforts, and for working capital and other general corporate purposes, including for costs and expenses associated with being a public company. See "Use of Proceeds."
Nasdaq Global Market symbol	"EGRX"
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.

Certain of our existing principal stockholders and their affiliated entities have agreed to purchase an aggregate of approximately $6.5 million in shares of our common stock in this offering at the initial public offering price.

The number of shares of our common stock to be outstanding after this offering is based on 10,568,742 shares of common stock outstanding as of December 31, 2013 (on a pro forma basis), and excludes:

- 841,104 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2013, under our 2007 Incentive Compensation Plan, or 2007 Plan, at a weighted average exercise price of $5.55 per share;
- 246,239 shares of common stock reserved for future grant or issuance under the 2007 Plan as of December 31, 2013; provided however, that in connection with this offering, the 2007 Plan will be terminated so that no further awards may be granted under the 2007 Plan;
- 974,311 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan, or the 2014 Plan, which will become effective as of the date of the effectiveness of this registration statement (including 246,239 shares of common stock reserved for issuance under our 2007 Plan that will be added to the shares reserved under the 2014 Plan upon termination of the 2007 Plan); and
- 180,943 shares of common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, or the ESPP, which will become effective as of the date of the effectiveness of this registration statement.

Unless otherwise indicated, all information contained in this prospectus assumes:

- the conversion of all our outstanding preferred stock into an aggregate of 7,487,928 shares of common stock in connection with the closing of this offering;

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the net exercise of preferred stock warrants that were outstanding as of December 31, 2013, based on an initial public offering price of $15.00, into 32,683 shares of common stock;

no exercise by the underwriters of their option to purchase up to an additional 502,500 shares of our common stock;

the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the closing of this offering; and

a one-for-6.41 reverse stock split of our common stock (that resulted in a proportional adjustment to the conversion ratio of our preferred stock).

We refer to our Series A, Series B, Series B-1 and Series C preferred stock collectively as "preferred stock" in this prospectus, as well as for financial reporting purposes and in the financial tables included in this prospectus. We refer to our outstanding warrants to purchase shares of our Series C preferred stock issued in August and September of 2012 as "preferred stock warrants" in this prospectus.

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SUMMARY FINANCIAL DATA

The following table summarizes certain of our financial data. We derived the summary statement of operations data for the fiscal years ended September 30, 2013 and 2012 from our audited financial statements and related notes appearing elsewhere in this prospectus. The summary financial data as of December 31, 2013, and for the three months ended December 31, 2013 and 2012, have been derived from our unaudited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire fiscal year. The summary financial data should be read together with our financial statements and related notes, "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

	Three Months Ended December 31,		Year Ended September 30,	
	2013	2012	2013	2012
Total revenue	$ 5,491,565	$ 1,483,066	$ 13,678,903	$ 2,539,402
Cost of revenue	4,624,193	211,156	7,380,825	3,166,593
Research and development	2,588,965	2,218,615	9,795,542	12,804,684
Selling, general and administrative	1,343,861	1,930,770	4,957,660	6,398,863
Total operating expenses	8,557,019	4,360,541	22,134,027	22,370,140
Loss from operations	(3,065,454)	(2,877,475)	(8,455,124)	(19,830,738)
Total other income/(expense), net	(189,688)	(503,713)	1,507,948	(333,164)
Loss before income tax benefit	(3,255,142)	(3,381,188)	(6,947,176)	(20,163,902)
Income tax benefit		898,703	898,703	781,261
Net loss	$ (3,255,142)	$ (2,482,485)	$ (6,048,473)	$ (19,382,641)
Less dividends to Series A, B, B-1 and C Convertible Preferred Stock	(1,132,222)	(819,134)	(3,836,777)	(3,933,425)
Net loss attributable to common stockholders	$ (4,387,364)	$ (3,301,619)	$ (9,885,250)	$ (23,316,066)
Basic and diluted net loss per common share[(1)]	$ (1.44)	$ (1.09)	$ (3.25)	$ (14.11)
Basic and diluted weighted average shares of common stock outstanding[(1)]	3,048,131	3,032,965	3,044,308	1,652,904
Pro forma basic and diluted loss per share	$ (0.31)		$ (0.63)	
Pro forma weighted average common shares outstanding basic and diluted	10,568,742		9,646,934	

(1) See Note 3 of our Notes to Financial Statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per common share and the number of shares used in the computation of the per share amounts.

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	As of December 31, 2013		
	Actual	Pro Forma[1]	Pro Forma as Adjusted[2]
Balance Sheet Data			
Cash and cash equivalents	$ 9,974,305	$ 9,974,305	$ 55,181,446
Working capital (deficit)	$ (299,975)	$ (299,975)	$ 44,907,166
Total assets	$ 18,010,088	$ 18,010,088	$ 62,566,988
Convertible Preferred Stock	$ 91,115,222		
Accumulated deficit	$ (106,523,421)	$ (106,523,421)	$ (106,523,421)
Total stockholders' equity (deficit)	$ (92,238,274)	$ 774,729	$ 45,464,629

(1) Pro forma amounts reflect the conversion of (i) all our outstanding shares of preferred stock as of December 31, 2013 into an aggregate of 7,487,928 shares of our common stock and (ii) the issuance of 32,683 shares of common stock upon conversion of the preferred shares issuable upon the net exercise of outstanding warrants that would otherwise expire upon the completion of this offering, based on an initial offering price of $15.00 per share.

(2) Pro forma as adjusted amounts reflect the pro forma conversion adjustments described in footnote (1) above, as well as the sale of 3,350,000 shares of our common stock in this offering at an initial public offering price of $15.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this prospectus, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

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 two 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 $3.3 million and $2.5 million for the three months ended December 31, 2013 and 2012, respectively. We have incurred significant net losses of $6.0 million and $19.4 million for the years ended September 30, 2013 and 2012, respectively. As of December 31, 2013, we had an accumulated deficit of $106.5 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 EP-1101 (argatroban) has 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 the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, may only be sufficient to fund our operations through the third quarter of fiscal year 2015.

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.

We estimate that the net proceeds from this offering will be approximately $44.7 million, based on an initial public offering price of $15.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Regardless of our expectations as to how long our net proceeds from this offering will fund our operations, changing circumstances beyond our

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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 occurence 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.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our independent registered public accounting firm stated that our financial statements for the fiscal years ended September 30, 2013 and 2012 were prepared assuming that we would continue as a going concern, and that certain matters raise substantial doubt about our ability to continue as a going

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concern. Such doubts are based on our recurring net losses, accumulated deficit and deficiency in working capital. We continue to experience losses. Our ability to continue as a going concern is subject to our ability to generate a profit and/or obtain necessary funding from outside sources, including by the sale of common stock in this offering, or obtaining loans from financial institutions or other financing arrangements. Our continued losses and "going concern" audit reports increase the difficulty of our meeting such goals and our efforts to continue as a going concern may not prove successful notwithstanding this offering.

Risks Related to Regulatory Approval

We are heavily dependent on the success of our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time), Ryanodex (dantrolene for MH) 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 short infusion time), Ryanodex (dantrolene for MH) 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) in the United States.

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 prospectus. 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, or 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

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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;

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- 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 is and completion of the trials is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;

patient referral practices of physicians; and

ability to monitor patients adequately during and after treatment.

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

As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although 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 undesireable 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

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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 one 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;

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- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

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

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may 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 EP-1101 (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) in the United States. 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.

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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 an application with the FDA for our EP-3101 (bendamustine RTD) product candidate through the 505(b)(2) regulatory pathway 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 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, 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 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

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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.

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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 healthcare 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 postmarket 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.

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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) healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 privacy regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The laws 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

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whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third party payors that are false or fraudulent or knowingly making 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 healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare 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 healthcare providers, health plans and healthcare 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 Payment 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 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 required by March 31, 2014 and by the 90th day of each subsequent calendar year;

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;

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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 healthcare 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 healthcare 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 healthcare 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, with differing effects.

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 healthcare laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable healthcare 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 healthcare 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 healthcare 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

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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;

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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 healthcare 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. Eagle has no 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;

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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.

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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, under the brand name Argatroban 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 expect the Treanda RTD product to enter the market before December 31, 2013. We filed a submission for our EP-3101 (bendamustine RTD) product with the FDA on September 6, 2013, including a paragraph IV certification of non-infringement of Teva's patents covering its Treanda product. 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 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, 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 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 pursuade 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).

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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 healthcare 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

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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 healthcare 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. 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 EP-1101 (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 healthcare 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 will require us to provide scientific and clinical 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.

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 healthcare 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 healthcare systems with the stated goals of containing healthcare costs,

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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 healthcare 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 healthcare programs that began in 2011;
- 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;
- 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 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;
- new requirements under the federal Physician Payment 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;
- a new requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners or to pharmacies of hospitals or other health care entities, effective April 1, 2012;
- expansion of healthcare 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 new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

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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.

In addition, other legislative changes have been proposed and adopted since ACA was enacted. 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. 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. 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 healthcare funding, 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.

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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

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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 for the manufacture of 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 occurence 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

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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 EP-1101 (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

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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

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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 are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our 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

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

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

As of December 31, 2013, we had a total of 20 full-time employees in the United States, 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 EP-1101 (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, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with EP-1101 (argatroban), other approved future products and our product candidates. If we cannot successfully

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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 EP-1101 (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 EP-1101(argatroban).

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 unforseen 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.

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We are involved in litigation in which Hikma has alleged breach of an asset purchase agreement entered into between us and Hikma and failure by us to disclose alleged manufacturing product defects. If Hikma prevails in this litigation, we could be required to pay substantial damages to Hikma.

In March 2012, Hikma purchased from us for $3.5 million certain assets relating to a generic drug, diclofenac/misoprostol tablets. That drug was the subject of an ANDA filed by us with the FDA. The ANDA is still pending before the FDA, and we continue to expect it to receive approval. The terms of the sale were set forth in a March, 2012 Asset Purchase Agreement, or Hikma APA. On June 24, 2013, Hikma Pharmaceutical Co., Ltd., or 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 prior to the execution of the Hikma APA. On August 27, 2013, we filed an answer to Hikma's complaint, which denied Hikma's claims, and asserted a counterclaim alleging that Hikma by its actions had repudiated the Hikma APA.

Should Hikma prevail on its claims that we breached the APA or intentionally failed to disclose alleged product defects, we could be required to pay substantial damages, including, but not limited to, the return of the $3.5 million purchase price plus interest and other damages, Hikma's lost profits from being unable to market the drug, and punitive damages. This outcome could result in a material adverse effect on our cash resources. Even if we were to prevail, this litigation could be costly and time-consuming, divert the attention of our management and key personnel from our business operations, which would also materially harm our business. During the course of litigation, we anticipate announcements of the results of hearings and motions, and other interim developments related to the litigation. If securities analysts or investors regard these announcements as negative, the market price of our common stock may decline.

We are vigorously defending these claims and do not believe that Hikma is entitled to damages because Hikma's purported termination violated the terms of the Hikma APA and we believe that the claims of non-disclosure of manufacturing product defects are without merit. Given the early stage in the litigation, we are unable to predict the likelihood of success of Hikma's contract breach and fraud claims.

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.

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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 EP-1101 (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

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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

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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 EP-1101 (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

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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 issuing.

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

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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 EP-1101 (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 EP-1101 (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 EP-1101 (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 EP-1101 (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 EP-1101 (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 EP-1101 (argatroban) and our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of EP-1101 (argatroban) and our product candidates that are different from ours and do not infringe our issued patents covering our products.

EP-1101 (argatroban) has 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.

EP-1101 (argatroban) has 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 USPTO, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common,

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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.

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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 this Offering and Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

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 EP-1101 (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;

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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 EP-1101 (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.

In addition, 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 these listed companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

Prior to this offering, there has not been a public market for our common stock. Although we have applied to have our common stock listed on Nasdaq, an active trading market for our shares may never develop or be sustained following this offering. 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. The initial public offering price for the shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of prices that will prevail in the trading market.

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

As of December 31, 2013, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own approximately 82.5% of our voting stock. Based upon the number of shares to be sold in this offering as set forth on the cover page of this prospectus, upon the closing of this offering, that same group will beneficially own approximately 66.0% of our outstanding voting stock. In addition to the above ownership, certain of our existing principal stockholders and their affiliated entities have agreed to purchase an aggregate of approximately $6.5 million in shares of our common stock in this offering at the initial public offering price. Therefore, even after this offering these stockholders will have the ability to influence us through this ownership position. These stockholders

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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 this prospectus and 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 this 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 consolidated financial statements or identify other areas for further attention

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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 will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and the Nasdaq have imposed various requirements on public companies. 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 will 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.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted book value (deficit) per share of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $11.73 per share, based on an initial public offering price of $15.00, per share and our pro forma as adjusted net tangible book value (deficit) as of December 31, 2013. For more information on the dilution you may suffer as a result of investing in this offering, see "Dilution."

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering and the exercise of stock options granted to our employees. The exercise of any of these options would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

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.

Substantially all of our existing stockholders are subject to lock-up agreements with the underwriters of this offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days after the date of this prospectus. The lock-up agreements limit the number of shares of

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common stock that may be sold immediately following the public offering. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of our outstanding shares prior to this offering will become eligible for sale upon expiration of the lock-up period, as calculated and described in more detail in the section of this prospectus entitled "Shares Eligible for Future Sale." In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. 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, subject to the 180-day lock-up arrangement described above. 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 intend to register all shares of common stock that we may issue under our stock-based compensation plans. As of December 31, 2013, options to purchase 841,104 shares of our common stock at a weighted average exercise price of $5.55 per share were outstanding. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements and the restrictions imposed under Rule 144 under the Securities Act, which may cause our stockholders to experience additional dilution.

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 this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this 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 this 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 prechange tax attributes, such as research tax credits, to offset its

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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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." 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 JOBS Act;

- our use of the proceeds from this 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.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss

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many of these risks in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. 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. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $44.7 million (or approximately $51.7 million if the underwriters' option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, based on an initial public offering price of $15.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use the net proceeds of this offering as follows:

- approximately $30 million to continue to invest in our research and development program;
- approximately $7 to $10 million to continue to expand our U.S. and international sales and marketing efforts; and
- the balance for working capital and general corporate purposes.

We may also use a portion of the net proceeds from this offering to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However we have no current plan, commitments or obligations to do so.

We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through at least the third quarter of fiscal year 2015.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our product candidate development programs, including our planned clinical trials, and whether we are able to enter into future collaboration arrangements. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

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CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities, and our capitalization as of December 31, 2013:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the conversion of all our outstanding preferred stock into an aggregate of 7,487,928 shares of our common stock upon the closing of this offering and (ii) the issuance of 32,683 shares of common stock upon the automatic net exercise of outstanding warrants that would otherwise expire upon the completion of this offering and the related mark-to-market adjustment that will be reflected in accumulated deficit;
- on a pro forma as adjusted basis, reflecting the pro forma adjustments discussed above and giving further effect to the sale by us of 3,350,000 shares of our common stock at an initial public offering price of $15.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our audited consolidated financial statements and the related notes appearing at the end of this prospectus, the sections entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information contained in this prospectus.

	As of December 31, 2013		
	Actual	Pro Forma	Pro Forma As Adjusted
		(unaudited)	
Cash and cash equivalents	$ 9,974,305	$ 9,974,305	$ 55,181,446
Convertible preferred stock	91,115,222		
Common stock; $.001 par value: 80,000,000 shares authorized, 3,048,131 shares issued and outstanding, actual; 80,000,000 shares authorized, 10,568,742 shares issued and outstanding, pro forma; 50,000,000 shares authorized, 13,918,742 shares issued and outstanding, pro forma as adjusted	3,048	10,569	13,919
Additional paid in capital	14,282,099	107,287,581	151,974,131
Accumulated deficit	(106,523,421)	(106,523,421)	(106,523,421)
Total stockholders' equity (deficit)	(92,238,274)	774,729	45,464,629
Total capitalization	$ (1,123,052)	$ 774,729	$ 45,464,629

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The number of common shares shown as issued and outstanding on a pro forma as adjusted basis in the table is based on 10,568,742 shares of common stock outstanding as of December 31, 2013, after giving effect to the conversion of our outstanding preferred shares into an aggregate of 7,487,928 shares of common stock and the net exercise of preferred stock warrants that were outstanding as of December 31, 2013, based on an initial public offering price of $15.00, into 32,683 shares of common stock, and excludes:

- 841,104 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2013 under the 2007 Plan at a weighted average exercise price of $5.55 per share;

- 246,239 shares of common stock reserved for future grant or issuance under the 2007 Plan as of December 31, 2013; provided however, that in connection with this offering, the 2007 Plan will be terminated so that no further awards may be granted under the 2007 Plan;

- 974,311 shares of common stock reserved for future issuance under the 2014 Plan, which will become effective as of the date of the effectiveness of this registration statement (including 246,239 shares of common stock reserved for issuance under our 2007 Plan that will be added to the shares reserved under the 2014 Plan upon termination of the 2007 Plan); and

- 180,943 shares of common stock reserved for issuance under the ESPP, which will become effective as of the date of the effectiveness of this registration statement.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of December 31, 2013 was approximately $(92.2) million, or $(30.26) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our liabilities and preferred stock which is not included within equity. Net historical tangible book value (deficit) per share is our historical net tangible book value (deficit) divided by the number of shares of common stock outstanding as of December 31, 2013. Our pro forma net tangible book value (deficit) as of December 31, 2013 was approximately $0.8 million, or $0.07 per share of common stock. Pro forma net tangible book value (deficit) gives effect to the conversion of all of our outstanding preferred stock into an aggregate of 7,487,928 shares of our common stock and the net exercise of preferred stock warrants that were outstanding as of December 31, 2013, based on an initial public offering price of $15.00, into 32,683 shares of common stock.

Pro forma as adjusted net tangible book value is our pro forma net tangible book value (deficit), plus the effect of the sale of 3,350,000 shares of our common stock in this offering at an initial public offering price of $15.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $3.20 per share to our existing stockholders, and an immediate dilution of $11.73 per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$ 15.00
Historical net tangible book value (deficit) per share as of December 31, 2013	$ (30.26)	
Pro forma increase in net tangible book value per share as of December 31, 2013 attributable to the conversion of preferred stock	30.33	
Pro forma net tangible book value per share as of December 31, 2013, before giving effect to this offering	0.07	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	3.20	
Pro forma as adjusted net tangible book value per share after this offering		3.27
Dilution per share to new investors participating in this offering		$ 11.73

If the underwriters exercise their option in full to purchase 502,500 additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value will increase to $3.64 per share, representing an immediate increase to existing stockholders of $3.57 per share and an immediate dilution of $11.36 per share to new investors participating in this offering.

The foregoing discussion is based on 10,568,742 shares of common stock outstanding as of December 31, 2013, after giving effect to the conversion of our outstanding preferred shares into an aggregate of 7,487,928 shares of common stock and the net exercise of preferred stock warrants that

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were outstanding as of December 31, 2013, based on an initial public offering price of $15.00, into 32,683 shares of common stock, and excludes:

- 841,104 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2013 under the 2007 Plan at a weighted average exercise price of $5.55 per share;
- 246,239 shares of common stock reserved for future grant or issuance under the 2007 Plan as of December 31, 2013; provided however, that in connection with this offering, the 2007 Plan will be terminated so that no further awards may be granted under the 2007 Plan;
- 974,311 shares of common stock reserved for future issuance under the 2014 Plan, which will become effective as of the date of the effectiveness of this registration statement (including 246,239 shares of common stock reserved for issuance under our 2007 Plan that will be added to the shares reserved under the 2014 Plan upon termination of the 2007 Plan); and
- 180,943 shares of common stock reserved for issuance under the ESPP, which will become effective as of the date of the effectiveness of this registration statement.

Effective immediately upon the closing of this offering, an aggregate of 1,155,254 shares of our common stock will be reserved for issuance under the 2014 Plan (including 246,239 shares of common stock reserved for issuance under our 2007 Plan that will be added to the shares reserved under the 2014 Plan upon termination of the 2007 Plan) and the ESPP. To the extent that any of these options are exercised, new options are issued under our equity incentive plans or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

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SELECTED FINANCIAL DATA

The following selected financial data should be read together with our financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. The selected financial data in this section is not intended to replace our financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results. The selected financial data as of September 30, 2013 and 2012 and for the years then ended have been derived from our financial statements included elsewhere in this prospectus. The selected financial data as of December 31, 2013, and for the three months ended December 31, 2013 and 2012, have been derived from our unaudited financial statements included elsewhere in this prospectus.

The unaudited financial data include, in the opinion of our management, all adjustments, consisting only of normal recurring adjustments that are necessary for a fair presentation of our financial position and results of operations for these periods. 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.

	Three Months Ended December 31,		Year Ended September 30,	
	2013	2012	2013	2012
Statement of Operations Data				
Product sales	$ 2,223,460	$ 255,320	$ 5,314,610	$ 1,155,358
Royalty income	3,268,105	1,227,746	8,364,293	1,384,044
Total revenue	5,491,565	1,483,066	13,678,903	2,539,402
Cost of revenue	4,624,193	211,156	7,380,825	3,166,593
Research and development	2,588,965	2,218,615	9,795,542	12,804,684
Selling, general and administrative	1,343,861	1,930,770	4,957,660	6,398,863
Total operating expenses	8,557,019	4,360,541	22,134,027	22,370,140
Loss from operations	(3,065,454)	(2,877,475)	(8,455,124)	(19,830,738)
Total other income/(expense), net	(189,688)	(503,713)	1,507,948	(333,164)
Loss before income tax benefit	(3,255,142)	(3,381,188)	(6,947,176)	(20,163,902)
Income tax benefit		898,703	898,703	781,261
Net loss	$ (3,255,142)	$ (2,482,485)	$ (6,048,473)	$ (19,382,641)
Less dividends to Series A, B, B-1 and C Convertible Preferred Stock	(1,132,222)	(819,134)	(3,836,777)	(3,933,425)
Net loss attributable to common stockholders	$ (4,387,364)	$ (3,301,619)	$ (9,885,250)	$ (23,316,066)
Basic and diluted net loss per common share	$ (1.44)	$ (1.09)	$ (3.25)	$ (14.11)
Basic and diluted weighted average shares of common stock outstanding	3,048,131	3,032,965	3,044,308	1,652,904

	December 31,	September 30,	
	2013	2013	2012
Balance Sheet Data			
Cash and cash equivalents	$ 9,974,305	$ 10,455,565	$ 5,066,886
Short term investments	$	$	$ 1,500,000
Working capital (deficit)	$ (299,975)	$ 3,140,602	$ (12,016,562)
Total assets	$ 18,010,088	$ 18,102,620	$ 9,438,048

Convertible Preferred Stock	$ 91,115,222	$ 89,983,000	$ 81,335,894
Accumulated deficit	$ (106,523,421)	$ (102,136,057)	$ (95,537,403)
Total stockholders' deficit	$ (92,238,274)	$ (87,929,014)	$ (93,433,932)

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business 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 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.

Since our inception, we have focused on identifying attractive product candidates for our approach under the 505(b)(2) regulatory pathway. As a result, our disclosed product portfolio now includes two approved products and six advanced product candidates. We currently have one commercialized product, EP-1101 (argatroban). Due to limited financial resources, we initially decided to collaborate with a commercial partners in order to commercialize EP-1101 (argatroban)and it is now currently marketed by The Medicines Company and Sandoz Inc. pursuant to separate agreements. As a result of our commercialization strategy, we have been able to minimize certain expenses, but also are required to share revenues from EP-1101 (argatroban) with our commercial partners.

In the future, we intend to commercialize our 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 intend to establish a small, specialty sales force that will target group purchasing organizations, hospital groups and key stakeholders in acute care settings, primarily hospitals and infusion centers. 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, and income from collaborative arrangement 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.

For the three months ended December 31, 2013, we had revenues of $5.5 million, representing an increase of $4.0 million as compared to the three months ended December 31, 2012, and a net loss of $3.2 million, an increase of $0.7 million as compared to the three months ended December 31, 2012. For the year ended September 30, 2013, we had revenues of $13.7 million, an increase of $11.1 million as compared to the year ended September 30, 2012 and a net loss of $6.0 million, a reduction in losses of $13.4 million as compared to the year ended September 30, 2012. We expect our revenue to continue to grow over the long term due to the launch of new products.

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Financial Operations Overview

Revenues

Revenues include 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 to our commercial partners. Such sales are typically made at little or no profit for resale by our commercial partners.

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 and royalty income are derived from the sale of EP-1101 (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 EP-1101 (argatroban) are:

- the level of orders submitted by our commercial partners Sandoz, and The Medicines Company;
- the level of institutional demand for EP-1101 (argatroban);
- unit sales prices; and
- the amount of gross-to-net sales adjustments realized by our marketing partners.

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 diclofena/misoprostal 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 and providing research and development services to our collaboration partners. In particular, our cost of revenue includes production costs of EP-1101 (argatroban) paid to a contract manufacturing organization coupled with shipping and customs charges, as well as royalty expense associated with the license of EP-2101 (topotecan) to Pfizer. Cost of revenue may also include the effects of product recalls, if applicable.

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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 to prepare for the commercial manufacture of products including EP-1101 (argatroban), Ryanodex (dantrolene for MH), EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time) and our other product candidates; payments made to third-party CROs, 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.

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 dantrolene in additional indications. 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. We are currently unable to determine our future research and development expenses related to dantrolene because the timing and outcome of the Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for Ryanodex (dantrolene for MH) is not currently known and the requirements of any additional clinical trials of dantrolene for additional indications has yet to be determined. The cost of clinical development may vary significantly due to factors such as the scope, rate of progress, expense and outcome of our clinical trials and other development activities.

We could incur additional research and development expenses for EP-3101 (bendamustine RTD), for which an NDA was filed with the FDA on September 6, 2013. FDA review of NDAs is governed by the Prescription Drug User Fee Act, or PDUFA, regarding response time to the application. The PDUFA goal date for EP-3101 (bendamustine RTD) is July 6, 2014. Any further actions requested by the FDA may result in additional research and development expenses. For additional information regarding the PDUFA review process, see "Business Government Regulation FDA Approval Process."

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. 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 move to a business model in which we commercialize our own products in the United States, as well as increased expenses associated with us becoming a public company.

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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 and short-term investments. Interest expense consists primarily of cash and non-cash interest costs related to our issuance of convertible notes in the fourth quarter of fiscal 2012, including the amortization of debt discounts and deferred financing costs.

Income Tax Benefit

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

Results of Operations

Comparison of Three Months Ended December 31, 2013 and 2012

The following table sets forth a summary of our product sales, royalty income and collaborative arrangements for the three months ended December 31, 2013 and 2012:

Revenues

	Three Months Ended December 31,		Increase/ (Decrease)
	2013	2012	
Product sales	$ 2,223,460	$ 255,320	$ 1,968,140
Royalty income	3,268,105	1,227,746	2,040,359
Total revenue	$ 5,491,565	$ 1,483,066	$ 4,008,499

Total revenues increased $4.0 million in the three months ended December 31, 2013 to $5.5 million as compared to $1.5 million in the three months ended December 31, 2012.

Product sales increased $2.0 million in the three months ended December 31, 2013 to $2.2 million as compared to $0.2 million in the three months ended December 31, 2012 due to the addition of Sandoz as a marketing partner and greater market penetration when compared to 2012.

Royalty income increased $2.0 million in the three months ended December 31, 2013 to $3.3 million as compared to $1.3 million in the three months ended December 31, 2012, as a result of higher royalty income from the end use sales of EP-1101 (argatroban) by our commercial partners.

Cost of Revenue

	Three Months Ended December 31,		Increase/ (Decrease)
	2013	2012	
Cost of revenue	$ 4,624,193	$ 211,156	$ 4,413,037

Cost of net revenues increased $4.4 million in the three months ended December 31, 2013 to $4.6 million as compared to $0.2 million in the three months ended December 31, 2012 as a result of the increased product sales of EP-1101 (argatroban) and royalty expense associated with our commercial and development partners. Of the $4.4 million increase in cost of revenues related to

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argatroban, approximately $2.4 million was attributable to increased product sales and approximately $2.0 million was attributable to royalty expense. Of the $2.0 million attributable to royalty expense, approximately $1.2 million was related to payables to SciDose and $0.8 million was related to payables to The Medicines Company under our agreements with those parties.

With respect to product sales, we experienced increased demand for the amount of product from our marketing partners in the quarter ended December 31, 2013 which resulted in an increase in the cost of revenue during that quarter. The volume of product delivered in the quarter ended December 31, 2013 increased by approximately 40% from the quarter ended September 30, 2013.

The significant increase in cost of revenue relating to royalty expense during the quarter ended December 31, 2013 is primarily attributable to the increased royalty expense related to our revenue sharing arrangement with SciDose. Under the terms of our agreement 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 equally with SciDose the net proceeds from royalty income we receive from the sale of such product. For additional information regarding this arrangement, see "Business License Agreements Development and License Agreement with SciDose (argatroban and bivalirudin)."

During the quarter ended September 30, 2013, we recouped all of our expenses related to the development of argatroban and cumulative revenue exceeded the recouped expenses. As a result, we recognized approximately $0.5 million of royalty expense during that quarter. By comparison, in the quarter ended December 31, 2013, during which all revenues were subject to the revenue sharing arrangement with SciDose, we had approximately $1.2 million of royalty expense.

We would expect that our cost of revenues as a percentage of revenues will remain consistent with the quarter ended December 31, 2013.

Research and Development

	Three Months Ended December 31,		Increase/ (Decrease)
	2013	2012	
Ryanodex (dantrolene for MH)	$ 411,852	$ 323,882	$ 87,970
EP-3101 (bendamustine RTD)	721,104		721,104
EP-4104 (dantrolene for EHS)	10,665	108,204	(97,539)
All other projects	714,588	878,031	(163,443)
Salary and other personnel related expenses	730,756	908,498	(177,742)
Total research and development	$ 2,588,965	$ 2,218,615	$ 370,350

Research and development expenses increased $0.4 million in the three months ended December 31, 2013 to $2.6 million as compared to $2.2 million in the three months ended December 31, 2012. Expenses in the three months ended December 31, 2013 were higher than in the three months ended December 31, 2012 as a result of increased project spending specifically for the EP-3101 (bendamustine RTD) and Ryanodex (dantrolene for MH) offset by reduction due to timing of completion of projects and limited funds, as well as lower personnel and related expenses.

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Selling General and Administrative

Selling, general and administrative expenses decreased $0.6 million in the three months ended December 31, 2013 to $1.3 million as compared to $1.9 million in the three months ended December 31, 2012. The decreased costs in the three months ended December 31, 2013 over the three months ended December 31, 2012 are due primarily to $0.6 million in lower legal costs related to the The Medicines Company arbitration.

Other Income (Expense)

	Three Months Ended December 31,		Increase/ (Decrease)
	2013	2012	
Interest income	$ 1,264	$ 638	$ 626
Interest expense		(148,162)	148,162
Deferred financing costs		(28,925)	28,925
Amortization of debt discount		(327,264)	327,264
Change in value of warrant liability	(190,952)		(190,952)
Total other income/(expense), net	$ (189,688)	$ (503,713)	$ 314,025

Other income and expense increased by $0.3 million in the three months ended December 31, 2013 to an expense of $0.2 million as compared to an expense of $0.5 million in the three months ended December 31, 2012. The other income and expense for the three months ended December 31, 2013 primarily included the recognition of the change in value of the warrant liability. In the three months ended December 31, 2012, other income and expense includes primarily interest expense and the amortization and write-off of deferred financing costs and debt discount related to the convertible notes that were issued in the fourth quarter of 2012 and converted into preferred stock in April 2013.

Income Tax Benefit

Income tax benefit decreased $0.9 million in the three months ended December 31, 2013 to a benefit of $0.0 as compared to a benefit of $0.9 million for the three months ended December 31, 2012. Income tax benefit declined due to the timing of sales of our New Jersey State net operating losses. On January 17, 2014, we sold New Jersey State net operating losses for $1,294,905 in net proceeds.

Net Loss

Net loss for the three months ended December 31, 2013 was $3.3 million as compared to net loss of $2.5 million, as a result of the factors discussed above.

Comparison of Years Ended September 30, 2013 and 2012

Revenues

	Year Ended September 30,		Increase/ (Decrease)
	2013	2012	
Product sales	$ 5,314,610	$ 1,155,358	$ 4,159,252
Royalty income	8,364,293	1,384,044	6,980,249
Total revenue	$ 13,678,903	$ 2,539,402	$ 11,139,501

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Total revenue increased $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 $4.2 million to $5.3 million as compared to $1.2 million in fiscal 2012 due to the longer period of time during which EP-1101 (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 in 2012 as compared to $1.4 million in fiscal 2012, as a result of the longer period of time during which EP-1101 (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 EP- 1101 (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/ (Decrease)
Cost of revenue	$ 7,380,825	$ 3,166,593	$ 4,214,232

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 EP-1101 (argatroban). Included in fiscal 2012 are approximately $1.6 million in costs associated with an EP-1101 (argatroban) product recall and related inventory write-offs.

Research and Development

	Year Ended September 30, 2013	2012	Increase/ (Decrease)
Ryanodex (dantrolene for MH)	$ 1,682,350	$ 2,931,892	$ (1,249,542)
EP-3101 (bendamustine RTD)	1,090,321	1,623,261	(532,940)
EP-4104 (dantrolene for EHS)	162,236	1,204,587	(1,042,351)
All other projects	3,552,996	2,973,585	579,411
Salary and other personnel related expenses	3,307,639	4,071,359	(763,720)
Total Research and Development	$ 9,795,542	$ 12,804,684	$ (3,009,142)

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 (dantrolene for MH), EP-4104 (dantrolene for EHS) and EP-3101 (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 $0.9 million in costs related to The Medicines Company arbitration described elsewhere in this prospectus, $0.2 million in market research activities and $0.3 million in miscellaneous expenses.

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Other Income and Expense

	Year Ended September 30, 2013	2012	Increase/ (Decrease)
Interest income	$ 3,212	$ 34,530	$ (31,318)
Net proceeds from MDCO Arbitration	4,050,252		4,050,252
Interest expense	(309,121)	(90,718)	(218,403)
Deferred financing costs	(96,417)	(19,283)	(77,134)
Amortization of debt discount	(1,090,878)	(218,176)	(872,702)
Change in value of warrant liability	(1,052,302)		(1,052,302)
Loss on subscription loan settlement		(51,379)	51,379
Other income, net	3,202	11,862	(8,660)
Total other income/(expense), net	$ 1,507,948	$ (333,164)	$ 1,841,112

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

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 $10.5 million, $5.1 million and $10.0 million at September 30, 2013, September 30, 2012 and December 31, 2013, respectively. Including short term investments, total cash, cash equivalents and short term investments were $10.5 million and $6.6 million at September 30, 2013 and 2012, respectively. There were no short term investments at December 31, 2013.

For the three months ended December 31, 2013, we incurred a net loss of $3.3 million. We had an accumulated deficit of $106.5 million as of December 31, 2013. In addition, as of December 31, 2013, we had a deficiency of working capital of $0.3 million. For the fiscal 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 $102.1 million as of September 30, 2013. In addition, as of September 30, 2013, we had a surplus of working capital of $3.1 million. For the fiscal year ended September 30, 2012, we incurred a net loss of $19.4 million. We had an accumulated a deficit of $95.5 million as of September 30, 2012. In addition, as of September 30, 2012, we had a deficiency of working capital of $12.0 million. The financial statements have been prepared on a going

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concern basis, assuming we had the ability to satisfy our obligations in the normal course of business. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. Our auditors included an explanatory paragraph in their audit report expressing substantial doubt about our ability to continue as a going concern.

We believe that future cash flows from operations, together with proceeds from this initial public offering will be sufficient to fund our currently anticipated working capital requirements through the third quarter of fiscal year 2015. 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 provided by operating activities for the three months ended December 31, 2013 was $23 thousand. Net loss for the period was $3.3 million offset by non-cash adjustments of approximately $0.3 million from the change in value of the warrant liability, depreciation, and stock-based compensation expense. Net changes in working capital increased cash from operating activities by approximately $23 thousand, primarily due to a decrease in prepaid expenses of $1.5 million ($0.7 million for prepaid product costs and $0.8 million for FDA user fees) offset by an increase in accounts receivable of $1.5 million and an increase in accounts payable and accrued expenses of $3.0 million. The total amount of accounts receivable at December 31, 2013 was approximately $6.5 million, which included approximately $1.5 million of product sales and approximately $5.0 million of royalty income, all with payment terms of 45 days. 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 December 31, 2013, our cumulative receivables related to royalty income consist of approximately $3.3 million in receivables from The Medicines Company and $1.7 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, the Company has 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, the Company has 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 December 31, 2013, we recorded a receivable from Sandoz of approximately $1.7 million and a payable to The Medicines Company of $0.9 million (based upon a 50% revenue split on Sandoz sales). At the same time, we recorded a receivable from The Medicines Company of approximately $1.6 million based on royalties owed to us by The Medicines Company. The net receivable from The Medicines Company for the quarter ended December 31, 2013 therefore would have been $0.7 million. The additional receivable of $1.7 million owing to us from The Medicines Company as of December 31, 2013 therefore represents the unpaid gross receivables from prior periods described above.

We believe that our accounts receivable as of December 31, 2013, 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 the ordinary course in the second fiscal quarter, and thus would not have a material effect on our liquidity.

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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 EP-1101 (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 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 EP-1101 (argatroban), a decrease in inventories of $1.1 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 three months ended December 31, 2013 and 2012, we invested $7 thousand and $0, respectively, for the purchase of property and equipment. In the years ended September 30, 2013 and 2012, we invested $40 thousand and $33 thousand, respectively, for the purchase of property and equipment.

In the three months ended December 31, 2013 and 2012 we redeemed $0 and $1.5 million, respectively of short term investments. In the years ended September 30, 2013 and 2012, we redeemed $1.5 million and $3.0 million, respectively of short term investments.

Financing Activities:

Net cash used for financing activities for the three months ended December 31, 2013 and 2012 was $0.5 million and $0, respectively, for professional fees related to IPO planning.

Net cash provided by financing activities in fiscal 2013 and 2012 was $9.8 million and $9.6 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:

		Fiscal Years Ended September 30,					
	Total	**2014**	**2015**	**2016**	**2017**	**2018**	**Beyond**
Operating lease obligations	$ 454,025	$ 272,415	$ 181,610	$	$	$	$

Quantitative and Qualitative Disclosures about Market Risk

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2013, we had cash and

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cash equivalents of $10.5 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents and short-term investments, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Recent Accounting Pronouncements

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

We have based our management's discussion and analysis of our financial condition and results of operations on our financial statements that have been prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. The preparation of these financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical trial expenses and stock-based compensation. We base our estimates on historical experience and on various other factors we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully discussed in Note 3 to our audited financial statements included in this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our board of directors.

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 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*.

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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 common stock warrant liability and embedded derivative are 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 its 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 adversely 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.

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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.

For the three months ended December 31, 2013 and 2012, we recognized employee stock-based compensation expense pertaining to the issuance of stock options of $78,104 and $104,393, respectively. For the years ended September 30, 2013 and 2012, we recognized employee stock-based compensation expense pertaining to the issuance of stock options of $317,192 and $402,289, respectively.

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.

Valuation of Common Stock

The fair market value of the common stock is determined on each grant date by our management and board of directors, and considers our most recently available valuation of common stock and our assessment of additional objective and subjective factors that we believe are relevant and which may change from the date of the most recent valuation through the date of the grant. In the absence of a public trading market for our common stock, our determination of the fair value of our common stock was performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. In addition, our board of directors considered various objective and subjective factors, along with input from management, to determine its best estimate of the fair value of our common stock as of each grant date, including the following:

- contemporaneous third-party valuations of our common stock;
- peer group trading multiples;
- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- our historical and forecasted performance and operating results;
- the status of our development programs;
- our stage of development and business strategy;
- the composition of, and changes to, our management team and board of directors;
- the lack of an active public market for our common and our preferred stock;
- the likelihood of achieving a liquidity event such as a sale of our company or an initial public offering given prevailing market conditions; and

external market conditions affecting the pharmaceutical and healthcare industry.

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Our common stock valuations have been prepared utilizing the probability-weighted expected return method, or PWERM. The value of common shares for this purpose was estimated using a probability weighted analysis of the present value of the returns afforded to shareholders under each of four possible future scenarios for us. Three of the scenarios assume a shareholder exit, either through initial public offering, sale, or dissolution. The fourth scenario assumes operations continue as a private company and no exit transaction occurs. The estimated values of common shares indicated under each scenario were probability weighted based upon management's estimate of the probabilities of occurrence of each of the scenarios, as of the valuation date. The discounted cash flow method was used with the assumptions and estimates provided by management, described more fully below. Further, discounts for lack of control and lack of marketability, to account for the illiquidity of the common stock, were applied to the indicated common stock value to estimate the fair market value of the common stock. The relative probability of each type of future event scenario was determined by management and our board of directors based on an analysis of market conditions at the time, including then-current initial public offering valuations of similarly situated companies, and expectations as to the timing and likely prospects of the future event scenarios.

An enterprise value at the valuation date was not determined. For each of the PWERM scenarios, as of a future liquidity event date (5 years subsequent to the valuation date), the hypothetical sale proceeds were added to the cumulative operating cash flows, and the total was allocated first to the preferred claims (including accrued dividends) and the remainder was allocated to the common shares. The common share proceeds were then discounted to present value using the applicable discount rate. To derive the value of the common stock for each scenario using the PWERM, the proceeds to the common stockholders were calculated based on the preferences and priorities of the preferred and common stock.

The discounted cash flow method within the income approach was used to estimate the present value of cash flows available to common shareholders, which includes the cash flows realized in the discrete projection period plus the terminal value. For the initial public offering PWERM scenario, the terminal value was calculated under the assumption that all outstanding preferred and common shares would be sold via a public offering. The adjusted enterprise value to earnings before interest, taxes, depreciation and amortization multiple derived from the guideline public companies was used only to estimate the sale proceeds available for distribution to shareholders at a future date.

The estimated values of common shares indicated under each scenario were probability weighted based upon management's estimate of the probabilities of occurrence of each of the scenarios, as of the valuation date.

The tables below include the following estimated probabilities under the PWERM:

Options granted on July 12, 2012 assumed probabilities for an initial public offering, merger / acquisition, no exit / private company, or dissolution, of 10%, 50%, 30%, and 10%, respectively. Prior to July 2012 we were party to a licensing deal which opened dialogue between us and a potential licensee for a possible merger or acquisition. As such, the estimated probability for a merger / acquisition was greater than in subsequent valuation dates. The licensing deal closed and assumed probabilities for a merger / acquisition were reduced in the next two valuations. In calculating the value of future cash flows after the terminal year of the forecast, we used the Gordon Growth Model and the estimates for risk free rate of return 3.61%, equity risk premium 15.35% and specific company premium 23.0% to develop an estimated cost of equity of 42.0% and a long term growth rate estimate of 5.0%, which was selected based on our analysis of national economic and industry trends and forecasts. To assist in quantifying the lack of control and marketability discounts, we reviewed numerous authoritative tests and studies of empirical market data. The control, marketable value of common stock indicated by the PWERM was reduced by a 25.0% discount for lack of

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control and 35.0% discount for lack of marketability. The discounted cash flow model included the following inputs: projections over a five year period; adjustments for working capital; accounts receivable; stock compensation; capital expenditures; and depreciation. Next, we added the total cash flow available to equity holders at the end of each year and subtracted accrued dividends under scenarios in which they would be paid. Then, we added the terminal value to the remaining cash flow available to equity holders by year and discounted back to the current year using the discount rate. Lastly, the value was applied to each of the security holders based on the liquidation preferences and the capitalization table.

Options granted on April 19, 2013 assumed probabilities for an initial public offering, merger / acquisition, no exit / private company, or dissolution, of 0%, 35%, 60%, and 5%, respectively. In calculating the value of future cash flows after the terminal year of the forecast, we used the Gordon Growth Model and the estimates for risk free rate of return 2.5%, equity risk premium 14.38% and specific company premium 24.0% to develop an estimated cost of equity of 41.0% and a long term growth rate estimate of 5.0%, which was selected based on our analysis of national economic and industry trends and forecasts. To assist in quantifying the lack of control and marketability discounts, we reviewed numerous authoritative tests and studies of empirical market data. The control, marketable value of common stock indicated by the PWERM was reduced by a 25.0% discount for lack of control and 35.0% discount for lack of marketability. The discounted cash flow model included the following inputs: projections over a five year period; adjustments for working capital; accounts receivable; stock compensation; capital expenditures; and depreciation. Next, we added the total cash flow available to equity holders at the end of each year and subtracted accrued dividends under scenarios in which they would be paid. Then, we added the terminal value to the remaining cash flow available to equity holders by year and discounted back to the current year using the discount rate. Lastly, the value was applied to each of the security holders based on the liquidation preferences and the capitalization table.

Options granted on November 21, 2013 assumed probabilities for an initial public offering, merger / acquisition, no exit / private company, or dissolution, of 15%, 20%, 60%, and 5%, respectively. The exercise price for grant date July 12, 2012 included assumptions weighted heavily toward a merger / acquisition. A merger / acquisition liquidity event did not take place and the estimated probabilities were normalized. Prior to the April 19, 2013 grant date, we closed on a Series C financing, which included further dilution, hence lowering the exercise price in combination with the normalized estimated probability. The November 21, 2013 grant date exercise price increased, when compared to April 19, 2013's grant date, which included a higher estimated probability for an initial public offering. In calculating the value of future cash flows after the terminal year of the forecast, we used the Gordon Growth Model and the estimates for risk free rate of return 4.58%, equity risk premium 14.93% and specific company premium 14.52% to develop an estimated cost of equity of 34.03% and a long term growth rate estimate of 5.0%, which was selected based on our analysis of national economic and industry trends and forecasts. To assist in quantifying the lack of control and marketability discounts, we reviewed numerous authoritative tests and studies of empirical market data. The control, marketable value of common stock indicated by the PWERM was reduced by a 25.0% discount for lack of control and a 35.0% discount for lack of marketability. The discounted cash flow model included the following inputs: projections over a five year period; adjustments for working capital; accounts receivable; stock compensation; capital expenditures; and depreciation. Next, we added the total cash flow available to equity holders at the end of each year and subtracted accrued dividends under scenarios in which they would be paid. Then, we added the terminal value to the remaining cash flow available to equity holders by year and discounted back to the current year using the discount rate. Lastly, the value was applied to each of the security holders based on the liquidation preferences and the capitalization table.

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The following table details stock options granted from July 1, 2012 to September 30, 2013:

Grant Date	Exercise Price	Number of Shares Granted	Black-Scholes
7/12/2012	$ 8.78	195,471	$ 3.40
4/19/2013	$ 4.42	194,065	$ 1.73

On November 21, 2013, additional options were granted.

Grant Date	Exercise Price	Number of Shares Granted	Black-Scholes
11/21/2013	$ 4.94	65,521	$ 2.63

At December 31, 2013, options to purchase 841,104 shares of our common stock were outstanding. The aggregate intrinsic value of these options was $7.9 million of which $4.6 million related to 468,787 vested options and $3.3 million related to 372,337 unvested options, based on an initial public offering price of $15.00 per share.

The guideline public companies selected for the purpose of deriving a valuation multiple as an input to the PWERM are relatively large capitalization companies with diversified product lines that produce relatively stable positive earnings. The guideline public companies include the following:

Actavis, Inc.

Allergan, Inc.

AstraZeneca PLC

Bristol-Meyers Squibb Company

Forest Laboratories, Inc.

Hospira, Inc.

Momenta Pharmaceuticals, Inc.

Mylan, Inc.

Sanofi SA

Teva

These guideline public companies all have similar characteristics to the company in one or all of the characteristics listed. The portfolios of these guideline public companies focus on in-licensing products or technology and developing, marketing and distributing branded generic and specialty pharmaceuticals either directly to customers or through wholesalers. Each of the companies has product approvals in more than one country outside the United States. The companies listed may compete with the company in more than one setting, e.g., hospital settings or infusion centers. To account for differences in the number of products, types of products, size, working capital, liquidity, etc., a quantitative adjustment factor was calculated and applied to each multiple for the selected earnings measures to arrive at an adjusted multiple.

The Black-Scholes option pricing model was used to calculate the fair value of stock options granted. This model requires us to estimate risk-free interest rate, volatility, expected term (in years), and expected dividend. The risk-free rate assumption was based on U.S. Treasury instruments whose term was consistent with the expected term of the stock options. The expected stock price volatility was determined by examining the historical volatilities for guideline public companies as we did not have any trading history in our common stock. To calculate the volatility of each selected company, we

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calculated the standard deviation of the difference in the natural logarithms of the daily closing prices for each company, pursuant to the expected term of each grant. A simple average of the selected companies' volatilities was then calculated to generate our expected stock price volatility. The expected term of stock options represents the average of the vesting period and the contractual life of the option for employees and the life of the option for consultants. The expected dividend assumption is based on our history and expectation of future dividend payouts. Changes in the estimated forfeiture rates are reflected prospectively.

Offering Price

Our initial public offering price is $15.00 per share. This per share price does not take into account the current lack of liquidity for our common stock. By comparison, our estimate of the fair value of our common stock was $4.94 per share as of November 21, 2013. We used the probability-weighted expected returns method to arrive at a single value estimate after using the direct to equity discounted cash flow method to calculate the present value of estimated cash flows available to the company in each of four scenarios: initial public offering; merger / acquisition; no exit / private company; and dissolution. The result was an allocation of possible future enterprise values and cash flows available to each security class. Additional discounts were applied to the common stock for lack of marketability and for lack of control. For additional information regarding the common stock valuation, see " Valuation of Common Stock."

The difference between the fair value of our common stock as of the most recent common stock valuation date and the initial public offering price for this offering is primarily the result of the anticipated conversion of all outstanding shares of our preferred stock into common stock upon completion of this offering, thus eliminating the superior rights and preferences of our preferred stock as compared to our common stock. The elimination of such superior rights and preferences, including accrued dividends (totaling approximately $17.1 million as of December 31, 2013), since inception of the Company and liquidation preferences, results in a larger portion of the value being assigned to the common stock.

Furthermore, we note that as is typical in initial public offerings, the initial public offering price for this offering was not derived using a formal determination of fair value, but was determined by negotiation between us and the underwriters. Among the factors that were considered in setting this price were the size of this offering, our prospects and the history of and prospects for our industry, the general condition of the securities markets and the recent market prices of, and the demand for, publicly-traded common stock of generally comparable companies. Other factors that contributed to the difference were:

- the public filing of a registration statement with the Securities and Exchange Commission,
- preparation to launch a roadshow for this offering,
- continued strength of the IPO market relative to the October and November 2013 timeframe, and
- the submission to the FDA of an NDA for Ryanodex in January 2014.

The initial public offering price reflects our discussions with the underwriters and the factors above and was not determined using the methodology used by management and the third party valuation firm to value our stock in November 2013 (or on any other valuation date). Because the initial public offering price was determined through discussions with the underwriters and was not determined using the methodology that management and the third party valuation firm used to value our stock in November 2013, we are not able to quantify the amount that any particular factor contributed to the determination of the initial public offering price.

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BUSINESS

Company Overview

We are a specialty pharmaceutical company focused on developing and commercializing injectable products, primarily in the critical care and oncology areas, using the FDA's 505(b)(2) 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. Through our senior management team's extensive knowledge of the marketplace, 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 launch of our novel formulation of EP-1101 (argatroban).

Our broad and diverse disclosed product portfolio includes two approved products and six distinct product candidates in late-stage development, which we plan to register globally. Our two most advanced product candidates are EP-3101 (bendamustine RTD), a proprietary intravenous version of the chemotherapeutic agent that is marketed by Teva under the brand name Treanda, and Ryanodex (dantrolene for MH), a proprietary intravenous version of an approved treatment for malignant hyperthermia. Our NDA for EP-3101 (bendamustine RTD) was submitted to the FDA on September 6, 2013, and we have a PDUFA goal date of July 6, 2014. We believe that bendamustine represents a

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branded peak annual sales opportunity in the United States of $608 million. We submitted an NDA for Ryanodex in January 2014. Our currently disclosed product portfolio consists of:

Product	U.S. Brand Reference Drug	Description	Indication	2012 U.S. Branded Sales	Status
EP-3101 (bendamustine ready to dilute, or RTD)	Treanda	Chemotherapeutic agent	Chronic lymphocytic leukemia; Indolent non-Hodgkin's lymphoma	$608 million[1]	NDA submitted
EP-3102 (bendamustine short infusion time)	Treanda	Chemotherapeutic agent	Chronic lymphocytic leukemia; Indolent non-Hodgkin's lymphoma	$608 million[1]	In pivotal clinical trials
Ryanodex (dantrolene for MH)	Dantrium/ Revonto	Muscle relaxant	Malignant hyperthermia	$20 million[2]	NDA submitted in January 2014; orphan drug designation received
EP-4104 (dantrolene for EHS)	No drug currently approved	Muscle relaxant	Exertional heat stroke	N/A	Orphan drug designation received for heat stroke
EP-6101 (bivalirudin)	Angiomax	Anti-Coagulant; thrombin inhibitor	Percutaneous transluminal angioplasty	$502 million[1]	Type C meeting with the FDA completed in the fourth quarter of 2013
EP-5101 (pemetrexed)	Alimta	Chemotherapeutic agent	Lung cancer and mesothelioma	$1,122 million[1]	Formulation work complete
EP-1101 (argatroban)	Argatroban	Anti-coagulant; thrombin inhibitor	Heparin-induced thrombocytopenia	$99 million[2]	Approved (US); marketed by The Medicines Company and Sandoz
EP-2101 (topotecan)	Hycamtin	Chemotherapeutic agent	Ovarian, cervical and small-cell lung cancer	$25 million[3]	Approved (EU); not marketed; no current plans to commercialize in the U.S.

(1) Based on publicly filed reports with the SEC.

(2) Based on independent market research and management's estimates extrapolated therefrom.

(3) Based on independent market research.

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Based on market data, we estimate that the U.S. generic injectable industry reported approximately $7.0 billion in sales in 2012 and grew at a compound annual growth rate of 17% over the last five years. Based on industry data, we believe that the U.S. generic injectable market will continue to grow at a compound annual growth rate of 11.6% 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 worlwide market for the branded reference drugs addressed by our disclosed product portfolio is approximately $4 billion and we have begun development of several additional products that could capture an additional share of the overall injectable market. We believe that, if our product candidates are approved, we can cost-effectively commercialize our product portfolio with our own specialty sales force in the United States, thereby maximizing our economics. Our targeted, specialty sales force will focus on GPOs, 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 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.

We are managed by a team with significant executive experience in branded and generic pharmaceuticals. Our senior management team has over 100 years of combined experience at leading pharmaceutical companies. We have developed company-wide knowledge in the key disciplines required for success of our model, including: the ability to choose product candidates, product development and formulation, the 505(b)(2) regulatory pathway and patent infringement and related patent litigation. Our senior management team includes Scott Tarriff, our President and Chief Executive Officer, David Riggs, our Chief Financial Officer, and other experienced executives. Prior to forming Eagle, Mr. Tarriff was President and Chief Executive Officer of Par Pharmaceutical Companies, Inc. from 1998 to 2006. Mr. Tarriff spearheaded the most successful product introductions in Par's history, including generic versions of Prozac, Paxil, Megace O/S, Ultracet and Par's first branded pharmaceutical product, Megace ES. David Riggs, our Chief Financial Officer, was previously the Chief Executive Officer of eXegenics Inc., a publicly-traded pharmaceutical company that is now OPKO Health Inc., and has served as the Chief Financial Officer of various private and publicly-traded and private pharmaceutical companies. Ken Degen, our Senior Vice President, Hospital Sales and Marketing, spent over 20 years with Schering-Plough Pharmaceuticals where he served in a variety of

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roles. Mr. Degen built a sales team that was involved in the promotion of multiple Schering-Plough brands with annual sales ranging from $50 million to approximately $1 billion. Dr. Peter Grebow, our Executive Vice President of Research and Development, held several key positions with Cephalon, Inc. (now Teva Pharmaceuticals), including Senior Vice President, Worldwide Business Development and Senior Vice President, Drug Development. Dr. Paul Bruinenberg, our Chief Medical Officer, has more than 28 years of experience in clinical operations and development.

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 $12.3 billion in 2012. 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 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

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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) an ANDA or 505(b)(2) 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, or 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) was essential to the approval of the application and was 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.

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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 bioequivelance 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
Paragraph IV Certification Required	Yes	Yes	No
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 two approved products and six distinct product candidates in advanced development. Together, our disclosed portfolio targets an overall U.S. market of approximately $4 billion in annual branded reference drug revenue. 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;

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reduction in the volume of drug needed to be injected, potentially expanding the application to additional medical situations;

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 has been 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 captured 28% of the total argatroban market. Our competitors' undifferentiated ANDAs referencing the branded drug remain tentatively approved by FDA and, because they have not been able to prove invalidity or noninfringement of the applicable patents, must await patent expiration on June 30, 2014 before full approval and commercialization. When these generic competitors do enter the market, our market share and product price could decline. The extent of the decline will depend upon such factors as the pricing for these generic products, the number of generic competitors, and our customer's willingness to use a product that does not provide the benefits provided by our version of argatroban.

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, or KOL's, to indentify 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. Our President and Chief Executive Officer, Scott Tarriff, who spearheaded the most successful product introductions in Par Pharmaceuticals' history, leads our management team in selecting drug candidates with significant branded product sales that can be optimized by creating new formulations of branded reference drugs and seeking approval via the 505(b)(2) pathway.

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 ten owned or exclusively-licensed U.S. issued patents and twelve filed U.S. patent applications, as well as several patent applications that have been filed in

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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 plan to establish a small, specialty sales force that will focus on GPOs, hospital systems and key stakeholders in acute care settings, primarily hospitals and infusion centers. 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.

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Continue to build a robust intellectual property portfolio. Our patent estate includes ten owned or exclusively-licensed U.S. issued patents and twelve 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, consisting 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 short infusion time) for Chronic Lymphocytic Leukemia and Non-Hodgkin's Lymphoma

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 are developing a ready to dilute, or RTD, liquid formulation of bendamustine in two presentations:

- Our first-generation product, 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 recently submitted a 505(b)(2) NDA and were assigned a July 6, 2014 PDUFA goal date; and

- Our second-generation product, EP-3102 (bendamustine short infusion time), is an RTD liquid that can be administered in a shorter time-frame than current drugs on the market.

Both EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time), if approved, will 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-Marketed Bendamustine Product

Teva currently markets its bendamustine product under the trade name Treanda. Treanda is currently available in two presentations: 25mg and 100mg single-use vials, both containing lyophilized powder that requires reconstitution with sterile water prior to administration. Both presentations, once reconstituted, are infused from a 500mL IV infusion bag for 30 minutes to patients with CLL and for 60 minutes to patients with NHL, on days one and two of a 28-day chemotherapy treatment cycle. Treanda was recently approved in a new RTD formulation, expected to be commercialized beginning in the first half of 2014. We expect that the commercialization of Teva's Treanda RTD formulation will successfully convert a large portion of the existing lyophilized market to a liquid RTD market. Upon launch of EP-3101 (bendamustine RTD), we believe that we will be able to effectively compete with Treanda RTD based on various factors, including price, without the added burden of transitioning customers from a lyophilized product. U.S. sales of Treanda in 2012 were $608 million. Due to Treanda's orphan drug and pediatric exclusivities for both the CLL and NHL indications, the FDA may be precluded from approving EP-3101 (bendamustine RTD) for those same indications until September 2015 (assuming resolution of the 30-month stay prior to that time) and May 2016, respectively.

Limitations of Treanda

There are currently several drawbacks with reconstituting a lyophilized oncology drug, such as Treanda. First, there is potential for dosing errors to occur when mixing Treanda with sterile water.

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The pharmacist or pharmacy technician may add too much or too little of the diluent, or even use the wrong diluent. 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. For these and other reasons, the Joint Commission on Accreditation of Healthcare Organizations, known as 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. In addition, the reconstitution of drugs such as Treanda is time consuming resulting in an inefficient work flow. 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.

Eagle's Solution: EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) Presentations

Both generations of our bendamustine product are liquid formulations, eliminating the need to reconstitute the drug prior to use. As a result, we believe there is less potential for dosing errors, less exposure to cytotoxic vapors and a more efficient work flow. EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) are both RTD formulations, as preferred by the Joint Commission. Also, because both EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) will be available in a multi-dose vial with extended vial stability of 28 days, they will reduce the amount of drug waste that typically occurs in oncology settings.

The following chart illustrates certain potential benefits of EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) over the currently marketed branded drug, Treanda:

Key Product Characteristics	**Treanda**	**EP-3101/EP-3102**	**EP-3101/EP-3102 Potential Benefits**
RTD	No, must be reconstituted	Yes, liquid formulation	Reduced risk of dosing errors, less exposure to cytotoxic vapors and time savings; Joint Commission preferred
Stability after first use	30 minutes in vial	28 days in vial	Reduced product waste
Infusion Time	30-60 minutes	Less than 30 minutes (EP-3102)	Less time in infusion chair for patient; greater office efficiencies due to less nursing time with each patient
Fluid Volume	500mL	Less than 500mL (EP-3102)	Less potential for patient fluid load and edema

We engaged two market research firms, Phoenix Marketing International and Healogix, to conduct market research with healthcare stakeholders regarding the value of our proposed bendamustine presentations. We commissioned three studies with over 100 oncologists and oncology nurses in total, the research objectives of which were to explore experiences and attitudes within oncology practices regarding the currently marketed lyophilized Treanda product, investigate the benefits and drawbacks of such product, and gauge reactions to both of our proposed bendamustine presentations. Based on the feedback received, there was a preference for both of our liquid bendamustine presentations. Specifically, oncologists and oncology nurses who regularly prepare and use the currently marketed lyophilized Treanda product appreciated the ease-of-use, increased safety profile of a liquid RTD product candidate (from both a drug exposure and a dosing error perspective), as well as the time savings associated with administering an RTD formulation. Also noted were the benefits of longer drug stability of EP-3101's (bendamustine RTD) and EP-3102's (bendamustine short infusion time) multi-dose vial.

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In addition, with respect to EP-3102's (bendamustine short infusion time) infusion bag administration, physicians and nurses were asked to compare the value of our short infusion RTD product candidate with the lyophilized Treanda product. On a scale of 1 to 10 (with 10 being the best), comparing the attributes of each product, oncologists rated the lyophilized Treanda product a 6.0 on average and our product candidate an 8.5 on average. Oncology nurses rated Treanda a 6.2 on average and our product candidate an 8.5 on average. We believe that this demonstrates the incremental value associated with our product candidate.

Finally, respondents noted that the additional benefits of administering EP-3102 (bendamustine short infusion time) in a RTD smaller infusion bag include: less time in the infusion chair for patients, improved workflow and increased productivity for oncology practices, less likelihood of weight gain and edema for all patients because of the smaller volume of liquid administered to patients, and the potential to treat elderly patients who suffer from renal impairment and who cannot handle 500mL of 0.9% sodium chloride typically infused during Treanda drug administration.

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

We have submitted a 505(b)(2) NDA for our first generation bendamustine product, EP-3101 (bendamustine RTD), and received a PDUFA goal date of July 6, 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 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 our second generation product candidate, EP-3102 (bendamustine short infusion time). We are currently dosing patients in our Phase 1 pivotal clinical trial for that product presentation.

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

Ryanodex (dantrolene) for Malignant Hyperthermia

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, or 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

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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.

Currently-Marketed Dantrolene Products for MH

The two current 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 worldwide market for MH drugs is approximately $40 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, or 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 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 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 for MH)

Eagle is developing a differentiated formulation that, if approved, will be sold under the brand name, Ryanodex, for the treatment of MH. The presentation will be a 5mL vial containing 250mg of dantrolene in lyophilized powder form.

We believe that the immediate benefits of our Ryanodex formulation will be clinically significant in critical care situations. Specifically, we expect Ryanodex (dantrolene for MH) will reduce the amount of time to reconstitute and administer dantrolene from the current 15 to 20 minutes, to one minute, as the anesthesiologist will be able to mix and administer a dose of 250mg from a single vial of Ryanodex (dantrolene for MH) in contrast to the current need to mix and administer up to 12 or more vials. 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 will also be reduced from up to 720mL or more with Dantrium and Revonto to only 5mL with Ryanodex (dantrolene for MH), 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 (dantrolene for MH) product. All

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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 Eagle's Ryanodex product candidate on a scale of 1 to 10 (10 being the best), anesthesiologists and pharmacists rated Ryanodex (dantrolene for MH) 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 (dantrolene for MH) and administer it to their patients.

Ryanodex Clinical Development and Regulatory Status

A pharmacokinetic study was completed on August 2013 after which we had a pre-NDA meeting with the FDA. At this meeting, the FDA asked us to provide additional clinical/nonclinical information to further evaluate the size of the safety database necessary at the time of NDA filing. A response to the requested information was submitted to the FDA in October 2013. We submitted our 505(b)(2) application for Ryanodex (dantrolene for MH) in January 2014. Our 505(b)(2) NDA will be based, in part, on efficacy data derived from animal studies in accordance with the FDA's "Animal Rule."

We also completed a pilot study that was designed to test whether Ryanodex would have a beneficial effect on treatment outcomes of a metabolic crisis. In the study, MH susceptible swine were anesthetized (using a non-MH triggering protocol) and their core temperatures were gradually increased to approximately 41.5°C from a baseline of approximately 38-39°C. At this point, all animals were removed from the warming blankets and assigned to one of three different treatment scenarios. One animal received no treatment and data from this animal showed a continued increase in core and skeletal muscle temperature, with a worsening of the pathophysiologic parameters, until the animal died of a cardiac arrest in under an hour. Three animals were provided with the current standard of care for EHS, which involved external cooling and IV hydration. This cooling technique was successful in reducing their core and skeletal muscle temperature, but only nominally. All three animals subsequently died or were euthanized within one hour. Five animals were provided with the same cooling techniques as the second group but were also given a 2.5 mg/kg dose of Ryanodex. In each of the five animals, a notable reversal in the pathophysiologic signs of the hypermetabolic crisis was observed within ten minutes of Ryanodex administration. The return of these parameters to baseline was accompanied with a more rapid cooling of both core and skeletal muscle temperature. All five animals were adjudged to be out of the metabolic crisis within one hour of Ryanodex administration. All five animals were taken off of mechanical ventilation once the anesthesia had worn off but one animal subsequently died as a result of post-extubation complications (which was not considered to be a direct consequence of the hypermetabolic crisis and not considered a reflection of failure to resolve the hypermetabolic crisis). The prompt administration of 2.5 mg/kg of Ryanodex, combined with the standard of care for EHS, produced dramatic improvement, if not full resolution, of the heat stroke and hypermetabolic crisis within one hour of Ryanodex administration.

EP-4104 (dantrolene) for Exertional Heat Stroke

Exertional heat stroke, or 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.

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EHS is one of the top three 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 Dantrolene 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 identical 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 (dantrolene for EHS) Clinical Development and Regulatory Status

EP-4104 (dantrolene for EHS) has completed a Phase 1 clinical study in human volunteers and we are currently designing a pivotal clinical study to support our NDA submission that we anticipate will start in mid-2014. Additionally, we were granted Orphan Drug designation for EP-4104 (dantrolene for EHS) in September 2012.

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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 in 2012 were approximately $2.6 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 form 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.

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EP-5101 (pemetrexed) Clinical Development and Regulatory Status

We are currently performing pre-clinical formulation and toxicology studies on EP-5101 (pemetrexed). We plan to seek EU and U.S. approval of EP-5101 (pemetrexed) for use in non-small cell lung cancer and mesothelioma. We are anticipating a hybrid application filing in 2015 to the European Medicines Agency, or EMA, closely followed by a 505(b)(2) NDA filing 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. Worldwide sales of Angiomax were approximately $548 million in 2012.

Limitations of Angiomax

The powder form of Angiomax must be reconstituted before administration at the beginning of a catheter laboratory, or 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. Pharmacopeia, 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.

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.

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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) Clinical 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. We anticipate submitting 505(b)(2) NDA in the first half of 2015.

EP-1101 (argatroban) for Heparin-Induced Thrombocytopenia

Argatroban is an anti-coagulant originally developed for the treatment of heparin-induced thrombocytopenia, or 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 Product

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.

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: EP-1101 (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. Based on the expected expiration date of patents covering GSK's branded reference product, generic formulations of the drug may not enter the market until mid-2014, unless they succeed in invalidating or proving non-infringement of Sandoz's patents in paragraph IV litigation.

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

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overall cost of treatment. Further, our argatroban product obtained meaningful exclusivity with respect to any generic versions of the branded reference products, given that it launched for commercial sale in September 2011, nearly three years prior to the anticipated June 2014 market entry for generic versions of the branded reference products, and only shortly after Sandoz obtained approval in May 2011 for its RTU 125mL presentation of argatroban and prior to West-ward's approval of its 250mL presentation of argatroban in January 2012. 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 28% that we expect to continue to grow.

EP-2101 (topotecan) for Ovarian, Cervical and Small-Cell Lung Cancers

Topotecan is a chemotherapeutic agent for use in ovarian, cervical and small-cell lung cancers. GlaxoSmithKline currently markets Hycamtin in the United States as the branded approved formulation of topotecan. The current market for Hycamtin is approximately $65 million per year. We currently own all rights to EP-2101, our proprietary formulation of topotecan, pursuant to an agreement with SciDose wherein we were assigned the rights to all intellectual property related to our formulation of topotecan. EP-2101 (topotecan) was approved by the EMA in December 2011 for use in Europe and is our second approved product. We have not yet launched EP-2101 (topotecan) in Europe and we cannot anticipate at this point in time when we will enter the European market. In August 2009, we submitted 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) in the United States. However, like EP-1101 (argatroban), we believe that the development, approval and commercialization of EP-2101 (topotecan) provides validation of our drug development expertise, regulatory strategy and business model.

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.

Product Commercialization

Historically, we have chosen to out-license the commercial rights for products we have developed, such as EP-1101 (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 EP-1101 (argatroban) with these important customers. For more information regarding this arrangement, see below under " License Agreements."

In the future, however, we intend to develop and 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

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portfolio, while participating in a meaningful way in the global economics of all drugs that we bring to the market. We believe that a small, focused specialty sales force will generally be sufficient to successfully commercialize our products because the nature of our products means that the majority of detailing points for our sales force are likely to be medium and large healthcare systems that operate multiple hospitals and purchase through group purchasing organizations, as well as hospital-based physicians and hospital pharmacists. We expect these contained detailing points will 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.

In addition to the above commercial execution strategy, following this offering, and assuming approval of Ryanodex on or about our scheduled PDUFA goal date in July 2014, we intend to launch Ryanodex (dantrolene for MH) into the U.S. market in 2014. The primary target audience for Ryanodex (dantrolene for MH) will be anesthesiologists and hospital pharmacists. Additionally, our sales representatives will call on nurse anesthetists, operating room nurses and also the purchasing department within these institutions. The sales team will be supported by a group of marketing individuals that will be providing materials to support product messaging.

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 dialogue 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 in two additional sites, one in the United States and the other in Italy.

Given the range of difficulties we may encounter in manufacturing our sterile injectable product candidates, we plan to seek FDA approval to manufacture our disclosed product candidates in an additional location for each product. Due to FDA guidelines, we will not submit for the approval of

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an additional manufacturing location until after the final FDA approval for a given product. Therefore, we expect to be dependent upon the single initial manufacturing site for approximately one year after approval. Upon approval of additional manufacturing locations, we will have back-up manufacturing sites for each product in the event that a given plant has difficulties. Where possible over time, we plan to add additional products to our back-up locations, although it may not be economically practical to follow this strategy for all of our product candidates.

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 three 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) 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 five pending U.S. patent applications, and six 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 no pending applications 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

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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-US 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-US Regions, our license in the applicable Ex-US 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-US Regions.

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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 exploit 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 $5,000,000. 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 under the agreement. 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.

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Settlement Agreement and Related Supply and Distribution Agreement with Sandoz

In January 2013, we entered into a settlement agreement with Sandoz Inc., or 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, or 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, sublicensable, 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

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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, or 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, or the Robert One (bendamustine) Subject Products, and granted us an exclusive, sublicensable, 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

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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, or the Robert One (pemetrexed) Subject Product and granted us an exclusive, sublicensable, 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 (permetrexed) Subject Products commercialized in the United States.

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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, or 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,

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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, or cGLP, regulations;
- submission to the FDA of an Investigational New Drug, or 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, or 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, or 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

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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

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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 REMS to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS 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 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.

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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, or 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

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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.

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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 pharmacologic 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

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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, or EU, we may seek marketing authorization under either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The European Medicines Agency, or 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,

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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, or OIG, the Office for Human Research Protections, or OHRP, and the Office of Research Integrity, or 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 an 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

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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 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 a federal healthcare program. 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.

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

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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 Payment Sunshine Act created under Section 6002 of the Affordable Care Act and its implementing regulations require that 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 is required by March 31, 2014 (and by the 90th day of each subsequent calendar year). Disclosure of such information is to be made on a publicly available 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.

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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 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 proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative 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 could affect our future results of 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, that began in 2011;

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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;

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;

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, effective April 1, 2012.

In addition, 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. 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. 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. 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

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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 December 31, 2013, we had a total of 20 full-time employees in the United States, two part time employees in the United States, and one full time consultant in India, of which ten were in research and development, 4 were in regulatory affairs and quality control compliance, one was in Sales and marketing, four were in administration and two 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.

Facilities

As of December 31, 2013 the Company conducted all of its 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 the Company was located at 470 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 since September 2007.

Legal Proceedings

In March 2012, Hikma purchased from us for $3.5 million certain assets relating to a generic drug, diclofenac/misoprostol tablets. That drug was the subject of an ANDA filed by us with the FDA. The ANDA is still pending before the FDA, and we continue to expect it to receive approval. The terms of the sale were set forth in a March 2012 Asset Purchase Agreement, or Hikma APA. On June 24, 2013, Hikma Pharmaceutical Co., Ltd., or 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. On August 27, 2013, we filed an answer to Hikma's complaint, which denied Hikma's claims, and asserted a counterclaim alleging that Hikma by its actions had repudiated the Hikma APA.

Should Hikma prevail on its claims that we breached the Hikma APA or intentionally failed to disclose alleged product defects, we could be required to pay substantial damages, including, but not limited to, the return of the $3.5 million purchase price plus interest and other damages.

We are vigorously defending these claims and we do not believe that Hikma is entitled to any damages because Hikma's purported termination violated the terms of the Hikma APA and believe that the claims of non-disclosure of manufacturing product defects are without merit. Given the early stage in the litigation, we are unable to predict the likelihood of success of Hikma's contract breach and fraud claims.

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In addition to the matter described above, from time to time, third parties may assert patent infringement claims against us in the form of letters, litigation, or other forms of communication; we may be subject to other legal proceedings and claims in the ordinary course of business, including claims of alleged infringement of trademarks, copyrights and other intellectual property rights; employment claims; and general contract or other claims. We may, from time to time, also be subject to various legal or government claims, disputes, or investigations. Such matters may include, but not be limited to, claims, disputes, or investigations related to breach of contract, employment, intellectual property, government regulation, or compliance or other matters.

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MANAGEMENT

Executive Officers, Directors and Key Employees

The following table sets forth certain information regarding our executive officers, directors and key employees as of December 31, 2013:

Name	Age	Position(s)
Executive Officers and Key Employees		
Scott Tarriff	54	President and Chief Executive Officer, Director
David E. Riggs	61	Chief Financial Officer
Paul Bruinenberg, M.D.	54	Chief Medical Officer
Steven L. Krill, Ph.D.	54	Chief Scientific Officer
Daniel O'Connor	33	Finance Director
Ken Degen	55	Senior Vice President, Hospital Sales and Marketing
Peter Grebow, Ph.D.	67	Executive Vice President of Research and Development
Non-Employee Directors		
Jay Moorin[2]	62	Director
Steven Ratoff[1]	71	Director
Sander Flaum[1]	76	Director
Michael Graves[1][2]	51	Director
Alain Schreiber, M.D.	58	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

Executive Officers and Key Employees

Scott Tarriff is the founder and has served as our President and Chief Executive Officer and as a member of our board of directors since our inception in January 2007. Prior to joining Eagle, Mr. Tariff held various executive positions at Par Pharmaceutical Companies, Inc., a publicly-traded developer, manufacturer and marketer of specialty pharmaceuticals, including as president and chief executive officer from September 2003 to September 2006, after joining Par in 1998. Mr. Tarriff also served on Par's board of directors from 2002 to September 2006. Prior to that, Mr. Tarriff held various positions with Bristol-Meyers Squibb, a publicly-traded biopharmaceutical company, including senior director-marketing. Mr. Tarriff has served as a director of Synthetic Biologics, Inc., a publicly-traded biotechnology company, since February 2012 and previously served on the board of directors of Clinical Data, Inc., a publicly-traded pharmaceutical company, from September 2009 to April 2011 when Clinical Data was acquired by Forest Laboratories, Inc. Mr. Tarriff holds a B.S. in marketing from Pennsylvania State University and an M.B.A. from Rider College. The board of directors believes that Mr. Tarriff's extensive knowledge of our business, his management experience in the pharmaceutical industry, as well as his operational expertise, qualifies him to serve on our board of directors and as our President and Chief Executive Officer.

David E. Riggs has served as our Chief Financial Officer since November 2013. From May 2010 to October 2013, Mr. Riggs served as a healthcare consultant at various biotechnology and pharmaceutical companies. From March 2006 to May 2010, Mr. Riggs served as chief financial officer of Ferring Pharmaceuticals Inc., a private biopharmaceutical company devoted to isolating, developing and marketing innovative products in the fields of reproductive health, urology, gastroenterology, endocrinology and osteoarthritis. From January 2003 to September 2005, Mr. Riggs held various positions at eXegenics Inc., a publicly-traded pharmaceutical company that is now OPKO Health, Inc.,

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including most recently as its chief executive officer. Mr. Riggs served as senior vice president and chief financial officer of Axys Pharmaceuticals, Inc., a publicly-traded pharmaceutical company, from March 2000 until it was acquired by Applera Corporation in November 2001. From February 1992 to February 2000, Mr. Riggs held various positions at Unimed Pharmaceuticals, Inc., a private company focused on developing and commercializing products in human immunodeficiency virus, oncology and urology specialty markets. Previously, Mr. Riggs held various positions at Fujisawa Pharmaceuticals, Inc., a private pharmaceutical company that was acquired by Astellas Pharma Inc., including treasurer and director of financial planning and analysis. Mr. Riggs holds a B.S. in accounting from the University of Illinois and an M.B.A. from DePaul University.

Paul Bruinenberg, M.D. has served as our Chief Medical Officer and Head of Research & Development since November 2011. From May 2007 to October 2011, Dr. Bruinenberg served as senior medical director of Aradigm Corporation, a publicly-traded pharmaceutical company developing and commercializing drugs delivered by inhalation for the treatment of severe respiratory disease, with responsibility for developing Aradigm's early stage respiratory compounds. From May 2006 to May 2007, Dr. Bruinenberg served as vice president of clinical research of Fulcrum Pharma Developments, Inc., a subsidiary of Fulcrum Pharma PLC that develops drugs, with responsibility for leading development teams. In April 2003, Dr. Bruinenberg founded Biotrack Consultancy, a provider of consulting and advising services in the areas of clinical research, development, regulatory compliance and clinical operating processes. Previously, Dr. Bruinenberg served as medical director Europe of Yamanouchi Pharmaceutical Co., Ltd., now part of Astellas Pharma Ltd., with responsibility for leading clinical teams in registering compounds worldwide. Beginning in 1995, Dr. Bruinenberg held several positions of increasing responsibility during a five-year tenure at F. Hoffmann-La Roche AG, a global healthcare company, including international medical manager in the areas of cystic fibrosis, asthma, chronic obstructive pulmonary disease and transplant and global business leader in the areas of respiratory and transplant. During this tenure at Roche, Dr. Bruinenberg played a pivotal role in bringing three products to the market, Pulmozyme®, Cellcept® and Zenapax®. Earlier in his career, Dr. Bruinenberg was a practicing physician and researcher for eight years and managed the Cardiac Care Unit in Amstelveen Hospital. Dr. Bruinenberg holds a medical degree from the medical school of the University of the Stellenbosch, South Africa, an M.B.A. from the University of Nijenrode in the Netherlands and an M.B.A. from Rochester University.

Steven L. Krill, Ph.D. has served as our Chief Scientific Officer since February, 2013. He held the position of Vice President of Pharmaceutical Development from October 2011 to February 2013. Dr. Krill served as the vice president of Scientific Affairs at Teva Parenteral Medicines from March 2009 to August 2011. Dr. Krill held the positions of Vice President Pharmaceutical Research and Development (December 2005 until March 2009) and Director of Pharmaceutics and Investigational Supplies (from May 2002 to December 2005) at Boehringer Ingelheim. Prior to that, Dr. Krill held various management positions at Lipocine Inc., Novartis Pharmaceuticals and Abbott Laboratories Dr. Krill is an author of over 30 publications and inventor of multiple patents in the area of drug delivery. Dr. Krill holds a B.S. in pharmacy and an M.S. in pharmaceutical sciences from the University of Cincinnati and a Ph.D. in Pharmaceutics from the University of Utah.

Daniel O'Connor joined our company in 2007 and served as our Finance Director since 2011. From May 2013 to November 2013 he also served as our Interim Chief Financial Officer. From January 2005 to October 2007, Mr. O'Connor held various management positions with Ethicon Inc., a Johnson & Johnson Company subsidiary that develops surgical products for laparoscopic and minimally invasive procedures, including senior analyst and analyst roles. During this time, Mr. O'Connor also acted as a lead finance liaison with Ethicon's joint venture with Omrix Biopharmaceuticals, Inc. From June 2002 to December 2004, Mr. O'Connor held several finance positions at Ranbaxy Pharmaceuticals Inc., a wholly-owned subsidiary of Ranbaxy Inc. that markets

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generic products in the U.S., including most recently, financial analyst. Mr. O'Connor holds a B.S. in business administration from West Virginia University and an M.B.A. from Rutgers University.

Ken Degen has served as our Senior Vice President, Sales and Marketing since January 2009. Prior to Eagle, Mr. Degen held various management positions in the areas of sales, marketing and managed care during his over 20-year tenure at Schering-Plough Pharmaceuticals, a prescription pharmaceutical manufacturer and marketer that merged with Merck & Co. in 2009, including as director of sales and marketing in Schering-Plough's Global Diversified Products Group, a $2 billion business unit, and as a co-chair of a research institute team charged with evaluating product life cycle management opportunities. Mr. Degen holds a B.S. in business administration from George Mason University.

Peter Grebow, Ph.D. has served as our Executive Vice President of Research and Development since October 2013. From 1991 to March 2011, Dr. Grebow held several senior management positions at Cephalon Inc., a biopharmaceutical company that was acquired and became a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. in 2011, including as executive vice president, Cephalon Ventures, executive vice president technical operations, senior vice president, worldwide business development and senior vice president, drug development. Dr. Grebow has served on the board of directors of Optimer Pharmaceuticals, a publicly-traded biopharmaceutical company, since February 2009, the board of directors of Q Therapeutics Holdings, Inc., a publicly-traded pharmaceutical company, since December 2011, the board of directors of GenSpera, Inc., a publicly-traded pharmaceutical company, since May 2012 and the board of directors of a private pharmaceutical company since December 2011. Dr. Grebow holds an A.B. degree in chemistry from Cornell University, an M.S. in chemistry from Rutgers University and a Ph.D. in physical biochemistry from the University of California, Santa Barbara.

Non-Employee Directors

Jay Moorin has served as a member of our board of directors since March 2007. In October 2013, our board of directors elected Mr. Moorin chairman of the board. Since 1998, Mr. Moorin has served as a founding general partner of ProQuest Investments, a healthcare venture capital firm. From 1991 to 1998, Mr. Moorin served as president and chief executive officer of Magainin Pharmaceuticals Inc., a publicly-traded biopharmaceutical company, and also served as chairman of its board of directors from 1996 to 1998. Previously, Mr. Moorin served as managing director of healthcare banking at Bear Stearns & Co. Inc. and vice president of marketing and business development at a division of the ER Squibb Pharmaceutical Company. Currently, Mr. Moorin serves on the board of directors of a private radiation therapy company, is an advisor to DPT Capital Management, LLC, an investment firm, and serves as a trustee of the Equinox Funds Trust. Mr. Moorin held the position of adjunct senior fellow of the Leonard Davis Institute of Health Economics at the University of Pennsylvania from 1997 to 2012. Previously, Mr. Moorin served on the board of directors of numerous public and private healthcare companies. Mr. Moorin holds a B.A. in economics from the University of Michigan. Our board of directors believes that Mr. Moorin's extensive senior management background and experience in the biotech, investment banking and pharmaceutical industries as well as his service on the board of directors of public and private companies qualifies him to serve on our board of directors.

Steven Ratoff has served as a member of our board of directors since March 2007. Since December 2004, Mr. Ratoff has served as a venture partner of ProQuest Investments. Since January 2010, Mr. Ratoff has served as president and chief executive officer of NovaDel Pharma Inc., a private specialty pharmaceutical company, and Mr. Ratoff has served in a number of interim executive positions since joining NovaDel's board of directors in May 2005. Mr. Ratoff has also served on NovaDel Pharma Inc.'s board of directors since May 2005 and currently serves as its chairman. Prior to NovaDel, Mr. Ratoff held various executive positions with Cima Labs, Inc., a publicly-traded

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pharmaceutical company that was acquired by Cephalon in 2004, MacroMed, Inc., a private drug development and manufacturing company that was acquired by Protherics PLC in 2007, and Brown-Forman Corporation. Mr. Ratoff holds a B.S. in business administration from Boston University and an M.B.A. from the University of Michigan. Our board of directors believes that Mr. Ratoff's extensive executive experience and background in the global pharmaceutical and consumer products industries as well as his strong financial background qualifies him to serve on our board of directors.

Sander Flaum has served as a member of our board of directors since March 2007. Since January 2005, Mr. Flaum has served as a principal of Flaum Navigators, a healthcare consultancy firm that he founded. Mr. Flaum has also served as the chief executive officer of Flaum Partners, Inc., a healthcare consultancy firm he founded, since August 2004. From 1991 to 2002, Mr. Flaum served as chief executive officer of Robert A. Becker EURO/RSCG, a predecessor to Euro RSCG Life. Prior to that, Mr. Flaum held various positions during an 18-year career at Lederle Laboratories, a private vaccine manufacturer that is now Wyeth Pharmaceuticals, including as marketing director of prescription products, vaccines and generics. Mr. Flaum is a member of the Euro RSCG Healthcare Global Network, and he has served as its co-chairman since 1998. Mr. Flaum also serves on the board of directors of The Fisher College of Business at The Ohio State University, The James Cancer Center at the OSU Medical Center and the Fordham Graduate School of Business. Mr. Flaum is an adjunct professor of leadership at the Fordham University Graduate School of Business, where he chairs the Fordham Leadership Forum. Mr. Flaum holds a B.A. from The Ohio State University and an M.B.A. from Fairleigh Dickinson University. Our board of directors believes that Mr. Flaum's extensive experience in the pharmaceutical and biotech industries qualifies him to serve on our board of directors.

Michael Graves has served as a member of our board of directors since November 2013. In January 2012 Mr. Graves joined the board of directors of RiboCor, Inc. and in December 2011, Mr. Graves was appointed chairman of the board of directors of Nanocopoeia, Inc., both private pharmaceutical companies. From May 2007 to July 2011, Mr. Graves served as the chief executive officer and president of Paddock Laboratories, Inc., a pharmaceutical company engaged in the manufacture, distribution and marketing of bioequivalent generic pharmaceuticals. From September 2005 to November 2006, Mr. Graves served as president of the generic products division at Par Pharmaceutical Companies, Inc., a publicly-traded developer, manufacturer and marketer of specialty pharmaceuticals. While at Par, Mr. Graves oversaw the strategy development of Par's generic pharmaceutical business. Beginning in 1998, Mr. Graves served as director of marketing and sales operations of Par, and in 20