

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**

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**\$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

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**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.

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	<b>Per Share</b>	<b>Total</b>
Public offering price	\$ 15.00	\$ 50,250,000
Underwriting discount <sup>(1)</sup>	\$ 1.05	\$ 3,517,500

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

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(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**

**Cantor Fitzgerald & Co.**

**William Blair**

**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 <sup>(1)</sup>	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](http://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.

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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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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
<b>Total operating expenses</b>	<b>8,557,019</b>	<b>4,360,541</b>	<b>22,134,027</b>	<b>22,370,140</b>
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)
<b>Net loss attributable to common stockholders</b>	<b>\$ (4,387,364)</b>	<b>\$ (3,301,619)</b>	<b>\$ (9,885,250)</b>	<b>\$ (23,316,066)</b>
Basic and diluted net loss per common share <sup>(1)</sup>	\$ (1.44)	\$ (1.09)	\$ (3.25)	\$ (14.11)
Basic and diluted weighted average shares of common stock outstanding <sup>(1)</sup>	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 <sup>(1)</sup>	Pro Forma as Adjusted <sup>(2)</sup>
<b>Balance Sheet Data</b>			
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 occurrence of any of these factors could have a material adverse effect on our business, operating results and prospects.

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

In order to raise additional funds to support our operations, we may sell additional equity or incur debt, which could adversely impact our stockholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

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

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

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

***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 undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other

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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 90<sup>th</sup> 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 persuade the FDA that our products, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

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

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

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational

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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 unforeseen disruption, then we may be prevented from effectively operating our business. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

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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 31<sup>st</sup>, 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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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 (unaudited)	Pro Forma As Adjusted
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.

Table of Contents**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.

Table of Contents**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
<b>Statement of Operations Data</b>				
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
<b>Balance Sheet Data</b>				
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

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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.

Table of Contents*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**

	<b>Three Months Ended December 31,</b>		<b>Increase/ (Decrease)</b>
	<b>2013</b>	<b>2012</b>	
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.

Table of Contents*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,		Increase/ (Decrease)
	2013	2012	
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,		Increase/ (Decrease)
	2013	2012	
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.

Table of Contents*Other Income and Expense*

	Year Ended September 30,		Increase/ (Decrease)
	2013	2012	
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)
<b>Total other income/(expense), net</b>	<b>\$ 1,507,948</b>	<b>\$ (333,164)</b>	<b>\$ 1,841,112</b>

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:

	Total	Fiscal Years Ended September 30,					
		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.

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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
<b>EP-3101</b> (bendamustine ready to dilute, or RTD)	Treanda	Chemotherapeutic agent	Chronic lymphocytic leukemia; Indolent non-Hodgkin's lymphoma	\$608 million <sup>(1)</sup>	NDA submitted
<b>EP-3102</b> (bendamustine short infusion time)	Treanda	Chemotherapeutic agent	Chronic lymphocytic leukemia; Indolent non-Hodgkin's lymphoma	\$608 million <sup>(1)</sup>	In pivotal clinical trials NDA submitted in January 2014; orphan drug designation received
<b>Ryanodex</b> (dantrolene for MH)	Dantrium/ Revonto	Muscle relaxant	Malignant hyperthermia	\$20 million <sup>(2)</sup>	Orphan drug designation received for heat stroke
<b>EP-4104</b> (dantrolene for EHS)	No drug currently approved	Muscle relaxant	Exertional heat stroke	N/A	Type C meeting with the FDA completed in the fourth quarter of 2013
<b>EP-6101</b> (bivalirudin)	Angiomax	Anti-Coagulant; thrombin inhibitor	Percutaneous transluminal angioplasty	\$502 million <sup>(1)</sup>	Formulation work complete
<b>EP-5101</b> (pemetrexed)	Alimta	Chemotherapeutic agent	Lung cancer and mesothelioma	\$1,122 million <sup>(1)</sup>	Approved (US); marketed by The Medicines Company and Sandoz
<b>EP-1101</b> (argatroban)	Argatroban	Anti-coagulant; thrombin inhibitor	Heparin-induced thrombocytopenia	\$99 million <sup>(2)</sup>	Approved (EU); not marketed;
<b>EP-2101</b> (topotecan)	Hycamtin	Chemotherapeutic agent	Ovarian, cervical and small-cell lung cancer	\$25 million <sup>(3)</sup>	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 worldwide 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 bioequivalence studies) that are essential to approval of the application Potential for 30-month stay for Orange Book-listed patents	Potential for five years for a new chemical entity, or three years for new clinical investigations
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 identify specific products where the characteristics described above present opportunities for product improvement. We evaluate the product opportunities presented by the stakeholders and determine whether or not they conform to our research and development planning. A key aspect of our evaluation is the intellectual property landscape for each product opportunity, including our ability to avoid infringing existing patents and the potential patentability of our modified version of the drug. We utilize our experienced team of formulators with extensive experience in branded and generic pharmaceuticals, including significant experience with injectable pharmaceuticals, and a track record of success in product development, regulatory relations, and quality assurance to develop improved products. 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:

<b>Key Product Characteristics</b>	<b>Treanda</b>	<b>EP-3101/EP-3102</b>	<b>EP-3101/EP-3102 Potential Benefits</b>
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<sub>2</sub> 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 powder 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 (pemetrexed) 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)
<b><i>Executive Officers and Key Employees</i></b>		
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
<b><i>Non-Employee Directors</i></b>		
Jay Moorin <sup>(2)</sup>	62	Director
Steven Ratoff <sup>(1)</sup>	71	Director
Sander Flaum <sup>(1)</sup>	76	Director
Michael Graves <sup>(1)(2)</sup>	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. Tarriff 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 eXgenics 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 2004, Mr. Graves was promoted to senior vice president of corporate development and strategic planning. Mr. Graves served in this position until his promotion to president of the generic products division in September 2005. Mr. Graves holds a B.S. from State University College of New York at Buffalo. The board of directors believes that Mr. Graves' extensive experience in marketing, sales, business development and operations qualifies him to serve on our board of directors.

*Alain Schreiber, M.D.* has served as a member of our board of directors since September 2012. Since 2000, Dr. Schreiber has served as a general partner of ProQuest Investments. From 1992 to 2000, Dr. Schreiber served as president, chief executive officer and a director of Vical, Inc., a publicly-traded biopharmaceutical company. Prior to that, Dr. Schreiber held various management positions with Rhône-Poulenc Rorer Inc., a French chemical and pharmaceutical company that is now Sanofi-Aventis, including senior vice president of discovery research. Dr. Schreiber served on the board of directors of Cadence Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company, from July 2004 to June 2007. Dr. Schreiber also served on the board of directors of Optimer Pharmaceuticals Inc., a publicly-traded biopharmaceutical company, from May 2001 to May 2010. Dr. Schreiber also currently serves on the board of directors of numerous private pharmaceutical companies. Dr. Schreiber holds a B.S. in chemistry and an M.D. from the Free University in Brussels, Belgium. Subsequently, he was a



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postdoctoral fellow at the Weizmann Institute of Science in Israel. Our board believes that Dr. Schreiber's extensive industry experience and a depth of drug development expertise, as well as his service on the board of directors of public and private companies, qualifies him to serve on our board of directors.

**Board Composition**

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that all of our directors other than Scott Tarriff are independent directors, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

Effective upon the closing of this offering, we will divide our board of directors into three classes, as follows:

Class I, which will consist of Michael Graves and Alain Schreiber, whose terms will expire at our annual meeting of stockholders to be held in 2014;

Class II, which will consist of Sander Flaum and Scott Tarriff, and whose terms will expire at our annual meeting of stockholders to be held in 2015; and

Class III, which will consist of Steven Ratoff and Jay Moorin, and whose terms will expire at our annual meeting of stockholders to be held in 2016.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently seven members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least  $66\frac{2}{3}\%$  of our voting stock.

**Board Leadership Structure**

Our board of directors is currently chaired by Jay Moorin. As a general policy, our board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Tarriff serves as our President and Chief Executive Officer while Jay Moorin serves as our Chairman of the board of directors but is not an officer. We expect and intend the positions of Chairman of the board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

**Role of the Board in Risk Oversight**

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their

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respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

**Board Committees**

*Our board of directors has established an audit committee and a compensation committee, and intends to form a nominating and corporate governance committee in connection with this offering, each of which has the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the management of our business.*

*Audit Committee*

Our audit committee currently consists of Steven Ratoff and Sander Flaum. Immediately following the closing of this offering, our audit committee will consist of Steven Ratoff, Sander Flaum and Michael Graves, each of whom our board of directors has determined satisfies the Nasdaq Stock Market and SEC independence requirements. The chairperson of our audit committee is currently Mr. Ratoff, and following the closing of this offering, Mr. Ratoff will continue to serve as the chair of our audit committee. The functions of this committee will include, among other things:

evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;

reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;

monitoring the rotation of partners of our independent auditors on our engagement team as required by law;

prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;

reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;

reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;

reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;

establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;



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preparing the report that the SEC requires in our annual proxy statement;

reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;

reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;

reviewing on a periodic basis our investment policy; and

reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that Steven Ratoff qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board has considered Mr. Ratoff's extensive financial experience and business background. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Our audit committee will operate under a written charter, to be effective immediately prior to the completion of this offering, that satisfies the applicable rules of the Securities and Exchange Commission, or SEC, and the listing standards of the Nasdaq Stock Market.

*Compensation Committee*

Our compensation committee currently consists of Jay Moorin and Michael Graves, and following the closing of this offering, the committee shall continue to consist of Messrs. Moorin and Graves. The chairperson of our compensation committee is currently Jay Moorin, and following the closing of this offering, Mr. Moorin will continue to serve as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Code and satisfies the Nasdaq Stock Market independence requirements. The functions of this committee include, among other things:

reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;

reviewing and approving the compensation and other terms of employment of our executive officers;

reviewing and approving performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;

reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;

evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;



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reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the type and amount of compensation to be paid or awarded to our non-employee board members;

establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation;

reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;

administering our equity incentive plans;

establishing policies with respect to equity compensation arrangements;

reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;

reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

reviewing the adequacy of its charter on a periodic basis;

reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC;

preparing the report that the SEC requires in our annual proxy statement; and

reviewing and assessing on an annual basis the performance of the compensation committee.

Our compensation committee will operate under a written charter, to be effective immediately prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Stock Market.

*Nominating and Corporate Governance Committee*

Prior to the closing of this offering, we will form a nominating and corporate governance committee that will consist of Alain Schreiber, Steven Ratoff and Sander Flaum, each of whom our board has determined satisfy the Nasdaq Stock Market independence requirements. The chairperson of our nominating and corporate governance committee will be Mr. Flaum. The functions of our nominating and corporate governance committee will include, among other things:

identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;

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determining the minimum qualifications for service on our board of directors;

evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;

evaluating, nominating and recommending individuals for membership on our board of directors;

evaluating nominations by stockholders of candidates for election to our board of directors;

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considering and assessing the independence of members of our board of directors;

developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;

considering questions of possible conflicts of interest of directors as such questions arise;

reviewing the adequacy of its charter on an annual basis; and

annually evaluating the performance of the nominating and corporate governance committee.

Our nominating and governance committee will operate under a written charter, to be effective immediately prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Stock Market.

***Compensation Committee Interlocks and Insider Participation***

None of the members of our compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

***Code of Business Conduct and Ethics***

In connection with this offering, we intend to adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Following the completion of this offering, the Code of Conduct will be available on our website at [www.eagleus.com](http://www.eagleus.com). The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.



Table of Contents**EXECUTIVE AND DIRECTOR COMPENSATION**

Our named executive officers for the fiscal year ended September 30, 2013, which consist of our principal executive officer and the next two most highly compensated executive officers who were serving as executive officers as of September 30, 2013, are:

Scott Tarriff, our President and Chief Executive Officer;

Paul Bruinenberg, M.D., our Chief Medical Officer; and

Steven L. Krill, Ph.D., our Chief Scientific Officer.

**Summary Compensation Table**

The following table provides information regarding the compensation provided to our named executive officers during the fiscal year ended September 30, 2013:

Name and Principal Position	Year	Salary (\$)	Option Awards \$( <sup>1</sup> )	All Other Compensation \$( <sup>2</sup> )	Total (\$)
Scott Tarriff. <i>President and Chief Executive Officer, Director</i>	2013	408,038		3,050	411,088
Paul Bruinenberg, M.D. <i>Chief Medical Officer</i>	2013	303,786	124,585	2,225	430,596
Steven L. Krill, Ph.D. <i>Chief Scientific Officer</i>	2013	272,592	116,547	3,050	392,189

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during 2013 computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 3 to our Financial Statements. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(2) Amount consists of premiums paid by us for group life and long term disability insurance for each named executive officer. For more information regarding these benefits, see below under " Perquisites, Health, Welfare and Retirement Benefits."

**Annual Base Salary**

The compensation of our named executive officers is generally determined and approved by our board of directors or our compensation committee of our board of directors (the Committee) effective as of April 1 of each year. The chart below reflects the base salaries approved by our board of directors and Committee for our named executive officers during fiscal year ended September 30, 2013.

Name	2013 Base Salary (\$) (effective from October 1, 2012 - March 31, 2013)	2013 Base Salary (\$) (effective from April 1, 2013 - September 30, 2013)
Scott Tarriff	424,360	424,360
Paul Bruinenberg, M.D.	310,000	322,369
Steven L. Krill, Ph.D.	260,000	298,700

We do not have a practice of providing, and we did not provide in fiscal year 2013, any bonuses or non-equity incentive based compensation to our named executive officers. We plan to adopt a performance-based bonus arrangement for our executive employees following the completion of this offering.

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**Equity-Based Incentive Awards**

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our named executive officers. The board of directors or the Committee is responsible for approving equity grants. We have generally granted stock options to our executive officers, employees and consultants as incentive compensation, however we previously granted restricted stock awards to certain individuals other than our named executive officers, none of which remain outstanding. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. We may grant equity awards to our employees and consultants from time to time, as determined appropriate by our board of directors or the Committee. In addition, our executives generally are awarded an initial option grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to this offering, we have granted all equity awards pursuant to the 2007 Incentive Compensation Plan, or the 2007 Plan, the terms of which are described below under " Equity Benefit Plans." All options are granted with a per share exercise price equal to no less than the fair market value of a share of our common stock on the date of grant of each award. Generally our stock option awards vest over a four-year period and are granted with an early exercise feature allowing the holder to exercise and receive unvested shares of our stock which are subject to our right to repurchase in accordance with the vesting schedule. Stock options and shares acquired by early exercising stock options that are subject to our repurchase right accelerate vesting upon the occurrence of change in control transactions under certain circumstances, as further described below under " Potential Payments Upon Termination or Change in Control" and " Equity Benefit Plans."

On April 19, 2013, the board of directors granted an option to purchase 23,428 shares of common stock to Dr. Bruinenberg and an option to purchase 21,917 shares to Dr. Krill, each of which has a four year vesting schedule subject to the executive's continued service with us. The exercise prices and detailed vesting terms of the 2013 option grants are described in the footnotes to the " Outstanding Equity Awards at Fiscal Year-End" table below.

**Agreements with our Named Executive Officers**

We entered into an employment agreement with Mr. Tarriff in March 2007 setting forth the terms of his employment. Pursuant to the agreement, Mr. Tarriff is entitled to an initial annual base salary of \$280,000, subject to increase by the board of directors, and is eligible to receive an annual bonus if determined by the board of directors. Mr. Tarriff is additionally entitled to certain severance and change in control benefits pursuant to his agreement, the terms of which are described below under " Potential Payments Upon Termination or Change in Control." During Mr. Tarriff's employment and for one year thereafter, Mr. Tarriff's may not solicit our employees or full-time consultants and he cannot be employed by or start a business that is in competition with us.

We entered into an offer letter agreement with Dr. Bruinenberg in September 2011 setting forth the terms of his employment. Pursuant to the agreement, Dr. Bruinenberg is entitled to an initial annual base salary of \$310,000, a signing bonus of \$30,000, which was paid to Dr. Bruinenberg in 2012, reimbursement up to \$20,000 for relocation costs, which was paid to Dr. Bruinenberg in 2012, and an option to purchase 35,881 shares of our common stock which was granted to Dr. Bruinenberg in October 2011. Such option vests over a four year period at 25% per year. As a condition to his employment, Dr. Bruinenberg was required to sign a standard Trade Secret, Non-Disclosure and Restrictive Covenant Agreement.

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We entered into an offer letter agreement with Dr. Krill in September 2011 setting forth the terms of his employment. Pursuant to the agreement, Dr. Krill is entitled to an initial annual base salary of \$260,000, reimbursement up to \$20,000 for relocation costs, which was paid to Dr. Krill in 2011, and an option to purchase 7,800 shares of our common stock, which was granted to Dr. Krill in September 2011. Such option vests over a four year period at 25% per year. As a condition to his employment, Dr. Krill was required to sign a standard Trade Secret, Non-Disclosure and Restrictive Covenant Agreement.

**Potential Payments Upon Termination or Change in Control**

Pursuant to Mr. Tarriff's employment agreement, if he is terminated without cause (and other than as a result of his death or disability) or if he resigns for good reason, he is entitled to receive continued payments of his base salary for 12 months following the date of his termination, provided that he continues to comply with certain restrictive covenants set forth in his employment agreement.

For purposes of Mr. Tarriff's employment agreement, "cause" generally means (1) his neglect or failure to perform his substantial duties or obligations, including his material breach of his employment agreement, after receiving prior written notice and an opportunity to cure, if applicable; (2) his willful misconduct that materially injures our reputation, business or business relationships; (3) his conviction of or plea of guilty or *nolo contendere* to any crime or offense involving our money or other property; (4) his conviction of or plea of guilty or *nolo contendere* to or acceptance of deferred adjudication or judgment to any crime constituting a felony; (5) his breach of any fiduciary duty prohibiting his self-dealing to improperly secure any personal profit or gain in connection with our business; or (6) entry of an order of a court or securities regulatory or self-regulatory body which enjoins or otherwise sanctions, limits or restricts his performance under his employment agreement, due to his misconduct.

For purposes of Mr. Tarriff's employment agreement, "good reason" generally means his termination of employment with us for any of the following reasons unless cured within a specified period of notice by Mr. Tarriff: (1) our failure to promptly pay him any undisputed compensation owed under his employment agreement; (2) any reduction in his employee benefits or bonus opportunity, other than one made generally for all senior executives or as a result of our impaired finances; (3) our material diminution in his duties, title, authority or responsibilities; (4) our assignment to him of duties that are inconsistent with the duties stated in his employment agreement; (5) our material breach of any provision of his employment agreement; (6) a requirement that he relocate as a result of moving his offices outside the greater New York City metropolitan area; or (7) our delivery of a written notice electing not to extend the term of his employment under his employment agreement.

In addition, each of our named executive officers holds stock options under the 2007 Plan that provide for acceleration of vesting and lapse of our repurchase right with respect to shares acquired by early exercising such options upon certain change in control transactions or such named executive officer's subsequent termination. A detailed description of the change in control and termination provisions of the 2007 Plan and stock option agreements is provided below under " Equity Benefit Plans."

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**Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth certain information regarding outstanding equity awards granted to our named executive officers that remain outstanding as of September 30, 2013.

	Grant Date	Option awards <sup>(1)</sup>			
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable <sup>(2)</sup>	Option Exercise Price Per Share (\$) <sup>(3)</sup>	Option Expiration Date
Scott Tarriff	10/02/2008	113,104		4.04	10/01/2018
	04/02/2009	124,804		4.04	04/01/2019
	05/03/2011	31,201	(4)	8.78	05/02/2021
Paul Bruinenberg, M.D.	10/31/2011	35,881	(5)	8.78	10/30/2021
	07/12/2012	15,600	(6)	8.78	07/11/2022
	04/19/2013	23,428	(7)	4.42	04/18/2023
Steven L. Krill, Ph.D.	09/26/2011	7,800	(8)	8.78	09/25/2021
	07/12/2012	5,460	(9)	8.78	07/11/2022
	04/19/2013	21,917	(7)	4.42	04/18/2023

- (1) All of the option awards listed in the table above were granted under the 2007 Plan, the terms of which are described below under " Equity Benefit Plans."
- (2) All of the option awards listed in the table above are fully exercisable on the date of grant and vest with respect to 25% of the shares one year following the date of grant and with respect to 1/36<sup>th</sup> of the remaining shares on each monthly anniversary thereafter over the following three years, subject to the executive's continuous service with us through the vesting date.
- (3) All of the option awards listed in the table above were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors with the assistance of a third-party valuation expert.
- (4) As of September 30, 2013, 13,000 shares were unvested.
- (5) As of September 30, 2013, 18,688 shares were unvested.
- (6) As of September 30, 2013, 11,050 shares were unvested.
- (7) As of September 30, 2013, all shares were unvested.
- (8) As of September 30, 2013, 3,900 shares were unvested.
- (9) As of September 30, 2013, 3,867 shares were unvested.

**Option Repricings**

We did not engage in any repricings or other modifications or cancellations with respect to the outstanding equity awards held by or granted to our named executive officers during the fiscal year ended September 30, 2013.

**Perquisites, Health, Welfare and Retirement Benefits**

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Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We provide the opportunity to participate in a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled " 401(k) Plan."

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We generally do not provide perquisites or personal benefits to our named executive officers, except in certain limited circumstances such as providing relocation benefits in connection with hiring a new executive. We did not provide any such perquisites or personal benefits in fiscal year 2013. We do, however, pay the premiums for group term life insurance, long-term disability, dental and health insurance for all of our employees, including our named executive officers. None of our named executive officers participate in non-qualified deferred compensation plans or qualified defined benefit pension plans sponsored by us. Our board of directors may elect to adopt such plans in the future if it determines that doing so is in our best interests.

**401(k) Plan**

We maintain a 401(k) profit sharing plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code. The plan provides that each participant may contribute up to the lesser of 75% of his or her compensation or the statutory limit, which was \$17,000 for calendar year 2012 and \$17,500 for calendar year 2013. Participants who are 50 years or older can also make "catch-up" contributions, which in calendar year 2012 and 2013 was up to an additional \$5,500 above the statutory limit. We did not make matching contributions or profit sharing contributions into the 401(k) plan on behalf of participants in fiscal year 2013. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

**Non-qualified Deferred Compensation**

None of our named executive officers participate in or have account balances in non-qualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

**Limitations on Liability and Indemnification Agreements**

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws, both of which will become effective upon the consummation of this offering, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

any breach of the director's duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or

any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek nonmonetary relief, such as injunctive relief or rescission. These provisions will not alter a director's

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liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation that will become effective upon the completion of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws to be effective upon the consummation of this offering will provide that:

we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;

we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and

the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we will enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.



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**Equity Benefit Plans**

*2014 Equity Incentive Plan*

Our board of directors adopted the 2014 Plan in November 2013, and we expect our stockholders will approve the plan prior to this offering and that the 2014 Plan will become effective before and contingent upon the date of the underwriting agreement pursuant to which our common stock is priced for our initial public offering. Once the 2014 Plan is effective, no further grants will be made under the 2007 Plan.

*Stock Awards.* The 2014 Plan provides for the grant of incentive stock options (ISOs), non-statutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2014 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

*Share Reserve.* Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2014 Plan after the 2014 Plan becomes effective is the sum of (i) 728,072 shares, plus (ii) the number of remaining shares reserved for issuance under our 2007 Plan at the time our 2014 Plan becomes effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to our 2007 Plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of our common stock reserved for issuance under our 2014 Plan will automatically increase on October 1 of each year, beginning on October 1, 2014 (assuming the 2014 Plan becomes effective before such date) and continuing through and including October 1, 2024, by four percent (4%) of the total number of shares of our capital stock outstanding on September 30 of the preceding fiscal year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2014 Plan is 1,948,622 shares.

No person may be granted stock awards covering more than 468,018 shares of our common stock under our 2014 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a performance stock award covering more than 468,018 shares or a performance cash award having a maximum value in excess of \$3,000,000. Such limitations are designed to help assure that any deductions to which we would otherwise be entitled with respect to such awards will not be subject to the \$1,000,000 limitation on the income tax deductibility of compensation paid to any covered executive officer imposed by Section 162(m) of the Code. In addition, a maximum of the greater of 39,001 shares of our common stock or such number of shares of our common stock that has a fair market value on the grant date equal to \$300,000 may be granted to any one non-employee director during any one calendar year pursuant to stock awards.

If a stock award granted under the 2014 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2014 Plan. In addition, the following types of shares under the 2014 Plan may become available for the grant of new stock awards under the 2014 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2014 Plan may be previously

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unissued shares or reacquired shares bought by us on the open market. As of the date hereof, no awards have been granted and no shares of our common stock have been issued under the 2014 Plan.

*Administration.* Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2014 Plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2014 Plan, our board of directors or the authorized committee, referred to herein as the Plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2014 Plan. Subject to the terms of our 2014 Plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

*Stock Options.* Incentive and non-statutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2014 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2014 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2014 Plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. Additionally, options generally terminate immediately in the event that the option holder breaches certain restrictive covenants set forth in the option agreement. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

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*Tax Limitations On Incentive Stock Options.* The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options (ISOs) that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as non-statutory stock options (NSOs). No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

*Restricted Stock Awards.* Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates, or (3) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

*Restricted Stock Unit Awards.* Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

*Stock Appreciation Rights.* Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2014 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2014 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of

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disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. Additionally, stock appreciation rights generally terminate immediately in the event that the option holder breaches certain restrictive covenants set forth in the option agreement. In no event may a stock appreciation right be exercised beyond the expiration of its term.

*Performance Awards.* The 2014 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the \$1,000,000 limitation on the income tax deductibility of compensation paid to a covered executive officer imposed by Section 162(m) of the Code. To help assure that the compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) earnings before interest, taxes, depreciation, amortization and legal settlements; (v) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (vi) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (vii) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (viii) total stockholder return; (ix) return on equity or average stockholder's equity; (x) return on assets, investment, or capital employed; (xi) stock price; (xii) margin (including gross margin); (xiii) income (before or after taxes); (xiv) operating income; (xv) operating income after taxes; (xvi) pre-tax profit; (xvii) operating cash flow; (xviii) sales or revenue targets; (xix) increases in revenue or product revenue; (xx) expenses and cost reduction goals; (xxi) improvement in or attainment of working capital levels; (xxii) economic value added (or an equivalent metric); (xxiii) market share; (xxiv) cash flow; (xxv) cash flow per share; (xxvi) share price performance; (xxvii) debt reduction; (xxviii) implementation or completion of projects or processes (including, without limitation, clinical trial initiation, clinical trial enrollment, clinical trial results, new and supplemental indications for existing products, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals, and product supply); (xxix) stockholders' equity; (xxx) capital expenditures; (xxxii) debt levels; (xxxiii) operating profit or net operating profit; (xxxiv) workforce diversity; (xxxv) growth of net income or operating income; (xxxvi) billings; (xxxvii) bookings; (xxxviii) employee retention; (xxxix) initiation of phases of clinical trials and/or studies by specific dates; (xl) budget management; (xli) submission to, or approval by, a regulatory body (including, but not limited to the U.S. Food and Drug Administration) of an applicable filing or a product candidate; (xlii) regulatory milestones; (xliii) progress of internal research or clinical programs; (xliv) progress of partnered programs; (xlv) partner satisfaction; (xlvi) timely completion of clinical trials; (xlvii) submission of INDs and NDAs and other regulatory achievements; (xlviii) research progress, including the development of programs; (xlix) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; (l) customer satisfaction; and (li) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in

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such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other non-recurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles and such other adjustments set forth in the 2014 Plan. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals and to define the manner of calculating the performance goals selected. The performance goals may differ from participant to participant and from award to award.

*Other Stock Awards.* The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

*Changes to Capital Structure.* In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2014 Plan, (b) the class and maximum number of shares by which the share reserve may increase automatically each year, (c) the class and maximum number of shares that may be issued upon the exercise of ISOs, (d) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2014 Plan pursuant to Section 162(m) of the Code), (e) (iv) the class(es) and maximum number of securities that may be awarded to any Non-Employee Director and (f) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;

arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;

accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;

arrange for the lapse of any reacquisition or repurchase right held by us;

cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or

make a payment equal to the excess of (a) the value of the property the participant would have received upon exercise of the stock award over (b) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

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Under the 2014 Plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a sale or other disposition of at least 90% of our outstanding securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

*Change in Control.* The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control. Under the 2014 Plan, a change in control is generally (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; or (iii) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

*Amendment and Termination.* Our board of directors has the authority to amend, suspend, or terminate our 2014 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2014 Plan.

***2007 Incentive Compensation Plan***

Our board of directors and our stockholders approved the 2007 Plan, which became effective in August 2008. As of December 31, 2013, there were 246,239 shares remaining available for the grant of stock awards under the 2007 Plan and there were outstanding stock awards covering a total of 841,104 shares that were granted under the 2007 Plan, all of which were stock options.

After the effective date of the 2014 Plan, no additional awards will be granted under the 2007 Plan, and all awards granted under the 2007 Plan that are repurchased, forfeited, expire or are cancelled will become available for grant under the 2014 Plan in accordance with its terms.

*Stock awards.* The 2007 Plan provides for the grant of ISO, NSOs, stock appreciation rights, restricted stock awards, deferred stock awards, shares granted as a bonus or in lieu of another award under the 2007 Plan, dividend equivalents and other forms of stock-based awards and performance awards (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors, and consultants of us and our related entities. ISOs may be granted only to employees. All other stock awards may be granted to employees, including officers, and to non-employee directors and consultants.

*Share Reserve.* The aggregate number of shares of our common stock reserved for issuance pursuant to stock awards under the 2007 Plan is 1,372,855 shares. The maximum number of shares that may be issued upon the exercise of ISOs under the 2007 Plan is 671,052 shares.

If a stock award granted under the 2007 Plan is forfeited, expires or otherwise terminates without being exercised in full, or is settled in cash or otherwise does not result in an issuance of all or part of the common stock for a stock award, the shares of our common stock not issued pursuant to the stock award again will become available for subsequent issuance under the 2007 Plan. In addition, the following types of shares under the 2007 Plan may become available for the grant of new stock

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awards under the 2007 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2007 Plan may consist, in whole or in part, of authorized and unissued shares or treasury shares.

*Administration.* The board of directors or the Committee has the authority to administer the 2007 Plan and may also delegate certain authority to one or more of our officers or managers. Subject to the terms of the 2007 Plan, our board of directors or the Committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted, and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted, and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under the 2007 Plan. However, subject to the terms of the 2007 Plan, the plan administrator has the authority, only with the approval of our stockholders, to reduce the exercise or strike price of any outstanding stock option or stock appreciation right, cancel any outstanding stock option or stock appreciation right with an exercise or strike price exceeding the fair market value of our common stock in exchange for other stock awards or take any other action with respect to stock options or stock appreciation rights that may be treated as a repricing.

*Stock Options.* Incentive and non-statutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2007 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2007 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2007 Plan, up to a maximum of 10 years. The terms of the stock option agreement provide for earlier termination upon certain circumstances. Generally, the stock option agreements provide that if an option holder's service relationship with us or any of our related entities ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. Additionally, options generally terminate immediately in the event that the option holder breaches certain restrictive covenants set forth in the option agreement. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option are determined by the plan administrator and generally include cash, check and shares of our common stock. Options will vest and become exercisable as determined by the plan administrator and set forth in the option agreement. Options granted under the 2007 Plan generally vest over a period of four years, subject to the option holder's continued service with us. Additionally, options generally may be exercised prior to vesting, and in such event, we have the right to repurchase any unvested shares upon the termination of the option holder's service with us for any reason other than death or disability at a price equal to the exercise price per share paid to purchase such shares.



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Unless the plan administrator provides otherwise, options generally are not transferable except by will and the laws of descent and distribution. However, an optionholder may be permitted to designate a beneficiary who may exercise the option following the optionholder's death.

*Tax Limitations on Incentive Stock Options.* The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed \$100,000. Options, or portions thereof, that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the option is not exercisable after the expiration of five years from the date of grant.

*Changes to Capital Structure.* In the event that there is a specified type of change in our capital structure, such as an extraordinary dividend or other distribution, recapitalization, stock split or other transaction that affects our common stock, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2007 Plan, (2) the class and maximum number of shares used to measure per person award limitations, (3) the class and maximum number of shares that may be issued upon the exercise of ISOs, and (3) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* In the event of any merger, consolidation or other reorganization in which we do not survive or in the event of any change in control, outstanding stock awards may be dealt with in accordance with any of the following approaches as determined by the agreement effecting the transaction or if not so determined, as determined by the plan administrator (1) such stock awards may be continued by us if we are the surviving entity; (2) such stock awards may be assumed or substituted for outstanding awards by the surviving entity or its parent or subsidiary; (3) such stock awards may be subject to full exercisability or vesting and accelerated expiration; or (4) such stock awards may be settled based on their value, in cash or cash equivalents or other property followed by cancellation. The plan administrator must give written notice of any proposed transaction prior to the closing date of such transaction in order for holders of stock awards to have a reasonable period of time to exercise any stock awards. If provided in the terms of an individual stock award or another written agreement between us and the holder of a stock award, in the event of a change in control, all outstanding stock options and stock appreciation rights shall become immediately vested and exercisable. However, if the successor company in the change in control assumes or substitutes for outstanding stock awards, then each outstanding option or stock appreciation right shall not be accelerated.

The terms of our outstanding stock option agreements provide that the stock option will terminate immediately in the event of our liquidation or dissolution or any reorganization, merger, consolidation or other form of corporate transaction in which we do not survive or our common stock is exchanged for or converted into securities issued by another entity or affiliate of such successor or acquirer, unless the successor or acquirer or an affiliate assumes the stock option or substitutes and equivalent stock option or right for the stock option and the plan administrator may give written notice to cancel any outstanding unexercised stock option effective upon the consummation of any change in control. In addition, the stock option agreements provide that upon a change in control during the award holder's service to us, any shares acquired through early exercise of a stock option that are unvested and subject to our repurchase right will become fully and immediately vested and released from our repurchase right. However, if the company that retains or succeeds our business in connection with such change in control assumes or substitutes another award for such unvested shares or for such stock option, to the extent not exercised, then the vesting of 50% of the unvested shares shall not be



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accelerated. Additionally, in the event the holder's employment with the successor company and its affiliates terminates for reasons other than by such successor for cause or by the holder without good reason within 24 months following such change in control, any unvested shares that did not vest in connection with the change in control will become immediately and fully vested and released from our repurchase right.

Under the 2007 Plan, a "change in control" is generally the occurrence of any of the following (1) the acquisition by a person or entity of a controlling interest in us, which means beneficial ownership of more than 50% of either our outstanding equity securities or combined voting power; (2) during any two consecutive years, individuals on our board of directors on the effective date of the 2007 Plan (or individuals whose election or nomination for election was approved by the vote of at least a majority of such directors) cease to constitute at least a majority of our board of directors; or (3) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar transaction involving us, a sale or other disposition or all or substantially all of our assets or the acquisition of assets or equity of another entity by us, in each case unless following such transaction certain conditions are met.

Under the 2007 Plan, "good reason" has the same definition as set forth in any employment or other agreement for the performance of services between an award holder and us and if there is no such definition, generally means with respect to an award holder (1) assignment of duties inconsistent in any material respect with such holder's duties or responsibilities as assigned by us or any other action by us that results in a material diminution in such duties or responsibilities; (2) any material failure by us to comply with our obligations to the holder as agreed upon; or (3) our requiring the holder to be based at any office or location outside of 30 miles from the holder's location of employment or service.

*Amendment and Termination.* The 2007 Plan will terminate earliest of (1) no common stock remains for issuance under the 2007 Plan; (2) on March 7, 2017; or (3) our board of directors exercises its authority to amend, suspend, or terminate the 2007 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent.

As noted above, in connection with this offering, our 2007 Plan will be terminated and no further awards will be granted thereunder.

***2014 Employee Stock Purchase Plan***

Our board of directors adopted the ESPP in November 2013 and we expect our stockholders will approve the ESPP prior to the execution and delivery of the underwriting agreement for this offering. The ESPP will become effective contingent upon the date of the underwriting agreement pursuant to which our common stock is priced for our initial public offering. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

*Share Reserve.* Following this offering, the ESPP authorizes the issuance of 180,943 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on October 1 of each fiscal year, from October 1, 2014 (assuming the ESPP becomes effective before such date) through October 1, 2024 by the least of (a) one percent (1%) of the total number of shares of our common stock outstanding on September 30 of the preceding fiscal year, (b) 180,943 shares, or (c) a number determined by our board of directors that is less than (a) and (b). The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of

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Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the ESPP.

*Administration.* Our board of directors has delegated its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 24 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase.

*Limitations.* Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors: (a) customarily employed for more than 20 hours per week, (b) customarily employed for more than five months per calendar year or (c) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

*Changes to Capital Structure.* In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large non-recurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (a) the number of shares reserved under the ESPP, (b) the maximum number of shares by which the share reserve may increase automatically each year and (c) the number of shares and purchase price of all outstanding purchase rights.

*Corporate Transactions.* In the event of certain significant corporate transactions, including: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of 90% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transaction, and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately.

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*Plan Amendments, Termination.* Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

**Director Compensation**

Historically, we have not paid cash or equity compensation to directors who are also our employees for service on our board of directors. We have provided equity compensation generally in the form of stock option grants under the 2007 Plan to our non-employee members of our board of directors. We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors. We do not maintain any agreements with our directors governing their services or compensation for their services on our board of directors.

On April 19, 2013 we granted an option under the 2007 Plan to purchase 2,340 shares to each of Mr. Flaum, Mr. Moorin, Mr. Nowak and Mr. Ratoff and an option to purchase 780 to Dr. Schreiber, each of which has an exercise price per share of \$4.42, is fully exercisable on the date of grant and vests with respect to 25% of the underlying shares on each of the one, two, three and four years following the date of grant, subject to the director's continued service with us through such date.

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the fiscal year ended September 30, 2013 to each of our non-employee directors:

Name <sup>(1)</sup>	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(2)</sup>	Total (\$)
Sander Flaum.		12,450	12,450
Jay Moorin		12,450	12,450
Reiner Nowak		12,450	12,450
Steven Ratoff		12,450	12,450
Alain Schreiber, M.D.		4,650	4,650
Hironori Hozoji			

(1) Mr. Tarriff was an employee director during 2013 and his compensation is fully reflected in the " Summary Compensation Table" above. Mr. Tarriff did not receive any compensation in 2013 for services provided as a member of our board of directors.

(2) Amounts listed in this column represent the aggregate grant date fair value of option awards granted during 2013 computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 3 to our Financial Statement. These amounts do not reflect the actual economic value that will be realized by our non-employee directors upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options. The aggregate number of shares subject to each non-employee director's outstanding option awards as of September 30, 2013 was as follows: Mr. Flaum: 14,040 outstanding and unexercised; Mr. Moorin: 14,040 outstanding and unexercised; Mr. Nowak: 14,040 outstanding and unexercised; Mr. Ratoff: 14,040 outstanding and unexercised; Dr. Schreiber: 780 outstanding and unexercised; Mr. Hozoji: 0 outstanding and unexercised.

Effective upon this offering, our board of directors adopted a new compensation policy that will be applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

an annual cash retainer of \$25,000, paid quarterly for service (other than as chairman) on the board of directors;

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an additional annual cash retainer of \$40,000, paid quarterly, for service as chairman of the board of directors;

an additional annual cash retainer of \$20,000, paid quarterly, for service as chairman of the audit committee;

an additional annual cash retainer of \$7,500, paid quarterly, for service as chairman of the compensation committee or the nominating and corporate governance committee;

an additional annual cash retainer of \$12,500, paid quarterly, for service (other than as chairman) on the audit committee;

an additional annual cash retainer of \$7,500, paid quarterly, for service on the executive committee;

an additional annual cash retainer of \$4,000, paid quarterly, for service (other than as chairman) on the compensation committee or the nominating and corporate governance committee;

an annual option grant to purchase 4,680 shares of our common stock vesting monthly over one year following the grant date; and

upon first joining our board of directors, an automatic initial grant of an option to purchase 9,360 shares of our common stock vesting monthly over three years following the grant date.

Each of the option grants described above will vest in full upon a change in control (as defined under our 2014 Plan). The term of each option will be 10 years. The options will be granted under our 2014 Plan, the terms of which are described in more detail above under "Equity Benefit Plans 2014 Equity Incentive Plan."

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The following includes a summary of transactions since October 1, 2010 to which we have been a party, in which the amount involved in the transaction exceeded \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Compensation Discussion and Analysis."

**Preferred Stock Financings***Series B-1 Preferred Stock Financing*

In February 2011 and July 2011, we issued an aggregate of 10,177,085 shares of our Series B-1 preferred stock (convertible into approximately 1,587,687 shares of common stock) at a purchase price of \$1.82 per share for aggregate consideration of \$18.5 million to 17 accredited investors pursuant to a preferred stock purchase agreement. The following table sets forth the names of our directors, executive officers and holders of more than 5% of our capital stock, and entities affiliated with them, who participated in the Series B-1 preferred stock financing.

<b>Related Party</b>	<b>Shares of Series B-1 Preferred Stock (#)</b>	<b>Aggregate Consideration Received (\$)</b>
Entities affiliated with ProQuest <sup>(1)</sup>	5,852,946	\$ 10,652,362
General Electric Pension Trust	1,352,453	2,461,464
Prudential Jennison Health Sciences Fund, a series of Prudential Sector Funds, Inc.	1,200,000	2,184,000
Scott Tarriff	549,451	1,000,001
Entities affiliated with Jay Moorin <sup>(2)</sup>	274,731	500,010
Sander Flaum	54,945	100,000
Steven Ratoff	54,945	100,000

(1) Represents 5,451,834 shares purchased by ProQuest Investments IV, L.P., 243,753 shares purchased by ProQuest Management, LLC DBPP FBO Jay Moorin and 157,359 shares purchased by ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin and other individuals. ProQuest Investments IV, L.P., ProQuest Management, LLC DBPP FBO Jay Moorin and ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin and other individuals are collectively referred to as entities affiliated with ProQuest. Jay Moorin and Alain Schreiber, M.D, two of our directors, are managing members of ProQuest Management LLC and ProQuest Associates IV LLC, the General Partner of ProQuest Investments IV, L.P. Steven Ratoff, a member of our board of directors, is a venture partner of ProQuest Investments.

(2) Represents 243,753 shares purchased by ProQuest Management, LLC DBPP FBO Jay Moorin and 30,978 shares purchased by ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin. ProQuest Management, LLC DBPP FBO Jay Moorin and ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin are collectively referred to as entities affiliated with Jay Moorin.

*Series C Preferred Stock Financing*

In April 2013, we issued an aggregate of 5,494,506 shares of our series C preferred stock (convertible into approximately 857,177 shares of common stock) at a purchase price of \$1.82 per share for aggregate consideration of \$10,000,001 million to JAFCO Super V3 Investment Limited Partnership, a holder of more than 5% of our capital stock.

**Bridge Debt Financing**

In August 2012 and September 2012 we sold and issued convertible promissory notes to existing investors in an aggregate principal amount of \$9.7 million and warrants to purchase shares of series C

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preferred stock, pursuant to a note and warrant purchase agreement. The convertible promissory notes accrued interest at the rate of 6% per annum. In April 2013, the principal and accrued interest on the convertible promissory notes were converted into an aggregate of 5,528,726 shares of our series C preferred stock (convertible into approximately 862,515 shares of common stock) at a conversion price of \$1.82 per share and the warrants to purchase shares of preferred stock became exercisable to purchase an aggregate of 944,210 shares of series C preferred stock (convertible into approximately 147,254 shares of common stock) at exercise prices of \$1.82 per share. The following table sets forth the names of our directors, executive officers and holders of more than 5% of our capital stock, and entities affiliated with them, who participated in this bridge debt financing.

Related Party	Aggregate Principal Amount of Notes (\$)	Shares of Series C Preferred Stock Issued upon Conversion of Notes (#)	Shares of Series C Preferred Stock Issuable upon Exercise of Preferred Warrants (#)
Entities affiliated with ProQuest Investments IV, L.P. <sup>(1)</sup>	\$ 6,482,375	3,710,742	641,112
Prudential Jennison Health Sciences Fund, a series of Prudential Sector Funds, Inc.	\$ 888,543	508,633	87,877
General Electric Pension Trust	1,358,583	777,701	134,365
Scott Tarriff	286,635	162,662	22,048
Entities affiliated with Jay Moorin <sup>(2)</sup>	71,797	41,098	7,100
Sander Flaum	29,676	16,305	2,210
Steven Ratoff	14,359	8,148	1,104

(1) Represents 3,650,758 shares and 630,746 warrants acquired by ProQuest Investments IV, L.P., 36,464 shares and 6,300 warrants acquired by ProQuest Management, LLC DBPP FBO Jay Moorin and 23,540 shares and 4,066 warrants acquired by ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin and other individuals.

(2) Represents 36,464 shares and 6,300 warrants acquired by ProQuest Management, LLC DBPP FBO Jay Moorin and 4,634 shares and 800 warrants acquired by ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin.

**Indebtedness of Management**

In February 2011 and August 2011, we lent Mr. Tarriff an aggregate of \$1.0 million to purchase shares of our series B-1 preferred stock. The original promissory notes evidencing this loan bore interest at a rate of 3.9% per annum, compounded annually, with payments due upon the earlier of the consummation of a debt financing or the second anniversary of the date of issuance of each promissory note. The promissory notes were secured by the 549,451 shares of our series B-1 preferred stock (convertible into approximately 85,717 shares of common stock) purchased by Mr. Tarriff. In August 2011, in connection with the bridge debt financing, we entered into a payoff and exchange agreement with Mr. Tarriff pursuant to which the aggregate principal amount and all accrued interest under the promissory notes was cancelled in exchange for Mr. Tarriff transferring the 549,451 shares of our series B-1 preferred stock (convertible into approximately 85,717 shares of common stock) held by Mr. Tarriff to us.

**Stockholder Agreements**

In connection with our preferred stock financings, we entered into a third amended and restated investor rights agreement, or the Investor Rights Agreement, a fourth amended and restated voting and drag-along agreement, or Voting Agreement, and a third amended and restated right of first refusal and co-sale agreement, or ROFR Agreement, to collectively provide for, among other things, registration rights, information rights, voting rights and obligations, and rights of first refusal with certain holders of our preferred stock and common stock, including JAFCO Super V3 Investment

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Limited Partnership, entities affiliated with ProQuest, Prudential Jennison Health Sciences Fund, a series of Prudential Sector Funds, Inc., Sander Flaum, entities affiliated with Jay Moorin, Steven Ratoff and Scott Tarriff. The ROFR Agreement, the Voting Agreement and portions of the Investor Rights Agreement will terminate in connection with the closing of this offering. The registration rights granted to certain holders of our preferred stock and common stock under our Investor Rights Agreement will continue following the closing of this offering as more fully described below in "Description of Capital Stock Registration Rights."

**Employment Arrangements**

We have entered into employment arrangements, with our executive officers, as more fully described in "Executive and Director Compensation Agreements with our Named Executive Officers," " Incentive Compensation" and " Potential Payments upon Termination or Change in Control."

**Stock Options Granted to Executive Officers and Directors**

We have granted stock options to our executive officers and directors, as more fully described in "Executive and Director Compensation."

**Indemnification Agreements**

We have entered into, and intend to continue to enter into, indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws and our amended and restated certificate of incorporation. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. For more information regarding these agreements, see the section of this prospectus entitled "Executive Compensation Limitations on liability and indemnification matters."

**Policies and Procedures for Transactions with Related Persons**

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We expect to adopt a related person transaction policy that will set forth our procedures for the identification, review, consideration and approval or ratification of related person transactions, which will become effective immediately prior to the completion of this offering. For purposes of our policy only, a "related-person transaction" will be defined as a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds \$120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director will not be considered related-person transactions under this policy. A related person will be defined as any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant

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stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors will take into account the relevant available facts and circumstances including, but not limited to:

the risks, costs and benefits to us;

the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;

the terms of the transaction;

the availability of other sources for comparable services or products; and

the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

The policy will require that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

All of the transactions described above were entered into prior to the adoption of the written policy.



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**PRINCIPAL STOCKHOLDERS**

The following table sets forth information regarding beneficial ownership of our capital stock by:

each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;

each of our directors;

each of our named executive officers; and

all of our current executive officers and directors as a group.

The numbers of shares beneficially owned and percentage ownership information under the column entitled "Before offering" is based on 10,536,059 shares of common stock outstanding as of December 31, 2013, assuming conversion of all outstanding shares of our preferred stock into 7,487,928 shares of common stock. The percentage ownership information under the column entitled "After offering" also gives effect to the sale of 3,350,000 shares of common stock in this offering, including purchases by existing principal stockholders and their affiliated entities in this offering, 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.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before March 1, 2014 which is 60 days after December 31, 2013. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

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Except as otherwise noted below, the address for each person or entity listed in the table is c/o Eagle Pharmaceuticals, Inc., 50 Tice Blvd. Suite 315, Woodcliff Lake, NJ 07677.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>5% or greater stockholders</b>			
ProQuest and its affiliates <sup>(1)</sup>	4,605,124	43.3%	34.9%
General Electric Pension Trust <sup>(2)</sup>	953,295	9.0	6.7
JAFCO Super V3 Investment Limited Partnership <sup>(3)</sup>	857,177	8.1	6.2
Accounts managed by Jennison Associates LLC <sup>(4)</sup>	623,475	5.9	5.1
<b>Directors and named executive officers</b>			
Scott Tarriff <sup>(5)</sup>	1,931,656	17.9	13.6
David E. Riggs		*	*
Paul Bruinenberg, M.D. <sup>(6)</sup>	26,032	*	*
Steven L. Krill, Ph.D. <sup>(7)</sup>	6,434	*	*
Sander Flaum <sup>(8)</sup>	37,589	*	*
Michael Graves		*	*
Jay Moorin <sup>(9)</sup>	4,605,124	43.3	34.9
Steven Ratoff <sup>(10)</sup>	27,564	*	*
Alain Schreiber, M.D. <sup>(11)</sup>	4,605,124	43.3	34.9
All current executive officers and directors as a group (9 persons) <sup>(12)</sup>	6,634,399	60.6%	48.0%

\*Represents beneficial ownership of less than one percent.

(1) Includes (a) 4,415,658 shares of common stock and 98,368 shares of common stock underlying a warrant that is exercisable within 60 days of December 31, 2013 held by ProQuest Investments IV, L.P., (b) 9,360 shares of common stock and 8,190 shares of common stock underlying options that are vested and exercisable within 60 days of December 31, 2013 held by ProQuest Management LLC, (c) 43,715 shares of common stock and 1,614 shares of common stock underlying a warrant that is exercisable within 60 days of December 31, 2013 held by ProQuest Management LLC DBPP FBO Jay Moorin, (d) 71,934 shares of common stock and 124 shares of common stock underlying a warrant that is exercisable within 60 days of December 31, 2013 held by ProQuest Management LLC Salary Savings Plan FBO Jay Moorin and for the benefit of certain other individuals. Jay Moorin and Alain Schreiber, M.D. two of our directors, are managing members of ProQuest Management LLC and ProQuest Associates IV, LLC, the General Partner of ProQuest Investments IV, L.P. and may be deemed to have shared voting, investment and dispositive power with respect to these shares. Pasquale DeAngelis and Messrs. Moorin and Schreiber are also trustees of ProQuest Management LLC DBPP FBO Jay Moorin and the ProQuest Management LLC Salary Savings Plan FBO Jay Moorin and for the benefit of certain other individuals and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. The principal address of each of the ProQuest entities is 90 Nassau Street, 4<sup>th</sup> Floor, Princeton, NJ 08542. The percentage owned after this offering listed above includes 333,333 shares of our common stock to be purchased in this offering at the initial public offering price.

(2) Includes 20,954 shares of common stock underlying a warrant that is exercisable within 60 days of December 31, 2013. General Electric Pension Trust (GEPT) is an employee benefit plan trust for the benefit of the employees and retirees of General Electric Company and its subsidiaries. GE Asset Management Incorporated (GEAM) is a registered investment adviser and acts as Investment Manager for GEPT. GEAM may be deemed to beneficially share ownership of the shares owned by GEPT, but has no pecuniary interest in such shares. GEAM, acting alone, has the power to direct the voting and disposition of the Company securities held by GEPT. GEAM has delegated responsibility for exercising voting and dispositive power over such securities to three of its officers: Don W. Torey, Patrick J. McNeela and Tony Pantuso. These three officers act on a consensus basis in determining how and when to exercise voting and dispositive power with respect to these securities. Any such exercise requires the consent of at least two of these three persons. General Electric Company, Messrs. Torey, McNeela and Pantuso expressly disclaim beneficial ownership of all shares owned by GEPT. The principal address of General Electric Pension Trust is c/o GE Asset Management Incorporated, 1600 Summer Street, Stamford, CT 06905.

*footnotes continued on following page*

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- (3) Shinichi Fuki, Hiroshi Yamada, Yoshimitsu Oura, Tsunenori Kano, Shuichi Kinoshita and Naoki Sato, as members of the Investment Committee of JAFCO Co., Ltd., General Partner of JAFCO Super V3 Investment Limited Partnership, may be deemed to have shared voting, investment and dispositive power with respect to those shares. The principal address of JAFCO Super V3 Investment Limited Partnership is Otemachi First Square, West Tower 11F, 1-5-1, Otemachi, Chiyoda-ku, Tokyo, 100-0004 Japan.
- (4) Jennison Associates LLC, or Jennison, serves as investment manager with power to direct investments and/or power to vote the shares owned by the accounts under its management ("Accounts"), including 694,577 shares held by the Prudential Jennison Health Sciences Fund, or Fund, a series of Prudential Sector Funds, Inc., and may be deemed to beneficially own the shares held by the Accounts. Prudential Financial, Inc. ("Prudential"), which is a publicly-traded financial services firm, is the parent company of Jennison and may also be deemed to be a beneficial owner of the shares. Both Jennison and Prudential expressly disclaim beneficial ownership of the shares. The percentage owned after this offering listed above includes 100,000 shares of our common stock to be purchased in this offering at the initial public offering price.
- (5) Includes (a) 150,222 shares of common stock held by Janney Montgomery Scott LLC CUST FBO Scott Tarriff IRA and (b) 262,797 shares of common stock underlying options and a warrant that are vested and exercisable within 60 days of December 31, 2013. Mr. Tarriff is a trustee of Janney Scott LLC CUST FBO Scott Tarriff IRA and, as such, may be deemed to share voting and investment power with respect to all shares held by such entity.
- (6) Includes 26,032 shares of common stock underlying options that are vested and exercisable within 60 days of December 31, 2013.
- (7) Includes 6,434 shares of common stock underlying options that are vested and exercisable within 60 days of December 31, 2013.
- (8) Includes 8,534 shares of common stock underlying options and a warrant that are vested and exercisable within 60 days of December 31, 2013.
- (9) Includes the shares of common stock held by the ProQuest entities referred to in footnote (1) above. Mr. Moorin is a managing member of ProQuest Management LLC and ProQuest Associates IV LLC, the General Partner of ProQuest Investments IV, L.P. and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. Mr. Moorin is also a trustee of ProQuest Management LLC DBPP FBO Jay Moorin and the ProQuest Management LLC Salary Savings Plan FBO Jay Moorin and for the benefit of certain other individuals and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. Mr. Moorin disclaims beneficial ownership of such shares except for 49,270 shares of common stock and 1,106 shares of common stock underlying warrants that held by ProQuest Management LLC DBPP FBO Jay Moorin and ProQuest Management LLC Salary Savings Plan FBO Jay Moorin, and otherwise except to the extent of his pecuniary interest therein.
- (10) Includes 8,362 shares of common stock underlying options and a warrant that are vested and exercisable within 60 days of December 31, 2013.
- (11) Includes the shares of common stock held by the ProQuest entities referred to in footnote (1) above. Mr. Schreiber is a managing member of the ProQuest Management LLC and ProQuest Associates IV LLC, General Partner of ProQuest Investments IV, L.P. and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. Mr. Schreiber is also a trustee of ProQuest Management LLC DBPP FBO Jay Moorin and the ProQuest Management LLC Salary Savings Plan FBO Jay Moorin and for the benefit of certain other individuals and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. Mr. Schreiber disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.
- (12) Includes 6,214,068 shares of common stock held by all current executive officers and directors as a group and 420,331 shares of common stock that all current executive officers and directors as a group have the right to acquire from us pursuant to the exercise warrants and options that are vested and exercisable within 60 days of December 31, 2013.

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**DESCRIPTION OF CAPITAL STOCK**

**General**

Upon the closing of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 50,000,000 shares of common stock, par value \$0.001 per share, and 1,500,000 shares of preferred stock, par value \$0.001 per share. All of our authorized preferred stock upon the closing of this offering will be undesignated. The following is a summary of the rights of our common and preferred stock and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

**Common Stock**

*Outstanding Shares*

On December 31, 2013, there were 10,536,059 shares of common stock outstanding, held of record by 48 stockholders, which assumes the conversion of all outstanding shares of preferred stock into shares of common stock immediately prior to the closing of this offering. Based on this number, and the issuance by us of 3,350,000 shares of common stock in this offering 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, there will be 13,918,742 shares of common stock outstanding upon the closing of this offering.

As of December 31, 2013, there were outstanding options to acquire 841,104 shares of common stock pursuant to our 2007 Incentive Compensation Plan, or 2007 Plan, and outstanding warrants to purchase approximately 147,254 shares of common stock, assuming the conversion of all outstanding preferred stock into common stock immediately prior to the closing of this offering.

*Voting*

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

*Dividends*

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

*Liquidation*

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

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*Rights and Preferences*

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

*Fully Paid and Nonassessable*

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

**Preferred Stock**

On December 31, 2013, there were 47,997,673 shares of preferred stock outstanding, held of record by 19 stockholders. Upon the closing of this offering, all outstanding shares of preferred stock will have been converted into 7,487,928 shares of our common stock.

Upon the closing of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 1,500,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock. We have no current plans to issue any shares of preferred stock.

**Options and Warrants**

As of December 31, 2013, options to purchase an aggregate of 841,104 shares of common stock were outstanding under the 2007 Plan. For additional information regarding the terms of this plan, see the section of this prospectus titled "*Executive and Director Compensation Equity Incentive Plans.*"

As of December 31, 2013, warrants to purchase an aggregate of 944,210 shares of our series C preferred stock (convertible into approximately 147,254 shares of common stock) at an exercise price of \$1.82 per share were outstanding. These warrants have a net exercisable provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the applicable warrant and receive a net amount of shares based on the fair market value of our stock at the time of exercise of the applicable warrant after deduction of the aggregate exercise price. Unless earlier exercised, these warrants will automatically net exercise in connection with this offering and the fair market value per warrant share will be the per share offering price of the common stock in this offering. The warrants

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also contain a provision for the adjustment of the exercise price and the number of shares issuable upon the exercise of the applicable warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations.

**Registration Rights**

Following the closing of this offering, the holders of an aggregate of 10,276,989 shares of our common stock, which includes those shares of our common stock that will be issued upon conversion of our preferred stock in connection with this offering and those shares of our common stock that are issuable upon exercise of outstanding warrants, will be entitled to the registration rights set forth below with respect to registration of the resale of such shares under the Securities Act. These shares are collectively referred to herein as registrable securities. These rights are provided under the terms of a third amended and restated investor rights agreement, or investor rights agreement, by and among us and certain of our stockholders, which was entered into in connection with our preferred stock financings, and include demand, piggyback and S-3 registration rights as described more fully below. These registration rights are assignable, subject to certain conditions, including that the assignee be bound by the terms and conditions of the investor rights agreement.

*Demand Registration Rights*

At any time beginning six (6) months following the effective date of this registration statement, the holders of at least 30% of the outstanding registrable securities (but excluding for such purposes than shares of common stock held by Mr. Tarriff), have the right to make up to two demands that we effect a registration under the Securities Act covering the majority of registrable securities then outstanding (or a lesser portion if the anticipated aggregate offering price of securities requested to be sold under such registration statement would exceed \$5.0 million, net of underwriting discounts and commissions). As of December 31, 2013, an aggregate of 8,954,837 registrable securities will be entitled to these demand registration rights. Additionally, as of December 31, 2013, Mr. Tarriff will be entitled to notice of any such demand registration with respect to the registrable securities held by him that are shares of common stock and will be entitled to include such shares of common stock in any such registration statement. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we will be required to use our reasonable best efforts to file the registration within 90 days.

*Form S-3 Demand Registration Rights*

If we are eligible to file a registration statement on Form S-3, holders of at least 10% of the outstanding registrable securities (but excluding for such purposes than shares of common stock held by Mr. Tarriff) have the right to demand that we file a registration statement on Form S-3 so long as the aggregate amount of securities to be sold under the registration statement on Form S-3 is at least \$3.0 million and we have not already effected one registration on Form S-3 within the preceding 6-month period. As of December 31, 2013, an aggregate of 8,954,837 registrable securities will be entitled to these Form S-3 registration rights. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we will be required to use our reasonable best efforts to file the registration within 90 days.

*"Piggyback" Registration Rights*

If we register any securities for public sale, holders of registration rights will each be entitled to notice of the registration and will have the right to include their shares in any such registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the

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right of the underwriters of any underwritten offering to limit the number of shares having registration rights to be included in the registration statement, but not below 30% of the total number of shares requested by the holders to be included in the registration statement, except this offering in which the holders have now waived any and all rights to have their shares included. As of December 31, 2013, an aggregate of 10,276,989 registrable securities will be entitled to these piggyback registration rights.

*Expenses of Registration*

Generally, we are required to bear all registration and selling expenses incurred in connection with the demand, piggyback and Form S-3 registrations described above, other than underwriting discounts and commissions.

*Expiration of Registration Rights*

The demand, piggyback and Form S-3 registration rights discussed above will terminate five (5) years following the closing of this offering or, as to a given holder of registrable securities, when such holder no longer holds any registrable securities.

**Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Bylaws and Delaware Law**

*Delaware Anti-Takeover Law*

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that such stockholder became an interested stockholder, unless:

prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66<sup>2</sup>/<sub>3</sub>% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

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subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

*Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws*

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

permit our board of directors to issue up to 1,500,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);

provide that the authorized number of directors may be changed only by resolution of the board of directors;

provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

divide our board of directors into three classes;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;

do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and

provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66<sup>2</sup>/<sub>3</sub>% of our then outstanding common stock.





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**Choice of Forum**

Our certificate of incorporation to be in effect upon the completion of this offering will provide that a state or federal court located within the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty owed by and of our directors, officers or employees to us or our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

**Nasdaq Global Market Listing**

Our common stock has been approved for listing on The Nasdaq Global Market under the symbol "EGRX."

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue Brooklyn, NY 11219.

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**SHARES ELIGIBLE FOR FUTURE SALE**

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of December 31, 2013, upon the closing of this offering, 13,918,742 shares of common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares, and after giving effect to the conversion of all of our shares of preferred stock into common stock, 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, and no exercise of options. All of the shares sold in this offering will be freely tradable unless held by an affiliate of ours. Except as set forth below, the remaining 10,568,742 shares of common stock outstanding after this offering will be restricted as a result of securities laws and lock-up agreements with us and/or the underwriters. These remaining shares will generally become available for sale in the public market as follows:

substantially all of these restricted shares will not be eligible for sale upon the closing of this offering through the duration of the lock-up period;

up to 10,568,742 restricted shares will be eligible for sale under Rule 144 or Rule 701 (subject to any applicable holding periods and restrictions on affiliate sales) upon expiration of lock-up agreements with us and/or the underwriters at least 180 days after the date of this offering; and

the remainder of the restricted shares will be eligible for sale, subject to restrictions under Rule 144 on affiliate sales, if applicable, from time to time thereafter upon expiration of their respective holding periods under Rule 144, as described below, but could be sold earlier if the holders exercise any available registration rights.

**Rule 144**

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or

the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

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Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

**Rule 701**

Under Rule 701, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold by:

persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and

our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

As of December 31, 2013, options to purchase a total of 841,104 shares of common stock were outstanding, of which 468,767 were vested. Of the total number of shares of our common stock issuable under these options, all are subject to contractual lock-up agreements with us or the underwriters described below under "Underwriting" and will become eligible for sale at the expiration of those agreements unless held by an affiliate of ours.

**Lock-Up Agreements**

We, along with our directors, executive officers and substantially all of our other stockholders and optionholders, have agreed that for a period of 180 days after the date of this prospectus, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock without the consent of Piper Jaffray & Co. and William Blair & Company, L.L.C. Upon expiration of the "lock-up" period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See "Registration Rights" below.

**Registration Rights**

Upon the closing of this offering, the holders of 10,276,989 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 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, except for shares purchased by affiliates, immediately upon the effectiveness of such registration statement. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See "Description of Capital Stock Registration Rights."

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**Equity Incentive Plans**

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock subject to stock awards outstanding or reserved for issuance under the 2007 Plan, 2014 Plan and the ESPP. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

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**MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO  
NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following discussion describes the material U.S. federal income and estate tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income and estate taxes that may be relevant to Non-U.S. Holders in light of their particular circumstances, does not deal with state, local and non-U.S. tax consequences and does not address U.S. federal tax consequences other than income and estate taxes. Rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code, such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment or other risk reduction strategy, partnerships and other pass-through entities, and investors in such pass-through entities or an entity that is treated as a disregarded entity for U.S. federal income tax purposes (regardless of its place of organization or formation). Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and U.S. Treasury Regulations, rulings and judicial decisions thereunder in effect as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income and estate tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following discussion, and there can be no assurance that the IRS will agree with such statements and conclusions. This discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income and estate tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences.

For the purposes of this discussion, a "Non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock that has not been excluded from this discussion and is not a U.S. Holder. A "U.S. Holder" means a beneficial owner of our common stock that is for U.S. federal income tax purposes (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person for federal income tax purposes. Partnerships, or other entities that are treated as partnerships for U.S. federal income tax purposes (regardless of their place of organization or formation) and entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their place of organization or formation) are not addressed by this discussion and are, therefore, not considered to be Non-U.S. Holders for the purposes of this discussion. If you are a partner of a partnership holding our common stock or the

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owner of a disregarded entity holding our stock, you should consult your tax advisor regarding the tax consequences of the acquisition, ownership and disposition of our common stock.

**Distributions**

Subject to the discussion below, distributions, if any, made on our common stock to a Non-U.S. Holder of our common stock to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of withholding under an applicable tax treaty, a Non-U.S. Holder generally will be required to provide us with a properly executed IRS Form W-8BEN certifying the Non-U.S. Holder's entitlement to benefits under that treaty. In the case of a Non-U.S. Holder that is an entity, U.S. Treasury Regulations and the relevant tax income treaty provide rules to determine whether, for purposes of determining the applicability of an income tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular graduated rates, unless a specific income tax treaty exemption applies. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first constitute a non-taxable return of capital and will reduce your adjusted basis in our common stock, but not below zero, and then will be treated as gain and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

**Gain on Disposition of Our Common Stock**

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a "United States real property holding corporation" ("USRPHC") within the meaning of Code

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Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period. In general, we would be a United States real property holding corporation if interests in U.S. real estate comprised (by fair market value) at least half of our business assets. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation, however, there can be no assurance that we will not become a U.S. real property holding corporation in the future. Even if we are or were to become a USRPHC, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance, however, that our common stock will qualify or continue to qualify as regularly traded on an established securities market.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S. source capital losses (even though you are not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

**Information Reporting Requirements and Backup Withholding**

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN or otherwise establishes an exemption. The current backup withholding rate is 28%.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds from a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or non-U.S., except that information reporting and such requirements may be avoided if the holder provides a properly executed IRS Form W-8BEN or otherwise meets documentary evidence requirements for establishing Non-U.S. Holder status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. If backup withholding is applied to you, you should consult with your own tax advisor to determine if you are able to obtain a tax benefit or credit with respect to such backup withholding.



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**Foreign Accounts**

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds from a disposition of our common stock to a foreign financial institution (as specifically defined for this purpose), including when the foreign financial institution holds our common stock on behalf of a non-U.S. Holder, unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply to dividends and the gross proceeds from a disposition of our common stock to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Holders are encouraged to consult with their own tax advisors regarding the possible implications of the legislation on their investment in our common stock.

The withholding provisions described above will generally apply to payments of dividends made on or after July 1, 2014 and to payments of gross proceeds from a sale or other disposition of common stock on or after January 1, 2017.

**Federal Estate Tax**

An individual Non-U.S. Holder who, at the time of death is not a citizen or resident of the United States and who is treated as the owner of, or has made certain lifetime transfers of, an interest in our common stock will be required to include the value thereof in his or her gross estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the United States for federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be "Non-U.S. Holders" for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

THE PRECEDING DISCUSSION OF U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW.

Table of Contents**UNDERWRITING**

Piper Jaffray & Co. and William Blair & Company, L.L.C. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of our common stock set forth opposite its name below.

Name	Number of Shares
Piper Jaffray & Co.	1,474,000
William Blair & Company, L.L.C.	1,474,000
Cantor Fitzgerald & Co.	402,000
Total	3,350,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus is a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

**Commissions and Discounts**

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$0.63 per share. After the initial offering, the public offering price, concession or any other term of this offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	\$ 15.00	\$ 50,250,000	\$ 57,787,500
Underwriting discount	\$ 1.05	\$ 3,517,500	\$ 4,045,125
Proceeds, before expenses, to us	\$ 13.95	\$ 46,732,500	\$ 53,742,375

The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters

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may be increased. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the table above bears to the total number of shares of common stock listed next to the names of all underwriters in the above table.

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$2.0 million, which includes legal, accounting and printing costs and various other fees associated with the registration and listing of our common stock. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to \$30,000 as set forth in the underwriting agreement.

**No Sales of Similar Securities**

We have agreed not to sell or transfer any shares of our common stock or securities convertible into, exchangeable for, exercisable for, or repayable with shares of our common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Piper Jaffray and William Blair & Company, L.L.C. Specifically, we have agreed, with certain limited exceptions, not to directly or indirectly:

offer, pledge, announce the intention to sell, sell or contract to sell any shares of our common stock;

sell any option or contract to purchase any shares of our common stock;

purchase any option or contract to sell any shares of our common stock;

grant any option, right or warrant to purchase any shares of our common stock;

otherwise transfer or dispose of, directly or indirectly, any shares of our common stock;

enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of our common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise; or

accelerate the vesting of any option or warrant or the lapse of any repurchase right.

Our executive officers and directors and certain of our other existing stock holders have agreed not to sell or transfer any shares of our common stock or securities convertible into, exchangeable for, exercisable for, or repayable with shares of our common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Piper Jaffray and William Blair & Company, L.L.C. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

offer, pledge, announce the intention to sell, sell or contract to sell any shares of our common stock;

sell any option or contract to purchase any shares of our common stock;

purchase any option or contract to sell any shares of our common stock;



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grant any option, right or warrant to purchase any shares of our common stock;

make any short sale or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock;

enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of our common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise;

make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for shares of our common stock; or

publicly disclose the intention to do any of the foregoing.

**Listing**

Our common stock has been approved for listing The Nasdaq Global Market under the symbol "EGRX." In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations among us and the representatives. In addition to prevailing market conditions, factors to be considered in determining the initial public offering price are

the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;

our financial information;

the history of, and the prospects for, our company and the industry in which we compete;

an assessment of our management, its past and present operations and the prospects for, and timing of, our future revenues;

the present state of our product development; and

the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares of our common stock may not develop. It is also possible that after this offering the shares of our common stock will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

**Price Stabilization, Short Positions and Penalty Bids**

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Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing shares of our common stock. However, the underwriters may engage in transactions that stabilize the price of our common stock, such as bids or purchases to peg, fix or maintain that price.

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In connection with this offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising this option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through this option. "Naked" short sales are sales in excess of this option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of our common stock made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose penalty bids. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

**Electronic Offer, Sale and Distribution of Shares**

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail. In addition, one or more of the underwriters may facilitate Internet distribution for this offering to certain of their internet subscription customers. Any such underwriter may allocate a limited number of shares for sale to its online brokerage customers. An electronic prospectus is available on the internet websites maintained by any such underwriter. Other than the prospectus in electronic format, the information on the websites of any such underwriter is not part of this prospectus.

**Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with

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us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

**Selling Restrictions**

*European Economic Area*

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

*United Kingdom*

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the "FSMA")) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and



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- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

*Canada*

The common shares may be sold only to purchasers purchasing as principal that are both "accredited investors" as defined in National Instrument 45-106 Prospectus and Registration Exemptions and "permitted clients" as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

*Hong Kong*

The common shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to common shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

*Singapore*

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common shares may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the common shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six

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months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except:

- i) to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- ii) where no consideration is or will be given for the transfer; or
- iii) where the transfer is by operation of law.

*Switzerland*

The common shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the "SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the common shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the common shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of common shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of common shares.

*United Arab Emirates*

This offering has not been approved or licensed by the Central Bank of the United Arab Emirates (the "UAE"), Securities and Commodities Authority of the UAE and/or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai Financial Services Authority ("DFSA"), a regulatory authority of the Dubai International Financial Centre ("DIFC"). The offering does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No 8 of 1984 (as amended), DFSA Offered Securities Rules and Nasdaq Dubai Listing Rules, accordingly, or otherwise. The common shares may not be offered to the public in the UAE and/or any of the free zones.

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The common shares may be offered and issued only to a limited number of investors in the UAE or any of its free zones who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned.

*France*

This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (Code monétaire et financier).

This prospectus has not been and will not be submitted to the French Autorité des marchés financiers (the "AMF") for approval in France and accordingly may not and will not be distributed to the public in France.

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

1. the transaction does not require a prospectus to be submitted for approval to the AMF;
2. persons or entities referred to in Point 2°, Section II of Article L.411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and
3. the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our common stock for their own account and undertake not to transfer, directly or indirectly, our common stock to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

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**LEGAL MATTERS**

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Boston, Massachusetts. The underwriters are being represented by Latham & Watkins LLP, Chicago, Illinois.

**EXPERTS**

The financial statements as of September 30, 2013 and 2012, included in the prospectus and elsewhere in the registration statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677 or telephoning us at (201) 326-5300.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at [www.eagleus.com](http://www.eagleus.com), at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is incorporated by reference in, and is not part of, this prospectus.

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EAGLE PHARMACEUTICALS, INC.**

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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders  
Eagle Pharmaceuticals, Inc.  
Woodcliff Lake, NJ

We have audited the accompanying balance sheets of Eagle Pharmaceuticals, Inc. as of September 30, 2013 and 2012 and the related statements of operations, changes in stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Eagle Pharmaceuticals, Inc. at September 30, 2013 and 2012, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations since its inception and has a significant stockholders' deficit at September 30, 2013, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

Woodbridge, NJ

November 25, 2013, except for Note 3 as to which the date is January 27, 2014

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## EAGLE PHARMACEUTICALS, INC.

## BALANCE SHEETS

	December 31, 2013		September 30, 2013	September 30, 2012
	Actual (unaudited)	Pro Forma (unaudited)		
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents	\$ 9,974,305	\$ 9,974,305	\$ 10,455,565	\$ 5,066,886
Short term investments				1,500,000
Accounts receivable, net of reserves of \$0, \$0 and \$25,891, respectively	6,592,276	6,592,276	5,124,182	1,580,845
Inventories				86,881
Deferred financing costs				96,417
Prepaid expenses and other current assets	368,803	368,803	1,902,660	533,968
<b>Total current assets</b>	<b>16,935,384</b>	<b>16,935,384</b>	<b>17,482,407</b>	<b>8,864,997</b>
Property and equipment, net	378,143	378,143	402,286	496,731
Other assets	46,320	46,320	46,320	76,320
Deferred IPO costs	650,241	650,241	171,607	
<b>Total assets</b>	<b>\$ 18,010,088</b>	<b>\$ 18,010,088</b>	<b>\$ 18,102,620</b>	<b>\$ 9,438,048</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>				
Current liabilities:				
Accounts payable	\$ 2,346,641	\$ 2,346,641	\$ 1,192,600	\$ 1,443,838
Accrued expenses	4,869,065	4,869,065	3,129,552	1,340,339
Notes payable, net of discount				8,571,877
Deferred revenue	10,019,653	10,019,653	10,019,653	9,499,653
Other liabilities				25,852
<b>Total current liabilities</b>	<b>17,235,359</b>	<b>17,235,359</b>	<b>14,341,805</b>	<b>20,881,559</b>
Redeemable Series C preferred stock warrants	1,897,781		1,706,829	654,527
Shares subject to redemption:				
Series A convertible preferred stock, \$0.001 par value; 14,948,506 shares authorized, 14,948,506, 14,948,506 and 20,237,911 issued and outstanding, subject to redemption, conversion or liquidation, as of December 31, 2013 and September 30, 2013 and 2012, respectively (includes accumulated dividends); no shares issued or outstanding, pro forma	20,279,354		20,056,790	26,035,170
Series B convertible preferred stock, \$0.001 par value; 12,694,561 shares authorized, 12,694,561, 12,694,561 and 16,052,343 shares, issued and outstanding, subject to redemption, conversion or liquidation, as of December 31, 2013 and September 30, 2013 and 2012, respectively (includes accumulated dividends); no shares issued or outstanding, pro forma	30,439,263		30,089,853	36,341,339
Series B-1 convertible preferred stock, \$0.001 par value; 9,331,374 shares authorized; 9,331,374, 9,331,374 and 9,627,634 shares issued and outstanding, subject to redemption, conversion or liquidation, as of December 31, 2013 and September 30, 2013 and 2012, respectively (includes accumulated dividends); no shares issued or outstanding, pro forma	19,631,125		19,374,285	18,959,385
Series C convertible preferred stock, \$0.001 par value; 11,901,336 shares authorized; 11,023,232, 11,023,232, and 0 shares issued and outstanding, subject to redemption, conversion or liquidation, as of December 31, 2013 and September 30, 2013 and 2012, respectively (includes accumulated dividends); no shares issued or outstanding, pro forma	20,765,480		20,462,072	
Commitments and contingencies				
Stockholders' deficit:				
Common stock, \$0.001 par value; 80,000,000 shares authorized; 3,048,131, 3,048,131 and 1,652,904 issued and outstanding as of December 31, 2013 and September 30, 2013 and 2012, respectively; 10,568,742 issued and	3,048	10,569	3,048	1,653

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outstanding, pro forma				
Additional paid in capital	14,282,099	107,287,581	14,203,995	2,101,818
Accumulated deficit	(106,523,421)	(106,523,421)	(102,136,057)	(95,537,403)
Total stockholders' deficit	(92,238,274)	774,729	(87,929,014)	(93,433,932)
Total liabilities and stockholders' deficit	\$ 18,010,088	\$ 18,010,088	\$ 18,102,620	\$ 9,438,048

See accompanying notes to financial statements.

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## EAGLE PHARMACEUTICALS, INC.

## STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended September 30,	
	2013 (unaudited)	2012 (unaudited)	2013	2012
<b>Revenue:</b>				
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
<b>Total revenue</b>	<b>5,491,565</b>	<b>1,483,066</b>	<b>13,678,903</b>	<b>2,539,402</b>
<b>Operating expenses:</b>				
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
<b>Total operating expenses</b>	<b>8,557,019</b>	<b>4,360,541</b>	<b>22,134,027</b>	<b>22,370,140</b>
Loss from operations	(3,065,454)	(2,877,475)	(8,455,124)	(19,830,738)
Interest income	1,264	638	3,212	34,530
Net proceeds from arbitration			4,050,252	
Interest expense		(148,162)	(309,121)	(90,718)
Deferred financing costs		(28,925)	(96,417)	(19,283)
Amortization of debt discount		(327,264)	(1,090,878)	(218,176)
Change in value of warrant liability	(190,952)		(1,052,302)	
Loss on subscription loan settlement				(51,379)
Other income/(expense), net			3,202	11,862
<b>Total other income/(expense), net</b>	<b>(189,688)</b>	<b>(503,713)</b>	<b>1,507,948</b>	<b>(333,164)</b>
<b>Loss before income tax benefit</b>	<b>(3,255,142)</b>	<b>(3,381,188)</b>	<b>(6,947,176)</b>	<b>(20,163,902)</b>
Income tax benefit		898,703	898,703	781,261
<b>Net loss</b>	<b>\$ (3,255,142)</b>	<b>\$ (2,482,485)</b>	<b>\$ (6,048,473)</b>	<b>\$ (19,382,641)</b>
Less dividends on Series A, B, B-1 and C Convertible Preferred Stock	(1,132,222)	(819,134)	(3,836,777)	(3,933,425)
<b>Net loss attributable to common stockholders</b>	<b>\$ (4,387,364)</b>	<b>\$ (3,301,619)</b>	<b>\$ (9,885,250)</b>	<b>\$ (23,316,066)</b>
Loss per share attributable to common stockholders Basic and diluted	\$ (1.44)	\$ (1.09)	\$ (3.25)	\$ (14.11)
Weighted average common shares outstanding Basic and diluted	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	

See accompanying notes to financial statements.

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**EAGLE PHARMACEUTICALS, INC.**  
**STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT**

	Common Stock			Accumulated Deficit	Total Stockholders' Deficit
	Number of Shares	Amount	Additional Paid-In Capital		
<b>Balance, September 30, 2011</b>	<b>1,701,396</b>	<b>\$ 1,702</b>	<b>\$ 1,044,953</b>	<b>\$ (72,221,337)</b>	<b>\$ (71,174,682)</b>
Stock-based compensation expense			402,289		402,289
Beneficial conversion value of notes payable			654,527		654,527
Forfeitures of stock	(48,492)	(49)	49		
Net loss				(19,382,641)	(19,382,641)
Dividends on Convertible Preferred Stock				(3,933,425)	(3,933,425)
<b>Balance, September 30, 2012</b>	<b>1,652,904</b>	<b>1,653</b>	<b>2,101,818</b>	<b>(95,537,403)</b>	<b>(93,433,932)</b>
Stock-based compensation expense			317,192		317,192
Conversion of Series A preferred to common stock	825,177	825	5,135,187		5,136,012
Conversion of Series B preferred to common stock	523,832	524	6,110,639		6,111,163
Conversion of Series B-1 preferred to common stock	46,218	46	539,159		539,205
Net loss				(6,048,473)	(6,048,473)
Dividends on Convertible Preferred Stock				(3,836,777)	(3,836,777)
Forfeitures of dividends on Convertible Preferred Stock				3,286,596	3,286,596
<b>Balance, September 30, 2013</b>	<b>3,048,131</b>	<b>\$ 3,048</b>	<b>\$ 14,203,995</b>	<b>\$ (102,136,057)</b>	<b>\$ (87,929,014)</b>
Stock-based compensation expense (unaudited)			78,104		78,104
Net loss (unaudited)				(3,255,142)	(3,255,142)
Dividends on Convertible Preferred Stock (unaudited)				(1,132,222)	(1,132,222)
<b>Balance, December 31, 2013 (unaudited)</b>	<b>3,048,131</b>	<b>\$ 3,048</b>	<b>\$ 14,282,099</b>	<b>\$ (106,523,421)</b>	<b>\$ (92,238,274)</b>

See accompanying notes to financial statements.

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## EAGLE PHARMACEUTICALS, INC.

## STATEMENTS OF CASH FLOWS

	Three Months Ended December 31,		Year Ended September 30,	
	2013 (unaudited)	2012 (unaudited)	2013	2012
<b>Cash flows from operating activities:</b>				
Net loss	\$ (3,255,142)	\$ (2,482,485)	\$ (6,048,473)	\$ (19,382,641)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>				
Depreciation expense	30,848	52,734	134,994	240,193
Stock-based compensation	78,104	104,393	317,192	402,289
Non-cash interest expense		148,162	309,121	90,419
Amortization of deferred financing costs		28,926	96,417	19,283
Amortization of debt discount		327,264	1,090,878	218,176
Change in fair value of warrant liability	190,952		1,052,302	
Loss on subscription loan settlement				51,379
<b>Changes in operating assets and liabilities:</b>				
Decrease (increase) in accounts receivable	(1,468,094)	241,492	(3,543,337)	(1,320,836)
Decrease in inventories			86,881	1,052,055
Decrease (increase) in prepaid expenses and other current assets	1,533,857	(886,068)	(1,368,692)	197,285
Decrease in other assets			30,000	
Increase (decrease) in accounts payable	1,154,041	917,276	(251,238)	(93,671)
Increase in deferred revenue			520,000	3,500,000
Increase (decrease) in accrued expenses and other liabilities	1,758,496	(260,300)	1,694,069	(521,446)
<b>Net cash provided by (used in) operating activities</b>	<b>23,062</b>	<b>(1,808,606)</b>	<b>(5,879,886)</b>	<b>(15,547,515)</b>
<b>Cash flows from investing activities:</b>				
Purchase of property and equipment	(6,705)		(40,548)	(32,695)
Proceeds from short term investments		1,500,000	1,500,000	3,000,000
<b>Net cash used for investing activities</b>	<b>(6,705)</b>	<b>1,500,000</b>	<b>1,459,452</b>	<b>2,967,305</b>
<b>Cash flows from financing activities:</b>				
Proceeds from Convertible Notes and Warrants				9,662,755
Proceeds from issuance of Series C Preferred Stock, net of offering costs of \$159,727			9,828,737	
Deferred financing costs				(115,700)
Deferred IPO costs	(497,617)		(19,624)	
<b>Net cash provided by (used for) financing activities</b>	<b>(497,617)</b>		<b>9,809,113</b>	<b>9,547,055</b>
<b>Net increase (decrease) in cash</b>	<b>(481,260)</b>	<b>(308,606)</b>	<b>5,388,679</b>	<b>(3,033,155)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>10,455,565</b>	<b>5,066,886</b>	<b>5,066,886</b>	<b>8,100,041</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 9,974,305</b>	<b>\$ 4,758,280</b>	<b>\$ 10,455,565</b>	<b>\$ 5,066,886</b>
<b>Supplemental disclosures of cash flow information:</b>				
<b>Cash paid during the period for:</b>				
Interest	\$	\$	\$	\$ 299
Financing costs			19,624	

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Franchise taxes	1,300	5,073	19,693	19,693
<b>Non-cash financing activities</b>				
Fair value of warrants issued with notes payable and the beneficial conversion feature				1,309,054
Conversion of note payable to Preferred Stock			10,062,296	
Conversion of Preferred Stock to Common Stock		12,605,529	15,623,157	3,933,425
Accrued IPO costs	133,000		151,983	

See accompanying notes to financial statements.

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)**

**1. Organization and Business Activities**

Eagle Pharmaceuticals, Inc. (the "Company") is a pharmaceutical company focused on the development and commercialization of specialty and generic pharmaceutical products, primarily in the injectable arena within the hospital segment. The Company has agreements in place with development partners under which products will be jointly developed and profits from the sales of the products will be shared by the parties. The Company has a number of products currently under development and one currently being sold in the United States.

**2. Going Concern**

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America applicable to a going concern, which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business.

For the fiscal year ended September 30, 2013, the Company incurred a net loss of \$6,048,473. The Company has sustained significant losses since its inception on January 2, 2007 and has an accumulated deficit of \$102,136,057 as of September 30, 2013. For the three months ended December 31, 2013, the Company incurred a net loss of \$3,255,142. The Company has an accumulated deficit of \$106,523,421 as of December 31, 2013.

Given the continuing significant losses, the Company's ability to realize its assets and discharge its liabilities depends on its ability to generate cash from capital financing, licensing activities and royalty revenues.

The Company plans to obtain funding to meet working capital needs for the foreseeable future. However, no assurances can be given that the financing will be completed within the next year. The Company continues its initiatives to increase revenues and generate cash in order to become cash-flow positive.

In light of the above, the financial statements have been prepared on a going concern basis, assuming the Company has the ability to satisfy its obligations in the normal course of business. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The following is a summary of the key events that the Company has done in the past and are necessary in the future to attain profitability and obtain liquidity:

The Company closed on a \$10 million equity infusion in April 2013, See Note 9.

The Company has opportunities to out-license products in its portfolio which can be utilized to generate near term cash and/or fund development activities for those products. Currently, the focus for out-licensing activities is concentrated outside the United States.

The Company has approximately fifteen products in various stages of development, including expanded indications. The Company has the ability to scale back or postpone development activities for certain products in order to conserve cash.



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EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**2. Going Concern (Continued)**

Management continually identifies opportunities to streamline its research and development project spending and general and administrative costs.

The Company explores financing opportunities through debt or equity to sustain its operations.

Management believes these factors will contribute toward achieving working capital requirements.

The Company's principal source of funding, since inception, has been its Series A, Series B, Series B-1 and Series C financings, issuance of Convertible Notes, and revenues from product sales and the out-licensing of products. The Company has raised approximately \$86 million from preferred stock offerings. Additionally, the Company has generated significant revenues from milestones in its portfolio. Since inception, the Company has generated \$28 million in proceeds from such collaborative arrangements.

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 the Company.

**3. Summary of Significant Accounting Policies**

**Stock Split** On January 27, 2014, the Company effected a one-for-6.41 reverse stock split of its common stock (that resulted in a proportional adjustment to the conversion ratio of the preferred stock). All references to common stock, common stock equivalents and per share amounts have been changed retroactively in these financial statements.

**Basis of Presentation**

The financial statements for the interim periods included herein are unaudited; however, they contain all adjustments (consisting of only normal recurring adjustments) which, in the opinion of Company management, are necessary to present fairly the financial position of the Company as of December 31, 2013, and the results of its operations and cash flows for the three months ended December 31, 2013 and 2012. The results of operations for the interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. The financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP, in accordance with the rules and regulations of the Securities and Exchange Commission for interim reporting. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in complete annual financial statements have been condensed or omitted.

**Unaudited Pro Forma Balance Sheet** The Company is preparing for an initial public offering of its shares of common stock. Upon the closing of the initial public offering, the Company's shares of preferred stock will convert into shares of common stock. The Company has presented an unaudited pro forma balance sheet as of December 31, 2013 to reflect the reverse stock split, the conversion of all outstanding shares of preferred stock as of that date into shares of common stock and the reclassification of the liability for warrants for redeemable convertible preferred stock to stockholders'



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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)**

**3. Summary of Significant Accounting Policies (Continued)**

equity, events which will occur upon the closing of the Company's initial public offering. The effect of this conversion is to reclassify \$91,115,222 of redeemable convertible preferred stock and \$1,897,781 of liabilities into stockholders' equity.

*Use of Estimates*

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

*Cash and Cash Equivalents*

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

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

*Fair Value of Financial Instruments*

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and notes payable. The carrying values of these financial instruments approximate their fair values due to their short term maturities.

*Short Term Investments*

Investments consisted of U.S. Treasury and agency securities that had an original maturity of greater than three months. The Company's investments were classified as Level 1 and available-for-sale and are recorded at fair value, based upon quoted market prices. No gains or losses on investments are realized until the sale occurs or a decline in fair value is determined to be other-than-temporary. If a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

*Fair Value Measurements*

GAAP establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)**

**3. Summary of Significant Accounting Policies (Continued)**

that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1: Quoted prices in active markets for identical assets or liabilities.

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

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value of interest-bearing cash and cash equivalents and short term investments are classified as Level 1 at December 31, 2013, September 30, 2013 and 2012.

The Company is required by GAAP to record certain assets and liabilities at fair value on a recurring basis.

The guidance in ASC 815 requires that the Company mark the value of its warrant liability (See Note 7) to market and recognize the change in valuation in its statement of operations each reporting period. Determining the warrant liability to be recorded requires the Company 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, the Company recognizes a warrant liability and estimates the fair value of these warrants using a Probability- Weighted Expected Returns valuation model. Therefore, the warrant liability is considered a level 3 measurement.

***Concentration of Major Customers and Vendors***

The Company's customers are its commercial and collaborative and licensing partners. The Company is dependent on these commercial partners to market and sell EP-1101 (argatroban), from which all of its revenues is currently derived; therefore, the Company's future revenues are highly dependent on these collaboration and distribution arrangements.

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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**3. Summary of Significant Accounting Policies (Continued)**

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

	Three Months Ended December 31,		Year Ended September 30,	
	2013	2012	2013	2012
<b>Net revenues</b>				
The Medicines Company	50%	100%	54%	100%
Sandoz, Inc.	50%	0%	46%	0%
	100%	100%	100%	100%

	December 31,		September 30,	
	2013	2013	2012	2012
<b>Accounts receivable, net</b>				
The Medicines Company		56%	58%	92%
Sandoz, Inc.		43%	40%	0%
EMET Pharmaceuticals, LLC		1%	2%	8%
		100%	100%	100%

Currently, for EP-1101 (argatroban), the Company uses one vendor as its sole source of product. Because of the unique equipment and process for manufacturing EP-1101 (argatroban), transferring manufacturing activities for EP-1101 (argatroban) to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that are capable of performing this function for the Company.

***Inventories***

Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. Inventory consists of raw materials and finished product. The Company periodically reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventory, the Company will record a write-down to net realizable value in the period that the decline in value is first recognized. In most instances, inventory is shipped from the Company's vendor directly to the Company's customers.

***Property and Equipment***

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

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)**

**3. Summary of Significant Accounting Policies (Continued)**

*Research and Development Expense*

Costs incurred for research and product development, including costs incurred for technology in the development stage, are expensed as incurred.

*Deferred Financing Costs*

Costs relating to obtaining Convertible Notes have been capitalized and amortized over the term of the related debt using the straight line method. Amortization of deferred financing costs charged to interest expense was \$0, \$28,925, \$96,417 and \$19,283 for the three months ended December 31, 2013 and 2012 and the years ended September 30, 2013 and 2012, respectively. The unamortized balance was \$0, \$0 and \$96,417 at December 31, 2013, September 30, 2013, and 2012, respectively.

*Deferred IPO Costs*

Costs incurred related to an initial public offering of the Company's common stock, primarily professional fees, are deferred until either the completion of the offering at which time such costs will be netted against proceeds received and reclassified to Additional Paid In Capital or the determination to abandon the offering at which time such costs will be recorded as expense.

*Advertising and Marketing*

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were immaterial for the three months ended December 31, 2013 and 2012 and for the years ended September 30, 2013 and 2012.

*Redeemable Convertible Preferred Stock*

The carrying value of redeemable convertible preferred stock is increased by periodic accretions, using the interest method so that the carrying amount will equal the redemption amount at the earliest redemption date.

*Accounting for Income Taxes*

The Company accounts for deferred taxes using the asset and liability method as specified by ASC 740, *Income Taxes*. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and the tax basis of assets and liabilities, operating losses and tax credit carry forwards. Deferred income taxes are measured using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

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EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

3. Summary of Significant Accounting Policies (Continued)

*Revenue Recognition*

*Product Revenue* The Company recognizes net revenue from products manufactured and supplied to its 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 manufactured products, the Company conducts initial product release and stability testing in accordance with cGMP. The Company's commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. The Company estimates its return reserves based on its experience with historical return rates. Historically, product returns have not been material.

*Royalties* The Company recognizes revenue from royalties based on its commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter and subsequently determines a true-up when it receives royalty reports from its commercial partners. Historically, these true-up adjustments have been immaterial.

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

The Company recognizes revenues from non-refundable up-front license fees received under collaboration agreements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development agreements, and contract period or longest patent life in the case of supply and distribution agreements). If the estimated performance period is subsequently modified, the Company will modify the period over which the upfront 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 its statements of operations. The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of its performance obligations under the collaboration agreement. No such revenue was recorded in 2013 or 2012.

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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**3. Summary of Significant Accounting Policies (Continued)***Stock-Based Compensation*

The Company accounts for stock-based compensation using the fair value provisions of ASC 718, *Compensation - Stock Compensation* that requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based payments including stock options and restricted stock. This topic requires companies to estimate the fair value of the stock-based awards on the date of grant for options issued to employees and directors. The Company uses a Black-Scholes valuation model as the most appropriate valuation method for pricing these options. Awards for consultants are accounted for under ASC 505-50, *Equity Based Payments to Non-Employees*. Any compensation expense related to consultants is marked-to-market over the applicable vesting period as they vest. There are customary limitations on the sale or transfer of the stock.

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

	Three Months Ended December 31,		Year Ended September 30,	
	2013	2012	2013	2012
Risk-free interest rate	1.75 - 8.25%	.82 - 3.23%	.95 - 2.53%	.82 - 3.23%
Volatility	64.00%	64.00%	64.00%	34.34% - 39.38%
Expected term (in years)	6.02 - 10.00 years	6.08 - 10.00 years	6.07 - 10.00 years	6.07 - 10.00 years
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

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 industry peers as the Company did not have any trading history for its common stock. Industry peers consist of those companies in the pharmaceutical industry similar in size, stage of life-cycle and financial leverage. 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 the Company's history and expectation of future dividend payouts. Changes in the estimated forfeiture rates are reflected prospectively.

*Net Loss Per Share*

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

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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**3. Summary of Significant Accounting Policies (Continued)**

earnings per share. Pro forma loss per share assume conversion of all our outstanding preferred stock to common stock and the net exercise of the preferred stock warrants to common stock at the initial public offering price. Since the Company has incurred net losses for all periods, basic loss per share and diluted loss per share are the same.

The anti-dilutive common shares equivalents outstanding at December 31, 2013 and 2012 and September 30, 2013 and 2012 were as follows:

	Three Months Ended December 31,		Year Ended September 30,	
	2013	2012	2013	2012
Series A	2,332,059	2,332,059	2,332,059	3,157,154
Series B	1,980,429	1,980,429	1,980,429	2,504,197
Series B-1	1,455,750	1,455,750	1,455,750	1,501,930
Series C	1,719,690		1,719,690	
Series C Warrants	147,254		147,254	30,971
Options	841,104	1,016,737	813,529	739,808
	8,476,286	6,784,975	8,448,711	7,934,060

**Reclassification**

Certain previously reported amounts have been reclassified to conform to the presentation used in the December 31, 2013 financial statements.

**4. Inventories**

Inventories consist of the following at December 31, 2013, September 30, 2013, and 2012:

	December 31,		September 30,	
	2013	2013	2012	
Raw materials	\$	\$	\$	86,881
	\$	\$	\$	86,881

As a result of the product recall in the first quarter of fiscal year 2012, the Company incurred losses in the aggregate amount of \$1,643,913 during the fiscal year ended September 30, 2012. Of the total cost, \$1,386,270 was attributable to cost of products returned, inventory write-offs and cost to administer the recall. The remaining expense of \$257,643 pertained to commercial rebates not recovered by its commercial partner. These amounts were charged to Cost of Revenue. The Company re-launched the product in the third quarter of 2012.

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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**5. Property and Equipment**

Property and equipment at December 31, 2013, September 30, 2013 and 2012 consist of the following:

	December 31,		September 30,		Estimated Useful Life (years)
	2013	2013	2012		
Furniture and equipment	\$ 297,458	\$ 297,458	\$ 297,458		7
Office equipment	299,569	292,864	292,864		3
Equipment	592,940	592,940	592,940		7
Leasehold improvements	40,548	40,548	480,003		2
	1,230,515	1,223,810	1,663,265		
Less accumulated depreciation	(852,372)	(821,524)	(1,166,534)		
Property and equipment, net	\$ 378,143	\$ 402,286	\$ 496,731		

Depreciation expense amounted to \$30,848, \$52,734, \$134,994 and \$240,193 for the three months ended December 31, 2013 and 2012 and for the years ended September 30, 2013 and 2012, respectively.

Included in equipment are assets held for future use which are not subject to depreciation. As of December 31, 2013, September 30, 2013 and 2012, this equipment amounted to approximately \$270,000.

**6. Balance Sheet Accounts***Prepaid and Other Current Assets*

Prepaid and other current assets consist of the following:

	December 31,		September 30,	
	2013	2013	2012	
Prepaid and Other Current Assets				
Prepaid Product Costs	\$	\$ 730,003	\$	
Prepaid FDA User Fee	216,556	1,023,291	273,705	
Prepaid Insurance	115,399	117,510	122,213	
All Other	36,848	31,856	138,050	
Total Prepaid and Other Current Assets	\$ 368,803	\$ 1,902,660	\$ 533,968	



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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**6. Balance Sheet Accounts (Continued)***Accrued Expenses*

Accrued expenses consist of the following:

	December 31,		September 30,	
	2013	2013	2012	
Accrued Expenses				
Royalties Due to The Medicines Company	\$ 2,583,330	\$ 1,724,061	\$	
Royalties Due to SciDose	1,204,416	546,756		
Accrued R&D expenses	579,356	282,682	573,800	
Accrued Professional Fees	303,483	274,566	327,194	
Accrued Salary Expenses	109,106	169,568		
Accrued Product Cost expenses		62,737	219,915	
All Other	89,374	69,182	219,430	
<b>Total Accrued Expenses</b>	<b>\$ 4,869,065</b>	<b>\$ 3,129,552</b>	<b>\$ 1,340,339</b>	

*Deferred Revenue*

Deferred revenue consists of the following:

	December 31,		September 30,	
	2013	2013	2012	
The Medicines Company	\$ 519,653	\$ 519,653	\$ (347)	
<i>Deferred Revenue for ongoing business</i>	519,653	519,653	(347)	
Hikma Pharmaceuticals, Co. Ltd	3,500,000	3,500,000	3,500,000	
Par Pharmaceuticals Companies, Inc.	5,500,000	5,500,000	5,500,000	
Par Pharmaceuticals Companies, Inc./Tech Transfer	500,000	500,000	500,000	
<i>Deferred Revenue from Asset Sales (see Note 13)</i>	9,500,000	9,500,000	9,500,000	
<b>Total Deferred Revenue, net</b>	<b>\$ 10,019,653</b>	<b>\$ 10,019,653</b>	<b>\$ 9,499,653</b>	

**7. Notes Payable****Convertible Notes**

The Company entered into a Convertible Note and Warrant Purchase Agreement (the "Convertible Notes"), pursuant to which it issued \$9,662,755 of Convertible Notes to existing preferred stockholders. The loan funding was completed in two tranches on August 2, 2012 and September 26, 2012, respectively. Holders of the Convertible Notes were entitled to cumulative interest at an annual rate of 6%. Such interest accrued daily and was cumulative from the respective date. In addition, the holders received warrants (the "Warrants") to purchase preferred stock, which accrued at a monthly



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EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
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**7. Notes Payable (Continued)**

rate of 2% of the principal amount until the completion of a Qualified Financing, as defined, or August 1, 2013, whichever was sooner.

The Convertible Notes and associated accrued interest were due and payable on August 1, 2013, unless the Notes converted earlier. Conversion could occur, upon certain triggering events or the holder elects to convert. Principal and interest accrued shall convert into shares of preferred stock: a) upon the attainment of a Qualified Financing, or b) on August 1, 2013, whichever is sooner. Upon conversion pursuant to (a), the aggregate amount converted will be divided by the offering price of the Qualified Financing to arrive at the amount of Preferred Stock that will be issued. Upon conversion pursuant to (b), the aggregate amount converted will be divided by \$1.82 to arrive at the amount of Preferred Stock that will be issued.

The Series C Preferred Share financing (See Note 9) represented a Qualified Financing whereby the Convertible Notes for those participating investors converted to Series C Preferred Shares.

The Convertible Notes agreement was structured such that a portion of the shares of the Company's Series A Preferred Stock, Series B Preferred Stock and Series B-1 Preferred Stock, collectively the "Special Conversion Preferred", held by a holder, that did not participate in the financing to the full extent of its pro rata share of Preferred Stock ownership (a "Non-Fully Participating Holder"), was converted into shares of the Company's Common Stock, and any dividends accumulated to date were forfeited.

The option for existing preferred stockholders to participate in the Convertible Notes expired on October 1, 2012. On October 2, 2012, 8,943,447 shares of Preferred Stock held by Non-Fully Participating Holders were converted into 1,395,226 shares of Common Stock. Upon conversion from preferred to common, those investors forfeited all accrued dividends from their investment date, which amounted to \$3.3 million.

*Warrants*

The Company accounts for the Warrants as liability instruments. The Company estimated the initial fair value of the warrants associated with the Notes to be \$654,527 using a Probability-Weighted Expected Returns valuation model. At each reporting period, any changes to the fair value of the warrants will be recorded in the statements of operations. As of December 31, 2013, September 30, 2013 and September 30, 2012, warrants to purchase 944,210, 944,210 and 198,534 shares of preferred stock, respectively, were issued and outstanding in connection with the Convertible Notes.

The valuation model considered three scenarios. Two of the scenarios assume a stockholder exit, either through sale, or dissolution. The third scenario assumes operations continue as a private company and no exit transaction occurs. The following assumptions were used in the valuation: exercise price of \$1.82; implied stock price of \$1.82; expected volatility of 64%; expected dividend rate of 6%; risk free interest rate of 0.83% and expiration date of six years.

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EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**7. Notes Payable (Continued)**

The following is a description of the key terms of the warrants:

*Exercise period* Exercisable, in whole or in part, during the six year term commencing on the earliest to occur of: (a) the consummation of a Qualified Financing, (b) immediately prior to the consummation of a Change of Control (but subject to and contingent upon such consummation of a Change of Control) and (c) the date one year after the Initial Closing or August 1, 2013.

*Exercise Price* The purchase price for the Warrant Shares issuable shall be: (a) \$1.82, or (b) the offering price of a Qualified Financing should this occur prior to August 1, 2013.

*No Rights as Stockholders* Prior to the exercise of the warrants, no holder of warrants (solely in its capacity as a holder of warrants) is entitled to any rights as a stockholder of the Company, including, without limitation, the right to vote, receive notice of any meeting of stockholders or receive dividends, allotments or other distributions.

*Warrant Liability*

As of December 31, 2013, the estimated fair value of the Convertible Note warrant liability was \$1,897,781 which resulted in a charge to other income and expense of \$190,952 for the three months ended December 31, 2013. As of September 30, 2013, the estimated fair value of the Convertible Note warrant liability was \$1,706,829 which resulted in a charge to other income and expense of \$1,052,302 for the year ended September 30, 2013. Upon completion of the qualified offering, the warrants became exercisable into Series C Preferred Shares. The increase in the fair value of the warrant liability is primarily attributable to the liquidation preference of the Series C Preferred Shares to receive 2 times the original investment upon a liquidation event under certain circumstances. As of September 30, 2012, the value of the warrant liability was unchanged from its inception; therefore, there were no charges recorded to other expense to reflect any decrease or increase in fair value of the preferred stock warrants issued. This liability will continue to be marked-to-market with adjustments reflected in results of operations. The future charges could be material.

*Debt Discount*

In connection with the Convertible Notes described above and as a result of the warrants issued with the Convertible Notes, the Company determined that a discount to the debt should be recorded in the amount of \$654,527, representing its fair value and recorded as a discount to the debt instrument and amortized over the life of the instrument. The amount recorded as interest expense during the three months ending December 31, 2012 and the year ended September 30, 2012 was approximately \$164,000 and \$109,000, respectively, in the statements of operations and approximately \$545,000 remained unamortized at September 30, 2012. Due to the conversion of the Convertible Notes to Preferred Stock, the balance of the unamortized debt discount was written off during the year ended September 30, 2013, resulting in interest expense of \$545,000.

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
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**7. Notes Payable (Continued)**

*Beneficial Conversion Feature*

A convertible financial instrument includes a beneficial conversion feature if the effective conversion price is less than the Company's market price of Preferred Stock on the commitment date. The effective price paid for a share is the amount allocated to the convertible instrument, divided by the number of shares the holder is entitled to upon conversion. If the convertible financial instrument is issued with warrants and/or other detachable instruments, the amount allocated to the convertible instrument is the face amount less the allocation to the detachable instruments.

In connection with the Convertible Notes described above and as a result of the warrants issued with the Convertible Notes, the Company determined that the conversion rate represented a beneficial conversion feature. Accordingly, a discount on the notes was recorded in the amount of \$654,527. The discount was amortized ratably with a corresponding non-cash charge to interest expense. The amount recorded as interest expense during the three months ending December 31, 2012 and the year ended September 30, 2012 was approximately \$164,000 and \$109,000, respectively, in the statements of operations and approximately \$545,000 remained unamortized at September 30, 2012. Due to the conversion of the Convertible Notes to Preferred Stock, the balance of the unamortized beneficial conversion feature was written off during the year ended September 30, 2013, resulting in interest expense of \$545,000.

**8. Related Party Transactions**

In 2011, the Company entered into agreements with Scott Tarriff, President and Chief Executive Officer to purchase 549,451 shares of Series B-1 Preferred Stock for \$1,000,001. The Company received promissory notes in the aggregate amount of \$1,000,001, which were netted against the Series B-1 convertible preferred stock in the balance sheets. Due to the consummation of the Convertible Notes (see Note 7) in August 2012, the promissory notes were settled, Mr. Tarriff relinquished 549,451 shares of Series B-1 Preferred Stock, and all interest accrued was forgiven. The Company recorded a loss on the settlement of debt in the amount of \$51,379.

**9. Shares Subject to Redemption - Convertible Preferred Stock**

*Series A Convertible Preferred Stock*

On March 8, 2007, the Company issued 20,237,911 shares of Series A Convertible Preferred Stock, par value \$0.001 (the "Series A Preferred Stock"). The outstanding shares of the Series A Preferred Stock (as amended in connection with the issuance of the Series B Preferred Stock) was redeemable after August 11, 2013 at a redemption price per share equal to the Original Issue Price of \$0.971 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding shares of the Series A Preferred Stock were recorded at their estimated fair value of \$19,651,000 which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of \$179,806. The fair value of the Series A Preferred Stock has been increased through periodic accretions using the interest method for dividends (see "Preferred Stock Dividends" below) so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on the Series A Preferred Stock were \$5,944,171, \$5,721,608 and \$6,563,976 as of December 31, 2013, September 30, 2013

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
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**9. Shares Subject to Redemption - Convertible Preferred Stock (Continued)**

and 2012, respectively. The liquidation value of the Series A Preferred Stock was \$20,459,159, \$20,236,596 and \$26,214,976 as of December 31, 2013, September 30, 2013 and 2012, respectively.

*Series B Convertible Preferred Stock*

On August 11, 2008, the Company issued 16,052,343 shares of Series B Convertible Preferred Stock, par value \$0.001 (the "Series B Preferred Stock"). The Series B Preferred Stock is redeemable as described above for the Series A Preferred Stock at a redemption price per share equal to the Original Issue Price of \$1.82 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding shares of the Series B Preferred Stock were recorded at their estimated fair value of \$29,215,266, which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of \$125,714. The fair value of the Series B Preferred Stock has been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on the Series B Preferred Stock were \$7,460,875, \$7,111,465 and \$7,251,787 as of December 31, 2013, September 30, 2013 and 2012, respectively. The liquidation value of the Series B Preferred Stock is \$30,564,977, \$30,215,567 and \$36,467,053 as of December 31, 2013, September 30, 2013 and 2012, respectively.

*Series B-1 Convertible Preferred Stock*

The Company consummated an offering of Series B-1 Convertible Preferred Stock, par value \$0.001 (the "Series B-1 Preferred Stock") to its existing investors in two stages in February 2011 and July 2011. The Company issued an aggregate of 10,177,085 shares of Series B-1 Preferred Stock. The Series B-1 Preferred Stock is redeemable at a redemption price per share equal to the Original Issue Price of \$1.82 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding shares of the Series B-1 Preferred Stock were recorded at their estimated fair value of \$17,522,294 which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of \$144,250. On August 2, 2012 the Company entered into a Payoff and Exchange Agreement with an Officer/Director (see Note 8). The Company accepted a total of 549,451 shares of Series B-1 Preferred Stock in exchange for satisfaction of the principal amount of debt. The total number of outstanding shares of Series B-1 Preferred Stock was 9,627,634 as of September 30, 2012. The fair value of the Series B Preferred Stock has been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on redeemable shares were \$2,792,274, \$2,535,434 and \$1,569,415 as of December 31, 2013, September 30, 2013 and 2012, respectively. The liquidation value of the Series B-1 Preferred Stock is \$19,775,375, \$19,518,535 and \$19,092,099 as of December 31, 2013, September 30, 2013 and 2012, respectively.

*Series C Convertible Preferred Stock*

The Company consummated an offering of Series C Convertible Preferred Stock, par value \$0.001 (the "Series C Preferred Stock") on April 11, 2013. The Company issued an aggregate of 11,023,232 shares of Series C Preferred Stock. The Series C Preferred Stock is redeemable at a redemption price per share equal to the Original Issue Price of \$1.82 per share plus accrued but unpaid dividends (see

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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**9. Shares Subject to Redemption - Convertible Preferred Stock (Continued)**

"Redemption" below). The outstanding shares of the Series C Preferred Stock were recorded at their estimated fair value of \$20,062,296 which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of \$167,465. The fair value of the Series C Preferred Stock has been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on redeemable shares were \$870,649 and \$567,241 as of December 31, 2013 and September 30, 2013, respectively. The liquidation value of the Series C Preferred Stock is \$20,932,945 and \$20,629,537 as of December 31, 2013 and September 30, 2013, respectively.

On October 2, 2012, holders of Preferred Stock who elected not to participate in the Convertible Notes (see "Notes Payable") had their Preferred Stock shares convert to Common Stock. Upon conversion from preferred to common, the investors forfeited all accumulated dividends from their investment date. 5,289,405 shares of Series A Preferred Stock were converted into 825,177 shares of Common Stock and \$1,718,102 in accumulated dividends was forfeited, 3,357,782 shares of Series B Preferred Stock were converted into 523,832 shares of Common Stock and \$1,519,922 in accumulated dividends was forfeited, and 296,260 shares of Series B-1 Preferred Stock were converted into 46,218 shares of Common Stock and \$48,572 in accumulated dividends was forfeited. Concurrent with the conversion, the Company reduced the amounts authorized for the Series A, Series B, and Series B-1 Preferred Stock to 14,948,506 shares, 12,694,561 shares and 9,331,374 shares, respectively.

***Preferred Stock Voting***

The holders of Preferred Stock have voting rights equal to the common stockholders.

***Redemption***

Redemption is subject to written election of at least two-thirds of Series A Preferred Stockholders, Series B Preferred Stockholders, Series B-1 Preferred Stockholders and Series C Preferred Stockholders voting as a single class. The redemption is to be paid in three installments: 33<sup>1</sup>/<sub>3</sub>% ninety (90) days after a redemption request on or after April 11, 2018, 50% on the one-year anniversary of the redemption request and the remaining amount on the two-year anniversary of the redemption request.

***Conversion***

Each share of Preferred Stock is convertible at the option of the holder, at any time after the date of issuance, into Common Stock on a one-for-one basis, subject to certain adjustments for dilution, if any, resulting from certain future stock issuances. Additionally, the Preferred Stock automatically converts into Common Stock concurrent with the closing of a firm commitment underwritten initial public offering ("Qualified IPO") of Common Stock under the Securities Act of 1933, as amended, in which the Company receives at least \$40,000,000 in gross proceeds and the offering price is not less than five times the Original Issue Price of Series A Preferred, Series B Preferred, Series B-1 Preferred Stock and Series C Preferred Stockholders, respectively. The Company reserved sufficient shares of Common Stock at December 31, 2013, September 30, 2013 and September 30, 2012 for issuance upon the conversion of the Preferred Stock.

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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**9. Shares Subject to Redemption - Convertible Preferred Stock (Continued)***Preferred Stock Dividends*

Holders of Series A, Series B, Series B-1 and Series C Preferred Stockholders are entitled to cumulative dividends at an annual rate of 6% when and if declared. Such dividends shall accrue daily and shall be cumulative from the respective date of issuance of each such share of Preferred Stock, whether declared or not.

Dividends will be paid only when declared by the Board of Directors out of legally available funds or upon the first to occur of (i) payment of the Original Issue Price of each share of Preferred Stock in connection with a redemption or liquidation event or (ii) upon conversion of the Preferred Stock into Common Stock, unless the conversion is done in connection with a Qualified IPO or the sale of the Company under certain conditions ("Qualified Sale"), which will cause the holder to forfeit such dividends.

No dividends have been declared as of or for any period prior to December 31, 2013. Accumulated dividends accrued for Series A, Series B, Series B-1 and Series C Preferred Stock was as follows:

	at December 31,		at September 30,	
	2013		2013	2012
Series A	\$ 5,944,171	\$	5,721,608	\$ 6,563,976
Series B	7,460,875		7,111,465	7,251,787
Series B-1	2,792,274		2,535,434	1,569,415
Series C	870,649		567,241	
<b>Total</b>	<b>\$ 17,067,969</b>	<b>\$</b>	<b>15,935,748</b>	<b>\$ 15,385,178</b>

*Liquidation Preference*

Upon any liquidation, dissolution or winding up (a "Liquidation Event") of the Company (including consolidation or merger), holders of Preferred Stock are entitled to be paid first out of the assets of the Company, prior to any payment to the holders of Common Stock in the following order of priority: first, the holders of Series C Preferred Stock will receive an amount two times (2x) the sum of (i) the Original Issue Price of such shares (such amount to be subject to proportionate adjustment in the event of any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification or other similar event affecting the Series C Preferred Stock, and occurring after the date of filing of this Restated Certificate), plus (ii) an amount equal to the aggregate of all dividends accrued but unpaid, or declared but unpaid, in respect of such shares of Series C Preferred Stock; second, the holders of Series B and Series B-1 Preferred Stock will receive an amount equal to the Original Issue Price of each share of such Preferred Stock plus all accrued but unpaid dividends; and third, the holders of Series A Preferred Stock will receive an amount equal to the Original Issue Price for each share of such Preferred Stock plus all accrued but unpaid dividends. Thereafter, the holders of Series A, Series B, Series B-1 and Series C Preferred Stock (each a "Class") will fully participate with holders of Common Stock on an "as converted" basis for all remaining assets distributable to stockholders. However, if the amount that each Class of preferred stock would receive is greater than



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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**9. Shares Subject to Redemption - Convertible Preferred Stock (Continued)**

three times the original issue price per share (the "Maximum Participation Amount"), then the holders would be entitled to receive, with respect to each share, the greater of (a) the Maximum Participation Amount or (b) the amount each holder would have received if the holder had converted the Preferred Stock into Common Stock immediately prior to the Liquidation Event.

**10. Common Stock and Stock-Based Compensation**

In December of 2007, the Company's Board of Directors approved an incentive compensation plan enabling the Company to grant multiple stock based awards to employees, directors and consultants, the most common being stock options and restricted stock awards. Awards vest equally over a period of four years from grant date. Vesting is accelerated under a change in control of the Company or in the event of death or disability to the recipient. In the event of termination, any unvested shares or options are forfeited. The Company has reserved and made available 1,372,885 shares for issuance under the plan.

The Company recognized share-based compensation in its statements of operations for the three months ended December 31, 2013 and 2012 and the years ended September 30, 2013 and 2012 as follows:

	Three Months Ended December 31,		Year Ended September 30,	
	2013	2012	2013	2012
Selling, general and administrative	\$ 40,616	\$ 62,707	\$ 152,740	\$ 280,964
Research & development	37,488	41,686	164,452	121,325
<b>Total</b>	<b>\$ 78,104</b>	<b>\$ 104,393</b>	<b>\$ 317,192</b>	<b>\$ 402,289</b>

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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**10. Common Stock and Stock-Based Compensation (Continued)**

The following table is a summary of the Company's stock options issued to employees, directors and consultants:

	Number of Stock Option Shares	Weighted Average Exercise Price	Non- Exercisable	Exercisable
<b>Outstanding at September 30, 2011</b>	<b>657,850</b>	<b>5.32</b>	<b>288,605</b>	<b>369,245</b>
Granted	195,471	8.78		
Exercised				
Forfeited or expired	(113,513)			
<b>Outstanding at September 30, 2012</b>	<b>739,808</b>	<b>\$ 6.22</b>	<b>304,226</b>	<b>435,582</b>
Granted	194,065	4.42		
Exercised				
Forfeited or expired	(120,614)			
<b>Outstanding at September 30, 2013</b>	<b>813,259</b>	<b>\$ 5.58</b>	<b>302,603</b>	<b>510,656</b>
Granted	65,521	4.94		
Exercised				
Forfeited or expired	(37,676)			
<b>Outstanding at December 31, 2013</b>	<b>841,104</b>	<b>\$ 5.55</b>	<b>372,337</b>	<b>468,767</b>

The weighted-average grant-date fair value of options granted during the three months ended December 31, 2013 and the fiscal years ended September 30, 2013 and 2012 was \$4.42, \$1.73 and \$3.40, respectively. As of December 31, 2013, there was \$464,153 of unrecognized compensation cost, which will be expensed over the next 4 fiscal years.

The weighted average contractual terms of options outstanding as of December 31, 2013, September 30, 2013 and 2012 was 7.6, 7.0 and 7.5 years, respectively.

The aggregate pre-tax intrinsic value of options outstanding as of December 31, 2013, September 30, 2013 and 2012 was \$456,954, \$178,857 and \$1,844,885, respectively.

**11. Income Taxes**

The benefit for income taxes shown in the statement of operations is net of \$0, \$1,840, \$1,840 and \$2,000 for minimum state taxes for the three months ended December 31, 2013 and 2012 and for the years ended September 30, 2013 and 2012, respectively.

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## EAGLE PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)

**11. Income Taxes (Continued)**

A reconciliation of income taxes at the U.S. federal statutory rate to the benefit for income taxes is as follows:

	Year Ended September 30,	
	2013	2012
Federal tax benefit at statutory rate	(34.00)%	(34.00)%
Non-cash interest and change in fair value of warrants liability	13.82%	0.00%
State tax benefit, net of Federal benefits	(14.87)%	(4.00)%
R&D Credit	(5.14)%	(0.72)%
Other	0.22%	0.07%
Net changes in valuation allowance	25.11%	34.65%
<b>Tax benefit</b>	<b>(14.86)%</b>	<b>(4.00)%</b>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets were as follows:

	September 30,	
	2013	2012
Deferred tax assets		
Net operating loss carryforward	\$ 26,984,000	\$ 26,343,000
Prepaid R&D expenses	2,573,000	2,821,000
Research & development credit	2,033,000	1,598,000
Advance billings	208,000	
Stock based compensation	688,000	553,000
Patent costs	77,000	84,000
Intangible assets	39,000	43,000
Fixed assets	161,000	133,000
Deferred rent expenses		4,000
Returns and allowances	24,000	10,000
Charitable contribution carryforward	28,000	27,000
Other	2,000	
Total deferred tax assets	32,817,000	31,616,000
Deferred tax liabilities		
Prepaid expenses	47,000	49,000
Total deferred tax liabilities	47,000	49,000
Net deferred tax assets	32,770,000	31,567,000
<b>Valuation allowance</b>	<b>\$ (32,770,000)</b>	<b>\$ (31,567,000)</b>

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
THREE MONTHS ENDED DECEMBER 31, 2013 AND 2012 IS UNAUDITED)**

**11. Income Taxes (Continued)**

Realization of the net deferred tax asset is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax asset has been offset by a full valuation allowance.

As of September 30, 2013, the Company had federal and state net operating loss carry forwards of \$72,794,131 and \$37,615,304 respectively. As of September 30, 2013, the Company also had federal and state research and development tax credit carry forwards of \$1,750,190 and \$282,678 respectively.

In July 2006, the Financial Accounting Standards Board ("FASB") issued ASC 740-10, *Uncertainty in Income Taxes*, which defines the threshold for recognizing the benefits of tax-return positions in the financial statements as "more-likely-than-not" to be sustained by the taxing authorities. This statement also requires explicit disclosure requirements about a Company's uncertainties related to their income tax position, including a detailed roll forward of tax benefits taken that do not qualify for financial statement recognition. There are no such amounts recorded due to the adoption of the tax standard.

The Company files income tax returns in the U.S. federal jurisdiction and New Jersey. The Company's tax years open to examination for federal are from 2010 and for state are from 2009. The Company has no amount recorded for any unrecognized tax benefits as of September 30, 2013 and 2012 nor did the Company record any amount for the implementation of ASC 740-10-25. The Company's policy is to record estimated interest and penalty related to the underpayment of income taxes or unrecognized tax benefits as a component of its income tax provision. During the years ended September 30, 2013 and 2012 the Company did not recognize any interest or penalties accrued for unrecognized tax benefits.

The Company received approval to sell a portion of the Company's New Jersey net operating losses ("NOL's") as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology firms with unused net operating loss carryovers and unused research and development credits are allowed to sell these benefits to other firms. In the year ended September 30, 2013, the Company sold net operating losses totaling \$11,028,914 for net proceeds of \$900,543 which is reflected as a tax benefit in fiscal 2013. In fiscal year 2012, the Company sold net operating losses totaling \$10,739,513 for net proceeds of \$783,181 which is reflected as a tax benefit in fiscal 2012. This program is subject to annual renewal and limitations.

**12. License Agreements of Development and Commercialization Rights**

*Development*

The Company has entered into several product development agreements with development partners whereby the Company acquired the exclusive rights in the United States and in most cases worldwide rights to a total of thirty three products for ten years following first commercial sale of each product. The Company will share varying percentages of the profits, after, in most cases, recapturing

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
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**12. License Agreements of Development and Commercialization Rights (Continued)**

development, legal and certain operating costs, from the sales of the products with the development partners if the products are commercialized. The Company expenses these costs as incurred.

***Commercialization Rights***

In May 2008, the Company entered into a collaborative product development agreement with a Branded product company, whereby the Company has agreed to develop a product for the Brand Company. Under the terms of the agreement, the Brand Company acquired the exclusive worldwide rights to market the product for ten years following approval. The Company will receive a royalty on net sales of the product, dependent upon the achievement of certain goals. In addition, the Company received \$750,000 upon signing which was non-refundable and recorded as revenue in the year it was received and it will receive milestones of up to \$13,000,000 upon the achievement of certain goals. The Brand Company is also required to pay all out of pocket costs related to the project and also made payments to the Company totaling \$2,000,000 for the development of the product, payable at \$200,000 per month commencing in April 2008. In July 2013, an arbitration settlement between the two companies was reached. The Company then terminated the contract; therefore no additional revenues will be recognized.

In September 2009, the Company entered into a licensing agreement with a Brand Company whereby the Brand Company has agreed to license a product developed by the Company. Under the terms of the agreement, the Brand Company acquired the exclusive U.S. and Canadian rights to market the product following regulatory approval. The Company received \$5,000,000 upon signing and will receive a royalty on net sales of the product for a period of ten years, with the royalty percentage varying depending upon certain events (see Note 3 Revenue Recognition.) The Company could not allocate the proceeds received at signing between completed research and development (R&D) and in-process R&D that the Company is continuing to work on. Therefore the payment amount of \$5,000,000 was bundled with all elements of the agreement and was amortized over the period when R&D expenditures were to occur. The Company recognized \$2,000,000 and \$3,000,000 in revenue under this arrangement for the years ended September 30, 2011 and 2010, respectively. Additional milestone payments will not be forthcoming as the achievements were not met with the timelines as they were defined.

**13. Asset Sales**

On March 28, 2012, the Company entered into an Asset Purchase Agreement with Hikma Pharmaceutical Co. LTD, or Hikma. Under the terms of the agreement Hikma acquired exclusive U.S. rights to market Diclofenac/Misoprostal following regulatory approval. The Company received \$3,500,000 upon signing the Asset Purchase Agreement. This amount is included in deferred revenue until approval, since it is refundable otherwise. In addition, the Company is entitled to receive another \$1,000,000 upon regulatory approval, validation batch manufacturing with inventory released for launch, and sufficient launch inventory. Before approval, this milestone will be reduced for each generic competitor that receives regulatory approval (excluding an "authorized generic" version of the Brand Product); however, shall not be reduced to an amount less than \$500,000. The Company will receive a royalty on Net Profits of the product for a period of ten years from the date of the first

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
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**13. Asset Sales (Continued)**

commercial sale of the product, with the royalty percentage varying depending upon certain events and competition.

On June 24, 2013, Hikma filed a lawsuit against the Company in the United States District Court for the Southern District of New York alleging that we (a) breached the Hikma, Asset Purchase Agreement (APA) by failing to refund the purchase price following Hikma's purported termination of the Hikma APA as a result of us failing to receive timely ANDA approval, and (b) intentionally failed to disclose alleged manufacturing product defects to Hikma. We believe we did not deny Hikma to receive timely ANDA approval entitled to Hikma to terminate the Hikma APA and thus receive a refund of the purchase price, and that the Company did not intentionally fail to disclose alleged manufacturing product defects to Hikma. Should Hikma prevail on its claims, the Company could be required to pay the return of the \$3,500,000 purchase price plus interest, as well as other damages. The Company cannot estimate the possible loss or range of loss related to the Hikma litigation beyond the \$3,500,000 purchase price. As of September 30, 2013, the \$3,500,000 is accrued as part of deferred revenue.

During fiscal year 2010 and 2011, the Company divested another non-core product and received proceeds of \$6,500,000, comprised of \$5,500,000 as a signing milestone which is recorded in deferred revenues and \$500,000 for the initiation of Tech Transfer of which \$250,000 remains in deferred revenues and a second payment of \$500,000 for the completion of the Tech Transfer of which \$250,000 remains in deferred revenues. Under the terms of this agreement, the licensor must obtain all of the following milestones in order for the Company to earn the revenues. These milestones are a) the receipt of an approvable letter from the FDA, b) acknowledgment from the FDA that no further clinical studies will be needed and c) an approval letter from the FDA. If these milestones are not met, then the \$6,000,000 in total included in deferred revenue on the balance sheet at September 30, 2013 and 2012 must be refunded and the product rights are returned to the Company. In addition, the Company may receive additional milestones of up to \$3,000,000 in the future, dependent on the licensor's actively selling the product in an exclusive market position.

See Note 6 for a summary of Deferred Revenue related to the Asset Sales.

**14. Commitments**

At December 31, 2013, the company has purchase obligations in the amount of \$1,074,173 which represent the contractual commitments under a Contract Manufacturing and Supply Agreement with a supplier. The obligation under the supply agreement is primarily for raw materials and research and development.

The Company moved its office space to a new location in May 2013. The Company leases its office space under a lease agreement that expires on May 31, 2015. Rental expense was \$68,104, \$314,105 and \$329,373 in the three months ended December 31, 2013 and the fiscal years ended September 30, 2013 and 2012, respectively. The remaining future lease payments under the operating lease are \$385,921 as of December 31, 2013, payable monthly through May 31, 2015.

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
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**15. Arbitration**

On October 26, 2011, the Company filed a Demand for Arbitration with the American Arbitration Association against a commercial partner that licensed one of its products. Eagle's claims include breach of contract relating to the development of a new formulation of the product and lack of effort to seek and obtain regulatory approval, ultimately impacting the marketing and sale of that new formulation. As a result, Eagle alleged that it had been significantly damaged. A three person arbitration panel was appointed. The trial was completed on January 25, 2013.

On July 19, 2013, the American Arbitration Association panel awarded the Company \$5,000,000 for damages plus \$23,900 for apportioned costs related to the arbitration for breach of contract. The Company received the funds in September 2013 and the amount was recorded in the results of operations, net of expenses of \$973,649 in the fourth quarter of fiscal year 2013.

**16. Legal Proceedings**

Claims and lawsuits may be filed against the Company from time to time. Although the results of pending claims are always uncertain, the Company believes that it has adequate reserves or adequate insurance coverage in respect of these claims, but no assurance can be given as to the sufficiency of such reserves or insurance coverage in the event of any unfavorable outcome resulting from such actions.

In September 2013, the Company filed a New Drug Application under Section 505(b)(2) for EP-3101 (bendamustine RTD) and notified Teva Pharmaceuticals, the holder of Treanda, the referenced approved drug in its application, of the Company's 505(b)(2) filing and paragraph IV certification. Teva filed a patent infringement lawsuit against the Company in the United States District Court for the District of Delaware on October 21, 2013 to defer the approval of the bendamustine indication. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of the Company's bendamustine product, which will delay FDA approval 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 the Company's 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 the Company's 505(b)(2) NDA due to Teva's unexpired orphan drug and pediatric exclusivities for Treanda. Specifically, 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 the Company cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, the Company 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.

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**EAGLE PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(FINANCIAL INFORMATION AS OF DECEMBER 31, 2013 AND FOR THE  
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**17. Subsequent Events**

The Company received approval to sell a portion of the Company's New Jersey net operating losses ("NOL's") as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology firms with unused net operating loss carryovers and unused research and development credits are allowed to sell these benefits to other firms. As of January 17, 2014, the Company sold net operating losses totaling \$20,285,120 for net proceeds of \$1,294,905 which will be reflected as a tax benefit in the second quarter of fiscal 2014.

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**3,350,000 Shares**

**Eagle Pharmaceuticals, Inc.**

**Common Stock**

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**PROSPECTUS**

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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.

**Piper Jaffray**

**William Blair**

**Cantor Fitzgerald & Co.**

February 11, 2014

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