Amphastar Pharmaceuticals, Inc.
Form S-1/A
June 13, 2014

Use these links to rapidly review the document

Table of Contents

As filed with the Securities and Exchange Commission on June 13, 2014.

Registration No. 333-196097

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 2
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

AMPHASTAR PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**33-0702205**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

11570 6th Street
Rancho Cucamonga, California 91730
(909) 980-9484
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Jason B. Shandell
President
Amphastar Pharmaceuticals, Inc.
11570 6th Street
Rancho Cucamonga, California 91730
(909) 980-9484

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

David B. Allen
Michael A. Hedge
K&L Gates LLP
1 Park Plaza, Twelfth Floor
Irvine, CA 92618
(949) 253-0900

Donna M. Petkanics
Wilson Sonsini Goodrich & Rosati,
Professional Corporation
650 Page Mill Road
Palo Alto, California 94304
(650) 493-9300

Approximate date of commencement of proposed sale to the public:
As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities	**Amount to be**	**Proposed**	**Proposed**	**Amount of**

to be Registered	Registered(1)	Maximum Offering Price Per Share	Maximum Aggregate Offering Price(1)(2)	Registration Fee(3)
Common Stock, par value $0.0001 per share	8,464,000	$12.00	$101,568,000	$13,082

(1) Estimated pursuant to Rule 457(a) under the Securities Act of 1933, as amended. Includes the aggregate offering price of an additional 1,104,000 shares the underwriters have the option to purchase in this offering to cover over-allotments, if any.

(2) Estimated solely for purposes of calculating the registration fee.

(3) The Registrant previously paid $12,880 of the total registration fee in connection with prior filings of this Registration Statement.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We and the selling stockholder may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 13, 2014

PRELIMINARY PROSPECTUS

7,360,000 Shares

Amphastar Pharmaceuticals, Inc.

Common Stock

We are offering 4,000,000 shares of our common stock and the selling stockholder is offering 3,360,000 shares of our common stock. We will not receive any proceeds from the sale of shares to be offered by the selling stockholder. This is our initial public offering and no public market currently exists for our common stock. We expect the initial public offering price to be between $10.00 and $12.00 per share. We have applied to list our common stock on the Nasdaq Global Market under the symbol "AMPH."

We are an "emerging growth company" under federal securities laws and are subject to reduced public company reporting requirements. Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 9 of this prospectus.

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

	PER SHARE	TOTAL
Public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds to Amphastar Pharmaceuticals, Inc. before expenses	$	$
Proceeds to the selling stockholder before expenses	$	$

(1) See the section entitled "Underwriting" for a description of the compensation payable to the underwriters.

Delivery of the shares of common stock is expected to be made on or about , 2014. We have granted the underwriters an option for a period of 30 days to purchase up to an additional 1,104,000 shares from us of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $ and the total proceeds to us, before expenses, will be $.

Jefferies **BMO Capital Markets** **Piper Jaffray**

Needham & Company

Prospectus dated , 2014.

Table of Contents

TABLE OF CONTENTS

Through and including , 2014, (the 25th day after the date of this prospectus), all dealers effecting transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Neither we, nor the selling stockholder, nor the underwriters have authorized anyone to provide any information or make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the selling stockholder are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

For investors outside the U.S.: Neither we, nor the selling stockholder, nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the U.S. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution and possession of this prospectus and any such free writing prospectus outside of the U.S.

The Amphastar Pharmaceuticals logo and other trademarks or service marks of Amphastar Pharmaceuticals, Inc., including, but not limited to Primatene® Mist, Amphadase® and Cortrosyn®, appearing in this prospectus are the property of Amphastar Pharmaceuticals, Inc. All other brand names or trademarks appearing in this prospectus are the property of their respective owners.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in the shares of common stock. You should read the entire prospectus carefully, including "Risk Factors," "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business," and our consolidated financial statements and related notes before deciding to invest in our common stock. References in this prospectus to "Amphastar," "our company," "we," "our," and "us" refer to Amphastar Pharmaceuticals, Inc. and our subsidiaries, unless the context indicates otherwise.

Amphastar Pharmaceuticals, Inc.

Business Overview

We are a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically-challenging generic and proprietary injectable and inhalation products. We currently manufacture and sell 15 products in the U.S. and are developing a portfolio of 13 generic and seven proprietary injectable and inhalation product candidates. We have achieved profitability for each of the past three years but have recorded a loss for the three months ended March 31, 2014. For the year ended December 31, 2013 and for the three months ended March 31, 2014, we recorded net revenues of $229.7 million and $45.9 million, respectively. We recorded net income of $11.9 million for the year ended December 31, 2013 and a net loss of $1.6 million for the three months ended March 31, 2014.

Our largest product by net revenues is enoxaparin sodium injection, the generic equivalent of Sanofi S.A.'s Lovenox. Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant and is indicated for multiple indications, including the prevention and treatment of deep vein thrombosis. We commenced sales of our enoxaparin product in January 2012, and for the year ended December 31, 2013 and the three months ended March 31, 2014, we recognized net revenues from the sale of our enoxaparin product of $145.9 million and $26.1 million, respectively. Enoxaparin is difficult to produce because the active pharmaceutical ingredient, or API, is not easily obtained, manufactured or characterized. We manufacture both the API and finished product for our enoxaparin product in-house. We believe that our enoxaparin product demonstrates our capabilities in characterizing complex molecules (which is a process that involves a determination of physiochemical properties, biological activity, immunochemical properties and purity), developing therapeutically equivalent generic versions of drugs with large, complex molecules and overcoming numerous regulatory hurdles.

In addition to our currently marketed products, we have a robust pipeline of 20 generic and proprietary product candidates in various stages of development which target a variety of indications. With respect to these product candidates, we have filed three abbreviated new drug applications, or ANDAs, one new drug application, or NDA, and one NDA supplement with the U.S. Food and Drug Administration, or FDA.

Our product candidate, Primatene Mist HFA, an over-the-counter epinephrine inhalation product, is intended to be used for the temporary relief of mild asthma symptoms and had a Prescription Drug User Fee Act, or PDUFA, date of May 2014. A PDUFA date sets the target date for the FDA to complete its review of an NDA. On May 22, 2014, we received a complete response letter, or CRL, from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted current Good Manufacturing Practices, or cGMP, deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment

Table of Contents

that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

Our Amphadase product candidate is a bovine sourced hyaluronidase injection. We received approval of our NDA from the FDA for Amphadase in 2004, but discontinued the product in 2009 due to a lack of API supply. We filed an NDA supplement in December 2013 to qualify our own manufactured API. There is no assurance that we will receive approval for these or any product candidates.

Our multiple technological capabilities enable the development of technically-challenging products. These capabilities include characterizing complex molecules, analyzing peptides and proteins, conducting immunogenicity studies, engineering particles and improving drug delivery through sustained-release technology. These technological capabilities have enabled us to produce bioequivalent versions of complex drugs and brand products and support the development and manufacture of a broad range of dosage formulations, including solutions, emulsions, suspensions and lyophilized products, as well as products administered via metered dose inhalers, or MDIs, and dry powder inhalers, or DPIs.

Our primary focus is to develop and commercialize products with high technical barriers to market entry. We are specifically focused on products that:

- leverage our research and development capabilities;
- require raw materials or an API for which we believe we have a competitive advantage in sourcing, synthesizing or manufacturing; and/or
- improve upon an existing drug's formulation with respect to drug delivery, safety and/or efficiency.

In addition, we will opportunistically develop and commercialize product candidates with lower technical barriers to market entry if, for example, our existing supply chain and manufacturing infrastructure allow us to pursue a specific product candidate in a competitive and cost-effective manner.

To complement our internal growth and expertise, we have made several strategic acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing and research and development capabilities including the ability to manufacture raw materials, APIs and other components for our products. On April 30, 2014, we completed our acquisition of Merck Sharpe & Dohme's, or Merck's, API manufacturing business in Éragny-sur-Epte, France, which manufactures porcine insulin API and recombinant human insulin API. In order to facilitate the acquisition, we established a subsidiary in France, Amphastar France Pharmaceuticals SAS, or AFP. We will continue the current site activities, which consist of the manufacturing and sale of porcine insulin API and recombinant human insulin API. As part of the transaction, we have entered into various additional agreements, including various supply agreements, as well as the assignment and licensing of patents Merck was operating under at this facility. In addition, certain existing customer agreements have been assigned to AFP.

Our Strengths

We have built our company by integrating the following capabilities and strengths that we believe enable us to compete effectively in the pharmaceutical industry:

Robust portfolio of products and product candidates. Including our enoxaparin product, we have 15 commercial products in the U.S. and 20 product candidates at different stages of development. Our enoxaparin product was introduced into the U.S. market in 2012 and for the year ended December 31, 2013 and the three months ended March 31, 2014 contributed $145.9 million and $26.1 million, respectively, of our net revenues. We believe we have an opportunity to further increase our enoxaparin market share.

Advanced technical capabilities and multiple delivery technologies. We have developed several advanced technical capabilities that we incorporate into our products and product candidates, including characterization of complex molecules, peptide and protein analysis, immunogenicity studies, particle engineering and sustained-release technology. Our injectable delivery technologies enable us to develop and manufacture generic and proprietary injectables in normal solution,

Table of Contents

lyophilized, suspension, jelly and emulsion forms, as well as in pre-filled syringes. Our inhalation technologies cover a variety of delivery methods, including DPIs and hydrofluoroalkane, or HFA, formulations of MDIs.

Vertically integrated infrastructure. Our infrastructure includes strong research and development expertise, sophisticated pharmaceutical engineering capabilities, comprehensive manufacturing capabilities (including the manufacture and synthesis of API for certain products), a strict quality assurance system, extensive regulatory and clinical experience and established marketing and distribution relationships.

Experienced management team with extensive scientific capabilities. Our management team has a successful track record in product development, project management, quality assurance and sales and marketing, as well as established relationships with our key customers, partners and suppliers. Our research and development leadership has deep expertise in areas such as pharmaceutical formulation, process development, *in vivo* studies, analytical chemistry, physical chemistry, drug delivery and clinical research.

Our Strategy

Our goal is to be an industry leader in the development, manufacturing and marketing of technically-challenging injectable and inhalation pharmaceutical products. To achieve this goal, we are pursuing the following key strategies:

Use our sales, marketing and distribution capabilities and relationships to further drive penetration of the market for our enoxaparin product. We believe that there remains a significant opportunity to increase our enoxaparin revenues by further expanding our share of the generic enoxaparin market. We intend to maintain our current relationships with group purchasing organizations, drug wholesalers and retailers and compete for additional group purchasing organization contracts.

Diversify our revenues by commercializing our product candidates. We have 20 product candidates in various stages of development, including 13 generic product candidates and seven proprietary product candidates. We also expect to expand our internal sales and marketing capabilities and, in some cases, enter into strategic alliances with other pharmaceutical companies in order to drive market penetration for our product candidates.

Focus on high-margin generic product opportunities. We believe that we have significant opportunities for growth driven by our technical expertise in the development of generic product candidates with high technical barriers to market entry. We believe that if these product candidates are commercialized, they are likely to face less competition than less technically-challenging generic products, which may enable us to earn higher margins for a longer period of time.

Develop proprietary products. We currently have seven proprietary product candidates at various stages of development targeting a broad range of indications. We believe that proprietary products tend to face less competition than generic products due to market exclusivity, intellectual property protection and other barriers to entry.

Leverage our vertically integrated infrastructure to drive operational efficiencies. We believe our vertically integrated infrastructure provides significant benefits including better operating efficiencies, accelerated product development and internal control over product quality. Our ability to manufacture our own API for certain products allows us to develop products that other companies may not focus on due to the uncertainty of supply for many APIs.

Target and integrate acquisitions of pharmaceutical companies, products and technologies. We have a demonstrated ability to identify, acquire and integrate pharmaceutical companies, products and technologies to complement our internal product development capabilities. We believe that our scientific and managerial expertise and our integration experience have improved the quality of the product lines and companies that we have acquired, which have had a positive effect on our results of operations.

Table of Contents

Other Marketed Products

In addition to enoxaparin, we have 14 other products that we currently market. Other marketed products include Cortrosyn (cosyntropin for injection), a lyophilized powder that is indicated for use as a diagnostic agent in the screening of patients with adrenocortical insufficiency, lidocaine jelly, a local anesthetic product used primarily for urological procedures, and our portfolio of emergency syringe products, which include critical care drugs such as atropine, calcium chloride, dextrose, epinephrine, lidocaine, naloxone and sodium bicarbonate, which are provided in pre-filled syringes and are designed for emergency use in hospital settings. We also manufacture and sell phytonadione injection for newborn use, lidocaine topical solution for use as a local anesthetic, morphine injections, epinephrine in vial form and a lorazepam injection. For the year ended December 31, 2013 and the three months ended March 31, 2014, we recorded net revenues from these other marketed products of $83.8 million and $19.8 million, respectively.

Our Product Candidates

Generic Product Candidates

We currently have 13 generic candidates at various development stages that leverage our various technical capabilities, including:

- injectable technologies including various delivery methods and sizes of pre-filled syringes, vials in solution, suspension and lyophilized forms;
- inhalation technologies, including MDIs and DPIs; and
- sophisticated analytical technologies, including characterization and immunogenicity studies for complex molecules, particle engineering, sustained-release technology and peptide and protein analysis.

Proprietary Product Candidates

We currently have seven proprietary drug candidates. These proprietary product candidates, which include two new chemical entity drug candidates, target indications including diabetes, asthma, osteoporosis and Alzheimer's disease. Because of the early stage of development of certain of these proprietary product candidates, we anticipate that it will be several years before we make any FDA regulatory filings or commence clinical trials with respect to these candidates.

Selected Risk Factors Associated with Our Business

An investment in our common stock involves substantial risks and uncertainties that may adversely affect our business, financial condition, results of operations and cash flows. You should fully read and consider the information set forth under the "Risk Factors" section and all other information included in this prospectus before investing in our common stock. Some of the more significant risks relating to an investment in our company include the following:

- our enoxaparin product represents a significant portion of our net revenues and if the sales volume or pricing of this product continues to decline, or if we are unable to satisfy market demand for this product, it could have a material adverse effect on our business, financial position and results of operations;
- we are currently experiencing declining revenue from some of our existing products and anticipate that we may operate at a loss in the near term while continuing to invest in developing new products;
- our success depends on our ability to develop and/or acquire and commercialize additional pharmaceutical products, and most of our current product candidates are at very early stages of development;

our success depends on the integrity of our supply chain, including multiple single source suppliers, the disruption of which could negatively impact our business;

Table of Contents

we face significant competition in the pharmaceutical industry with respect to both our proprietary and generic drugs, which may result in others developing or commercializing products before or more successfully than we do, which could significantly limit our growth and materially adversely affect our financial results;

the sale of our products is subject to regulatory approvals, and our business is subject to extensive regulatory requirements, and if we do not obtain these approvals or comply with these requirements, it could delay or prevent us from selling our products or these regulations may require us to cease sales of any of our products that may have previously been granted marketing approval; and

our ability to obtain approval of our NDA for Primatene Mist HFA will be affected by the CRL we received on May 22, 2014 from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted cGMP deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

Corporate Information

We incorporated in California under the name Amphastar Pharmaceuticals, Inc. in 1996 and merged our California corporation into Amphastar Pharmaceuticals, Inc., a newly formed Delaware corporation, in 2004. Our principal executive offices are located at 11570 6th Street, Rancho Cucamonga, California, 91730, and our telephone number is (909) 980-9484. Our website address is www.amphastar.com. The information that is contained on, or that can be accessed through, our website is not a part of this prospectus, and you should not consider information on our website to be part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company can take advantage of specified reduced reporting requirements that are otherwise generally applicable to public companies. These provisions include, but are not limited to, a requirement to have only two years of audited financial statements and related Management's Discussion and Analysis and reduced disclosure about executive compensation. We may take advantage of these provisions until such time that we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of:

the last day of the fiscal year following the fifth anniversary of the completion of this offering;

the last day of the fiscal year during which we have total annual gross revenue of at least $1.0 billion;

the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended, or the Exchange Act (we will qualify as a large accelerated filer as of the first day of the first fiscal year after we have (i) more than $700.0 million in outstanding common equity held by our non-affiliates and (ii) been public for at least 12 months; the value of our outstanding common equity will be measured each year on the last business day of our second fiscal quarter); or

the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt.

Table of Contents

THE OFFERING

Issuer	Amphastar Pharmaceuticals, Inc.
Common stock offered by us	4,000,000 shares
Common stock offered by the selling stockholder	3,360,000 shares
Total common stock offered	7,360,000 shares
Underwriters' over-allotment option	1,104,000 shares
Common stock to be outstanding after this offering	42,765,940 shares
Use of proceeds	We intend to use the net proceeds from this offering for product development, working capital and other general corporate purposes. We may also use a portion of the net proceeds for potential acquisitions of technologies, assets, products or businesses that expand or complement our current business; however, we currently do not have any agreements or commitments relating to any potential acquisitions for which we would use any of the net proceeds. We will not receive any of the proceeds from the sale of shares to be offered by the selling stockholder. See "Use of Proceeds."
Proposed Nasdaq Global Market symbol	"AMPH"
Risk factors	Investing in shares of our common stock involves a high degree of risk. See "Risk Factors" beginning on page 9 of this prospectus for a discussion of factors you should consider before making a decision to invest in our common stock.

The number of shares of our common stock to be outstanding after this offering is based on a total of 38,765,940 shares of our common stock outstanding as of March 31, 2014 and excludes:

- 11,745,577 shares of common stock issuable upon exercise of options outstanding as of March 31, 2014, with a weighted-average exercise price of $15.40 per share;
- 406,255 shares of common stock issuable upon delivery of deferred stock units, or DSUs, outstanding as of March 31, 2014; and
- 2,139,587 shares of common stock reserved for future grant under our stock incentive plans as of March 31, 2014.

Except as otherwise indicated, all share information contained in this prospectus assumes:

- the effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur in connection with the completion of this offering;
- no exercise of the underwriters' over-allotment option to purchase additional shares; and
- no exercise of outstanding options or vesting of DSUs subsequent to March 31, 2014.

Table of Contents

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the period ended on, the dates indicated. The consolidated statement of operations data for the years ended December 31, 2012 and 2013 and consolidated balance sheet data as of December 31, 2013 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the three month periods ended March 31, 2013 and 2014 and the consolidated balance sheet data as of March 31, 2014 are derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements were prepared on the same basis as the audited consolidated financial statements. Our management believes that the unaudited consolidated financial statements include all adjustments necessary to state fairly the information included in those statements and that the adjustments made consist only of normal recurring adjustments.

You should read this data together with our audited and unaudited consolidated financial statements and related notes to those statements appearing elsewhere in this prospectus and the information under the captions "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results and results for the three months ended March 31, 2014 are not necessarily indicative of results to be expected for the full year ending December 31, 2014.

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
			(unaudited)	
	(in thousands, except per share data)			
Consolidated Statements of Operations Data:				
Net revenues	$ 204,323	$ 229,681	$ 52,963	$ 45,870
Cost of revenues	114,020	142,725	33,406	33,362
Gross profit	90,303	86,956	19,557	12,508
Operating expenses:				
Selling, distribution and marketing	4,426	5,349	1,394	1,259
General and administrative	27,223	30,972	6,907	6,845
Research and development	31,163	33,019	8,904	6,209
Impairment of long-lived assets	2,094	126		164
Total operating expenses	64,906	69,466	17,205	14,477
Income (loss) from operations	25,397	17,490	2,352	(1,969)
Non-operating income (expense):				
Interest income	242	187	49	28
Interest expense	(784)	(958)	(305)	(180)
Other income (expense), net	1,023	508	95	(350)
Total non-operating income (expense)	481	(263)	(161)	(502)
Income (loss) before income taxes	25,878	17,227	2,191	(2,471)
Income tax expense (benefit)	7,784	5,365	(191)	(852)
Net income (loss)[(1)]	$ 18,094	$ 11,862	$ 2,382	$ (1,619)
Net income (loss) per common share[(1)]:				
Basic	$ 0.47	$ 0.31	$ 0.06	$ (0.04)
Diluted	$ 0.46	$ 0.31	$ 0.06	$ (0.04)
Weighted-average shares used to compute net income per common share:				
Basic	38,580	38,712	38,707	38,769

Diluted	38,940	38,883	38,845	38,769

(1) See Note 2 of "Notes to Consolidated Financial Statements" for a description of the method used to compute basic and diluted net income per share and the number of shares used in computing basic and diluted net income per share.

Table of Contents

Share-based compensation included in the consolidated statements of operations above is as follows:

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
			(unaudited)	
	(in thousands)			
Cost of revenues	$ 1,794	$ 1,503	$ 303	$ 293
Operating expenses:				
Selling, distribution and marketing	143	132	24	21
General and administrative	4,593	4,701	1,137	1,176
Research and development	895	699	118	126
Total share-based compensation	$ 7,425	$ 7,035	$ 1,582	$ 1,616

	March 31, 2014	
	Actual	Pro Forma as Adjusted(1)
	(unaudited)	
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents, restricted cash and short-term investments	$ 53,460	$ 90,771
Working capital	104,477	141,788
Total assets	345,109	382,420
Long-term debt and capital leases, including current portion	41,500	41,500
Retained earnings	72,190	72,190
Total stockholders' equity	251,542	288,853

(1) Reflects, on a pro forma as adjusted basis, the sale of 4,000,000 shares of common stock by us in this offering at an assumed initial public offering price of $11.00 per share, the midpoint of the range on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A $1.00 increase or decrease in the assumed initial public offering price of $11.00 per share would increase or decrease, as applicable, each of cash, cash equivalents, restricted cash and short-term investments, working capital, total assets and total stockholders' equity by approximately $3.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial price to the public and other terms of this offering determined at pricing.

Table of Contents

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this prospectus, including our consolidated financial statements and the related notes thereto, before making a decision to invest in our common stock. Our future operating results may vary substantially from anticipated results due to a number of risks and uncertainties, many of which are beyond our control. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. The following discussion highlights some of these risks and uncertainties and the possible impact of these risks on future results of operations. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the market value of our stock could decline substantially and you could lose part or all of your investment.

Risks Relating to Our Business and Industry

Our enoxaparin product represents a significant portion of our net revenues. If the sales volume or pricing of this product continues to decline, or if we are unable to satisfy market demand for this product, it could have a material adverse effect on our business, financial position and results of operations.

Sales from our enoxaparin product, which is our largest selling product, represented 64% and 57% of our total net revenues for the year ended December 31, 2013 and the three months ended March 31, 2014, respectively. We are currently experiencing declining revenue from enoxaparin and some of our other existing products and anticipate that we may operate at a loss in the near term while continuing to invest in developing new products. If the sales volume or pricing of enoxaparin continues to decline, or if we are unable to satisfy market demand for this product, our business, financial position and results of operations could be materially and adversely affected, and the market value of our common stock could decline. For example, due to intense pricing competition in the pharmaceutical industry, we have experienced significant declines in the per unit pricing and gross margins attributable to our enoxaparin product since its commercial launch, even during periods where we have increased market share and net revenues. This product could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including:

- decreasing average sales prices;
- development by others of new pharmaceutical products that are more effective than ours;
- entrance of new competitors into our markets;
- loss of key relationships with suppliers, group purchasing organizations or end-user customers;
- manufacturing or supply interruptions;
- changes in the prescribing practices of physicians;
- changes in third-party reimbursement practices;
- product liability claims; and
- product recalls or safety alerts.

Any factor adversely affecting the sale of enoxaparin may cause our revenues to decline, and we may not be able to achieve and maintain profitability.

Table of Contents

Our success depends on our ability to develop and/or acquire and commercialize additional pharmaceutical products.

Our financial results depend upon our ability to commercialize additional generic and proprietary pharmaceutical products that address unmet medical needs, are accepted by patients and physicians and are reimbursed by payers. Commercialization requires that we successfully and cost-effectively develop, test and manufacture or otherwise acquire both generic and proprietary products. All of our products must receive regulatory approval and meet (and continue to comply with) regulatory and safety standards. If health or safety concerns arise with respect to a product, we may be forced to withdraw it from the market. For example, as a result of environmental concerns over the use of chlorofluorocarbons, or CFCs, the FDA issued a final rule on January 16, 2009 that required the phase-out of the CFC formulation of our Primatene Mist product by December 31, 2011. As a result, in order to resume selling Primatene Mist we have developed a formulation of the product that will use HFA as the propellant and we are now seeking FDA approval for the modified product. There can be no guarantee that our investment in research and development activities will result in FDA approval or produce a commercially viable new product. See the risk factor entitled "The FDA approval process is time-consuming and complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all. Additionally, we may lose FDA approval and/or our products may become subject to foreign regulations."

The development and commercialization process, particularly with respect to our proprietary products, is time-consuming, costly and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to produce and market such products successfully and profitably. For example, we filed an ANDA for our enoxaparin product in March 2003, but FDA approval was not granted until September 2011 due to delays caused largely by our inclusion in lengthy litigation with Sanofi, the FDA's requirement that we perform immunogenicity studies and the receipt of an FDA Warning Letter by the supplier of the starting material for our enoxaparin product, who also became the subject of an FDA Import Alert. Following FDA approval, we became involved in litigation with Momenta Pharmaceuticals, Inc. and Sandoz, Inc., which further delayed the commercial launch of our enoxaparin product until January 2012. Delays in any part of the process, or our inability to obtain regulatory approval of our products, could adversely affect our operating results by restricting or delaying our introduction of new products, which could cause the market value of our products to decline. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially and adversely affected, and the market value of our common stock could decline.

Our ability to introduce new generic products also depends upon our success in challenging patent rights held by third parties or in developing non-infringing products. Due to the emergence and development of competing products over time, our overall profitability depends on, among other things, our ability to introduce new products in a timely manner, to continue to manufacture products cost-effectively and to manage the life cycle of our product portfolio. If we are unable to cost-effectively maintain an adequate flow of successful generic and proprietary products and new indications and/or delivery methods for existing products sufficient to cover our substantial research and development costs and the decline in sales of older products that either become subject to generic competition, or are displaced by competing products or therapies, this could have a material adverse effect on our business, financial condition or results of operations.

Table of Contents

Our success depends on the integrity of our supply chain, including multiple single source suppliers, the disruption of which could negatively impact our business.

Some of our products are the result of complex manufacturing processes, and some require highly specialized raw materials. Because our business requires outsourcing in some instances, we are subject to inherent uncertainties related to product safety, availability and security. For some of our key raw materials, components and API used in certain of our products, we have only a single, external source of supply, and alternate sources of supply may not be readily available. For example, we purchase heparin USP as the starting material for producing our enoxaparin product exclusively from a single source supplier and, in 2009, this supplier received a Warning Letter from the FDA and was the subject of an FDA Import Alert. The resulting shortage of heparin USP resulted in significant delays to the FDA approval process for our enoxaparin product. There are no guarantees our supplier will not receive Warning Letters in the future or that we will be able to replace this single source supplier with an alternate supplier on a commercially reasonable and timely basis, or at all, to prevent a shortage of heparin USP. Additionally, in 2013 our single source supplier of epinephrine API for our Primatene Mist HFA product candidate received a Warning Letter from the FDA, which our supplier has since addressed. In the future, it is possible that our suppliers will receive Warning Letters from the FDA and be unsuccessful in their efforts to address the issues raised in such Warning Letters on a timely basis, or at all, which would result in delays in commercialization and/or manufacturing of our products or product candidates, if FDA approval for such products or product candidates is received. Furthermore, we may be unable to replace such supplier with an alternate supplier on a commercially reasonable and timely basis, or at all.

If we fail to maintain relationships with our current suppliers, we may not be able to complete development, commercialization or marketing of our products, which would have a material and adverse effect on our business. Third-party suppliers may not perform as agreed or may terminate their agreements with us. For example, because these third parties provide materials to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our suppliers experience could delay or interrupt our supply of materials until the supplier cures the problem or until we locate, negotiate for, validate and receive FDA approval for an alternative source of supply, if one is available. In the near term, we do not anticipate that the FDA will approve alternative sources to back up our primary suppliers. Therefore, if our primary suppliers become unable or unwilling to manufacture or deliver materials, we could experience protracted delays or interruptions in the supply of materials. This would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

Additionally, any failure by us to forecast demand for, or to maintain an adequate supply of, the raw material and finished product could result in an interruption in the supply of certain products and a decline in sales of that product.

We face significant competition in the pharmaceutical industry with respect to both our proprietary and generic drugs, which may result in others developing or commercializing products before or more successfully than we do, which could significantly limit our growth and materially and adversely affect our financial results.

Our business operates in the pharmaceutical industry, which is an industry characterized by intense competition. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products and/or processes competitive with, or superior to, our own. We are concentrating the majority of our efforts and resources on developing product candidates utilizing our proprietary technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, labeling claims approved by the FDA for our products compared to claims approved for competitive products and the relative timing and sequence for commercial launch of new

Table of Contents

products by other companies that compete with our new products. If alternative technologies or other therapeutic approaches are adopted prior to our new product approvals, then the market for our new products may be substantially decreased, thus reducing our ability to generate future profits.

This intensely competitive environment requires an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of our products to healthcare professionals in private practice, group practices and managed care organizations. Our competitors vary depending upon product categories, and within each product category, upon dosage strengths and upon drug-delivery systems. Based on total assets, annual revenues and market capitalization, we are smaller than many of our national and international competitors with respect to both our generic and proprietary pharmaceutical products and product candidates. Many of our competitors have been in business for a longer period of time than us, have a greater number of products on the market and have greater financial and other resources than we do. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with them for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. It is possible that developments by our competitors will make our products or technologies noncompetitive or obsolete.

If we fail to obtain exclusive marketing rights for our generic pharmaceutical products or fail to introduce these generic products on a timely basis, our revenues, gross margin and operating results may decline significantly.

The Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act, or FFDCA, provide for a period of 180 days of generic marketing exclusivity for any applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding brand drug, which we refer to as a Paragraph IV certification. The holder of an approved ANDA containing a Paragraph IV certification that is successful in challenging the applicable brand drug patent(s) is often able to price the applicable generic drug to yield relatively high gross margins during this 180-day marketing exclusivity period. ANDAs that contain Paragraph IV certifications challenging patents, however, generally become the subject of patent litigation that can be both lengthy and costly. There is no certainty that we will prevail in any such litigation, that we will be the first-to-file and granted the 180-day marketing exclusivity period or, if we are granted the 180-day marketing exclusivity period, that we will not forfeit such period. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other ANDA applicants who submit Paragraph IV certifications. In addition, brand companies often authorize a generic version of the corresponding brand drug to be sold during any period of marketing exclusivity that is awarded, which reduces gross margins during the marketing exclusivity period. Brand companies may also reduce the price of their brand product to compete directly with generics entering the market, which similarly would have the effect of reducing gross margins. Furthermore, timely commencement of litigation by the patent owner imposes an automatic stay of ANDA approval by the FDA for 30 months, unless the case is decided in the ANDA applicant's favor during that period. Finally, if the court's decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires, and the applicant will not be granted the 180-day marketing exclusivity.

Accordingly, our revenues and future profitability are dependent, in large part, upon our ability or the ability of our development partners to file ANDAs with the FDA timely and effectively or to enter into contractual relationships with other parties that have obtained marketing exclusivity. We may not be able to develop and introduce successful products in the future within the time constraints necessary to be successful. If we or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or to

Table of Contents

partner with other parties that have obtained marketing exclusivity, our revenues, gross margin and operating results may decline significantly, and our prospects and business may be materially adversely affected.

Our generic products face and our generic product candidates will face additional competitive pressures that are specific to the generic pharmaceutical industry.

With respect to our generic pharmaceutical business, revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents and exclusivities protecting a brand name product expire, the first manufacturer to receive regulatory approval for a generic version of the product is generally able to achieve significant market penetration. Therefore, our ability to increase or maintain revenues and profitability in our generics business is largely dependent on our success in challenging patents and developing non-infringing formulations of proprietary products. As competing manufacturers receive regulatory approvals on generic products or as brand manufacturers launch generic versions of their products (for which no separate regulatory approval is required), market share, revenues and gross profit typically decline, often significantly and rapidly. Accordingly, the level of market share, revenue and gross profit attributable to a particular generic product normally is related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. For example, with respect to our enoxaparin product, Sandoz also markets the generic version of enoxaparin and Teva Pharmaceutical Industries Ltd. and Hospira, Inc. have filed ANDAs with the FDA for approval of their generic versions. The presence of these current and prospective competitive products may have an adverse effect on our market share, revenue and gross profit from our enoxaparin product. Since the commercial launch of our enoxaparin product, we have experienced significant declines in the per unit pricing and gross margins attributable to this product, even as we have increased market share and net revenues. Consequently, we must continue to develop and introduce new generic products in a timely and cost-effective manner to maintain our revenues and gross margins. We may have fewer opportunities to launch significant generic products in the future, as the number and size of proprietary products that are subject to patent challenges is expected to decrease in the next several years compared to historical levels. Additionally, as new competitors enter the market, there may be increased pricing pressure on certain products, which may result in lower gross margins. In addition to our enoxaparin product, we have experienced significant pricing pressure on many of our other products, including Cortrosyn, and we expect this trend to continue in the future.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. "Authorized generics" are generic pharmaceutical products that are introduced by brand companies, either directly or through partnering arrangements with other generic companies. Authorized generics are equivalent to the brand companies' brand name drugs, but are sold at relatively lower prices than the brand name drugs. An authorized generic product can be marketed during the 180-day exclusivity granted to the first manufacturer or manufacturers to submit an ANDA with a Paragraph IV certification for a generic version of the brand product. The sale of authorized generics adversely impacts the market share of a generic product that has been granted 180-day exclusivity. For example, with respect to our enoxaparin product, Sanofi currently markets an authorized generic enoxaparin product through its subsidiary, Winthrop. This is a significant source of competition for us because brand companies do not face any regulatory barriers to introducing authorized generics of their products. Because authorized generics may be sold during our exclusivity periods, if any, they can materially decrease the profits that we could otherwise receive as an exclusive marketer of a generic alternative. Such actions have the effect of reducing the potential market share and profitability of our generic products and may inhibit us from developing and introducing generic pharmaceutical products corresponding to certain brand name drugs.

Such competition can also result from the entry of generic versions of another product in the same therapeutic class as one of our drugs, or in another competing therapeutic class, or from the compulsory

Table of Contents

licensing of our products by governments, or from a general weakening of intellectual property laws in certain countries around the world.

If the market for a reference brand product, such as Lovenox, significantly declines, sales or potential sales of our generic and biosimilar products and product candidates may suffer and our business would be materially impacted.

Proprietary products face competition on numerous fronts as technological advances are made or new products are introduced. As new products are approved that compete with the reference proprietary product to our generic products and generic or biosimilar product candidates, such as Lovenox, which is the reference brand product for our enoxaparin product, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product obsolete. In addition, brand companies may pursue life cycle management strategies that also impact our generic products.

If the market for a reference brand product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

Health care providers may not be receptive to our products, particularly those that incorporate our proprietary drug delivery platforms.

The commercial success of our products will depend on acceptance by health care providers and others that such products are clinically effective, affordable and safe. Our products utilizing our proprietary drug delivery technologies may not be accepted by health care providers and others. Factors that may materially affect market acceptance of our products include but are not limited to:

- the relative therapeutic advantages and disadvantages of our products compared to competitive products;
- the relative timing of commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products and for competing products;
- the willingness of third party payers to reimburse for our prescription products;
- the willingness of pharmacy chains to stock our new products; and
- the willingness of consumers to pay for our products.

Our products, if successfully developed and commercially launched, will compete with both currently marketed products and new products launched in the future by other companies. Health care providers may not accept or utilize some of our products. Physicians and other prescribers may not be inclined to prescribe our prescription products unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. Pharmacy chains may not be willing to stock certain of our new products, and pharmacists may not recommend such products to consumers. Further, consumers may not be willing to purchase some of our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

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

Many of the existing and potential customers for our products have combined to form group purchasing organizations in an effort to lower costs. Group purchasing organizations negotiate pricing arrangements with medical supply manufacturers and distributors, and these negotiated prices

are made available to a group purchasing organization's affiliated hospitals and other members. Group purchasing organizations provide 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.

Table of Contents

Hospitals and other end-users contract with the group purchasing organization of their choice for their purchasing needs. We currently derive, and expect to continue to derive, our revenue from end-user customers that are members of group purchasing organizations. Maintaining our strong relationships with these group purchasing organizations will require us to continue to be a reliable supplier, offer a broad product line, remain price competitive, comply with FDA regulations and provide high-quality products. Although our group purchasing organization pricing agreements are typically multi-year in duration, most of them may be terminated by either party with 60 or 90 days notice. The group purchasing organizations with which we have relationships may have relationships with manufacturers that sell competing products, and such group purchasing organizations may earn higher margins from these competing products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our group purchasing organization relationships, sales of our products and revenue could decline.

Although we reported net income for fiscal 2012 and fiscal 2013, we have incurred losses in the first quarter of 2014.

We recorded a net loss of $1.7 million for the three months ended March 31, 2014, compared with net income of $2.4 million for the three months ended March 31, 2013. This loss resulted principally from a decrease in profit sharing revenues under our profit sharing agreement with Actavis, Inc., or Actavis, under which Actavis markets and distributes our enoxaparin product to the retail market in the U.S. We may continue to incur operating and net losses and negative cash flow from operations. Our business may generate operating losses to the extent Actavis reports decreased profit levels on their determined sales volumes and product pricing for enoxaparin, if we are unable to maintain and expand our relationships with group purchasing organizations or if we do not successfully commercialize our product candidates and generate sufficient revenues to support our level of operating expenses. Because of the numerous risks and uncertainties associated with our profit sharing agreement, our commercialization efforts and future product development, we are unable to predict whether we will be able to achieve and maintain profitability.

Consolidation in the health care industry could lead to demands for price concessions or for the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Because health care costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the health care industry to consolidate product suppliers and purchasers. As the health care industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations and large single accounts continue to use their market power to influence product pricing and purchasing decisions. As the U.S. payer market concentrates further and as more drugs become available in generic form, biopharmaceutical companies may face greater pricing pressure from private third-party payers, who will continue to drive more of their patients to use lower cost generic alternatives. This drive towards generic alternatives could adversely affect sales of our proprietary products and increase competition among generic manufacturers.

Sales of our products may be adversely affected by the continuing consolidation of our customer base.

A significant proportion of our sales are made to relatively few U.S. wholesalers and group purchasing organizations. These customers are continuing to undergo significant consolidation. Sales to three of these customers for the year ended December 31, 2013 and the three months ended March 31, 2014 accounted for approximately 54% and 58% of our total net revenues, respectively. Such consolidation has provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face. Additionally, the emergence of large buying groups representing independent

Table of Contents

retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to extract price discounts on our products.

Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. If one or more of our major customers experienced financial difficulties, the effect on us would be substantial. This could have a material adverse effect on our business, financial condition and results of operations.

Our net sales and quarterly growth comparisons may also be affected by fluctuations in the buying patterns of retail chains, major distributors and other trade buyers, whether resulting from seasonality, pricing, wholesaler buying decisions or other factors. In addition, because a significant portion of our U.S. revenues is derived from relatively few customers, any financial difficulties experienced by a single customer, or any delay in receiving payments from a single customer, could have a material adverse effect on our business, financial condition and results of operations.

If our business partners do not fulfill their obligations with respect to our distribution or collaboration agreements our revenues and our business will suffer.

Pursuant to certain distribution or collaboration agreements, the success of some of our products or product candidates also depends on the success of the collaboration with our business partners, who are responsible for certain aspects of researching, developing, marketing, distributing or commercializing our products or product candidates. If such an agreement were to be terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the agreement, revenues could be delayed or diminished from these products and our revenues and/or profit share for these products could be adversely impacted.

For example, we have a profit sharing agreement with Actavis to market and distribute our enoxaparin product to the retail market in the U.S. If Actavis fails to commit sufficient resources to market and distribute our products to the retail market, our profit sharing revenue from retail sales of enoxaparin could be severely impacted.

The revenues we earn and report from our profit sharing agreement with Actavis are subject to their marketing, pricing and reporting practices.

Under the terms of our profit sharing agreement, Actavis markets and distributes our enoxaparin product to the retail market in the U.S., we share in the profits from these activities as reported to us by Actavis. Accordingly, the amounts of profit sharing revenues we recognize each period are subject to Actavis' marketing, pricing and reporting practices. To the extent Actavis reports varying profit levels on their determined sales volumes and product pricing, our profit sharing revenue from retail sales of enoxaparin, financial position, results of operations and cash flows could be materially impacted.

We depend upon our key personnel, the loss of whom could adversely affect our operations. If we fail to attract and retain the talent required for our business, our business could be materially harmed.

We depend to a significant degree on our key management employees, including our Chief Executive Officer and Chief Science Officer, Jack Y. Zhang; Chief Operating Officer and Chief Scientist, Mary Z. Luo; President, Jason B. Shandell; Chief Financial Officer and Senior Vice President, William J. Peters; and Corporate Executive Vice President of Operations and President, International Medication Systems, Ltd., Marilyn J. Purchase. The loss of services from any of these persons may significantly delay or prevent the achievement of our product development or business objectives. Our officers all serve "at will" and we or they can terminate their employment with us at any time. We do not carry key man life insurance on any key personnel. Competition among pharmaceutical companies for qualified employees is intense, and the ability to attract and retain qualified individuals is critical to our success. We have experienced attrition among our executive officers in the past, although we do not believe that the departures of executive officers have had a materially adverse effect on our business. However, any future loss of key members of our organization, or any inability to continue to attract high-quality employees, may delay or prevent the achievement of major business objectives. Our productivity may be adversely affected if we do not integrate or train our new employees quickly and effectively.

Table of Contents

Competition for highly-skilled personnel is often intense, especially in Southern California, where we have a substantial presence and need for highly-skilled personnel. We may not be successful in attracting, integrating or retaining qualified personnel to fulfill our current or future needs. Also, to the extent we hire personnel from competitors, we may be subject to allegations that we have improperly solicited, or that they have divulged proprietary or other confidential information, or that their former employers own their inventions or work product.

Because a portion of our future manufacturing is expected to take place in China, a significant disruption in the construction or operation of our manufacturing facility in China or political unrest in China could materially and adversely affect our business, financial condition and results of operations.

We intend to invest in expansion of our manufacturing facility in China. Any disruption in construction of the facility or the inability of our manufacturing facility in China to produce adequate quantities of raw materials or APIs to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business. Furthermore, since this facility is located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the Chinese government, political unrest or unstable economic conditions in China. The nationalization or other expropriation of private enterprises by the Chinese government could result in the total loss of our investment in China. Any of these matters could materially and adversely affect our business and results of operations. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position.

We are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition.

We have operations both inside and outside the U.S. For example, we have suppliers in Asia and Europe, and we own manufacturing facilities in Nanjing, China and Éragny-sur-Epte, France. As a result, a significant portion of our operations are conducted by and/or rely on entities outside the markets in which our products are sold, and, accordingly, we import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of a closing of the borders of the countries in which we sell our products, or in which our operations are located, due to economic, legislative, political and military conditions in such countries.

International operations are subject to a number of other inherent risks, and our future results could be adversely affected by a number of factors, including:

- requirements or preferences for domestic products or solutions, which could reduce demand for our products;
- differing existing or future regulatory and certification requirements;
- management communication and integration problems resulting from cultural and geographic dispersion;
- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties in enforcing contracts;
- difficulties and costs of staffing and managing non-U.S. operations;
- the uncertainty of protection for intellectual property rights in some countries;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products;

greater risk of a failure of foreign employees to comply with both U.S. and foreign laws, including export and antitrust regulations, the U.S. Foreign Corrupt Practices Act and any trade regulations ensuring fair trade practices;

uneven electricity supply that can negatively impact manufacturing;

Table of Contents

- heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;

- potentially adverse tax consequences, including multiple and possibly overlapping tax structures; and

- political and economic instability, political unrest and terrorism.

In addition, the expansion of our existing international operations, including our facility expansion in Nanjing, China, and entry into additional international markets, including our recent acquisition of a manufacturing business in Éragny-sur-Epte, France, have required and will continue to require significant management attention and financial resources. These and other factors could harm our ability to gain future revenues and, consequently, materially impact our business, operations results and financial condition.

The Chinese government may exert substantial influence over the manner in which we conduct our business operations in China.

The Chinese government has exercised, and continues to exercise, substantial control over virtually every sector of the Chinese economy through regulation and state ownership. Our ability to conduct our proposed manufacturing operations in China may be harmed by changes in its laws and regulations, including those relating to taxation, import and export tariffs, environmental regulations, land use rights, property ownership and other matters. We believe that our operations in China are in material compliance with all applicable legal and regulatory requirements. However, the central or local governments of the jurisdictions in which we operate may impose new, stricter regulations or interpretations of existing regulations that would require additional expenditures and efforts on our part to ensure our compliance with such regulations or interpretations. Accordingly, government actions in the future, including any decision not to continue to support recent economic reforms and to return to a more centrally planned economy or regional or local variations in the implementation of economic policies, could have a significant effect on economic conditions in China or particular regions thereof and could require us to divest ourselves of any interest we then hold in Chinese properties or entities, including our Chinese operating subsidiary, Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP.

The Chinese legal system can be uncertain and could limit the legal protections available to us.

Unlike common law systems, such as the United States, the Chinese legal system is based on written statutes and decided legal cases have little precedential value. Our Chinese operating subsidiary, ANP, is subject to laws and regulations applicable to foreign investment in China in general and laws and regulations applicable to foreign invested enterprises in particular. ANP is also subject to laws and regulations governing the formation and conduct of domestic Chinese companies. Relevant Chinese laws, regulations and legal requirements may change frequently, and their interpretation and enforcement involve uncertainties. For example, we may have to resort to administrative and court proceedings to enforce the legal protections under law or contract. However, since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contract terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and our level of legal protection in China compared to other legal systems. Such uncertainties, including the inability to enforce our contracts and intellectual property rights, could materially and adversely affect our business and operations. In addition, confidentiality protections in China may not be as effective as in the U.S. or other countries. Accordingly, future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local requirements by national laws, could limit the legal protections available to us.

Table of Contents

We could be materially and adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We are currently expanding our operation abroad, including expanding our facilities in China, a country which has experienced governmental and private sector corruption to some degree, and in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. Our internal control policies and procedures may not always protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of these laws, or allegations of such violations, 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.

Movements in foreign currency exchange rates 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.

A portion of our revenues, indebtedness and other liabilities and our costs are denominated in foreign currencies, including the Chinese Yuan and the Euro. We report our financial results in U.S. dollars. Our results of operations and, in some cases, cash flows may in the future be adversely affected by certain movements in exchange rates. From time to time, we may implement currency hedges intended to reduce our exposure to changes in foreign currency exchange rates. However, our hedging strategies may not be successful, and any of our unhedged foreign exchange exposures will continue to be subject to market fluctuations. These risks could cause 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.

We may be exposed to product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by patients, health care providers or others who sell or consume our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale.

Our reputation is the foundation of our relationships with physicians, patients, group purchasing organizations and other customers. If we are unable to effectively manage real or perceived issues that could negatively impact sentiments toward us, our business could suffer. Our customers may have a number of concerns about the safety of our products whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. These concerns may be increased by negative publicity, even if the publicity is inaccurate. Any negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our products or product categories, whether involving us, a competitor or a reference drug, could materially reduce market acceptance of our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact.

We currently maintain a $10.0 million product liability insurance policy, which covers both Amphastar and International Medication Systems, Ltd., or IMS, products, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer from any product liability claims. 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. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could

Table of Contents

cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If serious adverse events or deaths are identified relating to any of our products once they are on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.

We are required to report to relevant regulatory authorities adverse events or deaths associated with our product candidates or approved products. Based on such events, regulatory authorities may withdraw their approvals of such products or take enforcement actions. We may be required to reformulate our products, and/or we may have to recall the affected products from the market and may not be able to reintroduce them into the market. Furthermore, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class actions suits. Any of these events could harm or prevent sales of the affected products and could have a material adverse effect upon our business and financial condition.

Any acquisitions of technologies, products and businesses may be difficult to integrate, could adversely affect our relationships with key customers and/or could result in significant charges to earnings.

We plan to regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, customer or employee base, including diversion of management's attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies that we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. If we are unable to successfully integrate technologies, products, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences.

Identifying, executing and realizing attractive returns on acquisitions is highly competitive and involves a high degree of uncertainty. We expect to encounter competition for potential target businesses from both strategic and financial buyers. Some of these competitors may be well established and have extensive experience in identifying and consummating business combinations. Some of these competitors may possess greater technical, human and other resources than us, and our financial resources may be relatively limited when contrasted with those of our competitors. We may lose acquisition opportunities if we do not match our competitors' pricing, terms and structure criteria for such acquisitions. If we are forced to match these criteria to make acquisitions, we may not be able to achieve acceptable returns on our acquisitions or may bear substantial risk of capital loss. In addition, target companies may not be willing to sell assets at valuations which are attractive to us. Furthermore, the terms of our existing or future indebtedness may hinder or prevent us from making additional acquisitions of technologies, products or businesses. Because of these factors, we may not be able to consummate an acquisition on attractive terms, if at all.

We intend to conduct an extensive due diligence investigation for any business we consider acquiring. Intensive due diligence is often time consuming and expensive due to the operations, finance and legal professionals who may be involved in the due diligence process. Even if we conduct extensive due diligence on a target business which we acquire, we may not identify all material issues that are present inside a particular target business. If our due diligence fails to discover or identify material issues relating to a target business, industry or the environment in which the target business operates, we may be forced to later

Table of Contents

write-down or write-off assets, restructure the target business's operations or incur impairment or other charges that could result in losses to us.

Charges to earnings resulting from acquisitions 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.

Under U.S. generally accepted accounting principles, or GAAP, business combination accounting standards, we recognize the identifiable assets acquired, the liabilities assumed and any non-controlling interests in acquired companies generally at their acquisition date fair values and, in each case, separately from goodwill. Goodwill as of the acquisition date is measured as the excess amount of consideration transferred, which is also generally measured at fair value, and the net of the acquisition date amounts of the identifiable assets acquired and the liabilities assumed. Our estimates of fair value are based upon assumptions believed to be reasonable but which are inherently uncertain. After we complete an acquisition, the following factors could result in material charges and adversely affect our operating results and may adversely affect our cash flows:

- costs incurred to combine the operations of companies we acquire, such as transitional employee expenses and employee retention, redeployment or relocation expenses;
- impairment of goodwill or intangible assets, including acquired in-process research and development;
- amortization of intangible assets acquired;
- a reduction in the useful lives of intangible assets acquired;
- identification of or changes to assumed contingent liabilities, including, but not limited to, contingent purchase price consideration, income tax contingencies and other non-income tax contingencies, after our final determination of the amounts for these contingencies or the conclusion of the measurement period (generally up to one year from the acquisition date), whichever comes first;
- charges to our operating results to eliminate certain duplicative pre-acquisition activities, to restructure our operations or to reduce our cost structure;
- charges to our operating results resulting from expenses incurred to effect the acquisition; and
- changes to contingent consideration liabilities, including accretion and fair value adjustments.

A significant portion of these adjustments could be accounted for as expenses that will decrease our net income and earnings per share for the periods in which those costs are incurred. Such charges could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of the common stock to decline.

The Affordable Care Act and certain new legislation and regulatory proposals may increase our costs of compliance and negatively impact our profitability over time.

In March 2010, President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as "the Affordable Care Act." The Affordable Care Act makes extensive changes to the delivery of health care in the U.S. We expect that the rebates, discounts, taxes and other costs resulting from the Affordable Care Act over time will have a negative effect on our expenses and profitability in the future. Furthermore, the Independent Payment Advisory Board created by the Affordable Care Act to reduce the per capita rate of growth in Medicare spending could potentially limit access to certain treatments or mandate price controls for our products. Moreover, expanded government investigative authority and increased disclosure

obligations may increase the cost of compliance with new regulations and programs.

Congress has also proposed a number of legislative initiatives, including possible repeal of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act, whether to certain provisions or its entirety. In addition, some details regarding the implementation of

Table of Contents

the Affordable Care Act are yet to be determined, and, at this time, the full effect that the Affordable Care Act would have on our business remains unclear.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, on August 2, 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. As a result of the failure of the Joint Select Committee to propose, and of Congress to enact, deficit reduction measures of at least $1.2 trillion for the years 2013 through 2021, the Budget Control Act provides for automatic cuts to be made to most federal government programs, which, with respect to Medicare, would include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Pursuant to the American Taxpayer Relief Act of 2012, which was enacted by Congress on January 1, 2013, the imposition of these automatic cuts began April 1, 2013. In addition, the new law, among other things, reduces Medicare inpatient payment amounts to hospitals and increases the statute of limitations for recovering overpayments from three years to five years. The full impact on our business of this new law, assuming it is implemented, is uncertain. Nor is it clear whether other legislative changes will be adopted or how such changes would affect the demand for our products.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. In particular, California has enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. California's electronic pedigree requirement is scheduled to take effect in January 2015. Compliance with California and future federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

President Barack Obama also signed into law the Food and Drug Administration Safety and Innovation Act. The new law and related agreements make several significant changes to the FFDCA and FDA's processes for reviewing marketing applications that could have a significant impact on the pharmaceutical industry, including, among other things, the following:

- reauthorizes the PDUFA, which increases the amount of associated user fees, and, for certain types of applications, increases the expected time frame for FDA review of NDAs;
- permanently reauthorizes and makes some revisions to the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which provide for pediatric exclusivity and mandated pediatric assessments for certain types of applications, respectively;
- revises certain standards and requirements for FDA inspections of manufacturing facilities and the importation of drug products from foreign countries;
- creates incentives for the development of certain antibiotic drug products;
- modifies the standards for accelerated approval of certain new medical treatments;
- expands the reporting requirements for potential and actual drug shortages;
- requires the FDA to issue a report on, among other things, ensuring the safety of prescription drugs that have the potential for abuse;
- requires the FDA to hold a public meeting regarding the potential rescheduling of drug products containing hydrocodone, which was held in October 2012; and

requires electronic submission of certain marketing applications following the issuance of final FDA regulations.

The full impact on our business of the new laws is uncertain; however, we anticipate that it will have an adverse effect on our results of operations.

Table of Contents

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the European Union, or EU, and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices.

If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms 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.

Global macroeconomic conditions may negatively affect us and may magnify certain risks that affect our business.

Our business is sensitive to general economic conditions, both inside and outside the U.S. Slower global economic growth, credit market crises, high levels of unemployment, reduced levels of capital expenditures, government deficit reduction, sequestration and other austerity measures and other challenges affecting the global economy adversely affect us and our distributors, customers and suppliers. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. Such uncertain economic times may have a material adverse effect on our revenues, results of operations, financial condition and, if circumstances worsen, our ability to raise capital at reasonable rates. If slower growth in the global economy or in any of the markets we serve continues for a significant period, if there is significant deterioration in the global economy or such markets or if improvements in the global economy don't benefit the markets we serve, our business and financial statements could be adversely affected.

Additionally, as a result of the current or a future global economic downturn, our third-party payers may delay or be unable to satisfy their reimbursement obligations. Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including government programs such as Medicare and Medicaid and private payer healthcare and insurance programs. A reduction in the availability or extent of reimbursement from government and/or private payer healthcare programs could have a material adverse effect on the sales of our products, our business and results of operations.

Current economic conditions may adversely affect the ability of our distributors, customers, suppliers and service providers to obtain the liquidity required to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with us, which could disrupt our operations, and could negatively impact our business and cash flow. Although we make efforts to monitor these third parties' financial condition and their liquidity, our ability to do so is limited, and some of them may become unable to pay their bills in a timely manner, or may even become insolvent, which could negatively impact our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to sovereign risk from business interactions directly with fiscally-challenged government payers.

At the same time, significant changes and volatility in the financial markets, in the consumer and business environment, in the competitive landscape and in the global political and security landscape make it increasingly difficult for us to predict our revenues and earnings into the future. As a result, any revenue or earnings guidance or outlook which we have given or might give may be overtaken by events, or may otherwise turn out to be inaccurate. Though we endeavor to give reasonable estimates of future revenues and earnings at the time we give such guidance, based on then-current conditions, there is a significant risk that such guidance or outlook will turn out to be, or to have been, incorrect.

Table of Contents

Significant balances of intangible assets, including goodwill, are subject to impairment testing and may result in impairment charges, which may materially and adversely affect our results of operations and financial condition.

A significant amount of our total assets is related to goodwill and intangible assets. As of March 31, 2014 the value of our goodwill and intangible assets net of accumulated amortization was $39.7 million. Goodwill and other intangible assets are tested for impairment annually when events occur or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. For example, for the year ended December 31, 2012 we had an impairment charge of $2.1 million primarily related to equipment for a production project that was suspended. Any future goodwill or other intangible asset impairment, if any, would be recorded in operating income and could have a material adverse effect on our results of operations and financial condition.

Our outstanding loan agreements contain restrictive covenants that may limit our operating flexibility.

Our loan agreements are collateralized by substantially all of our presently existing and subsequently acquired personal property assets, and subject us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We are also subject to certain covenants that require us to maintain certain financial ratios and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants and ratios, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of our lenders, which we may not be able to obtain. We may not be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and interest on our debt. In addition, upon the occurrence of an event of default, our lenders, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes our failure to pay any amount due and payable under the loan agreements, the occurrence of a material adverse change in our business as defined in the loan agreements, our breach of any covenant in the loan agreements, subject to a grace period in some cases, or an involuntary insolvency proceeding. Additionally, a lender could exercise its lien on substantially all of our assets and our future working capital, borrowings or equity financing may not be available to repay or refinance any such debt.

As a result of becoming a public company, we will be obligated to develop and maintain adequate internal controls and be able, on an annual basis, to provide an assertion as to the effectiveness of such controls. Failure to maintain adequate internal controls or to implement new or improved controls 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.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act of 2002. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

Table of Contents

If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the Securities and Exchange Commission, or SEC.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of the end of our fiscal year 2014. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting.

We will be required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" as defined in the JOBS Act if we take advantage of the exemptions contained in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future.

Additionally, to comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff, which may adversely affect our operating results and financial condition.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions or changes in accounting standards could lead to a restatement or revision to previously consolidated financial statements, which 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 preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in greater detail in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition, provision for wholesaler chargebacks, accruals for product returns, valuation of inventory, impairment of intangibles and long-lived assets, accounting for income taxes and share-based compensation. Furthermore, although we have recorded reserves for litigation related contingencies based on estimates of probable future costs, such litigation related contingencies could result in substantial further costs. Also, any new or revised accounting standards may require adjustments to previously issued financial statements. Any such changes could result in corresponding changes to the amounts of liabilities, revenues, expenses and income. Any such changes 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.

Changes in financial accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting

Table of Contents

pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our business and financial results.

Changes in income tax laws, tax rulings and other factors may have a significantly adverse impact on our effective tax rate and tax expense, which 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.

Potential changes to income tax laws in the U.S. include measures which would defer the deduction of interest expense related to deferred income; determine the foreign tax credit on a pooling basis; tax currently excess returns associated with transfers of intangibles offshore; and limit earnings stripping by expatriated entities. In addition, proposals were made to encourage manufacturing in the U.S., including reduced rates of tax and increased deductions related to manufacturing. We cannot determine whether these proposals will be modified or enacted, whether other proposals unknown at this time will be made or the extent to which the corporate tax rate might be reduced and ameliorate the adverse impact of some of these proposals. If enacted, and depending on its precise terms, such legislation could materially increase our overall effective income tax rate and income tax expense. This 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.

In addition to income taxes in the U.S. we are subject to income taxes in many foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. In the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. The final determination of any tax audits or related litigation could be materially different from our historical income tax provisions and accruals.

Additionally, increases in our effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by various taxing authorities and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which 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.

Counterfeit versions of our products could harm our patients and reputation.

Our industry has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. If a product of ours was the subject of counterfeits, we could incur substantial reputational and financial harm in the longer term.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials 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 results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or

Table of Contents

proprietary information, we may incur liability and the further development of our product candidates may be delayed.

In addition, we rely on complex information technology systems, including Internet-based systems, to support our supply chain processes as well as internal and external communications. The size and complexity of our systems make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes that may result in the loss of key information or the impairment of production and other supply chain processes. Such disruptions and breaches of security could adversely affect our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

The facilities we use for our headquarters, laboratory and research and development activities are located in earthquake-prone areas of California. A significant percentage of the facilities we use for our manufacturing, packaging, warehousing, distribution and administration offices are also located in these areas. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as our manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans.

Risks Relating to Regulatory Matters

The FDA approval process is time-consuming and complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all. Additionally, we may lose FDA approval and/or our products may become subject to foreign regulations.

The development, testing, manufacturing, marketing and sale of generic and proprietary pharmaceutical products and biological products are subject to extensive federal, state and local regulation in the U.S. and other countries. Satisfaction of all regulatory requirements, which typically takes years for drugs that have to be approved in ANDAs, NDAs, biological license applications, or BLAs, or biosimilar applications is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources for research (including qualification of suppliers and their supplied materials), development, *in vitro* and *in vivo* (including nonclinical and clinical trials) studies, manufacturing process development and commercial scale up. All of our products are subject to compliance with the FFDCA and/or the Public Health Service Act, or PHSA, and with the FDA's implementing regulations. Failure to adhere to applicable statutory or regulatory requirements by us or our business partners would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive as well.

We may encounter delays or agency rejections during any stage of the regulatory review and approval process based upon a variety of factors, including without limitation the failure to provide clinical data demonstrating compliance with the FDA's requirements for safety, efficacy and quality. Those requirements may become more stringent prior to submission of our applications for approval or during the review of our applications due to changes in the law or changes in FDA policy or the adoption of new regulations. After submission of an application, the FDA may refuse to file the application, deny approval of the application or require additional testing or data. The FDA can convene an Advisory Committee to assist the FDA in

Table of Contents

examining specific issues related to the application. In February 2014, the FDA held a joint meeting of its Nonprescription Drugs Advisory Committee and its Pulmonary Allergy Drugs Advisory Committee, which we refer to as the Committee, to discuss the NDA for Primatene Mist HFA. The Committee voted 14 to 10 that the data in the NDA supported efficacy, but voted 17 to 7 that safety had not been established for the intended over-the-counter use. The Committee also voted 18 to 6 that the product did not have a favorable risk-benefit profile for the intended over-the-counter use, and individual Committee members provided recommendations for resolving their concerns. Although the FDA is not required to follow the recommendations of its advisory committees, it usually does. On May 22, 2014, we received a CRL from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted cGMP deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

Under various user fee enactments, the FDA has committed to timelines for its review of NDAs, ANDAs, BLAs and biosimilar applications. However, the FDA's timelines described in its guidance on these statutes are flexible and subject to changes based on workload and other potential review issues that may delay the FDA's review of an application. Further, the terms of approval of any applications may be more restrictive than our expectations and could affect the marketability of our products.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the approval process for ANDAs, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions that may, among other things, close manufacturing plants that are not operating in conformity with cGMP and stop shipments of potentially violative products and to prosecute companies and individuals for violations of the FFDCA. In the event that the FDA takes any such action relating to our products or product candidates, such actions would have a material adverse effect on our operations and financial condition.

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to 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. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If any of our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

Table of Contents

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Our clinical trials may not demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

If clinical studies for our product candidates are unsuccessful or significantly delayed, we will be unable to meet our anticipated development and commercialization timelines, which would have an adverse impact our business.

Some of our new drug candidates must be approved in NDAs based on clinical studies demonstrating safety and/or effectiveness. For these types of studies, we rely on our investigational teams, who mainly are medical experts working in multicenter hospitals, to execute our study protocols with our product candidates. As a result, we have less control over our development program than if we were to perform the studies entirely on our own. Third parties may not perform their responsibilities according to our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization.

The commencement of clinical trials on our product candidates may be delayed for several reasons, including but not limited to delays in demonstrating sufficient pre-clinical safety required to obtain regulatory clearance to commence a clinical trial, reaching agreements on acceptable terms with prospective contract research organizations, clinical trial sites and licensees, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials, delays in recruiting sufficient subjects for a clinical trial and/or obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or by regulatory authorities for a variety of reasons, including without limitation ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials, a determination by us or regulatory authorities that continuing a trial presents an unreasonable health risk to participants, failure to conduct clinical trials in accordance with regulatory requirements, lower than anticipated recruitment or retention rate of patients in clinical trials, inspection of the clinical trial operations or trial sites by regulatory authorities, the imposition of a clinical hold by the FDA, lack of adequate funding to continue clinical trials and/or negative or unanticipated results of clinical trials.

Patient enrollment, a significant factor in the time required to complete a clinical study, is affected by many factors, including the size and nature of the study subject population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including without limitation therapies being investigated by other companies. Further, completion of a clinical study and/or the results of a clinical study may be adversely affected by failure to retain subjects who enroll in a study but withdraw due to, among other things, adverse side effects, lack of efficacy, improvement in condition before treatment has been completed or for personal issues or who fail to return for or complete post-treatment follow-up.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes. Protocol amendments may require us to resubmit protocols to institutional review boards for reexamination or renegotiate terms with contract research organizations and study sites and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

Clinical trials required by the FDA for approval of our products may not produce the results we need to move forward in product development or to submit or obtain approval of an NDA. Success in pre-clinical testing and early phase clinical trials does not assure that late phase clinical trials will be successful. Even if the results of any future Phase 3 clinical trials are positive, we may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we can submit NDAs or obtain FDA approval for our product candidates.

Table of Contents

Clinical trials are expensive and at times difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we or the FDA believes that participating patients are being exposed to unacceptable health risks, we may suspend the clinical trials. Failure can occur at any stage of the trials, and we could encounter problems that would cause us to abandon clinical trials and/or require additional clinical studies relating to a product candidate.

Even if our clinical trials and laboratory testing are completed as planned, their results may fail to provide support for approval of our products or for label claims that will make our products commercially viable.

Positive results in nonclinical testing and early phase clinical studies do not ensure that late phase clinical studies will be successful or that our product candidates will be approved by the FDA. To obtain FDA approval of our proprietary product candidates, we must demonstrate through nonclinical testing and clinical studies that each product is safe and effective for each proposed indication. Further, clinical study results frequently are susceptible to varying interpretations. Medical professionals, investors and/or regulatory authorities may analyze or weigh study data differently than we do. In addition, determining the value of clinical data typically requires application of assumptions and extrapolations to raw data. Alternative methodologies may lead to differing conclusions, including with respect to the safety or efficacy of our product candidates.

In addition, if we license to third parties rights to develop our product candidates in other geographic areas or for other indications, we may have limited control over nonclinical testing or clinical studies that may be conducted by such third-party licensees in those territories or for those indications. If data from third-party testing identifies a safety or efficacy concern, such data could adversely affect our or another licensee's development of such product.

There is significant risk that our products could fail to show anticipated results in nonclinical testing and/or clinical studies and, as a result, we may elect to discontinue the development of a product for a particular indication or altogether. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested may delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

The novel use of HFA for any of our product candidates, or any of our other product candidates requiring novel particle engineering, may not receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

We are engaging in particle engineering for certain product candidates, including and especially the use of HFA for our Primatene Mist HFA product candidate. With respect to Primatene Mist HFA, we have chosen to develop a formulation of the product candidate that will use HFAs as a propellant because of an FDA-mandated phase-out of drugs utilizing CFCs as propellants. Although HFAs have been used in other settings, using HFAs as a propellant in an epinephrine inhalation product is a novel use, and there is no guarantee that we will obtain regulatory approval or, upon commercialization, market acceptance of this product. In addition to Primatene Mist HFA, we are similarly engaging in particle engineering for additional product candidates and, similarly, there is no guarantee that we will obtain regulatory approval or, upon commercialization, market acceptance of these products.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulations by the FDA in the U.S. and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of an NDA from the FDA. NDA approvals may require extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must include significant information regarding the chemistry, manufacturing and

Table of Contents

controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. Any submissions may not be accepted for filing and review by the FDA. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require additional expensive and time-consuming post-approval clinical trials or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions. Obtaining regulatory approval for marketing of a product candidate in one country does not necessarily ensure that we will be able to obtain regulatory approval in any other country.

In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We also have plans to develop synthetic APIs. Our ongoing trials and studies may not be successful or regulators may not agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or approve the use of such synthetic APIs.

If we are unable to obtain approval from the FDA or other regulatory agencies for our product candidates or synthetic APIs, we will not be able to market such product candidates and our ability to achieve profitability may be materially impaired.

The commercial success of our NDA product candidates will depend in significant measure on the label claims that the FDA approves for such products.

The scientific foundation of our NDA products will be based on our various proprietary technologies and the commercial success of these product candidates will depend in significant measure upon our ability to obtain FDA approval of labeling describing such products' expected features or benefits. Failure to achieve FDA approval of product labeling containing adequate information on features or benefits will prevent or substantially limit our advertising and promotion of such features in order to differentiate our proprietary technologies from those products that already exist in the market. This failure would have a material adverse impact on our business.

Our ANDA products are also subject to FDA approval of their labeling.

Even if we are able to obtain regulatory approval for our generic products, state pharmacy boards or state agencies may conclude that our products are not substitutable at the pharmacy level for the reference listed drug. If our generic products are not substitutable at the pharmacy level for their reference listed drugs, this could materially reduce sales of our products and our business would suffer.

Although the FDA may determine that a generic product is therapeutically equivalent to a brand product and indicate this therapeutic equivalence by providing it with an "A" rating in the FDA's Orange Book, this designation is not binding on state pharmacy boards or state agencies. As a result, in states that do not deem our product candidates substitutable at the pharmacy level, physicians may be required to specifically prescribe our product or a generic product alternative in order for our product to be dispensed. Should this occur with respect to one of our generic product candidates, it could materially reduce sales in those states, which would substantially harm our business.

Table of Contents

Our investments in biosimilar products may not result in products that are approved by the FDA or other foreign regulatory authorities and, even if approved by such authorities, may not result in commercially successful products.

We plan to build on our existing platforms to produce biosimilar products in the future. In 2010, Congress amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to previously approved biologics notwithstanding minor differences in inactive components. The process for bringing a biosimilar product to market is uncertain and may be drawn out for an extended period of time. FDA has not yet promulgated regulations governing this process and no biosimilar application has yet been approved. Approval of biosimilar applications may be delayed by exclusivity on the BLA for the reference product for up to twelve years. Biosimilar applicants are also subjected to a patent resolution process that will require biosimilar applicants to share the contents of their application and information concerning its manufacturing processes with counsel for the company holding the BLA for the reference drug and to engage in a patent litigation process that could delay or prevent the commercial launch of a product for many years.

Biosimilar products are not presumed to be substitutable for the reference drug under the Biologics Price Competition and Innovation Act, or BPCIA. Biosimilar applicants must seek a separate FDA determination that they are "interchangeable" with the reference drug, meaning that they can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. The statutory standards for determining biosimilarity and interchangeability are broad and uncertain, and FDA has broad discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis.

Products approved based on biosimilarity without an FDA determination of interchangeability may not be substitutable at the retail pharmacy level. Some states have passed laws limiting pharmacy substitution to biosimilar products that FDA has determined to be interchangeable, as well as restrictions on the substitution of interchangeable biosimilar products. These restrictions include, among other things, requirements for informing the patient and the prescribing physician of the substitution or proposed substitution, authority for the prescribing physician and the patient to preclude substitution and recordkeeping requirements. There is no certainty that other states will not impose similar restrictions or that states will not impose further restrictions or preclude substitution of interchangeable biosimilar products entirely.

Our competitive advantage in this area will depend on our success in demonstrating to the FDA that platform technology provides a level of scientific assurance that facilitates determinations of interchangeability, reduces the need for expensive clinical or other testing and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a brand product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach as the FDA begins to implement the new law. BLA holders will develop strategies and precedents for delaying or impeding approvals of biosimilar products and determinations of interchangeability. For example, the lengthy 12-year exclusivity protection provides the BLA holder for the reference drug with an opportunity to develop and replace its original product with a modified product that may avoid a determination of interchangeability and that may qualify for an additional 12-year marketing exclusivity period, reducing the potential opportunity for substitution at the retail pharmacy level for interchangeable biosimilars. As brand and biosimilar companies gain greater understanding of and experience with the new regulatory pathway, we expect to see new and unexpected company strategies, FDA decisions and court decisions that will pose unexpected challenges that will prevent, delay or make more difficult biosimilar approvals. As an example, there is a currently pending Citizen Petition filed with the FDA that argues that approving a biosimilar that relies on a reference product approved under a BLA submitted prior to passage of the BPCIA would constitute a taking under the Fifth Amendment to the U.S. Constitution that requires just compensation. The Citizen Petition requests that the

Table of Contents

FDA not accept for filing, file, approve, discuss or otherwise take any action with regard to any investigational new drug application or BLA for a product for which the reference product BLA was submitted prior to passage of the BPCIA. Should this petition be granted, there would be far fewer approved biologics that could serve as reference products for biosimilar applications, which could have a significant adverse impact on our business.

In addition, the BPCIA was passed as part of the Affordable Care Act and there have been ongoing legislative proposals to repeal the Affordable Care Act. If the Affordable Care Act is amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected.

Some of our products are used with drug delivery or companion diagnostic devices which have their own regulatory, manufacturing, reimbursement and other risks.

Some of our products or product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. Our product candidates intended for use with such devices, or expanded indications that we may seek for our products used with such devices, may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some of these drug delivery devices are provided by single source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. We are also dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications. We filed a Field Alert Report for enoxaparin in June 2013, as required by the FDA for certain quality issues with safety implications, because the product did not meet functionality criteria. The needle-shielding component was breaking during shipping, preventing correct administration of the medication. While the specific issues related to this Field Alert Report were resolved, we may experience similar issues in the future. In addition, loss of regulatory approval or clearance of a device that is used with our product may result in the removal of our product from the market.

The drug delivery devices used with our products are also subject to many of the same reimbursement risks and challenges to which our products are subject. A reduction in the availability of, or the coverage and/or reimbursement for, drug delivery devices used with our products could have a material adverse effect on our product sales, business and results of operations.

If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and/or other efforts, our sales of generic products may suffer.

Many pharmaceutical companies producing proprietary drugs have increasingly used state and federal legislative and regulatory means to delay, impede and/or prevent generic competition. These efforts have included but are not limited to the following:

- making changes to the formulation of their product and arguing that potential generic competitors must demonstrate bioequivalence and/or comparable abuse-resistance to the reformulated brand product;

- pursuing new patents for existing products which may be granted immediately prior to the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;

Table of Contents

selling the brand product as an authorized generic, either by the brand company directly, through an affiliate or by a marketing partner;

using the FDA's Citizen Petition process to request amendments to FDA standards or otherwise delay generic drug approvals;

challenging FDA denials of Citizen Petitions in court and seeking injunctive relief to reverse approval of generic drug applications;

seeking changes to standards in the U.S. Pharmacopeia/National Formulary, which are compendial drug standards that are recognized by industry and, in some instances, are enforceable under the FFDCA;

attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled by DEA;

using the legislative and regulatory process to set standards and requirements for abuse deterrent formulations that are patented or that will otherwise impede or prevent generic competition;

seeking special patent-term extensions through amendments to non-related federal legislation;

engaging in initiatives to enact state legislation that would restrict the substitution of certain generic drugs, including products that we are developing;

entering into agreements with pharmacy benefit management companies that block the dispensing of generic products;

seeking patents on methods of manufacturing certain API;

settling patent lawsuits with generic companies in a manner that leaves the patent as an obstacle for approval of other companies' generic drugs;

settling patent litigation with generic companies in a manner that avoids forfeiture of or otherwise protects or extends the exclusivity period;

providing medical education or other information to physicians, third-party payers and federal and state regulators that takes the position that certain generic products are inappropriate for approval or for substitution after approval;

seeking state law restrictions on the substitution of generic and biosimilar products at the pharmacy level without the instruction or permission of a physician; and

seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products may decline. If we experience a material decline in generic product sales, our results of operations, financial condition and cash flows will suffer.

In the event that we are successful in bringing any products to market, our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers and administrators.

Our ability to successfully commercialize our products may depend in part on the availability of reimbursement for and insurance coverage of our prescription products from government health administration authorities, private health insurers and other third-party payers and administrators, including Medicaid and Medicare. Third-party payers and administrators, including state Medicaid programs and Medicare, have been recently challenging the prices charged for pharmaceutical products. Government and other third-party payers increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for some of our products candidates. The continuing efforts of government and third-party payers to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payers do not provide adequate coverage and reimbursement for certain of our products, health care providers may not prescribe them or

Table of Contents

patients may ask their health care providers to prescribe competing products with more favorable reimbursement.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Private third-party payers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. While these approaches generally favor generic products over brands, generic competition is stronger. Our existing products and our product candidates include proprietary products and generic products. Failure to obtain timely or adequate pricing or formulary placement for our products or obtaining such pricing or placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for proprietary pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as requiring prior authorization for a proprietary product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a proprietary medicine. We do not currently have any managed care organization agreements and do not intend to have managed care organization agreements in the future.

We must manufacture our product at our facilities in conformity with cGMP regulations; failure to maintain compliance with cGMP regulations may prevent or delay the manufacture or marketing of our products or product candidates and may prevent us from gaining approval of our products.

All of our products and product candidates for use in clinical studies must be manufactured, packaged, labeled and stored in accordance with cGMP. For our approved products, modifications, enhancements, or changes in manufacturing processes and sites may require supplemental FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain.

All facilities of Amphastar and our subsidiaries are periodically subject to inspection by the FDA and other governmental entities, and operations at these facilities could be interrupted or halted if the FDA or another governmental entity deems such inspections as unsatisfactory. In addition, our secondary heparin supplier in China has yet to be inspected by the FDA. Products manufactured in our facilities must be made in a manner consistent with cGMP or similar standards in each territory in which we manufacture. Compliance with such standards requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. Failure to comply with cGMP or with other state or federal requirements may result in unanticipated compliance expenditures, total or partial suspension of production or distribution, suspension of review of applications submitted for approval of our product candidates, termination of ongoing research, disqualification of data derived from studies on our products and/or enforcement actions such as recall or seizure of products, injunctions, civil penalties and criminal prosecutions of the company and company officials. Any suspension of production or distribution would require us to engage contract manufacturing organizations to manufacture our products or to accept a hiatus in marketing our products. Any contract manufacturing organization we engage will require time to learn our methods of production and to scale up to full production of our products. Any delays caused by the transfer of manufacturing to a contract manufacturing organization may have a material adverse effect on our results of operations. Additionally, any contract manufacturing organization that we engage will be subject to the same cGMP regulations as us, and any failure on their part to comply with FDA or other governmental regulations will result in similar consequences.

Table of Contents

Our operations are subject to environmental, health and safety and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, products and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations. For example, as a result of environmental concerns about the use of CFCs, the FDA issued a final rule on January 16, 2009 that required the phase-out of the CFC version of our Primatene Mist product by December 31, 2011. This phase out caused us to halt sales of the CFC version of our Primatene Mist product subsequent to December 31, 2011 and write off our inventory for the product, which had an adverse effect on our financial results.

We also must comply with data protection and data privacy requirements. Compliance with these laws, rules and regulations regarding privacy, security and protection of employee data could result in higher compliance and technology costs for us, as well as significant fines, penalties and damage to our global reputation and our brand as a result of non-compliance.

Our products may be subject to federal and state laws and certain initiatives relating to cost control, which may decrease our profitability.

In the U.S., we expect there may be federal and state proposals for cost controls. We expect that increasing emphasis on managed care in the U.S. will continue to put pressure on the pricing of pharmaceutical products. In addition, we are required to pay rebates to states, which are generally calculated based on the prices for our products that are paid by state Medicaid programs. Cost control initiatives could decrease the price that we charge, and increase the rebate amounts that we must provide, for any of our products in the future. Further, cost control initiatives could impair our ability to commercialize our products and our ability to earn significant revenues from commercialization. In the U.S., all of our pharmaceutical products are subject to increasing pricing pressures. Such pressures have increased as a result of the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, due to the enhanced purchasing power of the private sector plans that negotiate on behalf of Medicare beneficiaries. To date, we do not believe that federal and state cost control initiatives have had a direct impact on the pricing of our products, but they could have such an impact in the future. Similarly, rebate obligations have been relatively stable, but if such obligations increase, our revenue could be adversely affected. In addition, if the MMA or the Affordable Care Act were amended to impose direct governmental price controls and access restrictions, it would have a significant adverse impact on our business. Furthermore, managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would affect rebate levels and apply to broader segments of their populations that are not Medicaid-eligible. Further, there continue to be legislative proposals to amend U.S. laws to allow the importation into the U.S. of prescription drugs, which can be sold at prices that are regulated by the governments of various foreign countries. In addition to well-documented safety concerns, such as the increased risk of counterfeit products entering the supply chain, such importation could impact pharmaceutical prices in the U.S.

Table of Contents

Some of our products are marketed without FDA approval and may be subject to enforcement actions by the FDA.

A number of our prescription products are marketed without FDA approval. These products, like many other unapproved prescription drugs on the market, contain active ingredients that were first marketed prior to the enactment of the FFDCA. The FDA has assessed these products in a program known as the "Prescription Drug Wrap-Up" and has stated that these drugs cannot be lawfully marketed unless they comply with certain "grandfather" exceptions to the definition of "new drug" in the FFDCA. These exceptions have been strictly construed by FDA and by the courts, and the FDA has stated that it is unlikely that any of the unapproved prescription drugs on the market, including certain of our drugs, qualify for the exceptions. At any time, the FDA may require that some or all of our unapproved prescription drugs be approved and may direct that we recall these products and/or cease marketing the products until they are approved. The FDA may also take enforcement actions based on our marketing of these unapproved products, including but not limited to the issuance of an untitled letter or a warning letter, and a judicial action seeking injunction, product seizure and civil or criminal penalties. While the FDA has not undertaken any such enforcement actions against our unapproved drugs, the enforcement posture could change at any time and our ability to market such drugs would terminate with little or no notice. Moreover, our competitors may market FDA approved prescription products that compete against our unapproved prescription products. Such competitors have brought, and in the future may bring, claims against us alleging unfair competition or related claims.

As a result of our meetings with the FDA in 2009, we decided to discontinue all of our products that were subject to the Prescription Drug Wrap-Up program, with the exception of epinephrine in vial form. These products were all produced at our subsidiary, IMS. During the third quarter of 2010, the FDA requested that IMS reintroduce several of the withdrawn products to cope with a drug shortage, while IMS prepared and filed applications for approval of the products. Between August and October, 2010, IMS reintroduced atropine, calcium chloride, morphine, dextrose, epinephrine, lidocaine and sodium bicarbonate injections, and continues to market these products without FDA approval. For the year ended December 31, 2013 and the three months ended March 31, 2014, we recorded net revenues of $29.6 million and $6.9 million, respectively, from these products. IMS has received approval for one ANDA, filed three ANDAs and is preparing two additional ANDAs and one NDA with respect to these products for submission under an expedited review process by the FDA. We may not obtain approval for any of these products.

Our reporting and payment obligations under the Medicare and/or Medicaid drug rebate programs and other governmental purchasing and rebate programs are complex and may involve subjective decisions that could change as a result of new business circumstances, new regulatory guidance or advice of legal counsel. Any determination of failure to comply with those obligations could subject us to penalties and sanctions which could have a material adverse effect on our business, financial position and results of operations and the market value of our common stock could decline.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. The Affordable Care Act includes a provision requiring the Centers for Medicare and Medicaid Services, or CMS, to publish a weighted Average Manufacturer Price, or AMP, for all multi-source drugs. The provision was effective October 1, 2010; however, weighted average AMP's have not yet been published by CMS, except in draft form, and have not been implemented for use in the calculation of Federal Upper Limits. Although the weighted average AMP would not reveal our individual AMP, publishing a weighted average AMP available to customers and the public at large could negatively affect our leverage in commercial price negotiations.

Table of Contents

In addition, as also disclosed herein, a number of state and federal government agencies are conducting investigations of manufacturers' reporting practices with respect to Average Wholesale Prices, or AWP, in which they have suggested that reporting of inflated AWP has led to excessive payments for prescription drugs. Numerous pharmaceutical companies have been named as defendants in various actions relating to pharmaceutical pricing issues and whether allegedly improper actions by pharmaceutical manufacturers led to excessive payments by Medicare and/or Medicaid.

Any governmental agencies that have commenced, or may commence, an investigation of our business relating to the sales, marketing, pricing, quality or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs including Medicare and/or Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments and even in the absence of any such ambiguity a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions 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.

Proposed FDA labeling rules could result in additional liability risks for our products.

The FDA has recently proposed allowing generic drug manufacturers to independently update product labeling to reflect newly discovered safety data, which could result in failure-to-warn suits. This could increase our labeling obligations and potentially increase our liability risk for our products.

We may be subject to enforcement action if we engage in the off-label promotion of our products.

Our promotional materials and training methods must comply with the FFDCA and other applicable laws and regulations, including restraints and prohibitions on the promotion of off-label, or unapproved, use. Physicians may prescribe our products for off-label use without regard to these prohibitions, as the FFDCA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including but not limited to the issuance of an untitled letter or warning letter, and a judicial action seeking injunction, product seizure and civil or criminal penalties. It is also possible that other federal, state or non-U.S. enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

Table of Contents

The pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal healthcare programs' anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the FFDCA and similar laws regulating advertisement and labeling;

- the U.S. Foreign Corrupt Practices Act, which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials; and

- non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

The federal false claims laws have been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payer. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the Affordable Care Act without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has recently increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if a healthcare provider settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting

Table of Contents

requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

If the activities of any of our business partners are found to be in violation of these laws or any other federal and state fraud and abuse laws, they may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its activities with regard to the commercialization of our products, which could harm the commercial success of our products and materially affect our business, financial condition and results of operations. While we have implemented numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the corporate integrity agreement. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and adverse effect on our product sales, business and results of operations.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws and regulations will involve substantial costs. Any state or federal regulatory review of us or the third parties with whom we contract, regardless of the outcome, would be costly and time-consuming.

Table of Contents

Risks Relating to our Intellectual Property

Our success depends on our ability to protect our intellectual property.

In addition to obtaining FDA approval for our generic and proprietary drug candidates, our success also depends on our ability to obtain and maintain patent protection for new products developed utilizing our technologies, in the U.S. and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual issues. Any of our patent claims in our approved and pending non-provisional and provisional patent applications relating to our technologies may not be issued or, if issued, any of our existing and future patent claims may not be held valid and enforceable against third-party infringement. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims may be challenged, potentially invalidated, or potentially circumvented. Our patent claims may not afford us protection against our competitors. We currently have a number of U.S. and foreign patents issued. However, issuance of a patent is not conclusive evidence of its validity or enforceability. We may not receive patents for any of our pending patent applications or any patent applications that we may file in the future and our issued patents may not be upheld if challenged.

In March 2013, the U.S. transitioned to a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to receive a patent (rather than the first to invent as was the case under prior U.S. law). Accordingly, it is possible that potentially invalidating prior art may become available in between the time that we develop an invention and file a patent application that covers the invention. In addition, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

Past enforcement of intellectual property rights in countries outside the U.S., including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

We also rely on, or intend to rely on, our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register our own trademarks. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks or we may not have adequate resources to enforce our trademarks.

Table of Contents

With respect to our proprietary products, if we fail to adequately protect or enforce our intellectual property rights, we could lose sales to generic versions of our proprietary products which could cause 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 success of our proprietary products depends in part on our ability to obtain, maintain and enforce patents and trademarks, and to protect trade secrets, know-how and other proprietary information. Our ability to commercialize any proprietary product successfully will largely depend upon our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our proprietary products business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed patent applications covering compositions of, methods of making and/or methods of using, our proprietary products and proprietary product candidates. We may not be issued patents based on patent applications already filed or that we may file in the future, and if patents are issued, they may be insufficient in scope to cover our proprietary products. The issuance of a patent in one country does not ensure the issuance of a similar patent in any other country, or that we will even seek patent protection in all countries worldwide. Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been and remains the subject of much litigation. Legal standards relating to scope and validity of patent claims are evolving and may differ in various countries. Any patents we have obtained, or will obtain in the future, may be challenged, invalidated or circumvented. Moreover, the USPTO or any other governmental agency, as well as third parties, may commence interference, opposition or other related third party proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, could cause 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.

Our unpatented trade secrets, know-how, confidential and proprietary information and technology may be inadequately protected.

We rely on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, confidential information and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

There is a risk that our trade secrets and other confidential and proprietary information could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us.

If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also

Table of Contents

independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secret protections against them, which could have a material adverse effect on our business.

There can be no assurance of timely patent review and approval to minimize competition and generate sufficient revenues.

There can be no assurance that the USPTO will have sufficient resources to review and grant our patent applications in a timely manner. Consequently, our patent applications may be delayed for many years (if they issue as patents at all), which would prevent intellectual property protection for our products. If we fail to successfully commercialize our products due to the lack of intellectual property protection, we may be unable to generate sufficient revenues to meet or grow our business according to our expected goals and this may have a materially adverse effect on our profitability, financial condition and operations.

We may become involved in patent litigations or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights; in such case, we will need to defend against such proceedings. For example, the field of generic pharmaceuticals is characterized by frequent litigation that occurs in connection with generic pharmaceutical companies filing ANDAs, Paragraph IV certifications and attempting to invalidate the patents of the proprietary reference drug. Any non-generic products that we successfully develop may by subject to such challenge by third parties. As a generic pharmaceutical company, we also expect to file ANDAs, Paragraph IV certifications and to attempt to invalidate patents of third party reference drugs for which we seek to develop generic versions.

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

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

For example, we have been involved in litigation related to our sales of enoxaparin. A preliminary injunction was issued on October 28, 2011 that barred us from selling our generic enoxaparin until the injunction was stayed on January 25, 2012. After appeal, the U.S. Supreme Court denied certiorari and on July 19, 2013, the District Court granted our motion for summary judgment in accordance with the Federal Circuit opinion and denied Momenta and Sandoz's motion for leave to amend infringement contentions. See "Business Legal and Regulatory Proceedings" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for further details. Despite the ultimately favorable ruling in the litigation, the protracted litigation involved large legal expenses and the diversion of management's time and effort away

Table of Contents

from the business. Any future adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could result in substantial monetary damage awards and could prevent us from manufacturing and selling our products, which could have a material and adverse effect our financial condition.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is commonly referred to 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 as well as injunctive relief, which would halt our ability to market and sell such products altogether. 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 generic products, patented proprietary products generally realize a substantially higher profit margin than generic products. An adverse decision in a case such as this or in other similar 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.

We may be subject to claims that we, our board members, employees or consultants have used or disclosed alleged trade secrets or other proprietary information belonging to third parties and any such individuals who are currently affiliated with one of our competitors may disclose our proprietary technology or information.

As is commonplace in the biotechnology and pharmaceutical industries, some of our board members, employees and consultants are or have been employed at, or associated with, other biotechnology or pharmaceutical companies that compete with us. While employed at or associated with these companies, these individuals may become exposed to or involved in research and technology similar to the areas of research and technology in which we are engaged. We may be subject to claims that we, or our employees, board members or consultants have inadvertently, willfully or otherwise used or disclosed alleged trade secrets or other proprietary information of those companies. Litigation may be necessary to defend against such claims.

We have entered into confidentiality agreements with our executives and key consultants. However, we do not have, and are not planning to enter into, any confidentiality agreements with our non-executive directors because they have a fiduciary duty of confidentiality as directors. Our former board members, employees or consultants who are currently employed at, or associated with, one of our competitors may unintentionally or willfully disclose our proprietary technology or information.

Risks Related to this Offering and Ownership of Our Common Stock

There is no established public market for our stock and a public market may not be obtained or be liquid and therefore you may not be able to sell your shares.

Prior to this offering, there has not been a public market for our common stock. If an active trading market for our common stock does not develop following this offering, you may not be able to sell your shares quickly or at the market 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 subsequent trading market.

Table of Contents

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our operating results may be subject to quarterly and annual fluctuations as a result of a number of factors, including the following:

- the commercial success of our key products;
- results of clinical trials of our product candidates or those of our competitors;
- pricing actions by competitors;
- the timing of orders from our customers;
- manufacturing or supply interruptions;
- actions by regulatory bodies, such as the FDA, that have the effect of delaying or rejecting approvals of our product candidates;
- changes in the prescription practices of physicians;
- changes or developments in laws or regulations applicable to our product candidates;
- introduction of competitive products or technologies;
- failure to meet or exceed financial projections we provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of securities analysts or investors;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- general economic and market conditions and overall fluctuations in U.S. equity markets;
- developments concerning our sources of manufacturing supply;

disputes or other developments relating to patents or other proprietary rights;

litigation or investigations involving us, our industry, or both;

additions or departures of key scientific or management personnel;

issuances of debt, equity or convertible securities;

changes in the market valuations of similar companies;

major catastrophic events;

major changes in our board of directors or management or departures of key personnel; or

the other factors described in this "Risk Factors" section.

Any one of the factors above, or the cumulative effect of some of the factors referred to above, may result in significant fluctuations in our quarterly or annual operating results. This variability and unpredictability could result in our failing to meet our revenue, billings or operating results expectations or those of securities analysts or investors for any period. In addition, a significant percentage of our operating expenses are fixed in nature and based on forecasted revenue trends. Accordingly, in the event of revenue shortfalls, we are generally unable to mitigate the negative impact on operating results in the short term. If we fail to meet or exceed such expectations for these or any other reasons, our business could be materially adversely affected and our stock price could fluctuate or decline substantially.

In addition, if the market for pharmaceutical company stocks or the stock market in general experience a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. Our stock price may also be affected by the expiration of market stand-offs or contractual lock-up agreements or sales of large blocks of our stock.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become

Table of Contents

the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business, and this could have a material adverse effect on our business, operating results and financial condition.

If you purchase shares of common stock sold in this offering, you will incur immediate and substantial dilution.

If you purchase shares of common stock in this offering, you will incur immediate and substantial dilution in the amount of $5.17 per share, because the assumed initial public offering price of $11.00, which is the midpoint of the price range listed on the cover page of this prospectus, is substantially higher than the pro forma net tangible book value per share of our outstanding common stock. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares. Investors who purchase shares in this offering will contribute approximately 19.36% of the total amount of equity capital raised by us through the date of this offering, but will only own approximately 9.35% of our outstanding shares. In addition, you may also experience additional dilution upon future equity issuances or in the event the underwriters exercise their option to purchase additional shares. Additionally, you will experience additional dilution upon the exercise of stock options to purchase common stock or upon delivery of shares of common stock pursuant to DSUs granted to our employees, directors and consultants under our stock option and equity incentive plans. For additional information, see the "Dilution" section.

Future sales of our common stock may cause our stock price to decline.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the contractual lock-up and other legal restrictions on resale lapse, the trading price of our common stock could decline. Based upon shares outstanding as of May 30, 2014, after this offering, assuming no exercise of the underwriters' over-allotment option, approximately 42,795,940 shares of common stock will be outstanding. Of these shares, the shares of our common stock to be sold in this offering will be freely tradable, unless such shares are held by "affiliates," as that term is defined in Rule 144 of the Securities Act of 1933, as amended, or the Securities Act.

Our directors, officers and holders of substantially all of our capital stock and securities convertible into capital stock are subject to a 180-day market stand-off or a contractual lock-up agreement that prevents them from selling their securities prior to the expiration of the 180-day period. The underwriters may, in their sole discretion, permit securities subject to the lock-up to be sold prior to its expiration. Stockholders holding approximately 44% of our outstanding shares have executed an additional lock-up agreement pursuant to which such stockholders are prohibited from selling (i) 100% of their securities for 180 days, (ii) 95% of their securities for the period of 181 to 270 days, (iii) 75% of their securities for the period of 271 to 360 days, (iv) 50% of their securities for the period of 361 days to 450 days and (v) 25% of their securities for the period of 451 to 540 days, with each period being measured from the date of this prospectus. Jefferies LLC and BMO Capital Markets Corp. may, in their joint discretion, permit securities subject to this additional lock-up to be sold prior to its expiration.

After the market stand-offs and lock-up agreements pertaining to this offering expire, up to an additional 35,708,329 shares will be eligible for sale in the public market, of which 12,523,882 are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements.

In addition, following the completion of this offering, we intend to file a registration statement to register all shares subject to options outstanding or reserved for future issuance under our equity compensation plans. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. See the section titled "Shares Eligible for Future Sale" for additional information.

Table of Contents

Our management will 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 from this offering and our stockholders will not have the opportunity as part of their 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 and financial condition, which could cause our stock price to decline. Pending their uses, we plan to invest the net proceeds of this offering in short- and medium-term, interest-bearing obligations; investment-grade instruments; certificates of deposit; and/or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders.

Jack Y. Zhang and Mary Z. Luo, each of whom serves as a director and an executive officer, own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering and as of May 30, 2014, Jack Y. Zhang and Mary Z. Luo, each of whom serves as one of our directors and executive officers, and their affiliates beneficially own approximately 27.14% of our outstanding common stock. Our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, will own approximately 27.20% of the outstanding shares of our common stock after this offering, assuming no exercise of the underwriters' over-allotment option, based on the number of shares outstanding as of May 30, 2014 and after giving effect to the sale of shares by the selling stockholder in connection with this offering. As a result, these stockholders, if acting together, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

We do not intend to pay dividends for the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Our existing loan agreements restrict, and any future indebtedness may restrict, our ability to pay dividends. Investors seeking cash dividends should not purchase our common stock. Accordingly, if you purchase shares in this offering, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the NASDAQ Stock Market LLC and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company," as defined in the JOBS Act. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act

Table of Contents

requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. Although we have already hired additional employees to comply with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

We also expect that being a public company and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors and qualified executive officers.

As a result of disclosure of information in this prospectus and in filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be adversely affected. Even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

We may become involved in securities class action litigation that could divert management's attention from our business and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in this "Risk Factors" section, may cause the market price of our common stock to decline. 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 generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation is often expensive and could divert management's attention and resources from our primary business, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Table of Contents

We are an emerging growth company and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors may 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.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

As an emerging growth company we have also chosen to take advantage of certain provisions of the JOBS Act that allow us to provide you with less information in this prospectus than would otherwise be required if we are not an emerging growth company. As a result, this prospectus includes less information about us than would otherwise be required if we were not an emerging growth company within the meaning of the JOBS Act, which may make it more difficult for you to evaluate an investment in our company.

We would cease to be an emerging growth company upon the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (ii) the last day of the fiscal year during which we have annual gross revenue of at least $1.0 billion, (iii) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act (we will qualify as a large accelerated filer as of the first day of the first fiscal year after we have (a) more than $700.0 million in outstanding common equity held by our non-affiliates and (b) been public for at least 12 months; the value of our outstanding common equity will be measured each year on the last business day of our second fiscal quarter); or (iv) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Table of Contents

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.

Upon completion of this offering, provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of the Delaware General Corporation Law, or the DGCL, could depress the trading price of our common stock by making 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, including transactions in which stockholders might otherwise receive a premium for their shares. 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;
- 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;
- 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; and
- establishing a classified board of directors, whereby only one-third of the members of our board of directors are elected at one time.

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 DGCL, 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 delay or prevent a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our common stock.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" that involve substantial risks and uncertainties. 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." In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the sales and marketing of our products, including our enoxaparin product;
- our expectations regarding the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- the timing and likelihood of FDA approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- our ability to compete in the development and marketing of our products and product candidates;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies;
- the potential for our marketed products to be withdrawn due to patient adverse events or deaths, or if we fail to secure FDA approval for products subject to the Prescription Drug Wrap-Up program;
- our expectations in obtaining insurance coverage and adequate reimbursement for our products from third-party payers;
- the amount of price concessions or exclusion of suppliers adversely affecting our business;
- our ability to establish and maintain intellectual property on our products and our ability to successfully defend these in cases of alleged infringement;
- the implementations of our business strategies, product candidates and technology;

- the potential for exposure to product liability claims;
- our ability to expand internationally;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business both in the United States and internationally;
- our use of proceeds from this offering; and
- our financial performance expectations.

You should read this prospectus and the documents that we reference elsewhere 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 results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. We discuss many of these risks and uncertainties in greater detail under the section entitled "Risk Factors" and elsewhere in this prospectus. These forward-looking statements

Table of Contents

represent our estimates and assumptions only as of the date of this prospectus regardless of the time of delivery of this prospectus or any sale of our common stock. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus.

Table of Contents

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size, is based on information from various sources, including reports from IMS Health Incorporated, or IMS Health, on assumptions we have made based on such data and other similar sources and on our knowledge of the markets for our products. Any information in this prospectus provided by IMS Health is an estimate derived from the use of information under license from the following IMS Health information service: National Sales Perspectives for the period from October 2007 to February 2015. IMS Health expressly reserves all rights, including rights of copying, distribution and republication.

Table of Contents

USE OF PROCEEDS

We estimate that the net proceeds from our sale of 4,000,000 shares of common stock in this offering will be approximately $37.3 million (or $48.6 million if the underwriters exercise their over-allotment option in full), based upon an assumed initial public offering price of $11.00 per share, the midpoint of the range on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any proceeds from the sale of common stock by the selling stockholder. We will pay substantially all of the expenses of the selling stockholder other than underwriting discounts, fees and disbursements of counsel for the selling stockholder and any transfer taxes.

A $1.00 increase or decrease in the assumed initial public offering price of $11.00 per share would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $3.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial price to the public by these amounts would have a material effect on the uses of proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

We intend to use the net proceeds from this offering for product development, working capital and other general corporate purposes.

We may also use a portion of the net proceeds for potential acquisitions of technologies, assets, products or businesses that expand or complement our current business. We currently do not have any agreements or commitments relating to any potential acquisitions for which we would use any of the net proceeds.

As of the date of this prospectus, we cannot specify with any certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. The amount and timing of expenditures used generally or for any particular use may vary based on a number of factors, including our progress in developing our product candidates, which depends on the timing of regulatory approvals, litigation and clinical trials, and the amount of cash used in or provided by our operations. Pending their uses, we plan to invest the net proceeds of this offering in short- and medium-term, interest-bearing obligations; investment-grade instruments; certificates of deposit; and/or direct or guaranteed obligations of the U.S. government. We reserve the right to reallocate the proceeds of this offering in response to these and other contingencies. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

Table of Contents

DIVIDEND POLICY

We currently have 461 record holders of our common stock. In the past two fiscal years, and during the interim period, we have not paid cash dividends on our common stock. We do not anticipate paying cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Additionally, our ability to pay dividends on our common stock is limited by restrictions under the terms of our existing credit facilities. Any future determinations related to dividend policy will be made at the discretion of our board of directors.

Table of Contents

CAPITALIZATION

The following table sets forth our cash, cash equivalents, restricted cash and short-term investments and capitalization as of March 31, 2014:

- on an actual basis; and
- on a pro forma as adjusted basis to give effect to the completion of this offering.

The pro forma information set forth below is illustrative only and will change based upon the actual initial public offering price and other terms of this offering determined at pricing. You should read the following table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Description of Capital Stock" and our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	March 31, 2014	
	Actual	Pro Forma as adjusted(1)
	(unaudited) (in thousands, except share data)	
Cash, cash equivalents, restricted cash and short-term investments	$ 53,460	$ 90,771
Long-term debt and capital leases, including current portion	$ 41,500	$ 41,500
Stockholders' equity:		
Preferred stock, par value $0.0001 per share; 20,000,000 shares authorized, no shares issued and outstanding, actual; 20,000,000 shares authorized, no shares issued and outstanding, pro forma as adjusted		
Common stock, par value $0.0001 per share; 300,000,000 shares authorized, 38,765,940 shares issued and outstanding, actual, 300,000,000 shares authorized, 42,765,940 shares issued and outstanding, pro forma as adjusted	4	4
Additional paid-in capital	179,348	216,659
Retained earnings	72,190	72,190
Total stockholders' equity	251,542	288,853
Total capitalization	$ 293,042	$ 330,353

(1) A $1.00 increase or decrease in the assumed initial public offering price of $11.00 per share, the midpoint of the price range reflected on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted cash, cash equivalents, restricted cash and short-term investments, additional paid-in capital, total stockholders' equity and total capitalization by approximately $3.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be outstanding after this offering is based on a total of 38,765,940 shares of our common stock outstanding as of March 31, 2014, and excludes:

11,745,577 shares of common stock issuable upon exercise of options outstanding as of March 31, 2014, with a weighted-average exercise price of $15.40 per share;

406,255 shares of common stock issuable upon delivery of DSUs outstanding as of March 31, 2014; and

2,139,587 shares of common stock reserved for future grant under our stock incentive plans as of March 31, 2014.

Table of Contents

DILUTION

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

Investors participating in this offering will incur immediate and substantial dilution. Our net tangible book value as of March 31, 2014 was $211.9 million, or $5.46 per share of our common stock. Net tangible book value per share represents the amount of our total tangible assets (total assets less intangible assets) less total liabilities, divided by the number of shares of our common stock outstanding.

After giving effect to our sale in this offering of 4,000,000 shares of our common stock, at an assumed initial public offering price of $11.00 per share, the midpoint of the price range reflected on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2014 would have been $249.2 million, or $5.83 per share of our common stock. This represents an immediate increase in pro forma net tangible book value of $0.37 per share to our existing stockholders before this offering and an immediate dilution of $5.17 per share to new investors purchasing shares in this offering.

The following table illustrates this dilution:

Assumed initial public offering price per share		$ 11.00
Net tangible book value per common share as of March 31, 2014	$ 5.46	
Increase per share attributable to new investors	0.37	
Pro forma net tangible book value per share after this offering		5.83
Dilution per share to new investors		$ 5.17

The information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase or decrease in the assumed initial public offering price of $11.00 per share, the midpoint of the price range reflected on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted net tangible book value as of March 31, 2014 by $0.09 per share and the dilution in pro forma as adjusted net tangible book value to investors in this offering by $0.09 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table shows on a pro forma as adjusted basis, as of March 31, 2014, after giving effect to this offering on an assumed initial public offering price of $11.00 per share, the midpoint of the price range reflected on the cover page of this prospectus, the difference between existing stockholders and new investors with respect to the total number of shares of common stock purchased from us, the total consideration paid to us for these shares, and the average price per share paid, before deducting estimated underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	38,765,940	90.6%	$ 155,192,140	77.9%	$ 4.00
New investors	4,000,000	9.4	44,000,000	22.1	11.00
Total	42,765,940	100.0%	$ 199,192,140	100.0%	$ 4.66

57

Table of Contents

The information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease, as applicable, in the assumed initial public offering price of $11.00 per share, the midpoint of the price range reflected on the cover page of this prospectus, would increase or decrease, as applicable, total consideration paid by new investors and total consideration paid by all stockholders by approximately $3.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

There will be further dilution to new investors with respect to the shares issued pursuant to stock options or delivered pursuant to DSUs.

As of March 31, 2014, the aggregate intrinsic value of in-the-money vested and unvested options was $0.4 million and $0.3 million, respectively, and the aggregate value of our vested and unvested DSUs was $0.03 million and $4.4 million, respectively, based on the estimated fair value for our common stock of $11.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus. As of March 31, 2014, we had $14.4 million and $5.2 million of unrecognized share-based compensation expense, net of estimated forfeitures, related to stock options and DSUs, respectively, that we expect will be recognized over a weighted-average period of 2.6 years and 3.7 years, respectively.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' over-allotment option. If the underwriters exercise their over-allotment option in full, our existing stockholders would own 88.4% and our new investors would own 11.6% of the total number of shares of our common stock upon the completion of this offering, and the number of shares of common stock held by new investors participating in this offering will be increased to 5,104,000 shares or 11.6% of the total number of shares of common stock expected to be outstanding after this offering.

The number of shares of our common stock to be outstanding after this offering is based on a total of 38,765,940 shares of our common stock outstanding as of March 31, 2014, and excludes:

- 11,745,577 shares of common stock issuable upon exercise of options outstanding as of March 31, 2014, with a weighted-average exercise price of $15.40 per share;
- 406,255 shares of common stock issuable upon delivery of DSUs outstanding as of March 31, 2014; and
- 2,139,587 shares of common stock reserved for future grant under our stock incentive plans as of March 31, 2014.

Table of Contents

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited and unaudited consolidated financial statements and related notes included elsewhere in this prospectus. The selected consolidated financial data in this section is not intended to replace the audited and unaudited consolidated financial statements and accompanying notes.

We derived the selected consolidated financial data at December 31, 2012 and 2013 and for each of the three years in the period ended December 31, 2013 from the audited consolidated financial statements included elsewhere in this prospectus. We derived the selected consolidated financial data at December 31, 2009, 2010, 2011 and for each of the years ended December 31, 2009 and 2010 from our audited consolidated financial statements that are not included in this prospectus. We derived the consolidated statements of operations data for the three months ended March 31, 2013 and 2014 and the consolidated balance sheet data as of March 31, 2014 from the unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements were prepared on the same basis as the audited consolidated financial statements. Our management believes that the unaudited consolidated financial statements include all adjustments necessary to state fairly the information included in those statements and that the adjustments made consist only of normal recurring adjustments. Our historical results are not necessarily indicative of future results and results for the three months ended March 31, 2014 are not necessarily indicative of results to be expected for the full year ending December 31, 2014.

	Year Ended December 31,					Three Months Ended March 31,	
	2009	2010	2011	2012	2013	2013	2014
						(unaudited)	
	(in thousands, except per share data)						
Consolidated Statements of Operations Data:							
Net revenues	$ 148,609	$ 130,740	$ 118,356	$ 204,323	$ 229,681	$ 52,963	$ 45,870
Cost of revenues	90,559	80,575	90,252	114,020	142,725	33,406	33,362
Gross profit	58,050	50,165	28,104	90,303	86,956	19,557	12,508
Operating expenses:							
Selling, distribution and marketing	4,057	3,577	4,100	4,426	5,349	1,394	1,259
General and administrative	24,197	22,576	26,433	27,223	30,972	6,907	6,845
Research and development	25,938	30,232	31,049	31,163	33,019	8,904	6,209
Impairment of long-lived assets	1,232	192	67	2,094	126		164
Total operating expenses	55,424	56,577	61,649	64,906	69,466	17,205	14,477
Income (loss) from operations	2,626	(6,412)	(33,545)	25,397	17,490	2,352	(1,969)
Non-operating income (expense):							
Interest income	837	504	401	242	187	49	28
Interest expense	(1,352)	(810)	(584)	(784)	(958)	(305)	(180)
Other income (expense), net	(84)	1,032	1,841	1,023	508	95	(350)
Total non-operating income (expense)	(599)	726	1,658	481	(263)	(161)	(502)
Income (loss) before income taxes	2,027	(5,686)	(31,887)	25,878	17,227	2,191	(2,471)
Income tax expense (benefit)	17,119	4,970	(39,639)	7,784	5,365	(191)	(852)
Net income (loss)	$ (15,092)	$ (10,656)	$ 7,752	$ 18,094	$ 11,862	$ 2,382	$ (1,619)
Net income (loss) per common share:							
Basic	$ (0.39)	$ (0.27)	$ 0.20	$ 0.47	$ 0.31	$ 0.06	$ (0.04)
Diluted	$ (0.39)	$ (0.27)	$ 0.20	$ 0.46	$ 0.31	$ 0.06	$ (0.04)

Weighted-average shares used to compute net income (loss) per common share:							
Basic	38,694	38,869	38,513	38,580	38,712	38,707	38,769
Diluted	38,694	38,869	38,919	38,940	38,883	38,845	38,769

Table of Contents

Share-based compensation included in the consolidated statements of operations above is as follows:

	Year Ended December 31,					Three Months Ended March 31,	
	2009	2010	2011	2012	2013	2013	2014
						(unaudited)	
	(in thousands)						
Cost of revenues	$ 1,309	$ 1,417	$ 1,561	$ 1,794	$ 1,503	$ 303	$ 293
Operating expenses:							
Selling, distribution and marketing	100	103	144	143	132	24	21
General and administrative	4,639	6,798	5,449	4,593	4,701	1,137	1,176
Research and development	667	704	886	895	699	118	126
Total share-based compensation	$ 6,715	$ 9,022	$ 8,040	$ 7,425	$ 7,035	$ 1,582	$ 1,616

	December 31,					March 31,
	2009	2010	2011	2012	2013	2014
						(unaudited)
	(in thousands)					
Consolidated Balance Sheet Data:						
Cash, cash equivalents, restricted cash and short-term investments	$ 50,517	$ 56,333	$ 56,233	$ 52,101	$ 54,912	$ 53,460
Working capital	82,614	85,470	92,683	105,615	107,569	104,477
Total assets	262,061	258,111	282,174	317,477	338,748	345,109
Long-term debt and capital leases, including current portion	25,676	20,067	14,167	38,002	32,173	41,500
Retained earnings	46,757	36,101	43,853	61,947	73,809	72,190
Total stockholders' equity	200,629	195,402	208,518	233,439	251,545	251,542

Table of Contents

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

You should read this discussion and analysis together with our audited consolidated financial statements, the notes to such statements and the other financial information included in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section entitled "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically-challenging generic and proprietary injectable and inhalation products. We currently manufacture and sell 15 products in the U.S. and are developing a portfolio of 13 generic and seven proprietary injectable and inhalation product candidates. We have achieved profitability for each of the past three years but have recorded a loss for the three months ended March 31, 2014. We recorded net revenues of $118.4 million, $204.3 million and $229.7 million for the years ended December 31, 2011, 2012 and 2013, respectively, and $53.0 million and $45.9 million for the three months ended March 31, 2013 and 2014, respectively. We recorded net income of $7.8 million, $18.1 million and $11.9 million for the years ended December 31, 2011, 2012 and 2013, respectively, and $2.4 million for the three months ended March 31, 2013. We recorded a net loss of $1.6 million for the three months ended March 31, 2014.

Our largest product by net revenues is currently enoxaparin sodium injection, the generic equivalent of Sanofi S.A.'s Lovenox. Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant and is indicated for multiple indications, including the prevention and treatment of deep vein thrombosis. We commenced sales of our enoxaparin product in January 2012, and for the year ended December 31, 2013 and the three months ended March 31, 2014 we recognized net revenues from the sale of our enoxaparin product of $145.9 million and $26.1 million, respectively.

In addition to our currently marketed products, we have a robust pipeline of 20 generic and proprietary product candidates in various stages of development which target a variety of indications. With respect to these product candidates, we have filed three abbreviated new drug applications, one new drug application, or NDA, and one NDA supplement with the U.S. Food and Drug Administration, or FDA.

Our product candidate, Primatene Mist HFA, an over-the-counter epinephrine inhalation product, is intended to be used for the temporary relief of mild asthma symptoms and had a Prescription Drug User Fee Act, or PDUFA, date of May 2014. A PDUFA date sets the target date for the FDA to complete its review of an NDA. On May 22, 2014, we received a complete response letter, or CRL, from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted current Good Manufacturing Practices, or cGMP, deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

Our Amphadase product candidate is a bovine sourced hyaluronidase injection. We received approval of our NDA from the FDA for Amphadase in 2004, but discontinued the product in 2009 due to lack of active pharmaceutical ingredient, or API, supply. We filed an NDA supplement in December 2013 to qualify our own manufactured API. There is no assurance that we will receive approval for these product candidates.

Table of Contents

For the U.S. retail market for our enoxaparin product, which consists of chain retail pharmacies and independent retail pharmacies, we have an agreement with Actavis, Inc., or Actavis, to distribute our enoxaparin product, which is marketed under Actavis' label. For the non-retail market, which consists of hospitals and clinics, we have agreements with established group purchasing organizations and a wholesaler network to distribute our enoxaparin product, which is marketed under our own label.

To complement our internal growth and expertise, we have made several strategic acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing and research and development capabilities including the ability to manufacture raw materials, APIs and other components for our products.

Factors Affecting our Business

The success of our operations depends on many factors, including our ability to diversify our revenues by commercializing our product candidates, compete successfully in the pharmaceutical industry, manage our supply chain and comply with the various regulatory requirements applicable to our business.

Diversifying our Revenues by Commercializing our Product Candidates

Our revenues are dependent on our product sales. The majority of our currently marketed products are generic products, including our enoxaparin product, which represented 64% and 57% of our total net revenues for the year ended December 31, 2013 and the three months ended March 31, 2014, respectively. Any factor adversely affecting the sale of enoxaparin may adversely affect our revenues and profitability. We have 20 product candidates in various stages of development that will allow us to diversify our sources of revenues in the future if we are successful in developing, receiving necessary regulatory clearances for and commercializing these product candidates. We are currently experiencing declining revenue from some of our existing products and anticipate that we may operate at a loss in the near term while continuing to invest in developing new products.

Competition

Our business operates in the pharmaceutical industry which is an industry characterized by intense competition. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products and/or processes competitive with, or superior to, our own. We are concentrating the majority of our efforts and resources on developing product candidates utilizing our proprietary technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, labeling claims approved by the FDA for our products compared to claims approved for competitive products, and the relative timing and sequence for the commercial launch of new products by other companies that compete with our new products. If alternative technologies or other therapeutic approaches are adopted prior to our new product approvals, then the market for our new products may be substantially decreased, thus reducing our ability to generate future profits. In addition, due to intense pricing competition in the pharmaceutical industry, we have experienced significant declines in the per unit pricing and gross margins attributable to several of our products, including enoxaparin and Cortrosyn, even as we have increased market share and net revenues. We expect this pricing pressure to continue in future periods.

Supply Chain Management

Our finished products are manufactured at our own facilities and our API or raw materials are either manufactured at our own facilities or obtained through supply agreements with third parties. Some of our products are the result of complex manufacturing processes, and some require highly specialized raw materials. Because our business requires outsourcing in some instances, we are subject to inherent uncertainties related to product safety, availability and security. For some of our key raw materials, components and API used in certain of our products, we have only a single, external source of supply, and alternate sources of supply may not be readily available. We may be unable to replace these single suppliers with an alternate supplier on a commercially reasonable and timely basis, or at all. Additionally, any failure

Table of Contents

by us to forecast demand for, or to maintain an adequate supply of, the raw material and finished product could result in an interruption in the supply of certain products and a decline in sales of that product.

Regulatory Compliance

The sale of our products is subject to regulatory approvals, and our business is subject to extensive regulatory requirements, and if we do not obtain these approvals or comply with these requirements, it could delay or prevent us from selling our products. These regulations may also require us to cease sales of any of our products that may have previously been granted marketing approval.

Financial Overview

Net Revenues

Our net revenues consist principally of revenues generated from the sale of our pharmaceutical products and profit sharing revenues received under our profit sharing agreement with Actavis. We also generate a small amount of revenues from contract manufacturing. Included in net revenues are adjustments for estimated product returns and wholesaler chargebacks. The following table lists the net revenues attributable to our products for each of the last three fiscal years and for the three months ended March 31, 2013 and 2014:

Product	Year Ended December 31,			Three Months Ended March 31,	
	2011	2012	2013	2013	2014
			(in thousands)	(unaudited)	
Enoxaparin	$ (1,325)	$ 127,703	$ 145,923	$ 33,798	$ 26,072
Primatene Mist CFC	53,257				
Cortrosyn	14,034	13,788	12,326	3,539	2,439
Lidocaine Jelly	14,193	14,740	14,782	3,183	3,530
Other Products[(1)]	38,197	48,092	56,650	12,443	13,829

(1) None of our other products individually represented in excess of 10% of our total net revenues during any of the periods presented.

Most of our revenues during fiscal 2013 and the three months ended March 31, 2014 were derived from our enoxaparin product. Our sales of the chlorofluorocarbon, or CFC, formulation of Primatene Mist ceased on December 31, 2011, due to an FDA determination that the CFC formulation of Primatene Mist could not be marketed or sold in the U.S. We are currently experiencing declining revenue from some of our existing products and anticipate that we may operate at a loss in the near term while continuing to invest in developing new products.

At the time of FDA approval in September 2011 of our enoxaparin product, we had inventory that was close to expiration. Our customers were reluctant to purchase inventory that was considered short-dated and we therefore arranged for sales of this inventory with special terms. These terms included the ability of the customers to return the inventory at a return price that was greater than the initial selling price. We recorded $7.8 million of revenues of enoxaparin in 2011, which was fully reserved as of December 31, 2011. The sales return reserve that was created for this product resulted in a general increase in the level of sales reserve accrual for December 31, 2011 compared to prior periods. A temporary restraining order and preliminary injunction obtained by a competitor barred us from selling our enoxaparin product for a short time, causing the return of this short-dated inventory by our customers in early 2012. This resulted in negative sales of $1.3 million for the year ended December 31, 2011. The total sales reserve for this transaction was $9.1 million as of December 31, 2011 and was comprised of a sales reserve of $7.8 million and a reserve for the additional return liability of $1.3 million.

After January 25, 2012, we commenced sales of enoxaparin under our normal terms of sale. The amount of short-dated inventory sold in 2012 was immaterial to our financial statements. We did not include any unusual terms of sale for this product that were material to sales in 2013 or during the three months ended March 31, 2014.

63

Table of Contents

Cost of Revenues and Gross Profit

Our cost of revenues consist of labor, raw materials, components, packaging, quality assurance and control and manufacturing overhead costs. The following is a more detailed list of some of the key items that comprise our cost of revenues. These costs are capitalized as part of inventory and expensed as cost of materials and production when products are sold:

- costs of the necessary API and supporting ingredients of the pharmaceuticals products we manufacture and various types of packaging material;
- overhead costs, including utilities, maintenance of production equipment and other support expenses associated with the production of our products;
- salaries and benefits for personnel directly involved in production activities, including share-based compensation; and
- depreciation of property, plant and equipment used for production purposes.

We also have a policy to expense, on a quarterly basis, manufacturing variances, which represent manufacturing costs associated with under-utilized manufacturing plant capacity relative to normal production capacity.

Gross profit represents net revenues, less the cost of revenues and will vary from period to period depending on a variety of factors, including product pricing, manufacturing costs and the mix of products sold.

We expect our cost of revenues and our gross profit to increase in absolute dollars as we continue to grow, although they may fluctuate as a percentage of net revenues.

Selling, Distribution and Marketing Expenses

Selling, distribution and marketing expenses consist primarily of freight and shipping costs, salaries and other personnel-related expenses, costs for travel, trade shows, conventions, promotional materials, catalogs, advertising and promotions. We believe that our selling, distribution and marketing expenses will continue to increase as our net revenues grow and will increase due to expenses associated with product introductions.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits for executive management, legal, accounting, human resources and finance personnel, as well as professional services fees for legal, auditing, accounting and consulting services, facilities and other corporate overhead costs. After this offering, we anticipate increases in general and administrative expenses as we add personnel, become subject to reporting obligations applicable to publicly held companies and continue to develop and prepare for commercialization of our product candidates.

Research and Development

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. Research and development costs consist primarily of costs associated with the research and development of our product candidates, such as salaries and other personnel-related expenses for employees involved with research and development activities, manufacturing pre-launch inventory, clinical trials, FDA fees, testing, operating and lab supply, depreciation and amortization and other related expenses. We expense research and development costs as incurred.

Table of Contents

The following table sets forth our research and development expenses for the years ended December 31, 2011, 2012, 2013 and the three months ended March 31, 2013 and 2014:

	Year Ended December 31,			Three Months Ended March 31,	
	2011	2012	2013	2013	2014
			(in thousands)	(unaudited)	
Salaries and personnel-related expenses	$ 7,921	$ 8,878	$ 9,703	$ 2,106	$ 2,798
Pre-launch inventory	3,721	3,167	3,439	1,761	683
Clinical trials	9,642	3,667	41	113	
FDA fees			4,169		
Testing, operating and lab supply	3,615	8,614	8,824	3,597	1,135
Depreciation and amortization	1,721	2,106	3,242	621	717
Other expenses	4,429	4,731	3,601	706	876
Total research and development expenses	$ 31,049	$ 31,163	$ 33,019	$ 8,904	$ 6,209

We expect research and development expenses to increase in future periods in absolute dollars and the relative mix of research and development expenses to fluctuate from period to period based on the development phase or phases of specific product candidates. In particular, we expect categories such as manufacturing pre-launch inventory, clinical trial expense, FDA fees and testing, operating and lab supply to be highly variable from period to period depending on the nature of our research and development activities during such periods.

We are developing a number of new product candidates. The successful development of pharmaceutical products depends on many factors. Product candidates that appear to be promising at their early phases of research and development may fail to be commercialized for various reasons, including the failure to obtain the necessary regulatory approvals. The process of conducting basic research and various stages of tests and trials of a new innovative pharmaceutical product before obtaining regulatory approval and commercializing the product may require several years. There is no assurance that our research and development projects will produce commercially viable products. Even if such products can be successfully commercialized, they may not achieve the level of market acceptance that we expected, and our business and profitability could be materially adversely affected. As a result of these uncertainties, we are unable to determine with any significant degree of certainty the duration and the completion costs of our research and development projects or when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates.

We may produce inventories prior to or with the expectation of receiving marketing authorization in the near term, based on operational decisions about the most effective use of existing resources. This inventory is referred to as pre-launch inventory. Our policy is to expense pre-launch inventory as research and development costs, as incurred, until the drug candidate receives marketing authorization. As a result of the policy, while marketing authorization may have been received by the end of a reporting period, any inventories produced prior to such authorization are expensed. If marketing authorization is received and previously expensed pre-launch inventory is sold, such sales may contribute up to a 100% margin to our operating results. Pre-launch inventory costs include cost of work in process materials and finished drug products. There were no net sales of pre-launch inventory for the year ended December 31, 2011. In connection with the approval and launch of enoxaparin in 2012, we recognized higher margins on the sales of $7.7 million of previously-expensed pre-launch inventory.

Table of Contents

Impairment of Long-Lived Assets

We review long-lived assets and identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Such events and circumstances include decisions by the FDA regarding evidence of effectiveness of proprietary drug candidates or bioequivalence (sameness) of our generic product candidates as compared to the reference drug, communication with the regulatory agencies regarding the safety and efficacy of our products under review, the use of the asset in current research and development projects, any potential alternative uses of the asset in other research and development projects in the short-to-medium term, clinical trial results and research and development portfolio management options. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount exceeds the fair value of the assets (assets to be held and used) or fair value less cost to sell (assets to be disposed of).

Other Income (Expense), net

Other income (expense), net, consists primarily of the effect of foreign exchange gains and losses and proceeds that we receive or are required to pay as a result of legal settlements. We expect other income (expense), net to vary each reporting period as a result of currency exchange rate fluctuations and the results of legal proceedings.

Provision for Income Tax Expense (Benefit)

Our provision for income taxes consists primarily of federal and state income taxes in the U.S. and income taxes in foreign jurisdictions where we conduct business. We estimate income taxes in each of the jurisdictions in which we operate. This process involves determining income tax expense together with calculating the deferred income tax expense related to temporary differences resulting from the differing treatment of items for tax and accounting purposes. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. These temporary differences result in deferred tax assets and liabilities, which are included within the consolidated balance sheets. Deferred tax assets are recognized for deductible temporary differences, along with net operating loss and credits carryforwards, if it is more likely than not that the tax benefits will be realized. As of March 31, 2014, we have no valuation allowance provided against our deferred tax assets.

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. In some cases, changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition and results of operations will be affected. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis. We refer to accounting estimates of this type as critical accounting policies, which we discuss further below. While our significant accounting policies are more fully described in Note 2 to our audited consolidated financial statements, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our audited consolidated financial statements.

Table of Contents

Revenue Recognition

Our net revenues consist principally of revenues generated from the sale of our pharmaceutical products and profit sharing revenues received under our profit sharing agreement with Actavis. We also generate a small amount of revenues from contract manufacturing services. Generally, we recognize revenues at the time of product delivery to our customers. In some cases, revenues are recognized at the time of shipment when stipulated by the terms of the sale agreements. We also record profit-sharing revenues which are included in net revenues, from a distribution agreement with Actavis at the time Actavis sells the products to its customers. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, after the customer has accepted test samples of the products to be shipped.

We do not recognize product revenues unless the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) transfer of title has occurred, (iii) the price to the customer is fixed or determinable and (iv) collection is reasonably assured. Furthermore, we do not recognize revenues until all customer acceptance requirements have been met. We estimate and record reductions to revenues for early-payment discounts, product returns, administrative and management fees, rebates and pricing adjustments, such as wholesaler chargebacks, in the same period that the related revenues are recorded.

If actual future payments for the discounts, returns, fees, rebates and chargebacks exceed the estimates we made at the time of sale, our financial position, results of operations and cash flows would be negatively impacted. As discussed under "Accrual for Product Returns" below, we are generally obligated to accept from our customers the return of pharmaceuticals that have or will soon reach their expiration dates. We establish reserves for such amounts based on historical experience and other information available at the time of sale, but the actual returns will not occur until several years after the sale. We have significant experience with returns of our products other than enoxaparin, but since we only began selling our enoxaparin product in January 2012, we have limited experience with returns of expired enoxaparin. Although we believe that our estimates and assumptions are reasonable as of the date when made, actual results may differ significantly from these estimates. Our financial position, results of operations and cash flows may be materially and negatively impacted if actual returns exceed our estimated allowances for returns.

We establish allowances for estimated chargebacks and product returns based on a number of qualitative and quantitative factors, including:

- contract pricing and return terms of our agreements with customers;
- wholesaler inventory levels and turnover;
- historical chargeback and product return rates;
- shelf lives of our products, which is generally two years, as is the case with enoxaparin;
- direct communication with customers;
- anticipated introduction of competitive products or authorized generics;
- anticipated pricing strategy changes by us and/or our competitors; and
- impact of changes in state and federal regulations.

We generally do not increase list prices or offer promotional or volume discounts to our customers. When we do, the increases and discounts tend to be small and do not significantly alter the customers' overall purchase patterns. Therefore, we recognize the related revenues under our regular accounting policy and include the sales in estimating our various product related allowances. In the event that sales represent purchases of inventory in excess of ordinary levels for a given customer, the potential impact on product returns exposure would be specifically evaluated

and, if warranted, we would record an increased reserve for potential returns, which in turn would be reflected as a reduction in revenues at the time of such sale.

Table of Contents

Under the terms of our profit sharing agreement, Actavis markets and distributes our enoxaparin product to the retail market in the U.S., and we share in the profits from these activities as reported to us by Actavis. Accordingly, the amounts of profit sharing revenues we recognize each period are subject to Actavis' marketing, pricing and reporting practices. To the extent Actavis reports varying profit levels on their determined sales volumes and product pricing, our profit sharing revenue from retail sales of enoxaparin, financial position, results of operations and cash flows may be materially impacted.

Provision for Wholesaler Chargebacks

The provision for chargebacks is a significant estimate used in the recognition of revenues. As part of our sales terms with wholesale customers, we agree to reimburse wholesalers for differences between the wholesale prices, at which we sell our products to wholesalers, and the lower prices at which the products are resold under our various contractual arrangements with third parties such as hospitals and group purchasing organizations. We estimate chargebacks at the time of sale to wholesalers based on wholesaler inventory stocking levels, historic chargeback rates and current contract pricing.

The provision for chargebacks is reflected in net revenues and a reduction to accounts receivable. The following table is an analysis of our chargeback provision:

	Year Ended December 31,		Three Months Ended March 31,
	2012	2013	2014
			(unaudited)
	(in thousands)		
Beginning balance	$ 3,874	$ 11,898	$ 18,104
Provision related to sales made in the current period	131,967	213,075	41,642
Credits issued to third parties	(123,943)	(206,869)	(47,427)
Ending balance	$ 11,898	$ 18,104	$ 12,319

Changes in the chargeback provision from period to period are primarily dependent on our sales to wholesalers, the level of inventory held at the wholesalers and the wholesalers' customer mix. The approach that we use to estimate chargebacks has been consistently applied for all periods presented. Variations in estimates have been historically small. We continually monitor the provision for chargebacks and make adjustments when we believe that the actual chargebacks may differ from the estimates. The settlement of chargebacks generally occurs within 30 days after the sale to wholesalers. While we believe the estimates incorporated within our chargeback provision reflect the most reasonable likely outcomes of actual chargeback experience, as a sensitivity measure, a 1% decrease in estimated end-user contract selling prices would reduce net revenues for the year ended December 31, 2013, by $0.1 million and a 1% increase in wholesale units pending chargeback for the year ended December 31, 2013, would reduce net revenues by approximately $0.2 million.

Accrual for Product Returns

We offer most customers the right to return qualified excess or expired inventory for partial credit; however, products sold to Actavis are non-returnable. Our product returns primarily consist of the returns of expired products from sales made in prior periods. Returned products cannot be resold. At the time product revenues are recognized, we record an accrual for estimated returns. The accrual is based, in part, upon the historical relationship of product returns to sales and customer contract terms. We also assess other factors that could affect product returns including market conditions, product obsolescence and the introduction of new competition. Although these factors do not normally give our customers the right to return products outside of the regular return policy, we realize that such factors could ultimately lead to increased returns.

Table of Contents

We analyze these situations on a case-by-case basis and make adjustments to the product return reserve as appropriate.

When we do not have specific historical experience with actual returns for a product, we consider other available information to record a reasonable product return reserve. If we already sell products that are similar to a newly launched product, we estimate the new product return rate using historical experience of similar products. If there are similar products on the market produced by other companies, we may also consider the additional relevant industry data in calculating our estimate. The criteria used to make the determination of whether a new product is similar to existing products includes whether it: (i) is used for the treatment of a similar type of disease or indication, (ii) has a comparable shelf life, (iii) has similar frequency of dosing, (iv) has similar types of customers, (v) is distributed in a similar manner and (vi) has similar rights of return and other comparable sales incentives. We also consider whether we have the ability to monitor inventory levels in our distribution channels to determine the underlying patient demand for a new product. We analyze the product's sell-through cycle based on wholesaler chargeback claims and customers' re-ordering patterns to determine whether the estimated product return rate is reasonable. Additionally, we consider factors such as size and maturity of the market prior to launch and the introduction of additional competition. If the available information is not sufficient to record a reasonable product return accrual, revenues from the sales of the new product would be deferred until the product is consumed by the end customer or rights of return granted under the return policy have expired. Historically, we have not deferred revenues on any of our products.

On each balance sheet date, we classify that portion of our accrual for product returns that is attributable to products that are eligible for return within 12 months following the balance sheet date as a current obligation and the remainder as a long-term obligation.

The provision for product returns is reflected in net revenues. The following table is an analysis of our product return liability:

	Year Ended December 31,		Three Months Ended March 31,
	2012	2013	2014 (unaudited)
	(in thousands)		
Beginning balance	$ 14,833	$ 2,673	$ 4,592
Provision for product returns	1,178	2,711	140
Credits issued to third parties	(13,338)	(792)	(313)
Ending balance	$ 2,673	$ 4,592	$ 4,419

For the years ended December 31, 2012 and 2013 and for the three months ended March 31, 2014, our aggregate product return rate was 1.7%, 1.4% and 1.3% of qualified sales, respectively.

If the product return provision percentage were to increase by 0.1% of qualified sales, then an additional provision of $0.6 million, $0.9 million and $1.0 million would result for the years ended December 31, 2012 and 2013, respectively and for the three months ended March 31, 2014.

Table of Contents

Inventory

Inventories, net of allowances, are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. Inventories are reviewed periodically for slow-moving or obsolete status. We adjust our inventory to reflect situations in which the cost of inventory is not expected to be recovered. We would record a reserve to adjust inventory to its net realizable value: (i) if a launch of a new product is delayed and inventory may not be fully utilized and could be subject to impairment, (ii) when a product is close to expiration and not expected to be sold, (iii) when a product has reached its expiration date, or (iv) when a product is not expected to be sellable. In determining the reserves for these products, we consider factors such as the amount of inventory on hand and its remaining shelf life and current and expected market conditions, including management forecasts and levels of competition.

We have evaluated the current level of inventory considering historical trends and other factors, and based on our evaluation, we have recorded adjustments to reflect inventory at its net realizable value. These adjustments are estimates, which could vary significantly from actual results if future economic conditions, customer demand, competition or other relevant factors differ from expectations. These estimates require us to make assessments about the future demand for our products in order to categorize the status of such inventory items as slow-moving, obsolete or in-excess-of-need. These future estimates are subject to the ongoing accuracy of our forecasts of market conditions, industry trends, competition and other factors. If we overestimate or underestimate the amount of inventory that will not be sold prior to expiration, there may be a material impact on our consolidated financial condition and results of operations.

Impairment of Intangibles and Long-Lived Assets

We review long-lived assets and identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Such events and circumstances include decisions by the FDA regarding evidence of effectiveness of proprietary drug candidates or bioequivalence (sameness) of our generic product candidates as compared to the reference drug, communication with the regulatory agencies regarding the safety and efficacy of our products under review, the use of the asset in current research and development projects, any potential alternative uses of the asset in other research and development projects in the short-to-medium term, clinical trial results and research and development portfolio management options. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount exceeds the fair value of the assets (assets to be held and used) or fair value less cost to sell (assets to be disposed of).

Indefinite-lived intangibles, which includes goodwill and the Primatene Mist trademark acquired in June 2008, are tested for impairment annually or more frequently if indicators of impairment are present. An impairment loss is recorded if the asset's fair value is less than its carrying value. We also periodically review the Primatene Mist trademark to determine if events and circumstances continue to support an indefinite useful life. If the life is no longer indefinite, the asset is tested for impairment. The carrying value, after recognition of any impairment loss, is amortized over its remaining useful life.

Since December 31, 2011 we are no longer allowed to distribute the CFC formulation of our Primatene Mist product related to this intangible asset. However, we have developed a hydrofluoroalkane, or HFA, version of this product, which we plan to market under the same trade name. We filed an NDA in 2013 and had a PDUFA date of May 2014. In February 2014, the FDA held a joint meeting of its Nonprescription Drugs Advisory Committee and its Pulmonary Allergy Drugs Advisory Committee, which we refer to as the Committee, to discuss the NDA for Primatene Mist HFA. The Committee voted 14 to 10 that the data in the NDA supported efficacy, but voted 17 to 7 that safety had not been established for the intended over-the-counter use. The Committee also voted 18 to 6 that the product did not have a favorable risk-benefit profile for the intended over-the-counter use, and individual Committee members provided recommendations for resolving their concerns. Although the FDA is not required to follow the

Table of Contents

recommendations of its advisory committees, it usually does. On May 22, 2014, we received a CRL from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted cGMP deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

All of our impairments relate primarily to the write-off of certain manufacturing equipment related to abandoned projects. For the years ended December 31, 2011, 2012 and 2013 and for the three months ended March 31, 2014, we recorded impairment losses of $0.1 million, $2.1 million, $0.1 million and $0.2 million, respectively. For the three months ended March 31, 2013 we did not record any impairment loss. The $2.1 million charge in 2012 was primarily related to equipment for a production project that was suspended. Since we periodically assess our product candidates and make changes to product development plans, we incur impairment charges from time to time. These charges can fluctuate significantly from period to period.

Deferred Income Taxes

We utilize the liability method of accounting for income taxes. Under the liability method, deferred taxes are determined based on the temporary differences between the financial statements and tax basis of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized. We have adopted the with-and-without methodology for determining when excess tax benefits from the exercise of share-based awards are realized. Under the with-and-without methodology, current year operating loss deductions and prior year operating loss carryforwards are deemed to be utilized prior to the utilization of current year excess tax benefits from share-based awards.

A number of years may elapse before an uncertain tax position for which we have established a tax reserve is audited and finally resolved. The number of years for which we can be subject to audit varies depending on the tax jurisdiction. While it is often difficult to predict the final outcome or the timing of the resolution of an audit, we believe that our reserves for uncertain tax benefits reflect the outcome of tax positions that is more likely than not to occur. The resolution of a matter could be recognized as an adjustment to our provision for income taxes and our effective tax rate in the period of resolution, and may also require a use of cash.

Share-Based Compensation

Options issued under our Amended and Restated 2005 Equity Incentive Award Plan, or the 2005 Plan, are generally granted at prices equal to or greater than the fair value of the underlying shares on the date of grant and vest based on continuous service. The options have a contractual term of five to ten years and generally vest over a three- to five-year period. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the option and the vesting date. The awards of restricted common stock such as DSUs are valued at fair value on the date of grant. We use the Black-Scholes option pricing model to determine the fair value of share-based awards. The Black-Scholes option pricing model has various inputs such as the estimated common share price, the risk-free interest rate, volatility, expected life and dividend yield, all of which are estimates. We also record share-based compensation expense net of expected forfeitures. The change of any of these inputs could significantly impact the determination of the fair value of our options and thus could significantly impact our results of operations. There are no significant awards with performance conditions and no awards with market conditions.

Table of Contents

Valuation models and significant assumptions for share-based compensation are as follows:

Determining Fair Value. We use the Black-Scholes formula to estimate the fair value of our share-based payments using a single option award approach. The application of this valuation model involves assumptions that are judgmental and sensitive in the determination of compensation expense. Key assumptions and estimation methodologies for inputs to the Black-Scholes calculation are developed in accordance with ASC Topic 718. We amortize share-based compensation expense over the requisite service period, which in most cases is the vesting period of the award.

A primary factor in the valuation of equity awards is the fair value of the underlying common stock at the time of grant. Since our common stock is not traded in a public stock market exchange, our board of directors considers numerous factors including recent cash sales of our common stock to third-party investors, new business and economic developments affecting us and independent appraisals, when appropriate, to determine the fair value of our common stock. Independent appraisal reports are prepared based on a discounted cash flow analysis using conventional valuation techniques, such as discounted cash flow analyses and the guideline company method using revenues and earnings multiples for comparable publicly traded companies, and a calculation of total option proceeds, from which a discount factor for lack of marketability is applied. This determination of the fair value of the common stock is performed on a contemporaneous basis. Our board of directors determines our common stock fair market value on a quarterly basis and in some cases more frequently when appropriate.

Expected Volatility. As a private entity, we have limited data regarding company-specific historical or implied volatility of our share price. Consequently, we estimate our volatility based on the average of the historical volatilities of peer group companies from publicly available data for sequential periods approximately equal to the expected terms of our option grants. Management considers factors such as stage of life cycle, competitors, size, market capitalization and financial leverage in the selection of similar entities.

Expected Term. The expected term represents the period of time in which the options granted are expected to be outstanding. We estimate the expected term of options granted based on the midpoint between the vesting date and the end of the contractual term under the "short-cut" or simplified method permitted by the SEC implementation guidance for "plain vanilla" options. Applying this method, the weighted-average expected term of our options is approximately five years. The use of the short-cut method is permitted by the SEC beyond December 31, 2007, under certain circumstances, as described in the SEC implementation guidance. We will continue to use the short-cut method, as permitted, until we have developed sufficient historical data for employee exercise and post-vesting employment termination behavior after our common stock has been publicly traded for a reasonable period of time.

Forfeitures. We estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual experience differs from those estimates. For the years ended December 31, 2011, 2012 and 2013 and for the three months ended March 31, 2013 and 2014, we estimated an average overall forfeiture rate of 9%, 9%, 8%, 8% and 8%, respectively, based on historical forfeitures since 1998. Forfeiture rates are separately calculated for our (1) directors and officers, (2) management personnel and (3) other employees. Share-based compensation is recorded net of expected forfeitures. We periodically assess the forfeiture rate and the amount of expense recognized based on estimated historical forfeitures as compared to actual forfeitures. Changes in estimates are recorded in the period they are identified.

Risk-Free Rate. The risk-free interest rate is selected based upon the implied yields in effect at the time of the option grant on U.S. Treasury zero-coupon issues with a term approximately equal to the expected life of the option being valued.

Dividends. We do not anticipate paying cash dividends in the foreseeable future. Consequently, we use an expected dividend yield rate of zero.

Table of Contents

Tax benefits resulting from tax deductions in excess of the share-based compensation cost recognized (excess tax benefits) are recorded in the statements of cash flows as financing activities.

The weighted-averages for key assumptions used in determining the fair value of options granted during the years ended December 31, 2011, 2012 and 2013 and for the three months ended March 31, 2013 and 2014 are as follows:

	Year Ended December 31,			Three Months Ended March 31,	
	2011	2012	2013	2013(2)	2014
				(unaudited)	
Expected volatility	34.0%	32.6%	28.6%	0.0%	27.8%
Risk-free interest rate	1.6%	0.7%	1.3%	0.0%	1.3%
Weighted-average expected life in years[(1)]	5.3	4.8	4.5		4.3
Dividend yield rate	0.0%	0.0%	0.0%	0.0%	0.0%
Weighted average fair value of options granted	$ 4.28	$ 3.01	$ 2.79	$	$ 3.20

(1) The weighted-average expected life is calculated using the simplified method.

(2) We did not grant any stock options during the three months ended March 31, 2013.

Common Stock Valuation

We are required to estimate the fair value of the common stock underlying our share-based awards when performing the fair value calculations with the Black-Scholes option-pricing model. The fair values of the common stock underlying our share-based awards were determined by our board of directors, with input from management and contemporaneous third-party valuations. We believe that our board of directors has the relevant experience and expertise to determine the fair value of our common stock. As described below, the exercise price of our share-based awards was determined by our board of directors based on the most recent third-party valuation report as of the grant date. For valuations after completion of this initial public offering, our board of directors will determine the fair value of each share of the underlying common stock based on the closing price of our common stock as reported on the Nasdaq Global Market on the date of grant.

Given the absence of a public trading market of our common stock, and in accordance with the *American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, our board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock including:

- valuations of our common stock performed by unrelated third-party specialists;
- our launch of new products into the market and forward looking assumptions of our pipeline;
- results of litigation;
- receipt of FDA approvals and PDUFA dates;

lack of marketability of our common stock;

our actual operating and financial performance and forward looking assumptions;

current business conditions and projections;

hiring of key personnel and the experience of our management;

our company history and the introduction of new products;

our stage of development;

likelihood of achieving a liquidity event, such as an initial public offering or a merger or acquisition of our company given prevailing market conditions;

Table of Contents

the market performance of comparable publicly traded companies; and

the U.S. and global capital market conditions.

The dates of our valuation reports, which were prepared on a quarterly basis, were not always contemporaneous with the grant dates of our share-based awards. Therefore, in those cases where the report was not contemporaneous with the grant date of the stock based awards, we considered the amount of time between the valuation report date and the grant date to determine whether to use the latest common stock valuation report for the purposes of determining the fair value of our common stock for financial reporting purposes. If share-based awards were granted a short period of time preceding the date of a valuation report, we assessed the fair value of such share-based awards used for financial reporting purposes after considering the fair value reflected in the subsequent valuation report and other facts and circumstances on the date of grant as discussed below. There were significant judgments and estimates inherent in these valuations, which included assumptions regarding our future operating performance, the time to completing an initial public offering or other liquidity event and the determinations of the appropriate valuation methods to be applied. If we had made different estimates or assumptions, our share-based compensation expense, net loss and net loss per share attributable to common stockholders could have been significantly different from those reported in this prospectus.

In valuing our common stock, our board of directors determined the equity value of our business using generally accepted valuation methodologies including discounted cash flow analysis and comparable public company analysis.

Discounted cash flow analysis measures the value of a company by the present value of its future economic benefits. These benefits can include earnings, cost savings, tax deductions and proceeds from disposition. Value indications are developed by discounting expected cash flows to their present value at a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation and risks associated with the particular investment.

The comparable public company analysis measures the value of a company through the analysis of recent sales of comparable companies focused on the sale of pharmaceuticals as traded in the public markets. This method of valuation involves analyzing transaction and financial data of publicly-traded companies to develop multiples. These multiples, usually of estimated sales, earnings before interest, taxes, depreciation and amortization, or EBITDA, and net income, are then applied to the subject company to develop an indication of value. For purposes of our comparable public company analysis, our peer group of U.S.-based publicly traded companies used for valuation estimates, including the determination of the discount rate, volatility assumptions and market trading multiples is comprised of companies that focus primarily on the sale of pharmaceutical products. More specifically, we focused on companies with similar pharmaceutical product offerings in the injectable and inhalation markets. From time to time, we updated the set of peer group companies as new or more relevant information became available. Within each valuation report, this peer group was used for valuation estimates, including the determination of the discount rate, volatility assumptions and market trading multiples. While we believe that these groups of comparable companies were appropriate, there are differences in size or stage of maturity between many of our selected peer public companies and us. Therefore, had a different set of peer companies been used, a different valuation may have resulted.

Once calculated, the board determines the midpoint of the results of the discounted cash flow and the market comparable approach and then weights the two methodologies to determine an estimated enterprise value.

Once an enterprise value was determined, we utilized the option pricing method, or OPM, to allocate the equity value to our common stock. The OPM values each equity class by creating a series of call options on our equity value, with exercise prices based on the strike prices of derivatives. This method is generally preferred when future outcomes are difficult to predict and dissolution or liquidation is not imminent. The

Table of Contents

inability to readily sell shares of a company increases the owner's exposure to changing market conditions and increases the risk of ownership. Because of the lack of marketability and the resulting increased risk associated with ownership of a privately-held stock, an investor typically demands a higher return or yield in comparison to a similar but publicly-traded stock. An indication of the discount for lack of marketability can be developed using a put option model. A put option model values what the illiquid security holder lacks, the ability to sell his or her shares. Theoretically, a holder of an illiquid security and a put option, and a holder of an identical, but liquid security, are in the same financial position. The put option model has the benefit of being company-specific (through the use of a company-specific volatility rate), verifiable and has relatively few inputs (risk free rate, term and volatility).

We granted awards with the following exercise prices between January 1, 2013 and the date of this prospectus:

Grant Date	Options or DSUs	Number of Shares Subject to Awards Granted	Exercise Price(1)	Fair Value Per Share of Common Stock
May 30, 2013	Options	36,000	$ 10.73	$ 10.73
June 3, 2013	Options	66,866	10.73	10.73
July 5, 2013	Options	196,132	10.93	10.93
July 5, 2013	Options	2,025,348	12.02	10.93
July 5, 2013	DSUs	47,558	N/A	10.93
July 30, 2013	Options	704,500	10.93	10.93
August 19, 2013	Options	6,000	10.93	10.93
August 29, 2013	DSUs	20,374	N/A	10.93
September 9, 2013	Options	15,273	10.93	10.93
October 7, 2013	Options	20,765	13.68	13.68
October 7, 2013	Options	44,501	13.68	13.68
October 10, 2013	Options	6,000	13.68	13.68
December 20, 2013	Options	231,540	14.66	14.66
December 20, 2013	DSUs	32,743	N/A	14.66
December 27, 2013	Options	245,800	14.66	14.66
January 10, 2014	Options	4,000	14.66	14.66
March 19, 2014	Options	161,050	14.40	14.40
March 27, 2014	Options	116,790	14.40	14.40
March 27, 2014	Options	739,520	15.84	14.40
March 27, 2014	DSUs	307,760	N/A	14.40
April 14, 2014	Options	521,949	14.40	14.40
April 14, 2014	DSUs	92,386	N/A	14.40
April 21, 2014	Options	118,553	14.40	14.40
April 21, 2014	DSUs	14,722	N/A	14.40

(1) Options issued to two of our executive officers, Dr. Jack Y. Zhang and Dr. Mary Z. Luo, are issued at an exercise price equal to 110% of the exercise price listed in the table.

As of March 31, 2014, the aggregate intrinsic value of in-the-money vested and unvested options was $0.4 million and $0.3 million, respectively, and the aggregate value of our vested and unvested DSUs was $0.03 million and $4.4 million, respectively, based on the estimated fair value for our common stock of $11.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus.

Table of Contents

The following discussion relates primarily to our determination of the fair value per share of our common stock for purposes of calculating share-based compensation costs since January 1, 2013. No single event caused the valuation of our common stock to increase or decrease through May 30, 2014. Instead, a combination of the factors described below in each period led to the changes in the fair value of our common stock. We believe reliance on the valuation report and the underlying methodology in such report was a reasonable method to determine the exercise prices for share-based awards on the grant date.

May and June 2013 Awards

We granted options to purchase 36,000 shares of our common stock to our key employees in May 2013. In June 2013, we granted options to purchase 66,866 shares of our common stock to a key employee. Our board of directors set an exercise price of $10.73 per share for these options based, in part, on a valuation report with a valuation date of March 8, 2013. The stock price had a nominal change from the previous price.

We obtained an independent valuation which determined that the fair value of our common stock was $10.73 per share as of March 8, 2013. The enterprise value was derived utilizing a weighted combination of the discounted cash flow analysis, and the comparable public company analysis weighted at 60% and 40%, respectively. The discounted cash flow analysis applied a discount rate of 12% based on the risks attributable to our size, industry and operations. The comparable company analysis utilized multiples of actual 2012 sales, EBITDA and net income, as well as estimated 2013 sales, EBITDA and net income, and then added back in net debt to calculate an enterprise value. The enterprise value was then allocated to the common stock utilizing a Black-Scholes put option model which assumed a term of 0.65 years, volatility of 30.0% and a risk free rate of 0.12%. Additionally, a discount for lack of marketability of 10.0% was selected.

Our board of directors considered our most recent operating results, as well as the valuation report, when it determined the fair value of our common stock was $10.73 per share for purposes of the May and June 2013 awards.

July, August and September 2013 Awards

We granted options to purchase 900,632 shares of our common stock to our key employees in July 2013. In August 2013, we granted options to purchase 6,000 shares of our common stock to a key employee and in September 2013, we granted options to purchase 15,273 shares of our common stock to a key employee. Our board of directors set an exercise price of $10.93 per share for these options based, in part, on a valuation report with a valuation date of June 4, 2013. In addition, we granted options to purchase 2,025,348 shares of our common stock to our Chief Executive Officer and Chief Operating Officer, in aggregate, in July 2013. Our board of directors set an exercise price of $12.02 per share, in accordance to the provision of the 2005 Plan, in which, options granted to our Chief Executive Officer and Chief Operating Officer are granted at 110% of fair market value. The stock price increased from the previous price as a result of higher market multiples of comparable public companies.

In July 2013, we granted 47,558 DSUs to key employees which, by definition, do not have an exercise price. The DSU award have a four-year vesting requirement from the date of grant, and the award entitles the grantee to receive shares of our common stock on each vesting anniversary date, provided that the grantee continues to be an employee. In August 2013, we granted 20,374 DSUs to key employees. The DSUs entitle the grantee to receive shares of our common stock on August 29, 2014, provided that they remain an employee. These DSUs were issued as replacement awards prior to the expiration of the stock options held by the key employees of equal fair value.

We obtained an independent valuation which determined that the fair value of our common stock was $10.93 per share as of June 4, 2013. The enterprise value was derived utilizing a weighted combination of the discounted cash flow analysis, and the comparable public company analysis weighted at 60% and 40%, respectively. The discounted cash flow analysis applied a discount rate of 12% based on the risks attributable to our size, industry and operations. The comparable company analysis utilized multiples of

Table of Contents

actual 2012 sales, EBITDA, and net income, and estimated 2013 sales, EBITDA and net income and then added back in net debt to calculate an enterprise value. The enterprise value was then allocated to the common stock utilizing a Black-Scholes put option model which assumed a term of 0.58 years, volatility of 35.0% and a risk free rate of 0.09%. Additionally, a discount for lack of marketability of 11.0% was selected.

Our board of directors considered our most recent operating results, as well as the valuation report, when it determined the fair value of our common stock was $10.93 per share for purposes of the July, August and September 2013 awards.

October 2013 Awards

We granted options to purchase 71,266 shares of our common stock to our key employees in October 2013. Our board of directors set an exercise price of $13.68 per share for these options based, in part, on a valuation report with a valuation date of September 10, 2013. The stock price increased from the previous price as the result of several factors, including the fact that in August and early September 2013, we commenced activities toward our initial public offering, which increased the likelihood of a potential liquidity event for our stockholders and slightly reduced our assumed illiquidity discount. In addition, in the context of discussions with investment bankers and other industry professionals related to our initial public offering process, we refined our operating forecasts that were utilized in the independent valuation report to reflect significantly lower anticipated operating expenses than we had previously assumed. The lower operating expense forecast increased the value implied by the discounted cash flow analysis. Finally, the public markets in August and September 2013 were very favorable, resulting in higher implied peer group multiples for the public company analysis.

We obtained an independent valuation which determined that the fair value of our common stock was $13.68 per share as of September 10, 2013. The enterprise value was derived utilizing a weighted combination of the discounted cash flow analysis, and the comparable public company analysis weighted at 40% and 60%, respectively. The weighting of the analyses changed from the previous report because we commenced activities towards our initial public offering, which we determined made the comparable public company analysis more relevant than in earlier periods. The discounted cash flow analysis applied a discount rate of 15% based on the risks attributable to our size, industry and operations. The comparable company analysis utilized multiples of the last twelve months sales, EBITDA and net income, estimated 2014 sales and EBITDA. The enterprise value was then allocated to the common stock utilizing a Black-Scholes put option model which assumed a term of 0.50 years, volatility of 35.0% and a risk free rate of 0.04%. Additionally, a discount for lack of marketability of 10.0% was selected.

Our board of directors considered our most recent operating results, as well as the valuation report, when it determined the fair value of our common stock was $13.68 per share for purposes of the October 2013 awards.

December 2013 and January 2014 Awards

We granted options to purchase 477,340 shares of our common stock to our directors and key employees in December 2013. In January 2014, we granted options to purchase 4,000 shares of our common stock to key employees. Our board of directors set an exercise price of $14.66 per share for these options based, in part, on a valuation report with a valuation date of December 3, 2013. In addition, we also granted a total of 32,743 DSUs to key employees and our board of directors in December 2013, which by definition do not have an exercise price. The 6,822 DSUs issued to a key employee have a three-year vesting requirement from the date of grant, and the award entitles the grantees to receive shares of our common stock on each vesting anniversary date, provided that the grantee continues to be an employee. The 25,921 DSUs issued to the board of directors entitles the grantee to receive shares of our common stock on the earlier of December 20, 2013 or our next stockholder meeting. The stock price increased from the previous price as the result of several factors, including the fact that in October 2013 we held our organizational meeting with investment bankers for our initial public offering, which increased the likelihood of a potential liquidity event for our stockholders and slightly reduced our assumed illiquidity discount. In addition, based on

Table of Contents

receiving a PDUFA date of May 2014 for Primatene Mist HFA, we refined our sales forecasts to show higher revenue and EBITDA margin forecasts relative to the prior financial projections. The higher sales and margin forecast increased the value implied by the discounted cash flow analysis.

We obtained an independent valuation which determined that the fair value of our common stock was $14.66 per share as of December 3, 2013. The enterprise value was derived utilizing a weighted combination of the discounted cash flow analysis, and the comparable public company analysis weighted at 40% and 60%, respectively. The discounted cash flow analysis applied a discount rate of 15% based on the risks attributable to our size, industry and operations. The comparable company analysis utilized multiples of the last twelve months sales, EBITDA and net income, as well as estimated 2014 sales and EBITDA. The enterprise value was then allocated to the common stock utilizing a Black-Scholes put option model which assumed a term of 0.41 years, volatility of 35.0% and a risk free rate of 0.08%. Additionally, a discount for lack of marketability of 9.0% was selected. Our board of directors considered our most recent operating results, as well as the valuation report, when it determined the fair value of our common stock was $14.66 per share for purposes of the December 2013 and January 2014 awards.

March and April 2014 Awards

We granted options to purchase 277,840 shares of our common stock to our key employees in March 2014. Our board of directors set an exercise price of $14.40 per share for these options based, in part, on a valuation report with a valuation date of February 28, 2014. In addition, we granted options to purchase a total of 739,520 shares of our common stock to our Chief Executive Officer and Chief Operating Officer in March 2014. Our board of directors set an exercise price of $15.84 per share, in accordance to the provision of the 2005 Plan, in which options granted to our Chief Executive Officer and Chief Operating Officer are granted at 110% of fair market value. We also granted a total of 307,760 DSUs to key employees and our Chief Executive Officer and Chief Operating Officer in March 2014, which by definition do not have an exercise price. The 307,760 DSUs issued to a key employee have a four-year vesting requirement from the date of grant, and the award entitles the grantee to receive shares of our common stock on each vesting anniversary date, provided that the grantee continues to be an employee. The stock price decreased from the previous price primarily as the result of changes in the market for enoxaparin, as well as the results of the joint meeting of the Committee in February 2014 regarding Primatene Mist HFA.

In April 2014, we granted options to purchase 521,949 shares of our common stock to our key employees and 118,553 to our Chief Financial Officer. Our board of directors set an exercise price of $14.40 per share for these options. In addition, we granted 92,386 DSUs to our key employees and 14,722 DSUs to our Chief Financial Officer. These DSUs have a four-year vesting requirement from the date of grant, and the award entitles the grantee to receive shares of our common stock on each vesting anniversary date, provided that the grantee continues to be an employee.

We obtained an independent valuation which determined that the fair value of our common stock was $14.40 per share as of February 28, 2014. The enterprise value was derived utilizing a weighted combination of the discounted cash flow analysis, and the comparable public company analysis weighted at 40% and 60%, respectively. The discounted cash flow analysis applied a discount rate of 15% based on the risks attributable to our size, industry and operations. The comparable company analysis utilized multiples of the last twelve months sales, and EBITDA, as well as estimated 2014 sales and EBITDA. The enterprise value was then allocated to the common stock utilizing a Black-Scholes put option model which assumed a term of 0.21 years, volatility of 35.0% and a risk free rate of 0.04%. Additionally, a discount for lack of marketability of 6.0% was selected.

Our board of directors considered our most recent operating results, as well as the valuation report, when it determined the fair value of our common stock was $14.40 per share for purposes of the March and April 2014 awards.

Table of Contents

JOBS Act Accounting Election

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act 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.

Recent Accounting Pronouncements

In February 2013, the FASB issued an Accounting Standard Update to the accounting guidance for presentation of comprehensive income to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments do not change the current requirements for reporting net income or other comprehensive income, but do require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where the net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under GAAP that provide additional detail about these amounts. This new standard is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2012. The adoption of this standard did not impact our financial statements as our comprehensive income (loss) is equal to our net income (loss) for all periods presented.

In July 2013, the FASB issued guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance did not have a material impact on our consolidated financial statements.

Results of Operations

Comparison of the three months ended March 31, 2013 and 2014 (unaudited)

Net Revenues

	Three Months Ended March 31,		Change	
	2013	2014	$	%
	(in thousands, except percentages)			
Net revenues	$ 52,963	$ 45,870	$ (7,093)	(13)%
Cost of revenues	33,406	33,362	(44)	0%
Gross profit	$ 19,557	$ 12,508	$ (7,049)	(36)%
as % of net revenues	*37%*	*27%*		

Net revenues were $53.0 million and $45.9 million for the three months ended March 31, 2013 and 2014, respectively, representing a decrease of $7.1 million, or 13%. The decrease is primarily due to a decrease of $7.7 million in sales of enoxaparin, which is primarily due to a decrease in profit sharing

Table of Contents

revenues under our profit sharing agreement with Actavis, partially offset by an increase in sales of critical care drugs.

Non-retail sales of enoxaparin decreased $3.7 million, or 23% during the three months ended March 31, 2014 compared to the same period in 2013, due to decreased unit sales volume and a decrease in average net sales price. Retail sales of enoxaparin decreased $4.0 million, or 22% during the three months ended March 31, 2014 compared to the same period in 2013, primarily due to a decrease in profit sharing revenue of $6.5 million compared to the three months ended March 31, 2013, partially offset by an increase in unit sales volume.

Cost of Revenues and Gross Margin

Cost of revenues were $33.4 million and $33.4 million for the three months ended March 31, 2013 and 2014, respectively.

Gross margins were 37% and 27% for the three months ended March 31, 2013 and 2014, respectively. The decrease in gross margin is primarily due to the decrease in total net revenues of enoxaparin relating to the decrease in profit sharing revenue.

Selling, Distribution and Marketing

	Three Months Ended March 31,		Change	
	2013	2014	$	%
	(in thousands, except percentages)			
Selling, distribution and marketing	$ 1,394	$ 1,259	$ (135)	(10)%
as % of net revenues	*3%*	*3%*		

Selling, distribution and marketing expenses were $1.4 million and $1.3 million for the three months ended March 31, 2013 and 2014, respectively, representing a decrease of $0.1 million, or 10%.

General and Administrative

	Three Months Ended March 31,		Change	
	2013	2014	$	%
	(in thousands, except percentages)			
General and administrative	$ 6,907	$ 6,845	$ (62)	(1)%
as % of net revenues	*13%*	*15%*		

General and administrative expenses were generally consistent with the prior period and were $6.9 million and $6.8 million for the three months ended March 31, 2013 and 2014, respectively, representing a decrease of $0.1 million, or 1%.

Table of Contents

Research and Development

	Three Months Ended March 31,		Change	
	2013	2014	$	%
	(in thousands, except percentages)			
Research and development	$ 8,904	$ 6,209	$ (2,695)	(30)%
as % of net revenues	*17%*	*14%*		

Research and development expenses were $8.9 million and $6.2 million for the three months ended March 31, 2013 and 2014, respectively, representing a decrease of $2.7 million, or 30%. The decrease is primarily due to a decrease in testing, operating, and pre-launch expense related to the timing of purchases of materials and other research and development supplies.

Impairment of Long-Lived Assets

	Three Months Ended March 31,		Change	
	2013	2014	$	%
	(in thousands, except percentages)			
Impairment of long-lived assets	$	$ 164	$ 164	100%

Impairment of long-lived assets expense was $0.2 million for the three months ended March 31, 2014. There was no impairment of long-lived asset expense during the three months ended March 31, 2013. The write-off for the three months ended March 31, 2014 was related to capitalized costs associated with a project that was suspended.

Other Income (expense), net

	Three Months Ended March 31,		Change	
	2013	2014	$	%
	(in thousands, except percentages)			
Other Income (expense), net	$ 95	$ (350)	$ (445)	(468)%

Other income, net, was $0.1 million for the three months ended March 31, 2013. Other expense, net was $0.3 million for the three months ended March 31, 2014. The other expense was primarily related to losses as a result of changes in exchange rates.

Table of Contents

Provision for Income Tax benefit

	Three Months Ended March 31,		Change	
	2013	2014	$	%
	(in thousands, except percentages)			
Income tax benefit	$ 191	$ 852	$ 661	346%
Effective tax rate	*(9)%*	*34%*		

Income tax benefit was $0.2 million and $0.9 million for the three months ended March 31, 2013 and 2014, respectively, representing an increase of $0.7 million. The increase in income tax benefit is primarily related to the increase in pre-tax loss that occurred during the three months ended March 31, 2014.

Comparison of the years ended December 31, 2012 and 2013

Net Revenues

	Year ended December 31,		Change	
	2012	2013	$	%
	(in thousands, except percentages)			
Net revenues	$ 204,323	$ 229,681	$ 25,358	12%
Cost of revenues	114,020	142,725	28,705	25%
Gross profit	$ 90,303	$ 86,956	$ (3,347)	(4)%
as % of net revenues	*44%*	*38%*		

Net revenues were $204.3 million and $229.7 million for the years ended December 31, 2012 and 2013, respectively, representing an increase of $25.4 million, or 12%. The increase is primarily due to increases of $18.2 million in sales of enoxaparin and $7.2 million in sales of our other products.

Non-retail sales of enoxaparin increased $8.6 million, or 15% during the year ended December 31, 2013 compared to the same period in 2012, due to increased sales volume, which was partially offset by a decrease in average net sales price.

Retail sales of enoxaparin increased $9.6 million, or 14% during the year ended December 31, 2013 compared to the same period in 2012, primarily due to increased sales volume, as well as an increase in our transfer price to Actavis. This increase was partially offset by a decrease in profit sharing revenues with Actavis.

Sales of our other products increased primarily due to increased sales volume, as a result of a temporary shortage by one of our competitors in the market place for these products, which we do not expect to recur in future periods.

Cost of Revenues and Gross Margin

Cost of revenues were $114.0 million and $142.7 million for the years ended December 31, 2012 and 2013, respectively, representing an increase of $28.7 million, or 25%.

The product cost of enoxaparin increased $31.1 million, or 60% during the year ended December 31, 2013, compared to the same period in 2012, primarily due to an increase in sales volume. In addition, during the year ended December 31, 2012, we benefitted from the effect of having previously expensed

82

Table of Contents

$7.7 million of enoxaparin inventory costs in 2011 as pre-launched inventory. The product cost of our other products increased $6.5 million, primarily due to increased sales volume.

Manufacturing variances decreased by $8.5 million, or 68% during the year ended December 31, 2013, compared to the same period in 2012, primarily due to higher production volumes.

Gross margins were 44% and 38% for the years ended December 31, 2012 and 2013, respectively. The decrease in gross margin is primarily due to the effect of having previously expensed $7.7 million of enoxaparin inventory costs in 2011 as pre-launched inventory. The decrease in gross margins also resulted from a decrease in average net sales price of enoxaparin during 2013.

Selling, Distribution and Marketing

	Year Ended December 31,		Change	
	2012	2013	$	%
	(in thousands, except percentages)			
Selling, distribution and marketing	$ 4,426	$ 5,349	$ 923	21%
as % of net revenues	*2%*	*2%*		

Selling, distribution and marketing expenses were $4.4 million and $5.3 million for the years ended December 31, 2012 and 2013, respectively, representing an increase of $0.9 million, or 21%. The increase is primarily due to the increase in shipping and freight costs related to sales of our enoxaparin product.

General and Administrative

	Year Ended December 31,		Change	
	2012	2013	$	%
	(in thousands, except percentages)			
General and administrative	$ 27,223	$ 30,972	$ 3,749	14%
as % of net revenues	*13%*	*13%*		

General and administrative expenses were $27.2 million and $31.0 million for the years ended December 31, 2012 and 2013, respectively, representing an increase of $3.8 million, or 14%. The increase is primarily due to an increase of $2.4 million in payroll expense which primarily relates to the bonuses paid to executive management and salary increase adjustments for key employees and an accrual of $1.0 million related to the retirement of our former Chief Financial Officer in the year ended December 31, 2013.

Research and Development

	Year Ended December 31,		Change	
	2012	2013	$	%
	(in thousands, except percentages)			
Research and development	$ 31,163	$ 33,019	$ 1,856	6%
as % of net revenues	*15%*	*14%*		

Table of Contents

Research and development expenses were $31.2 million and $33.0 million for the years ended December 31, 2012 and 2013, respectively, representing an increase of $1.8 million, or 6%. The increase is primarily due to $4.2 million in submission fees paid to the FDA during 2013 and an increase of $0.7 million relating to payroll as a result of an increase in headcount in research and development. This increase was partially offset by a decrease of $3.6 million in clinical trial expense.

Impairment of Long-Lived Assets

	Year Ended December 31,		Change	
	2012	2013	$	%
	(in thousands, except percentages)			
Impairment of long-lived assets	$ 2,094	$ 126	$ (1,968)	(94)%

Impairment of long-lived assets was $2.1 million and $0.1 million for the years ended December 31, 2012 and 2013, respectively, representing a decrease of $2.0 million, or 94%. The write-off for the year ended December 31, 2012 was primarily related to equipment for a production project that was suspended.

Other Income, net

	Year Ended December 31,		Change	
	2012	2013	$	%
	(in thousands, except percentages)			
Other Income, net	$ 1,023	$ 508	$ (515)	(50)%

Other income, net, was $1.0 million and $0.5 million for the years ended December 31, 2012 and 2013, respectively, representing a decrease of $0.5 million, or 50%. This decrease was primarily related to the resale of supplies during the year ended December 31, 2012. This decrease was partially offset by higher re-measurement gains.

Provision for Income Tax Expense

	Year Ended December 31,		Change	
	2012	2013	$	%
	(in thousands, except percentages)			
Income tax expense	$ 7,784	$ 5,365	$ (2,419)	(31)%
Effective tax rate	*30%*	*31%*		

Income tax expense was $7.8 million and $5.4 million for the years ended December 31, 2012 and 2013, respectively, representing a decrease in income tax expense of $2.4 million, or 31%. The decrease in income tax expense is primarily related to the retroactive application in the year ended December 31, 2013 of the federal research and development tax credit for the 2012 tax year. The legislation renewing the allowance of the federal R&D tax credit for 2012 was not passed into law until January 2013, therefore, the R&D tax credit was not factored into our 2012 income tax expense. Also, the decrease in income tax expense is related to a decrease in taxable income.

Table of Contents

Comparison of the years ended December 31, 2011 and 2012

Net Revenues

	Year Ended December 31,		Change	
	2011	2012	$	%
	(in thousands, except percentages)			
Net revenues	$ 118,356	$ 204,323	$ 85,967	73%
Cost of revenues	90,252	114,020	23,768	26%
Gross profit	$ 28,104	$ 90,303	$ 62,199	221%
as % of net revenues	*24%*	*44%*		

Net revenues were $118.4 million and $204.3 million for the years ended December 31, 2011 and 2012, respectively, representing an increase of $86.0 million, or 73%. The increase was primarily due to increases of $129.0 million in sales of enoxaparin and $9.6 million in sales of other products. This increase was partially offset by a decrease of $52.7 million in sales of the CFC formulation of our Primatene Mist product, which we have not sold since December 31, 2011.

Of the $129.0 million increase in sales of enoxaparin, $70.5 million were retail sales and $58.5 were non-retail sales.

The increases in sales of other products were primarily due to temporary nationwide drug shortages of one of our competitor's products that began in the second quarter of 2012 for certain products and in the fourth quarter of 2011 for certain other products. We do not expect these shortages to recur in future periods.

Cost of Revenues and Gross Margins

Cost of revenues was $90.3 million and $114.0 million for the years ended December 31, 2011 and 2012, respectively, representing an increase of $23.7 million, or 26%.

Product costs increased in 2012 as compared to 2011 by $70.5 million primarily due to increased sales volume. This increase was partially offset by a decrease of $20.6 million of the CFC formulation of our Primatene Mist product cost due to the absence of sales in the year ended December 31, 2012, resulting from the discontinuance of this product as of December 31, 2011. Additionally, manufacturing variances decreased by $20.3 million primarily due to higher production volumes. Also, included in the year ended December 31, 2011 was a $3.0 million charge related to an enoxaparin inventory reserve and a $6.1 million write-off of the CFC formulation of our Primatene Mist product inventory that we did not expect to sell by the end by December 31, 2011.

Gross margin was 24% and 44% for the years ended December 30, 2011 and 2012, respectively. The increase in gross margin was primarily related to the sales of our enoxaparin product in the year ended December 31, 2012 and the inventory reserve charge and write-off of the CFC formulation of our Primatene Mist product inventory in 2011.

Table of Contents

Selling, Distribution and Marketing

	Year Ended December 31, 2011	2012	Change $	%
	(in thousands, except percentages)			
Selling, distribution and marketing	$ 4,100	$ 4,426	$ 326	8%
as % of net revenues	*3%*	*2%*		

Selling, distribution and marketing expenses were $4.1 million and $4.4 million for the years ended December 31, 2011 and 2012, respectively, representing an increase of $0.3 million, or 8%. The increase is primarily due to the increase in shipping and freight costs related to our enoxaparin product that was launched in the first quarter of 2012.

General and Administrative

	Year Ended December 31, 2011	2012	Change $	%
	(in thousands, except percentages)			
General and administrative	$ 26,433	$ 27,223	$ 790	3%
as % of net revenues	*22%*	*13%*		

General and administrative expenses were $26.4 million and $27.2 million for the years ended December 31, 2011 and 2012, respectively, representing an increase of $0.8 million, or 3%. The increase was primarily due to an increase of $1.5 million in legal expenses, which included costs to defend a patent infringement litigation case in the year ended December 31, 2012. This increase was partially offset by a decrease of $0.7 million in payroll expense. In 2011 we paid a discretionary bonus that was related to the FDA approval of our enoxaparin product and no such bonus was paid in 2012.

Research and Development

	Year Ended December 31, 2011	2012	Change $	%
	(in thousands, except percentages)			
Research and development	$ 31,049	$ 31,163	$ 114	0%
as % of net revenues	*26%*	*15%*		

Research and development expenses were $31.0 million and $31.2 million for the years ended December 31, 2011 and 2012, respectively, representing an increase of $0.2 million. The increase was primarily due to increases of $5.6 million in testing, operating and pre-launch expenses for Primatene Mist HFA related to the purchases of materials and other research and development supplies and $0.7 million in expense related to a write-off of the leasehold improvements to a previously leased building that was purchased in the year ended December 31, 2012. This increase was partially offset by a decrease of $6.0 million in clinical trials expense in 2012 compared to 2011, which decrease primarily related to clinical trials expense for Primatene Mist HFA incurred in the year ended December 31, 2011.

Table of Contents

Impairment of Long-Lived Assets

	Year Ended December 31,		Change	
	2011	2012	$	%
	(in thousands, except percentages)			
Impairment of long-lived assets	$ 67	$ 2,094	$ 2,027	3,025%

Impairment of long-lived assets was $0.1 million for the year ended December 31, 2011, compared to $2.1 million for the year ended December 31, 2012, representing an increase of $2.0 million. The write-off for the year ended December 31, 2012 was primarily related to equipment for a production project that was suspended.

Other Income, net

	Year Ended December 31,		Change	
	2011	2012	$	%
	(in thousands, except percentages)			
Other income, net	$ 1,841	$ 1,023	$ (818)	(44)%

Other income, net, was $1.8 million and $1.0 million for the years ended December 31, 2011 and 2012, respectively, representing a decrease of $0.8 million, or 44%. In the year ended December 31, 2011, we recognized $1.0 million of other income, net, as a result of a litigation settlement with one of our suppliers.

Provision for Income Tax Expense (Benefit)

	Year Ended December 31,		Change	
	2011	2012	$	%
	(in thousands, except percentages)			
Income tax expense (benefit)	$ (39,639)	$ 7,784	$ 47,423	120%
Effective tax rate	*(124)%*	*30%*		

Income tax benefit was $39.6 million for the year ended December 31, 2011 and income tax expense was $7.8 million for the year ended December 31, 2012, representing an increase in income tax expense of $47.4 million, or 120%. The increase was primarily related to an increase in pre-tax income in 2012 and a tax benefit that we recognized in 2011 as a result of the reversal of a valuation allowance against our historical deferred tax assets, resulting from the 2011 approval of our enoxaparin product.

Table of Contents

Quarterly Results of Operations

The following tables set forth unaudited quarterly consolidated statements of operations for each of the nine quarters in the period ended March 31, 2014. We have prepared the statement of operations data for each of these quarters on the same basis as the audited consolidated financial statements included elsewhere in this prospectus and, in the opinion of management, each statement of operations includes all adjustments, consisting solely of normal recurring adjustments, necessary for the fair statement of the results of operations for these periods. This information should be read in conjunction with the audited consolidated financial statements and related notes included elsewhere in this prospectus. These quarterly operating results are not necessarily indicative of our operating results for any future period.

	2012				2013				2014
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
	(unaudited)								
	(in thousands, except per share data)								
Consolidated Statements of Operations Data:									
Net revenues	$ 46,241	$ 49,413	$ 56,619	$ 52,050	$ 52,963	$ 62,524	$ 59,318	$ 54,876	$ 45,870
Cost of revenues	22,778	25,981	34,981	30,280	33,405	35,035	39,038	35,247	33,362
Gross profit	23,463	23,432	21,638	21,770	19,558	27,489	20,280	19,629	12,508
Operating expenses:									
Selling, distribution and marketing	987	1,027	1,242	1,170	1,394	1,203	1,462	1,290	1,259
General and administrative	7,375	6,705	6,484	6,659	6,907	6,513	9,546	8,006	6,845
Research and development	6,710	8,998	7,488	7,967	8,904	7,791	9,041	7,283	6,209
Impairment of long-lived assets	2	4	1,802	286			6	120	164
Total operating expenses	15,074	16,734	17,016	16,082	17,205	15,507	20,055	16,699	14,477
Income (loss) from operations	8,389	6,698	4,622	5,688	2,353	11,982	225	2,930	(1,969)
Non-operating income (expense):									
Interest income	116	43	37	46	49	47	49	42	28
Interest expense, net	(130)	(136)	(226)	(292)	(305)	(237)	(195)	(221)	(180)
Other income, net	463	45	282	233	95	127	255	31	(350)
Total non-operating income (expense)	449	(48)	93	(13)	(161)	(63)	109	(148)	(502)
Income before income taxes	8,838	6,650	4,715	5,675	2,192	11,919	334	2,782	(2,471)
Income tax expense (benefit)	3,299	1,739	1,433	1,313	(191)	4,109	494	953	(852)
Net income (loss)	$ 5,539	$ 4,911	$ 3,282	$ 4,362	$ 2,383	$ 7,810	$ (160)	1,829	$ (1,619)
Net income (loss) per common share:									
Basic	$ 0.14	$ 0.13	$ 0.09	$ 0.11	$ 0.06	$ 0.20	$ 0.00	$ 0.05	$ (0.04)
Diluted	$ 0.14	$ 0.13	$ 0.08	$ 0.11	$ 0.06	$ 0.20	$ 0.00	$ 0.05	$ (0.04)
Weighted-average shares used to compute net income (loss) per common share:									
Basic	38,516	38,540	38,598	38,668	38,707	38,708	38,709	38,724	39,797
Diluted	39,095	39,105	38,848	38,836	38,845	38,847	38,709	39,141	39,797

Table of Contents

Liquidity and Capital Resources

Overview

Our primary uses of cash are to fund working capital requirements, product development costs, operating expenses, commercialization activities related to our products and product candidates and potential strategic acquisitions of complementary companies, products and technologies. For the years ended December 31, 2011, 2012 and 2013 and for the three months ended March 31, 2013 and 2014, our product sales and borrowing activities produced sufficient liquidity for our operations and growth. As of March 31, 2014, we had cash and cash equivalents of $52.1 million and $29.4 million of outstanding borrowings under our credit facilities. We expect that our current cash balances, cash provided by operating activities and borrowing capacity under our existing lines of credit will be sufficient to fund our operations for the next 12 months. Sales from our enoxaparin product were $145.9 million and $26.1 million for the year ended December 31, 2013 and the three months ended March 31, 2014, comprising 64% and 57%, respectively, of our total net revenues. Significant changes in sales of enoxaparin will likely have a significant effect on our overall financial position.

We intend to use the net proceeds from this offering for general corporate purposes, funding the development of our product candidates, investing in equipment and facilities to accommodate new product development and working capital. See "Use of Proceeds."

Cash Flows

Overview

The following table summarizes the key elements of our financial position as of December 31, 2012, 2013 and March 31, 2014.

	December 31, 2012	2013	March 31, 2014 (unaudited)
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash, cash equivalents, restricted cash and short-term investments	$ 52,101	$ 54,912	$ 53,460
Working capital	105,615	107,569	104,477
Total assets	317,477	338,748	345,109
Long-term debt and capital leases, including current portion	38,002	32,173	41,500

Table of Contents

The following table summarizes our cash flows used in operating, investing and financing activities for the years ended December 31, 2011, 2012 and 2013 and for the three months ended March 31, 2013 and 2014.

	Year Ended December 31,			Three Months Ended March 31,	
	2011	2012	2013	2013	2014
			(in thousands)	(unaudited)	
Statement of Cash Flow Data:					
Net cash provided by (used in)					
Operating activities	$ 19,096	$ (1,650)	$ 31,042	$ 1,527	$ (5,835)
Investing activities	(10,535)	(25,112)	(18,298)	(7,123)	(4,797)
Financing activities	(8,576)	23,237	(9,370)	9,542	9,180
Net increase (decrease) in cash and cash equivalents	$ (15)	$ (3,525)	$ 3,374	$ 3,946	$ (1,452)

Sources and Uses of Cash

Operating Activities

Net cash provided by operating activities was $19.1 million for the year ended December 31, 2011, which included net income of $7.8 million and non-cash items comprised of $11.2 million of depreciation and amortization and $8.0 million of share-based compensation expense, and an increase of $28.1 million in working capital. This was partially offset by changes of $29.7 million in net deferred tax assets primarily due to the release of the entire valuation allowance and $6.3 million in reserve for income taxes primarily due to the reversal of a reserve for an uncertain tax position, as a result of the expiration of the statute of limitations.

Net cash used in operating activities was $1.7 million for the year ended December 31, 2012, which included net income of $18.1 million and non-cash items comprised of $11.5 million of depreciation and amortization, $7.4 million of share-based compensation expense, $2.1 million of impairment of long-lived assets and a $8.3 million change in deferred taxes and other tax related items. This is offset by a decrease of $49.1 million from changes in other operating assets and liabilities, primarily as a result of the increase in accounts receivable and inventory.

Net cash provided by operating activities was $31.0 million for the year ended December 31, 2013, which included net income of $11.9 million and non-cash items comprised of $13.1 million of depreciation and amortization, $7.0 million of share-based compensation expense, and a $2.1 million change in deferred taxes and other tax related items. This is partially offset by a decrease of $3.1 million from changes in other operating assets and liabilities.

Net cash provided by operating activities was $1.5 million for the three months ended March 31, 2013, which included net income of $2.4 million and non cash items comprised of $3.0 million of depreciation and amortization, and $1.6 million of share based compensation expense. This is partially offset by a decrease of $5.5 million from changes in other operating assets and liabilities.

Net cash used in operating activities was $5.8 million for the three months ended March 31, 2014, which included a net loss of $1.6 million and non cash items comprised of $3.4 million of depreciation and amortization, $0.2 million of impairment of long-lived assets, and $1.6 million of share based compensation expense. This is offset by a decrease of $9.4 million from changes in other operating assets and liabilities, which is primarily due to an increase in enoxaparin inventory.

Table of Contents

Investing Activities

Net cash used in investing activities of $10.5 million for the year ended December 31, 2011 primarily related to purchases of machinery and equipment, including the associated capitalized labor and interest on self-constructed assets.

Net cash used in investing activities of $25.1 million for the year ended December 31, 2012 primarily related to $23.6 million in purchases of property, machinery and equipment, including the associated capitalized labor and interest on self-constructed assets, and $1.5 million in the purchase of intangible assets related to land-use rights.

Net cash used in investing activities of $18.3 million during the year ended December 31, 2013 primarily related to $18.3 million in purchases of property, machinery and equipment, including the associated capitalized labor and interest on self-constructed assets. Also, $0.5 million in deposits were made for machinery and equipment. Additionally, $0.5 million in sales of short term investments were related to a decrease in the required amount of restricted cash needed to collateralize a stand-by letter of credit for a workers' compensation insurance policy.

Net cash used in investing activities of $7.1 million during the three months ended March 31, 2013 primarily related to $6.4 million in purchases of property, machinery and equipment, including the associated capitalized labor and interest on self constructed assets. Additionally, $0.7 million in deposits were made for machinery and equipment.

Net cash used in investing activities of $4.8 million during the three months ended March 31, 2014 primarily related to $4.2 million in purchases of property, machinery and equipment, including the associated capitalized labor and interest on self constructed assets. Also, $0.6 million in deposits were made for machinery and equipment.

Financing Activities

Net cash used in financing activities of $8.6 million for the year ended December 31, 2011 primarily related to an aggregate of $5.9 million in principal payments on long-term debt and $1.0 million in tax benefit of stock options exercised. In the year ended December 31, 2011, we repurchased $1.8 million of our stock related to employee grants. The purpose of the stock repurchase was to buy back a quantity of shares with a value equal to the minimum tax withholdings required from the stock option exercises and the delivery of deferred stock unit shares.

Net cash provided by financing activities of $23.2 million for the year ended December 31, 2012 primarily related to $54.0 million in additional borrowing from our line of credit. This was partially offset by $29.3 million in repayments related to our line of credit, $0.9 million in principal payments on long-term debt and $0.6 million in payments on repurchases of common stock to cover employees' minimum payroll tax withholding requirements.

Net cash used in financing activities of $9.4 million for the year ended December 31, 2013 primarily related to $66.0 million in additional borrowing from our lines of credit. This is offset by $71.0 million in repayments related to our line of credit, $2.2 million in principal payments made on long-term debt, $1.4 million in IPO-related expenditures and $0.6 million relating to tax benefit of options exercised.

Net cash provided by financing activities was $9.5 million for the three months ended March 31, 2013 primarily related to $20.0 million in additional borrowing from our lines of credit. This is offset by $10.0 million in repayments related to our line of credit, $0.3 million in principal payments made on long term debt, and $0.2 million in IPO related expenditures.

Net cash provided by financing activities of $9.2 million for the three months ended March 31, 2014 primarily related to $25.0 million in additional borrowing from our lines of credit. This is offset by

Table of Contents

$15.0 million in repayments related to our line of credit, $0.6 million in principal payments made on long term debt, and $0.2 million in IPO related expenditures.

Indebtedness

Line of Credit Facility Due March 2016

In March 2012, we entered into a $10.0 million line of credit facility with East West Bank. Borrowings under the facility are secured by inventory and accounts receivable. Borrowings under the facility bear interest at the prime rate as published by *The Wall Street Journal*. This facility was to mature in July 2014. In April 2014, we extended the maturity date to March 2016. As of March 31, 2014, we had $10.0 million outstanding under this facility.

Revolving line of Credit Due May 2016

In April 2012, we entered into a $20.0 million revolving line of credit facility with Cathay Bank. Borrowings under the facility are secured by inventory, accounts receivables, and intangibles held by us. The facility bears interest at the prime rate as published by *The Wall Street Journal* with a minimum interest rate of 4.00%. This revolving line of credit was to mature in May 2014. In April 2014, we modified the facility to extend the maturity date to May 2016. As of March 31, 2014, we had $15.0 million outstanding under this facility.

Line of Credit Facility Due January 2019

In July 2013, we entered into an $8.0 million line of credit facility with East West Bank. Borrowings under the facility are secured by equipment. We will pay monthly interest-only payments on the loan until January 2015, after which we begin making 48 monthly principal and interest payments. The facility bears interest at the prime rate as published in *The Wall Street Journal* plus 0.25% and matures in January 2019. As of March 31, 2014, we did not have any amounts outstanding under this facility.

Financial Covenants under Lines of Credit

At December 31, 2012, 2013 and March 31, 2014, we were in compliance with our debt covenants, which include a minimum current ratio, minimum debt service coverage, minimum tangible net worth and maximum debt-to-effective-tangible-net-worth ratio, computed on a consolidated basis in some instances and on a separate-company basis in others.

Weighted-Average Interest Rates Under Lines of Credit

The weighted-average interest rates on lines of credit as of December 31, 2012, 2013 and March 31, 2014 were 4.4%, 4.1% and 3.7%, respectively.

Acquisition Loan with Cathay Bank Due April 2019

On April 22, 2014, in conjunction with our acquisition of Merck's API manufacturing business in Éragny-sur-Epte, France, we entered into a secured term loan with Cathay Bank as lender. The principal amount of the loan is $21.9 million and bears a variable interest rate at the prime rate as published by *The Wall Street Journal*, with a minimum interest rate of 4.00%. Beginning on June 1, 2014 and through the maturity date, April 22, 2019, we must make monthly payments of principal and interest equal to the then outstanding amount of the loan amortized over a 120-month period. On April 22, 2019, all amounts outstanding under the loan become due and payable, which would be approximately $12.0 million based upon an interest rate of 4.00%. The loan is secured by 65% of the issued and outstanding shares of stock in Amphastar France Pharmaceuticals SAS, or AFP, a subsidiary we established in France in order to facilitate the acquisition, and certain assets of ours, including accounts receivable, inventory, certain investment property, goods, deposit accounts and general intangibles but not including our equipment and real property.

The loan includes customary restrictions on, among other things, our ability to incur additional indebtedness, pay dividends in cash or make other distributions in cash, make certain investments, acquire other companies, create liens, sell assets and make loans. The loan also contains customary financial

Table of Contents

covenants, computed on a consolidated basis, which include a minimum tangible net worth, a maximum total liabilities to tangible net worth ratio, a minimum current ratio, a minimum profitability and a minimum fixed charge coverage ratio.

The loan also includes customary events of defaults, the occurrence and continuation of any of which provide Cathay Bank the right to exercise remedies against us and the collateral securing the loan. These events of default include, among other things, our failure to pay any amounts due under the loan, our insolvency, the occurrence of any default under certain other indebtedness or material agreements and a final judgment against us that is not discharged in 30-days.

Agreements with Corporate Partners

In May 2005, we entered into an agreement to grant certain exclusive marketing rights for our enoxaparin product to Andrx Pharmaceuticals, Inc., or Andrx, which generally extends to the U.S. retail pharmacy market. To obtain such rights, Andrx made a non-refundable, upfront payment of $4.5 million to us upon execution of the agreement. Under the agreement, we are paid a fixed cost per unit sold to Andrx and also receive a percentage between 50% and 55% of the gross profits from Andrx's sales of the product in the U.S. retail pharmacy market. In November 2006, Watson Pharmaceuticals, Inc., or Watson, acquired Andrx and all of the rights and obligations associated with the agreement. The $4.5 million upfront payment is classified as deferred revenues on our December 31, 2011 consolidated balance sheet as there had been no sales of our enoxaparin product through December 31, 2011. In January 2013, Watson adopted Actavis as its new global name. The agreement has a term that expires in January 2019 and can be extended by Actavis for an additional three years. The agreement may only be terminated prior to the end of the term by either party in the case of a breach of contract or insolvency of the other party, by us if Actavis fails to purchase a minimum number of units and by Actavis if an infringement claim is made against Actavis.

We manufacture our enoxaparin product for the retail market according to demand specifications of Actavis. Upon shipment of enoxaparin to Actavis, we recognize product sales at an agreed transfer price and record the related cost of products sold. Based on the terms of our distribution agreement with Actavis, we are entitled to a share of the ultimate profits based on the eventual net revenue from enoxaparin sales by Actavis to the end user less the agreed transfer price originally paid to us by Actavis. Actavis provides us with a quarterly sales report that calculates our share of Actavis' enoxaparin gross profit. We record our share of Actavis' gross profit as a component of net revenue.

Contractual Obligations

Set forth below are our contractual payment obligations (including interest obligations but excluding intercompany obligations) as of December 31, 2013:

Contractual Obligations(1)	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(in thousands)		
Long-term debt[2]	$ 31,862	$ 22,325	$ 9,105	$ 432	$
Operating leases	4,993	2,750	1,970	273	
Capital leases	1,438	357	632	449	
Facility construction in Nanjing, China[3]	15,000		15,000		
Purchase obligations[4]	15,068	15,068			
	$ 68,361	$ 40,500	$ 26,707	$ 1,154	$

(1) The table above excludes (i) our liability for uncertain tax position of $4.2 million because the timing of any related payments cannot be reasonably estimated and (ii) any obligations pertaining to our April 30, 2014 acquisition of an API manufacturing business in Éragny-sur-Epte, France.

Table of Contents

(2) Long-term debt includes accrued and unpaid interest. As of December 31, 2013, the weighted average interest rate on our long-term debt was 4.6%.

(3) Obligation to develop a facility in Nanjing, China. Please see " Investment in China" below for further discussion.

(4) The purchase obligations principally relate to inventory and pharmaceutical manufacturing and laboratory equipment. We anticipate meeting these purchase obligations through a combination of cash on hand, future cash flows from operations and debt and lease facilities. We have made deposits related to equipment purchases on these obligations totaling $14.1 million as of December 31, 2013.

Investment in China

We entered into agreements with a Chinese governmental entity to acquire land-use rights to real property in Nanjing, China. Under the terms of these agreements, we are obligated to invest capital in our wholly-owned subsidiary, Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP, and to develop these properties as a manufacturing facility. In conjunction with these agreements, ANP modified its business license on July 3, 2012 to increase its authorized capital. As of March 31, 2014, we have invested approximately $37.8 million in ANP of its registered capital commitment of $61.0 million. We are obligated to invest an additional $23.2 million in ANP, which is due by September 2014. This requirement to invest in China will result in cash being transferred from Amphastar to ANP.

Per these agreements, in January 2010 we acquired certain land-use rights with a carrying value of $1.2 million. In addition, we purchased additional land-use rights in November 2012 for $1.3 million. We are committed to spend approximately $15.0 million in land development. The agreements require the construction of fixed assets on the property and specified a timetable for the construction of these fixed assets. The current pace of development of the property is behind the schedule described in the purchase agreement and, per the purchase agreement, potential monetary penalties could result if the development is delayed or not completed in accordance with the guidelines stated in the purchase agreements. We are currently engaged in ongoing discussions with the Chinese governmental entity regarding the investment and the development of the properties. We believe that the Chinese governmental entity will accept our development plans for ANP.

Anticipated Liquidity

We expect our cash requirements to increase significantly in the foreseeable future as we move forward with our product candidates, pursue strategic acquisitions of businesses or assets and as we sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our current development-stage product candidates.

We expect that cash flows from ongoing operations borrowing capacity under our existing lines of credit will enable us to meet our obligations as they become due in the next 12 months and in the foreseeable future, including scheduled debt and lease payments. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the regulatory approval for any product candidates we are developing or the timing of any product introductions, which could be lengthy.

Off-Balance Sheet Arrangements

We do not have any relationships or financial partnerships with unconsolidated entities, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Table of Contents

Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our primary exposure to market risk is interest-rate-sensitive investments and credit facilities, which are affected by changes in the general level of U.S. interest rates. Due to the nature of our short-term investments (i.e., certificates of deposit), we believe that we are not subject to any material interest rate risk with these investments.

As of December 31, 2013, we had $32.2 million in long-term debt and capital leases outstanding. Of this amount, $26.3 million had variable interest rates with a weighted average interest rate of 4.0% at December 31, 2013. A 1% (100 basis points) increase in the index underlying these rates would increase our annual interest expense on the variable-rate debt by approximately $0.3 million per year. As of March 31, 2014, we had $41.5 million in long term debt and capital leases outstanding. Of this amount, $35.7 million had variable interest rates with a weighted average interest rate of 3.8% at March 31, 2014. A 1% (100 basis points) increase in the index underlying these rates would increase our annual interest expense on the variable rate debt by approximately $0.4 million per year.

Foreign Currency Rate Risk

Historically, less than 1% of our sales come from outside the U.S. All foreign sales have been negotiated with payment terms in Canadian dollars. Therefore, we have limited exposure to foreign currency price fluctuation. Further, we have no derivative financial instruments.

Our Chinese subsidiary, ANP, maintains their books of record in Chinese Yuan, or CNY. These books are remeasured into the functional currency of U.S. dollars, or USD, using the current or historical exchange rates. The resulting currency re-measurement adjustments and other transactional foreign exchange gains and losses are reflected in our statement of operations.

Our French subsidiary, AFP, will maintain their books of record in Euros. These books are remeasured into the functional currency of USD using the current or historical exchange rates. The resulting currency re-measurement adjustments and other transactional foreign exchange gains and losses will be reflected in our statement of operations.

We have no comprehensive income (loss) adjustments related to foreign currency translation because ANP's functional and reporting currency are both, and AFP's functional and reporting currency will both be, denominated in USD. Additionally, we do not undertake hedging transactions to cover our foreign currency exposure.

As of December 31, 2013 and March 31, 2014, ANP had receivables denominated in CNY in the amount of U.S. $5.6 million and U.S. $4.3 million, respectively.

Table of Contents

BUSINESS

Overview

We are a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically-challenging generic and proprietary injectable and inhalation products. We currently manufacture and sell 15 products in the U.S. and are developing a portfolio of 13 generic and seven proprietary injectable and inhalation product candidates. We have achieved profitability for each of the past three years but have recorded a loss for the three months ended March 31, 2014. For the year ended December 31, 2013 and the three months ended March 31, 2014, we recorded net revenues of $229.7 million and $45.9 million, respectively. We recorded net income of $11.9 million for the year ended December 31, 2013 and a net loss of $1.6 million for the three months ended March 31, 2014.

Our largest product by net revenues is currently enoxaparin sodium injection, the generic equivalent of Sanofi S.A.'s Lovenox. Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant and is indicated for multiple indications including the prevention and treatment of deep vein thrombosis. We commenced sales of our enoxaparin product in January 2012, and for the year ended December 31, 2013 and the three months ended March 31, 2014 we recognized net revenues from the sale of our enoxaparin product of $145.9 million and $26.1 million, respectively. We believe that our enoxaparin product demonstrates our capabilities in characterizing complex molecules (which is a process that involves a determination of physiochemical properties, biological activity, immunochemical properties and purity), developing therapeutically equivalent generic versions of drugs with large, complex molecules and overcoming numerous regulatory hurdles.

In addition to our currently marketed products, we have a robust pipeline of 20 generic and proprietary product candidates in various stages of development which target a variety of indications. With respect to these product candidates, we have filed three abbreviated new drug applications, one new drug application, or NDA, and one NDA supplement with the U.S. Food and Drug Administration, or FDA.

Our product candidate, Primatene Mist HFA, an over-the-counter epinephrine inhalation product, is intended to be used for the temporary relief of mild asthma symptoms and had a Prescription Drug User Fee Act, or PDUFA, date of May 2014. A PDUFA date sets the target date for the FDA to complete its review of an NDA. On May 22, 2014, we received a complete response letter, or CRL, from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted current Good Manufacturing Practices, or cGMP, deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

Our Amphadase product candidate is a bovine sourced hyaluronidase injection. We received approval of our NDA from the FDA for Amphadase in 2004, but discontinued the product in 2009 due to lack of active pharmaceutical ingredient, or API, supply. We filed an NDA supplement in December 2013 to qualify our own manufactured API. There is no assurance that we will receive approval for these or any of our other product candidates.

Our multiple technological capabilities enable the development of technically-challenging products. These capabilities include characterizing complex molecules, analyzing peptides and proteins, conducting immunogenicity studies, engineering particles and improving drug delivery through sustained-release

Table of Contents

technology. These technological capabilities have enabled us to produce bioequivalent versions of complex drugs and support the development and manufacture of a broad range of dosage formulations, including solutions, emulsions, suspensions and lyophilized products, as well as products administered via metered dose inhalers, or MDIs, and dry powder inhalers, or DPIs.

Our primary strategic focus is to develop and commercialize products with high technical barriers to market entry. We are specifically focused on products that:

- leverage our research and development capabilities;
- require raw materials or an API for which we believe we have a competitive advantage in sourcing, synthesizing or manufacturing; and/or
- improve upon an existing drug's formulation with respect to drug delivery, safety and/or efficiency.

Not all of our products will include all of these characteristics. Moreover, we will opportunistically develop and commercialize product candidates with lower technical barriers to market entry if, for example, our existing supply chain and manufacturing infrastructure allow us to pursue a specific product candidate in a competitive and cost-effective manner.

To complement our internal growth and expertise, we have made several strategic acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing and research and development capabilities including the ability to manufacture raw materials, APIs and other components for our products.

On April 30, 2014, we completed our acquisition of Merck Sharpe & Dohme's, or Merck's, API manufacturing business in Éragny-sur-Epte, France, which manufactures porcine insulin API and recombinant human insulin API. The purchase price of the transaction totals 24.8 million Euros, or U.S. $34.4 million, subject to certain customary post-closing adjustments and currency exchange fluctuations. The terms of the purchase include multiple payments over four years as follows:

	Euros (in thousands)	U.S. Dollars
At Closing, April 2014	€13,252	$ 18,352
December 2014	4,866	6,738
December 2015	3,130	4,334
December 2016	3,093	4,284
December 2017	479	664
	€24,820	$ 34,372

In order to facilitate the acquisition, we established a subsidiary in France, Amphastar France Pharmaceuticals SAS, or AFP. We will continue the current site manufacturing activities, which consist of the manufacturing and sale of porcine insulin API and recombinant human insulin API. As part of the transaction, we have entered into various additional agreements, including various supply agreements, as well as the assignment and licensing of patents Merck was operating under at this facility. In addition, certain existing customer agreements have been assigned to AFP. We financed the closing payment under the Merck acquisition with a secured term loan with Cathay Bank as lender.

Table of Contents

Our Markets

We primarily target products with high technical barriers to market entry, with a particular focus on the injectable and inhalation markets.

Injectable market. Based on an IMS Health National Sales Perspective Report, the U.S. generic injectable drug market in 2012 was approximately $7.0 billion. The injectable market requires highly technical manufacturing capabilities and compliance with strict cGMP requirements, which create high barriers to market entry. Due to these high barriers to market entry, there are a limited number of companies with the technology and experience needed to manufacture injectable products. There have also been a number of quality issues over the past several years that have disrupted the ability of certain injectable manufacturers to produce sufficient product quantity to meet market demand. As such, the supply of injectables has been constrained, even as demand for injectable products has continued to increase.

Inhalation market. Based on an IMS Health National Sales Perspective Report, the U.S. inhalation drug market in 2012 was approximately $18.0 billion. Inhalation drug therapy is used extensively to treat respiratory conditions such as asthma and chronic obstructive pulmonary disease. The MDI is the most widely used device to deliver inhalation therapies. It uses pressurized gas, historically chlorofluorocarbons, or CFCs, and more recently hydrofluoroalkanes, or HFAs, to release its dose when the device is activated by the patient. The DPI, which does not rely on a propellant, is also widely used. As in the case of injectables, there are significant technical barriers to manufacturing inhalation products. The evolution of inhalation delivery technologies from nebulizers and CFCs to HFAs and DPIs has required manufacturers of inhalation products to re-formulate their products, which in many cases may require technical engineering capabilities, additional regulatory approvals and modified delivery devices. Additionally, the development of generic HFA and DPI products will require bioequivalence studies for FDA approval.

Our Strengths

We have built our company by integrating the following capabilities and strengths that we believe enable us to compete effectively in the pharmaceutical industry:

Robust portfolio of products and product candidates. Including our enoxaparin product, we have 15 commercial products in the U.S. and 20 product candidates at different stages of development. Our enoxaparin product was introduced into the U.S. market in 2012 and for the year ended December 31, 2013 and the three months ended March 31, 2014 contributed to $145.9 million and $26.1 million of our net revenues, respectively. We believe we have an opportunity to further increase our enoxaparin market share. We also continue to develop our product candidates, which represent our longer-term growth opportunities.

Advanced technical capabilities and multiple delivery technologies. We have developed several advanced technical capabilities that we incorporate into the development of our products and product candidates, including characterization of complex molecules, peptide and protein analysis, immunogenicity studies, particle engineering and sustained-release technology. In addition, we apply these capabilities across our injectable and inhalation delivery technologies. Our injectable delivery technologies enable us to develop and manufacture generic and proprietary injectables in normal solution, lyophilized, suspension, jelly and emulsion forms, as well as in pre-filled syringes. Our inhalation technologies cover a variety of delivery methods, including DPIs and HFA formulations of MDIs. These technical capabilities form the foundation for our strategy to develop products with high barriers to market entry targeting a wide range of indications.

Vertically integrated infrastructure. We are a vertically integrated company with the demonstrated ability to advance a product candidate from the research stage through commercialization. Our capabilities include strong research and development expertise, sophisticated pharmaceutical engineering capabilities, comprehensive manufacturing capabilities, including the ability to synthesize and manufacture our own API, a strict quality assurance system, extensive regulatory and clinical

Table of Contents

experience and established marketing and distribution relationships. We believe our vertical integration allows us to achieve better operating efficiencies, accelerated product development and internal control over product quality.

Experienced management team with deep scientific expertise. Our management team has a successful track record in product development, project management, quality assurance and sales and marketing, as well as established relationships with our key customers, partners and suppliers. Our research and development leadership has deep expertise in areas such as pharmaceutical formulation, process development, *in vivo* studies, analytical chemistry, physical chemistry, drug delivery and clinical research. We believe that our scientific and technical expertise, coupled with our management team's experience and industry relationships, will enable us to successfully expand our position with respect to our current products and establish a meaningful market position for our product candidates.

Our Strategy

Our goal is to be an industry leader in the development, manufacturing and marketing of technically-challenging injectable and inhalation pharmaceutical products. To achieve this goal, we are pursuing the following key strategies:

Use our sales, marketing and distribution capabilities and relationships to further drive penetration of the market for our enoxaparin product. We believe that there remains a significant opportunity to increase our enoxaparin revenues by further expanding our share of the generic enoxaparin market. We have established relationships with major group purchasing organizations, drug wholesalers and retailers in the U.S. that deliver products to our end customers. We intend to maintain these long-term relationships and to compete for additional group purchasing organization contracts to expand sales of our enoxaparin product, which has only been commercialized since January 2012. For the year ended December 31, 2013 and the three months ended March 31, 2014 we recognized net revenues from the sale of our enoxaparin product of approximately $145.9 million and $26.1 million, respectively.

Diversify our revenues by commercializing our product candidates. Assuming we are successful in developing and obtaining regulatory approvals, we plan to commercialize our product candidates and thereby diversify our sources of revenues. We have 20 product candidates in various stages of development, including 13 generic product candidates and seven proprietary product candidates. We also expect to expand our internal sales and marketing capabilities and, in some cases, enter into strategic alliances with other pharmaceutical companies, to drive market penetration for our product candidates.

Focus on high-margin generic product opportunities. We believe that we have significant opportunities for growth driven by our technical expertise in the development of generic product candidates with high technical barriers to market entry. We believe that if these product candidates are commercialized, they are likely to face less competition than less technically-challenging generic products, which may enable us to earn higher margins for a longer period of time. We believe that generic competition for these products is likely to be limited because of challenges in product development, manufacturing or sourcing of raw materials or APIs.

Develop proprietary products. We currently have seven proprietary product candidates at various stages of development targeting a broad range of indications. We believe that proprietary products tend to face less competition than generic products due to market exclusivity, intellectual property protection and other barriers to entry. For these reasons, we believe that our proprietary products will provide us with the opportunity for higher margins and long-term revenue growth.

Table of Contents

Leverage our vertically integrated infrastructure to drive operational efficiencies. We believe our vertically integrated infrastructure provides significant benefits including better operating efficiencies, accelerated product development and internal control over product quality. Our ability to manufacture our own API allows us to develop products that other companies may not focus on due to the uncertainty of API supply. In addition, our vertically integrated infrastructure, including our research and development capabilities, allows us to conduct technically-challenging studies in-house. We believe this vertically integrated infrastructure has led and will continue to lead to a competitive portfolio of products and product candidates.

Target and integrate acquisitions of pharmaceutical companies, products and technologies. We have a demonstrated ability to identify, acquire and integrate pharmaceutical companies, products and technologies to complement our internal product development capabilities. We have acquired International Medication Systems, Limited, or IMS, Armstrong Pharmaceuticals, Inc., or Armstrong, and Nanjing Puyan Pharmaceutical Technology Co., Ltd. (which we renamed Amphastar Nanjing Pharmaceuticals Co., Ltd.), or ANP, products such as Cortrosyn and Epinephrine Mist, and trade names such as Primatene Mist. We believe that our scientific and managerial expertise and our integration experience have improved the quality of the product lines and companies that we have acquired, which have had a positive effect on our results of operations. For example, if approval is received from the FDA, we plan to have our acquired subsidiary ANP provide us with access to certain raw materials for the manufacture of the API for our enoxaparin product and eventually to manufacture API for our other products and product candidates.

Our Technical Capabilities

We develop, manufacture, market and sell generic and proprietary products targeting injectable and inhalation markets.

Injectable. Our injectable product technologies enable us to develop and manufacture generic and proprietary injectables in liquid, lyophilized, suspension and emulsion forms, as well as pre-filled syringes. We have multiple injectable facilities that include aseptic filling lines dedicated to the sterile manufacture and fill of injectable products. Additionally, we maintain compliance with cGMP regulations which has enabled us to obtain regulatory approvals and support commercial supply.

Inhalation. We are focused on developing a range of generic and proprietary inhalation products utilizing a variety of delivery technologies. We have expertise in formulating HFA based MDIs as well as packaging our inhalation drugs in DPIs, blister packs and other forms for loading in a variety of inhalation devices. As with our injectable products, we maintain compliance with cGMP regulations which we believe will enable us to obtain regulatory approvals and support commercial supply.

We have advanced capabilities that enable us to focus on developing technically-challenging products.

Characterization of complex molecules. Characterization of complex molecules includes a determination of physiochemical properties, biological activity, immunochemical properties and purity. Such characterization is important in the development of a generic product that is the same as a reference drug product, which in turn allows the generic developer to demonstrate "sameness" to the FDA. Complex molecule drugs typically have large molecules that are composed of a mixture of molecules that differ very slightly from one another. These slight variances make complex molecules difficult to characterize. We have developed analytical tools that have enabled us to characterize complex molecules in our products and product candidates. We believe we have the technology to develop a variety of additional analytical tools that will enable us to characterize other complex molecules, including peptide and protein based products.

Immunogenicity. The ability of an antigen to elicit immune responses is called immunogenicity. Unwanted immunogenicity occurs when a patient mounts an undesired immune response against a drug therapy. Unwanted immunogenicity is strongly linked with protein drug products. As a result, the FDA has signaled that they may require immunogenicity studies as part of the new pathway for

Table of Contents

biosimilars and biogenerics, and in the past the FDA has required these studies in connection with the approval of products with complex molecules. We gained expertise in immunogenicity by performing immunogenicity studies in connection with the FDA approval process for our enoxaparin product. We believe that our experience in conducting these difficult immunogenicity studies will be of primary importance in our future efforts to develop complex molecules, biosimilar and biogeneric product candidates.

Peptide and protein product development and production. The development of peptide and protein drug products utilizes characterization technology and immunogenicity studies as well as recombinant DNA, or rDNA, API manufacturing technology. We have experience in the use of rDNA manufacturing technology which includes the genetic engineering of host cells, fermentation to promote cell culture growth and isolation and purification of the desired protein from the cell culture. Through each step, testing is required to ensure that only the desired protein is included in the finished product. We believe that this technology will allow us to develop protein and peptide drug products.

Particle engineering. Particle engineering is important in the field of pulmonary drug delivery as there is a direct relationship between the properties of a particle and its absorption by the lungs. We believe our expertise and technology applicable to particle engineering and physical chemistry allows us to engineer the size, shape, surface smoothness and distribution of particles to develop inhalation products that are more easily dispersed through targeted areas. We believe this expertise will allow us to formulate difficult to disperse inhalation products.

Sustained-release. We have developed technology aimed at improving drug delivery through sustained-release injectable products. The purpose of our sustained-release technology is to create products that require less dosing frequency and that we believe can diminish the fluctuations of drug concentrations in a patient's blood stream that otherwise require more frequent dosing. We plan to use our sustained-release technology to develop both generic and proprietary products.

Our Marketed Products

We currently manufacture and sell 15 products. The following is a description of products in our existing portfolio.

Enoxaparin

Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant which is indicated for multiple indications, including the prevention and treatment of deep vein thrombosis. Enoxaparin is difficult to produce in part because the API is not easily obtained or manufactured. We manufacture the API for our enoxaparin product and perform all subsequent manufacturing of the finished product in-house. We believe that it will be difficult for other companies to obtain or manufacture the API and prove "sameness." In January 2012, we commenced sales of our enoxaparin product. For the year ended December 31, 2013 and the three months ended March 31, 2014, we recorded net revenues from enoxaparin of $145.9 million and $26.1 million, respectively.

Other Marketed Products

We have 14 other products that we currently market. Other marketed products include Cortrosyn (cosyntropin for injection), a lyophilized powder that is indicated for use as a diagnostic agent in the screening of patients with adrenocortical insufficiency, lidocaine jelly, a local anesthetic product used primarily for urological procedures and our portfolio of emergency syringe products, which include critical care drugs, such as atropine, calcium chloride, dextrose, epinephrine, lidocaine, naloxone and sodium bicarbonate, which are provided in pre-filled syringes and are designed for emergency use in hospital settings. We also manufacture and sell phytonadione injection for newborn use, lidocaine topical solution for use as a local anesthetic, morphine, epinephrine in vial form and a lorazepam injection. For the year ended December 31, 2013 and the three months ended March 31, 2014, we recorded net revenues from these other marketed products of $83.8 million and $19.8 million, respectively.

Table of Contents

Our Product Candidates

We seek to develop product candidates with high technical barriers to market entry that leverage our technical capabilities and competitive advantages. We are focused on injectable and inhalable product candidates in categories that include both generics and proprietary products. The product candidates in our pipeline are in various stages of development, with a number of these candidates still in early stages of development. We currently have 20 product candidates in our pipeline, including 13 generic product candidates and seven proprietary product candidates.

The development, regulatory approval for and commercialization of our product candidates are subject to numerous risks. See "Risk Factors" for additional information.

Generic Product Candidates

We generally employ a strategy of developing generic product candidates that possess a combination of factors that present technical barriers, including difficult formulations, complex characterizations, difficult manufacturing requirements and/or limited availability of raw materials that we believe will make these product candidates less susceptible to competition and pricing pressure. We currently have 13 generic product candidates at various development stages that leverage our various technical capabilities, including:

- injectable technologies, including various delivery methods and sizes of pre-filled syringes, vials in solution, suspension and lyophilized forms;
- inhalation technologies, including MDIs and DPIs; and
- sophisticated analytical technologies, including characterization and immunogenicity studies for complex molecules, particle engineering, sustained-release technology and peptide, protein and DNA analysis.

The following table summarizes our current portfolio of 13 generic product candidates in development.

Our generic product candidates are at various stages of development, ranging from early formulation work to bioequivalence studies or the filing of an ANDA. Of these product candidates, five are in early stage development prior to bioequivalence studies.

Proprietary Product Candidates

Our integrated technical skills and expertise provide a strong basis for the development of proprietary drug candidates. These skills include new chemical entity assessment, synthesis technology, formulation development, characterization analysis and immunogenicity studies, among others.

With respect to our proprietary pipeline strategy, we currently have seven proprietary drug candidates at various development stages that leverage our various technical capabilities. The following table summarizes our late-stage proprietary product candidates.

Table of Contents

Primatene Mist HFA

Primatene Mist HFA, an over-the-counter epinephrine inhalation product candidate, is intended to be used for the temporary relief of mild symptoms of intermittent asthma. We developed Primatene Mist HFA to replace the over-the-counter CFC formulation of our Primatene Mist product which was withdrawn for environmental reasons under the Montreal Protocol. We acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene Mist, and the associated CFC inventory, from Wyeth Consumer Healthcare Division in 2008 for $33.1 million. At the time of the transaction the Environmental Protection Agency was reviewing a possible ban on all CFC formulated products. In our first full year of sales of the CFC formulation of Primatene Mist, we generated cash flows from sales of the product in excess of the purchase price. We filed an investigational new drug application, or IND, for Primatene Mist HFA for mild symptoms of intermittent asthma in October 2009. We filed an NDA for Primatene Mist HFA in 2013 and had a PDUFA date of May 2014. In February 2014, the FDA held a joint meeting of the Nonprescription Drugs Advisory Committee and its Pulmonary Allergy Drugs Advisory Committee, which we refer to as the Committee, to discuss the NDA for Primatene Mist HFA. The Committee voted 14 to 10 that the data in the NDA supported efficacy, but voted 17 to 7 that safety had not been established for the intended over-the-counter use. The Committee also voted 18 to 6 that the product did not have a favorable risk-benefit profile for the intended over-the-counter use, and individual Committee members provided recommendations for resolving their concerns. Although the FDA is not required to follow the recommendations of its advisory committees, it usually does. On May 22, 2014, we received a CRL from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted cGMP deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

Amphadase (Hyaluronidase Injection)

Amphadase is a bovine sourced hyaluronidase injection. Other formulations of hyaluronidase injection include Vitrase and Hylenex which are marketed by Bausch & Lomb and Halozyme, respectively. We received our NDA approval for Amphadase in 2004, but we discontinued the product in 2009 due to lack of API supply. We filed an IND in February 2004 for Amphadase as an adjuvant in subcutaneous fluid administration for achieving hydration, to increase absorption and dispersion of other injected drugs, and in subcutaneous urography for improving resorption of radiopaque agents. We reactivated this IND in April 2012 to allow studies of the new API to be supplied by IMS. We filed an NDA supplement in December 2013 to qualify such API.

Other Proprietary Product Candidates

In addition to the late-stage product candidates described above, we have five proprietary product candidates, which include two new chemical entity drug candidates, at earlier stages of development. These proprietary product candidates target indications including diabetes, asthma, anticoagulants, osteoporosis and Alzheimer's disease. These product candidates incorporate a wide variety of our technical capabilities, such as particle engineering, sustained-release technology and peptide and protein analysis and utilize our inhalation and injectable delivery technologies. Because of the early stage of development of these proprietary product candidates, we anticipate that it will be several years before we make any FDA regulatory filings or commence clinical trials with respect to these candidates.

Table of Contents

Research and Development

We have approximately 226 employees dedicated to research and development with expertise in areas such as pharmaceutical formulation, process development, toxicity study, analytical, synthetic and physical chemistry, drug delivery, device development, equipment and engineering, clinical research statistical analysis, etc. Our focus on developing products with high barriers to market entry requires a significant investment in research and development, including clinical development. In particular, developing proprietary products that are reformulations of existing proprietary compounds often requires clinical trials to gain regulatory approval. We have a team dedicated to designing and managing clinical trials. We have successfully completed several clinical trials for some of our product candidates and are in the process of planning clinical trials for other product candidates under development.

We have made, and will continue to make, substantial investments in research and development. Research and development costs for the years ended December 31, 2011, 2012 and 2013 were $31.0 million, $31.2 million and $33.0 million, respectively, which represent 26%, 15% and 14% of our net revenues for that period, respectively. For the three months ended March 31, 2014, research and development costs were $6.2 million, which represent 14% of our net revenues for that period.

Manufacturing and Facilities

Our manufacturing facilities are located in Rancho Cucamonga and South El Monte, California; Canton, Massachusetts; Éragny-sur-Epte, France; and Nanjing, China. We own or lease a total of 59 buildings at six locations in the U.S., France and China, that comprise 1.34 million square feet of manufacturing, research and development, distribution, packaging, laboratory, office and warehouse space. Our facilities are regularly inspected by the FDA in connection with our product approvals, and we believe that all of our facilities are being operated in material compliance with the FDA's cGMP regulations.

We are currently expanding our facility in Nanjing, China and we expect that the investment in expanding our facility in China will require a total of up to approximately $15.0 million. We currently have contractual commitments with third parties obligating us to undertake this investment.

We recently acquired Merck's API manufacturing business in Éragny-sur-Epte, France, which manufactures porcine insulin API and recombinant human insulin API, and expect to continue the current site activities.

The following table provides a summary of our owned properties:

Location	Aggregate Facility Size (in square feet)	Primary Use
Rancho Cucamonga, CA	267,674	Headquarters, research and development, laboratories, manufacturing, packaging, warehousing and administration offices
Éragny-sur-Epte, France	251,983	Manufacturing, laboratories, warehousing and administration offices
Canton, MA	251,750	Manufacturing, packaging, warehousing, distribution and administration offices
Nanjing, China	66,890	Manufacturing, research and development and warehousing
Chino, CA[(1)]	57,968	Research and development and laboratories
South El Monte, CA	10,000	Manufacturing

(1) In October 2012, we purchased a building in Chino, California that we had originally leased from MicroScience Institute, a related-party, for $7.4 million.

Table of Contents

The properties leased by us have expiration dates ranging from 2014 to 2025 (including certain renewal options). The following table provides a summary of our leased properties:

Location	Aggregate Facility Size (in square feet)	Primary Use
Nanjing, China	43,023	Procurement, manufacturing, laboratories and administration offices
Rancho Cucamonga, CA	94,545	Warehousing, distribution and administration offices
South El Monte, CA	295,258	Manufacturing, packaging, warehousing, distribution and administration offices

We believe that our current manufacturing capacity is adequate for the near term. We have in the past approached capacity at one of our facilities largely as a result of the FDA's request that we reintroduce certain previously discontinued products to help cope with a nation-wide shortage of these products. We believe that these capacity issues have been ameliorated as a result of certain other manufacturers re-entering the market and increasing the production of the products that were subject to the shortage.

Raw Material and Other Suppliers

We depend on suppliers for raw materials, APIs and other components that are subject to stringent FDA requirements. In some cases, we obtain raw materials, components or API used in certain of our products from single sources. Currently we obtain the starting material, heparin USP, for our enoxaparin product, epinephrine for our Primatene Mist HFA product candidate and API for certain of our other marketed products from single sources. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's quality system regulation, or QSR, cGMPs or other applicable laws or regulations, we would be required to find alternative suppliers. Obtaining the required regulatory approvals to use alternative suppliers may be a lengthy and uncertain process during which we could lose sales. If our primary suppliers become unable or unwilling to perform, we could experience protracted delays or interruptions in the supply of materials which would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

If our suppliers encounter problems during manufacturing, establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Further, a significant portion of our raw materials may be available only from foreign sources, which are subject to the special risks of doing business abroad. For example, heparin USP is the starting material for the production of the API in our enoxaparin product. We have established a supply chain for heparin that originates in China and have implemented validated technology processes designed to screen and test incoming starting material, which includes methods currently required by the FDA. However, the FDA has required companies importing heparin to test imported heparin using specific screening methods to detect certain contaminants and it has increased its scrutiny of Chinese facilities that produce heparin for the U.S. market. For example, in August 2008, the FDA inspected two facilities in China belonging to suppliers in our heparin supply chain and issued warning letters, one of which needed to be resolved as a precondition to approving the ANDA for our enoxaparin product candidate in September 2011. If our ANP subsidiary is qualified by the FDA, we plan to have this entity provide us with starting materials for the manufacture of API for enoxaparin. We also plan to have our IMS subsidiary eventually manufacture APIs for not only enoxaparin, but also our other products and product candidates. In May 2013 our single source supplier of epinephrine received a warning letter from the FDA relating to the facility where epinephrine is manufactured. If this supplier is not successful in resolving, in a timely manner, the issues raised by the FDA in its warning letter, we may be unable to obtain approval to market Primatene Mist HFA from the FDA on the anticipated timeline and we may have difficulty in obtaining sufficient quantities of epinephrine API to support our expected launch and related commercialization activities for Primatene Mist HFA.

Table of Contents

Sales and Marketing

Our products are primarily marketed and sold to hospitals, long-term care facilities, alternate care sites, clinics and doctors' offices. Most of these facilities are members of one or more group purchasing organizations, which negotiate collective purchasing agreements on behalf of their members. These facilities purchase products through specialty distributors and wholesalers. We have relationships with the major group purchasing organizations in the U.S. We also have relationships with major specialty distributors, wholesalers and retailers who distribute pharmaceutical products nationwide. The following table provides information regarding the percentage of our net revenues that is derived from each of our major customers and partners:

	% of Net Revenues Year Ended December 31,			% of Net Revenues Three Months Ended March 31,	
	2011	2012	2013	2013	2014
				(unaudited)	
Actavis, Inc.[1][2]		35%	35%	34%	30%
AmerisourceBergen Corporation	13%	14%	15%	15%	15%
Cardinal Health, Inc.	13%	13%	13%	15%	15%
McKesson Corporation	14%	27%	26%	25%	28%
Wal-Mart[3]	13%				
Walgreens[3]	8%				

(1) Previously Watson Pharmaceuticals, Inc.

(2) In 2012, Actavis Inc., or Actavis, began purchasing enoxaparin under a distribution agreement.

(3) Sales to these customers ceased due to the discontinuance of our CFC formulation of our Primatene Mist product. We filed an NDA in 2013 and had a PDUFA date of May 2014 for the HFA version of Primatene Mist. On May 22, 2014, we received a CRL from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted cGMP deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

Our marketing department is responsible for establishing and maintaining contracts and relationships with the group purchasing organizations, distributors, retailers, wholesalers and, occasionally, directly to hospitals or long-term care facilities. One or more of our proprietary product candidates may require deployment of a sales force either directly or through a strategic partner.

Under an agreement with Actavis we are paid a fixed cost per unit of our enoxaparin product sold to Actavis and also share in the gross profits from Actavis' sales of the product in the U.S. retail pharmacy market. We may enter into similar agreements with distributors or strategic partners in the future.

Competition

The majority of our marketed products are generic products. We face and will face significant competition for our products and product candidates from pharmaceutical companies that focus on the generic injectable and inhalation markets such as Hospira, Inc., Akorn, Inc., Sandoz Inc., Mylan Inc. and Teva Pharmaceutical Industries Ltd. Competition in the generic pharmaceutical industry has increased as producers of branded products have entered the business by creating generic drug subsidiaries, purchasing generic drug companies, or licensing their products to generic manufacturers prior to patent expiration

Table of Contents

and/or as their patents expire. Therefore, our competitors also include the innovator companies of our generic drug products. For example, enoxaparin is currently marketed by Sanofi, under the brand name Lovenox. Sanofi also markets their authorized generic enoxaparin product through their subsidiary, Winthrop. Sandoz also markets a generic version of enoxaparin. Teva and Hospira have filed ANDAs with the FDA for approval of their generic versions of enoxaparin.

Similarly, we will face significant competition for our proprietary product candidates. Our competitors vary depending upon product categories, and within each product category, upon dosage strengths and drug-delivery systems. Based on total assets, annual revenues and market capitalization, we are smaller than many of our national and international competitors with respect to both our generic and proprietary products and product candidates. Many of our competitors have been in business for a longer period of time, have a greater number of products on the market and have greater financial and other resources than we do. It is also possible that developments by our competitors will make our generic or proprietary products and product candidates noncompetitive or obsolete.

For pharmaceutical companies, the most important competitive factors are scope of product line, ability to timely develop new products and relationships with group purchasing organizations, retailers, wholesalers and customers. Sales of generic pharmaceutical products tend to follow a pattern based on regulatory and competitive factors. As patents for brand-name products and related exclusivity periods expire, the first generic pharmaceutical manufacturer to receive regulatory approval for generic versions of products is typically able to achieve significant market penetration and higher margins. As competing generic manufacturers receive regulatory approval on the same products, market size, revenue and gross profit typically decline. The level of market share and price will be affected, which will in turn affect the revenue and gross profit attributable to a particular generic pharmaceutical product. This impact is normally related to the number of competitors in that product's market and the timing of that product's regulatory approval. We must develop and introduce new products in a timely and cost-effective manner and identify products with significant barriers to market entry in order to grow our business.

Government Regulation and Price Constraints

In the United States

General

Pharmaceutical companies and their prescription brand and generic pharmaceutical products are subject to extensive pre- and post-market regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FFDCA, the Public Health Service Act of 1944, or PHSA, and regulations implementing those statutes, with regard to the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of such products, and by comparable agencies and laws in foreign countries. For many drugs (drugs falling within the definition of "new drug" in the FFDCA), FDA approval is required before the product can be marketed in the U.S. All applications for FDA approval must contain, among other things, comprehensive and scientifically reliable information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control. These applications must also contain data and information related to safety, effectiveness, bioavailability and/or bioequivalence.

In addition, many of our activities are subject to the jurisdiction of other federal regulatory and enforcement departments and agencies, such as the Department of Health and Human Services, or HHS, Office of the Inspector General, or OIG, the Federal Trade Commission (which also has the authority to regulate the advertising of consumer healthcare products, including OTC drugs), the Department of Justice, the Drug Enforcement Administration, or DEA, the Veterans Administration, the Centers for Medicare and Medicaid Services and the Securities and Exchange Commission, or SEC. Individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws.

Table of Contents

Reimbursement Legislation

Our sales are largely dependent upon the availability of coverage and reimbursement from third-party payers, including federal, state and private organizations. Thus, our business may be significantly impacted by changes in coverage and reimbursement policies and legislation aimed at reducing health care payments from these payers.

To participate in the Medicaid program, pharmaceutical manufacturers must enter into a contract under which they remit a rebate, equal to a certain percentage of their revenue arising from Medicaid-reimbursed, qualifying outpatient drug sales to Medicaid recipients in the individual states. Under the drug rebate program, Medicaid covers the pharmaceutical manufacturer's FDA-approved drugs (with some exceptions).

Recently Enacted Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as "the Affordable Care Act," was enacted in the U.S. The provisions of the Affordable Care Act are effective on various dates. The principal provisions affecting us and the biopharmaceutical industry include:

- an increase, from 15.1% to 23.1%, of the reported Average Manufacturer Price, or AMP, in the minimum rebate on branded prescription drugs purchased by Medicaid beneficiaries (effective January 1, 2010);
- an increase from 11% to 13% of the AMP, for each of our generic products purchased by Medicaid beneficiaries;
- extension of Medicaid prescription drug rebates to drugs dispensed to enrollees in certain Medicaid Managed Care Organizations (effective March 23, 2010);
- expansion of the types of institutions eligible for the "Section 340B discounts" for outpatient drugs provided to hospitals serving a disproportionate share of low-income individuals and meeting the qualification criteria under Section 340B of the Public Health Service Act of 1944 (effective January 1, 2010);
- discounts on branded prescription drug sales to Medicare Part D participants who are in the Medicare "coverage gap," also known as the "doughnut hole" (effective January 1, 2011); and
- a fee payable to the federal government (which is not deductible for U.S. income tax purposes) based on our prior-calendar-year share relative to other companies of branded prescription drug sales to specified government programs (effective January 1, 2011, with the total fee to be paid each year by the pharmaceutical industry increasing annually through 2018).

Changes in Marketing Activity Disclosure

The Affordable Care Act expands the government's investigative and enforcement authority and increases the penalties for fraud and abuse, including amendments to both the False Claims Act and the Anti-Kickback Statute, to make it easier to bring suit under these statutes. The Affordable Care Act also allocates additional resources and tools for the government to police healthcare fraud, with expanded subpoena power for HHS, additional funding to investigate fraud and abuse across the healthcare system and expanded use of recovery audit contractors for enforcement.

Starting in 2013, we and all other applicable pharmaceutical manufacturers are required to record any transfers of value made to doctors and teaching hospitals and to disclose such data to HHS. We timely filed this required disclosure to HHS, which was due no later than March 31, 2014. In addition to civil penalties for failure to report transfers of value to physicians or teaching hospitals, there will be criminal penalties if a manufacturer intentionally makes false statements in such reports. The payment data will be posted by HHS on a publicly available website.

Table of Contents

Medicare

Medicare Part B pays for a limited number of products, including certain drugs administered by physicians in their offices and some drugs administered during hospital outpatient encounters. Medicare pays for single source drugs (brands) covered under Medicare Part B at 104% of the average sales price, or ASP, of the product or, for new drugs that are not subject to ASP, the wholesale acquisition cost. Multiple source drugs (generics) covered under Medicare Part B are paid at 104% of the manufacturer's ASP, in both cases calculated by a formula that accounts for the ASP to purchasers of the product from the manufacturer. The Medicare reimbursement reflects a 2% reduction from earlier rates of 106% as a result of the automatic federal spending reductions (sequestration) which were recently extended through 2024 pursuant to the Bipartisan Budget Act of 2013, Pub. L. No. 113-67 as amended by Pub. L. 113-82 (Feb. 15, 2014).

Medicare Part D went into effect on January 1, 2006. Elderly and disabled beneficiaries have access to the Medicare drug benefit through private plans approved by the federal government. Beneficiaries with low incomes and modest assets are eligible for assistance with Medicare Part D plan premiums and cost sharing

The Affordable Care Act made some important changes to the Part D drug benefit, which include, in particular, phasing out the coverage gap by 2020. Prior to the Affordable Care Act, beneficiaries who reached a certain level of spending on prescription medications (the Medicare Part D coverage gap or "doughnut hole") had to pay 100% of the cost of their drugs until personal out-of-pocket spending reached a level qualifying them for catastrophic coverage. The Medicare Part D Coverage Gap Discount Program uses public and private funding to relieve the financial burden facing beneficiaries who fall into this coverage gap. Beginning in 2011, branded pharmaceutical companies paid 50% of the cost of the branded drugs in the gap and the government paid 7% of the cost of the generic drugs in the gap. As a result, rather than paying 100% of the total cost of their drugs when they reached the coverage gap, enrollees paid 50% of the total cost of branded drugs and 93% of the total cost of generic drugs. The contribution from the government for generic drugs grew to 14% in 2012, and will grow steadily over time until reaching 75% in 2020. In addition, starting in 2013, the 50% discount from branded pharmaceutical companies will be supplemented by a contribution from the government, which will also grow steadily over time until reaching 25% in 2020. That means that by 2020, enrollees will pay only 25% of the cost of their branded and generic drugs in the gap.

Biosimilars

As part of the Affordable Care Act, Congress also passed the Biologics Price Competition and Innovation Act, or BPCIA, which created a framework for the approval of biosimilars (also known as follow-on biologics). The BPCIA provided an abbreviated approval pathway for biosimilars based on approved biological reference drugs, as well as exclusivity and patent protections for the reference drug. The FDA is responsible for implementation of the legislation, which will require the FDA to address such key topics as the type, scope and quality of data needed to establish biosimilarity and to establish interchangeability with the reference product; the naming convention for biosimilars; the tracking and tracing of adverse events; and the acceptability of data using a non-U.S. licensed comparator to demonstrate biosimilarity and/or interchangeability with a U.S.-licensed reference product. The FDA has begun to address some of these issues with the February 2012 release of three draft guidance documents. Specifically, the FDA has clarified that biosimilar applicants may use a non-U.S. licensed comparator in certain studies to support a demonstration of biosimilarity to a U.S.-licensed reference product.

FDA Approval and Regulatory Considerations

Prescription generic and branded pharmaceutical products are subject to extensive regulation by the FDA under the FFDCA and PHSA and regulations implementing those statutes, with regard to the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of such products, and regulation by other state, federal and foreign agencies under the laws that they enforce. For many drugs (drugs falling within the definition of "new drug" in the FFDCA), including the drugs in our current drug portfolio, FDA approval is required before marketing in the U.S. Applications for FDA drug

Table of Contents

approval must generally contain, among other things, information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, quality control and either safety and effectiveness or bioequivalence. There are two drug approval processes under the FFDCA an ANDA approval process for generic drugs and an NDA approval process for new drugs that cannot be approved in ANDAs. For drugs that are "biological products" within the meaning of the PHSA, there are two different approval processes a biological license application, or BLA, approval process for original biological products and a biosimilar application approval process for biosimilar products that are approved based on their similarity to biologicals that were previously approved in BLAs.

The ANDA Approval Process

Our generic drug product candidates cannot be lawfully marketed unless we obtain FDA approval. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as "the Hatch-Waxman Act," established abbreviated FDA approval procedures for drugs that are shown to be bioequivalent to drugs previously approved by the FDA through its NDA process, which are commonly referred to as the "innovator" or "reference" drugs. Approval to market and distribute these bioequivalent drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the API, drug product formulation, specifications, stability, analytical methods, manufacturing process validation data, quality control procedures and bioequivalence. Rather than demonstrating safety and effectiveness, an ANDA applicant must demonstrate that its product is bioequivalent to an approved reference drug. In certain situations, an applicant may submit an ANDA for a product with a strength or dosage form that differs from a reference drug based upon FDA approval of an ANDA Suitability Petition. The FDA will approve an ANDA Suitability Petition if it finds that the product does not raise questions of safety and efficacy requiring new clinical data. ANDAs generally cannot be submitted for products that are not bioequivalent to the referenced drug or that are labeled for a use that is not approved for the reference drug. Applicants seeking to market such products can submit an NDA under Section 505(b)(2) of the FFDCA with supportive data from clinical trials.

Upon approval of an NDA or ANDA, the FDA lists the product in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly known as the "Orange Book." In the case of an NDA, the FDA also lists patents identified by the NDA applicant as claiming the drug or an approved method of using the drug. Any applicant who files an ANDA must certify to the FDA with regard to each relevant patent that (1) no patent information has been submitted to the FDA; (2) the patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the ANDA 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 refers. If the NDA holder submits the patent information to FDA prior to submission of the ANDA and the NDA holder or patent owner(s) sues the ANDA applicant for infringement within 45 days of its receipt of the certification notice, the FDA is prevented from approving that ANDA until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. An ANDA applicant that is sued for infringement may file a counterclaim to challenge the listing of the patent or information submitted to FDA about the patent.

Generally, if an ANDA applicant (1) files a substantially complete ANDA with a Paragraph IV certification on the first day that any ANDA applicant files an application with such a certification based on the same reference drug and (2) provides appropriate notice to the NDA holder, and all patent owner(s) for a particular generic product, the applicant may be awarded a delay in the approval of other subsequently filed ANDAs with Paragraph IV certifications based on the same reference drug. This statutory delay is commonly referred to as 180-day exclusivity. A substantially complete ANDA is one that contains all the information required by the statute and the FDA's regulations, including the results of any required bioequivalence

Table of Contents

studies. The FDA may refuse to accept the filing of an ANDA that is not substantially complete or may determine during substantive review of the ANDA that additional information, such as an additional bioequivalence study, is required to support approval. Such a determination may affect an applicant's first to file status and eligibility for 180-day exclusivity. The MMA provides that the 180-day exclusivity delay ends 180 days after the first commercial marketing of the ANDA product. This exclusivity may be forfeited under a number of different circumstances, including: (1) failure to market within certain prescribed periods of time following certain events related to submission of the application, approval of the application, court decisions and settlements and patent withdrawals from the Orange Book; (2) an amendment or withdrawal of the Paragraph IV certification or certifications upon which the exclusivity was based; (3) failure to obtain tentative approval within certain prescribed time periods (30, 36, or 40 months after submission of the ANDA); (4) an agreement with the NDA holder, patent owner or another ANDA applicant that is determined by a court or the FTC to violate provisions of antitrust laws; (5) withdrawal of the ANDA; or (6) expiration of patent or patents upon which exclusivity is based.

The 180-day exclusivity provisions described above were passed in the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, and do not apply where the first ANDA with a Paragraph IV certification submitted for the reference drug was filed before December 8, 2003. In this circumstance, the pre-MMA exclusivity provisions apply. Under these provisions, the 180-day exclusivity delay ends 180 days after the first commercial marketing of the ANDA product or a court decision holding the patent invalid, unenforceable or not infringed, whichever comes first. In addition, under the pre-MMA exclusivity provisions, exclusivity is awarded separately to the first applicant or applicants submitting an ANDA with a paragraph IV certification for each patent, resulting in the possibility that different ANDA applicants will hold different exclusivities on different patents, resulting in situations in which an applicant that holds an exclusivity on one patent is subject to another applicant's exclusivity on a different patent. The FDA has addressed these situations through policies involving exclusivity sharing. The pre-MMA exclusivity provisions do not provide for exclusivity forfeiture.

ANDA approvals can be delayed by exclusivities awarded to the holder of the NDA for the reference drug. The FFDCA provides five-year exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity generally prohibits the submission of an ANDA for any drug product containing the same active moiety during the five-year exclusivity period. However, submission of an ANDA with a Paragraph IV certification is permitted after four years, and if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the ANDA is delayed until 7.5 years after the NCE approval date. The FFDCA also provides three-year exclusivity for the approval of new and supplemental NDAs for product changes that require new clinical investigations (other than bioavailability studies) that were conducted or sponsored by the applicant. These changes include, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug and new uses.

ANDA approvals can also be delayed by orphan drug exclusivity, pediatric exclusivity and exclusivity for certain new antibiotic drugs. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug, for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or an ANDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be

Table of Contents

granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued written request for such a study. The FFDCA also provides exclusivity for certain antibiotic drugs for serious or life-threatening infections that FDA designates as "qualified infectious disease products." This exclusivity extends other exclusivities for the same drug by five years, but does not extend patent-related delays in approval.

The NDA Approval Process

The NDA approval process is generally far more demanding than the ANDA process, depending on whether the applicant is submitting a "full NDA" containing all of the data and information required for approval of a new drug or a "Section 505(b)(2) NDA" which is a more limited submission that is generally utilized for modifications to previously approved products.

The "Full NDA"

The approval process for a full NDA generally involves:

- completion of preclinical laboratory and animal testing in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must satisfy the FDA and become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the 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 produced to assess compliance with the FDA's cGMP regulations; and
- submission to and approval by the FDA of an NDA.

Before human clinical trials can begin on a new drug, the results of preclinical tests, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND and the FDA must permit the IND to become effective. Each clinical trial under an IND must be reviewed and approved by an independent Institutional Review Board, or IRB. Human clinical trials are typically conducted in three sequential phases that may overlap. These phases generally include:

- Phase 1, during which the drug is introduced into healthy human subjects or, on occasion, patients and is tested for safety, stability, dose tolerance and metabolism;
- Phase 2, during which the drug is introduced into a limited patient population to determine the efficacy of the product in specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks; and
- Phase 3, during which the clinical trial is expanded to a larger and more diverse patient group at geographically dispersed clinical trial sites to further evaluate the drug and ultimately to demonstrate effectiveness.

The IND sponsor, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including failure to follow appropriate ethical trial protocols, failure to provide adequate protections for trial participants or a belief that the subjects are being exposed to an unacceptable health risk.

The results of preclinical animal studies and human clinical studies, together with other detailed (e.g., information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, quality control) are submitted to the FDA in the NDA.

The Section 505(b)(2) NDA

For modifications to products previously approved by the FDA, an applicant may file an NDA under Section 505(b)(2) of the FFDCA. This section permits the filing of an NDA where some or all of the data required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Under this section, an applicant may rely on the approval of another NDA or on studies published in the scientific literature. The applicant may be required to conduct

Table of Contents

additional studies or provide additional information to fully demonstrate the safety and effectiveness of its modification to the approved product.

Where a Section 505(b)(2) applicant relies on the FDA's approval of another NDA, the applicant is required to submit the same types of patent certifications as are required for an ANDA. As in the case of an ANDA, a Paragraph IV certification challenging one or more of the patents listed for the reference drug will require notice to the patent owner(s) and NDA holder and will permit a patent infringement suit that may result in a 30-month stay in the approval of the Section 505(b)(2) NDA. The approval of a Section 505(b)(2) NDA may also be delayed by the NCE, three-year, orphan drug, pediatric and new antibiotic exclusivities that are applicable to ANDAs as discussed above.

The Biosimilar Application Approval Process

The BPCIA, passed by Congress in 2010, amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to biologics that have been approved in BLAs under the PHSA notwithstanding minor differences in clinically inactive components. A biosimilar application must contain information demonstrating (1) biosimilarity to the reference product, (2) sameness of strength, dosage form, route of administration and mechanism(s) of action with the reference product (where known), (3) approval of the reference product for the indication(s) proposed for the biosimilar product and (4) appropriate manufacturing facilities. FDA will approve the application based on a finding of biosimilarity or interchangeability with the reference product. A finding of biosimilarity must be based on (1) a demonstration that the products are "highly similar" notwithstanding minor differences in clinically inactive components, (2) animal studies, including an assessment of toxicity, and (3) a clinical study or studies (including an assessment of immunogenicity and pharmacokinetics or pharmacodynamics) sufficient to show the safety, purity and potency of the proposed product for one or more "appropriate" conditions of use for which licensure is sought and for which the reference product is licensed, unless FDA waives a specific requirement. The definition of "biosimilar" requires that there be no clinically meaningful differences between the biosimilar and reference product with regard to safety, purity and potency.

An applicant with a pending or approved biosimilar application may seek an FDA determination that its product is interchangeable with the reference drug. In addition to demonstrating biosimilarity to the reference product, the biosimilar applicant must demonstrate that its product can be expected to yield the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar and reference products is not greater than the risk of continued administration of the reference product. The PHSA provides that a determination of interchangeability means that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The first biosimilar determined to be interchangeable with a particular reference product for any condition of use is protected by an exclusivity that delays an FDA determination of interchangeability with regard to any other biosimilar application. The exclusivity delays the subsequent interchangeability determination until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable biosimilar biological product, if an expedited patent action was commenced against the applicant under section 351(l)(6) and the litigation is still pending; or (4) 18 months after approval of the first interchangeable product if the reference product sponsor did not sue the biosimilar applicant for infringement under the patent resolution provisions of the PHSA.

The PHSA provides a number of exclusivity protections for reference products that may delay submission and approval of biosimilar applications. The PHSA delays submission of a biosimilar application until four years after the date on which the reference product was first licensed and delays final approval of a biosimilar application until twelve years after the first licensure of the reference product. The first-licensure

Table of Contents

requirement precludes an additional period of exclusivity for a supplement to the original application for the reference product. It also precludes exclusivity for an entirely new BLA in certain circumstances. A new BLA submitted by a sponsor or manufacturer of a previously approved biologic would not be protected by exclusivity for (1) a non-structural change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or (2) a structural change that does not result in a change in safety, purity or potency. As in the case of NDAs approved under the FFDCA, BLAs may be entitled to orphan exclusivity and to pediatric exclusivity.

The BPCIA amended the definition of biological product to include proteins (other than synthetic polypeptides). Applications for biological products, including proteins, must now be approved under the PHSA rather than under the FFDCA. The BPCIA provides a grandfather exception for biologics falling within a product class for which FDA has approved an application under the FFDCA. Applications for approval of these types of proteins may be submitted under the FFDCA until March 23, 2020 unless there is a biological product licensed under the PHSA that could serve as a reference product for a biosimilar application.

Under the PHSA, patents are not listed in the Orange Book and companies submitting biosimilar applications are not required to submit patent certifications. Patent disputes are resolved outside of the FDA regulatory process. The biosimilar applicant must share the contents of its biosimilar application and information on its manufacturing processes with counsel for the company holding the BLA for the reference drug. The biosimilar applicant and BLA holder must exchange information about relevant patents and seek agreement on patents to be litigated under an expedited litigation procedure.

The BLA Approval Process

The BLA approval process is similar to the "Full NDA" approval process and generally involves:

- completion of preclinical laboratory and animal testing in compliance with the FDA's GLP regulations;
- submission to the FDA of an IND for human clinical testing, which must satisfy FDA and become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the 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 produced to assess compliance with the FDA's cGMP regulations; and
- submission to and approval by the FDA of a BLA.

FDA Action on an Application for Approval

If applicable statutory or regulatory requirements are not satisfied, the FDA may deny approval of an NDA, ANDA, BLA, or biosimilar application, or the FDA may require additional data or information. After approval of the application, the FDA may suspend or withdraw the approval based on various criteria, including new information related to safety or effectiveness or failure to comply with post-approval requirements. In addition, the FDA may in some instances require post-marketing studies on approved products and may take actions to limit marketing of the product based on the results of those studies.

The new drug and biological product approval processes may take years, and the time may vary substantially based upon the type of application and the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer's activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or complete withdrawal of the product from the market.

Table of Contents

Manufacturing (cGMP) Requirements

We and our contract manufacturers and other suppliers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. These cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA before FDA will approve our products and we must continue to meet these requirements after our products are approved. We and our third-party manufacturers and other suppliers are subject to periodic inspections of facilities by the FDA and other authorities to assess our compliance with applicable regulations.

Other Regulatory Requirements

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies. After approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements.

In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals, as well as consumers, including industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

FDA Enforcement Authority

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions (which may in some circumstances involve restitution, disgorgement or profits, recalls and/or total or partial suspension of production or distribution), seizure of products, withdrawal of approvals, refusal to approve pending applications and criminal prosecution of the company and company officials that may result in fines and incarceration. FDA has authority to inspect manufacturing facilities as well as other facilities in which drug products are held, packaged or stored, to determine compliance with cGMP and other requirements under the FDCA. 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, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

115

Table of Contents

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 has broad regulatory and enforcement powers, including 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 materially adverse effect on us.

Foreign Regulatory Requirements

Outside the U.S., our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of safety, quality and efficacy.

DEA Regulation

We maintain registrations with the DEA that enable us to receive, manufacture, store and distribute controlled substances in connection with our operations. Controlled substances are those drugs that appear on one of five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA. DEA scheduling is based on potential for abuse. The CSA governs, among other things, the distribution, recordkeeping, handling, security and disposal of controlled substances. We are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess our ongoing compliance with DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation or the denial of renewal of our DEA registration, injunctions or civil or criminal penalties.

Prescription Drug Wrap-Up

When Congress passed the FFDCA in 1938, it required that "new drugs" be approved based on their safety. In 1962, Congress amended the FFDCA to require that sponsors demonstrate that new drugs are effective, as well as safe, in order to receive FDA approval. We refer to these provisions as the "1962 Amendments." The 1962 Amendments also required the FDA to conduct a retrospective evaluation of the efficacy of the drug products that the FDA approved between 1938 and 1962 on the basis of safety alone. The FDA contracted with the National Academy of Science/National Research Council, or the NAS/NRC, to make an initial evaluation of the efficacy of many of these drug products. The FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation, or the DESI.

Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA did not challenge the marketing of these drugs without approval. In 1984, however, spurred by serious adverse reactions to one of these products and concerns expressed by Congress, FDA undertook an assessment of the products under an initiative known as the "Prescription Drug Wrap-Up." Most of these drugs contain active ingredients that were first marketed prior to the enactment of the FFDCA. Several of our marketed pharmaceutical products fall within this category.

The FDA has asserted that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally unless they fall within two "grandfather" exceptions to the new drug definition. The first is a provision in the new drug definition exempting drugs that were on the market prior to the passage of the FFDCA and that contain the same representations concerning the conditions of use as they did prior to passage of the FFDCA. The 1962 Amendments also exempt drugs that were not new drugs prior to the passage of the 1962 Amendments and that have the same composition and labeling as they had prior to the passage of the 1962 Amendments. The FDA and the courts have interpreted these two exceptions very narrowly. Therefore, the FDA could commence enforcement action at any time regarding any or all of our unapproved prescription products.

Table of Contents

The FDA has adopted a risk-based enforcement policy that prioritizes enforcement of new drug requirements for these and other unapproved drugs that pose safety concerns, lack evidence of efficacy, prevent patients from pursuing effective therapies, are marketed fraudulently, violate other provisions of the FFDCA, such as cGMP requirements, or directly compete with approved drugs. The FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may trigger agency enforcement of the new drug requirements. Once the FDA issues an approved NDA for one of the drug products at issue or completes the efficacy review for that drug product, it may require other manufacturers to also obtain approval for that same drug in order to continue marketing it in the U.S. While the FDA generally provides sponsors a one-year grace period, the agency is not statutorily required to do so.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws to eliminate fraud and abuse in federal health care programs. Our business is subject to compliance with these laws.

Anti-Kickback Statutes

The federal health care programs' Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as Medicare or Medicaid. The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered businesses, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal health care programs. In addition some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are otherwise lawful in businesses outside of the health care industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the OIG of the U.S. Department of Health and Human Services to issue a series of regulations known as "safe harbors." These safe harbors, issued by the OIG beginning in July 1991, set forth provisions that, if all their applicable requirements are met, will assure health care providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy on applicable safe harbor may result in increased scrutiny by government enforcement authorities such as OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on the marketing of health care services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Table of Contents

Federal False Claims Act

Another development affecting the health care industry is the increased use of the federal False Claims Act, and in particular, action brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery. In recent years, the number of suits brought against health care providers by private individuals has increased dramatically. In addition, various states have enacted false claims law analogous to the False Claims Act, many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal health care program.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $5,500 and $11,000 for each separate instance of false claim. 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 federal government has used the False Claims Act to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the False Claims Act in connection with off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices of our products, 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 may be subject to scrutiny under these laws. While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

The Sunshine Act

The Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Affordable Care Act, requires all pharmaceutical manufacturers that participate in Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made by that entity, or by a third party as directed by that entity, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. The final rule implementing the Sunshine Act requires data collection on payments to begin on August 1, 2013. We have timely filed our first annual report, comprised of data collected from August 1, 2013 to December 31, 2013, which was due March 31, 2014. The statute requires the federal government to make reported information available to the public starting September 2014. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1.0 million). Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Sunshine Act and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals.

Table of Contents

HIPAA and Other Fraud and Privacy Regulations

Among other things, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: health care fraud and false statements relating to health care matters. The HIPAA health care fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

Environmental Considerations

We are subject to environmental laws, including those promulgated by the Occupational Safety and Health Administration, the Environmental Protection Agency, the Department of Health and Human Services and the Air Quality Management District, that govern activities and operations that may have adverse environmental effects such as discharges to air, soil and water, as well as handling and disposal practices for solid and hazardous wastes. These laws impose strict liability for the costs of cleaning up, and for damages resulting from, sites of past spills, disposals or other releases of hazardous substances and materials and for the investigation and remediation of environmental contamination at properties operated by us and at off-site locations where we have arranged for the disposal of hazardous substances. If it is determined that our operations or facilities are not in compliance with current environmental laws, we could be subject to fines and penalties, the amount of which could be material.

We have made and will continue to make expenditures to comply with current and future environmental laws. We anticipate that we will incur additional capital and operating costs in the future to comply with existing environmental laws and new requirements arising from new or amended statutes and regulations. We cannot accurately predict the impact and costs that future regulations will impose on our business.

Intellectual Property

Our success depends on our ability to operate without infringing the patents and proprietary rights of third parties. However, we cannot determine with certainty whether patents or patent applications of other parties will have a materially adverse effect on our ability to make, use, or sell any products. A number of pharmaceutical companies, biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover aspects of our, or our licensors' products, product candidates, or other technologies.

We primarily rely on trade secrets, unpatented proprietary know-how and continuing technological innovation to protect our products and technologies, especially where we do not believe patent protection is appropriate or obtainable. Although in some cases we seek patent protection to preserve our competitive position, our current patent portfolio does not cover the majority of our existing products and product candidates. We own several U.S. and foreign patents covering processes and equipment used in the manufacture of a few of our products. The expiration dates of these patents range from 2020 to 2027.

In addition, we own a United States patent covering Primatene Mist HFA: United States Patent Number 8,367,734, or the "'734 patent," which issued on February 5, 2013, and expires in January 2026. Additionally, we have several patent applications that are currently pending in the U.S. and other countries, including China, but which have not yet issued as patents. Accordingly, other than the '734 patent covering Primatene Mist HFA, none of our significant products or product candidates are covered by any United States or foreign patents related to formulations or compositions. Indeed, many of our products and product candidates are generic products, and therefore may not be eligible for patent protection. For example, our enoxaparin product is a generic product, and as such, it is not covered by any United States

Table of Contents

or foreign patents. Other of our products, including Amphadase, are based on compounds for which any applicable patents have expired, or which were not patented by Amphastar in the first instance because they are older compounds. As for the remainder of our product candidates that are not intended to be generic products, these are early stage product candidates currently under development, for which we intend to seek to obtain patent rights or rely on trade secret protection (but in any case, are not currently covered by any United States or foreign patents). In addition, with respect to such product candidates, we may seek patent rights for various potential technology platforms (or rely on trade secret protection), which could apply across multiple product candidates (but again, such potential technology platforms currently are not covered by any United States or foreign patents).

We may not be able to obtain patent or other forms of protection for inventions or other intellectual property developed by our officers, employees, or consultants because we might not have been the first to file or to invent the patentable technology or others may have independently developed similar or alternative technology. We also own several trademarks registered with the USPTO and one trademark registered with the Canadian Intellectual Property Office.

Despite our efforts to protect our proprietary information through the use of confidentiality and non-disclosure agreements, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary. Other parties may also independently develop know-how or obtain unauthorized access to our technologies.

Intellectual property protection is highly uncertain and involves complex legal and factual questions. Our patents and those for which we have or will license rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if a patent application is filed, some or all of the patent claims may not be allowed, the patent itself may not issue, or in the event of issuance, the issued claims may not be sufficient to protect the technology owned by or licensed to us.

Third-party patent applications and patents could reduce the coverage of the patents licensed, or that may be licensed to, or owned by us. If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from the commercialization of products or be required to obtain licenses to these patents or to develop or obtain alternative technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or those of our licensors.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. USPTO interference proceedings may be necessary if we and another party both claim to have invented the same subject matter. Even if we ultimately prevail, we could incur substantial costs and our management's attention would be diverted if:

- litigation is required to defend against patent suits brought by third parties;
- we participate in patent suits brought against or initiated by our licensors;
- we initiate suits against third parties who are infringing on our patents; or
- we participate in an interference or other similar USPTO proceeding.

However, even if we pursue litigation or other action to protect our intellectual property rights, we may not prevail in any of these actions or proceedings.

Employees

As of March 31, 2014, we had a total of 1,217 full-time employees.

Table of Contents

Legal and Regulatory Proceedings

Enoxaparin Patent Litigation

In September, 2011, Momenta, a Boston-based pharmaceutical company, and Sandoz, the generic division of Novartis, initiated litigation against us for alleged patent infringement of two patents related to testing methods for batch release of enoxaparin, which we refer to as the "`886 patent" and the "`466 patent." The lawsuit was filed in the United States District Court for the District of Massachusetts, or the District Court. In October 2011, the District Court issued a preliminary injunction barring us from selling our generic enoxaparin product and also requiring Momenta and Sandoz to post a $100.1 million bond. The preliminary injunction was stayed by the United States Court of Appeals for the Federal Circuit, or Federal Circuit, in January 2012 and reversed by the Federal Circuit in August 2012.

In January 2013 we moved for summary judgment of non-infringement of both patents. Momenta and Sandoz subsequently withdrew their allegations as to the `466 patent and, in July 2013, the District Court granted our motion for summary judgment of non-infringement of the `886 patent and denied Momenta and Sandoz's motion for leave to amend infringement contentions. On January 24, 2014 the District Court judge entered final judgment in our favor on both patents. Momenta and Sandoz also filed a motion to collect attorney's fees and costs relating to a discovery motion which the District Court granted. The parties have briefed the amount of attorney's fees that should be imposed, which we believe should not exceed an amount of approximately $40,000. On January 30, 2014 Momenta and Sandoz filed a notice of appeal to the Federal Circuit appealing the court's final judgment including summary judgment denying Momenta and Sandoz's motion for leave to amend their infringement contentions. We intend to attempt to collect the $100.1 million bond posted by Momenta and Sandoz following the appeal.

False Claims Act Litigation

In January 2009, we filed a qui tam complaint in the U.S. District Court for the Central District of California alleging that Aventis Pharma S.A., or Aventis, through its acquisition of a patent through false and misleading statements to the U.S. Patent and Trademark Office, overcharged the federal and state governments for its Lovenox. If we are successful in this litigation, we could be entitled to a portion of any damage award that the government ultimately may recover from Aventis. In October 2011, the Court unsealed our complaint. Since the complaint was unsealed, this case has steadily progressed and remains pending with discovery underway. The District Court has set an evidentiary hearing for July 7, 2014 on the "original source" issue, a key element under the False Claims Act.

Other Litigation

We are also subject to various other claims and lawsuits arising in the ordinary course of business. In the opinion of management, the ultimate resolution of these matters is not expected to have a materially adverse effect on our financial position, results of operations, or cash flows; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Table of Contents

MANAGEMENT

Directors and Executive Officers

Our directors and executive officers and their ages and positions as of May 30, 2014 are as follows:

Name	Age	Position(s)
Jack Yongfeng Zhang, Ph.D.	67	Chief Executive Officer, Chief Science Officer and Director
Mary Ziping Luo, Ph.D.	64	Chief Operating Officer, Chief Scientist and Chairman of the Board of Directors
Jason B. Shandell, J.D., M.B.A.	40	President and Director
William J. Peters	46	Chief Financial Officer, Senior Vice President and Treasurer
Marilyn J. Purchase	64	Corporate Executive Vice President of Operations and President, International Medication Systems, Ltd.
Diane G. Gerst	54	President, Amphastar Nanjing Pharmaceuticals Co., Ltd. and Corporate Senior Vice President of Quality Assurance
Richard Koo, CPA[2]	73	Director
Richard Prins[3]	57	Director
Howard Lee, Ph.D.[1][2]	52	Director
Michael A. Zasloff, M.D., Ph.D.[1]	68	Director
Floyd F. Petersen, M.P.H.[1][3]	70	Director
Stephen B. Shohet, M.D.[2][3]	79	Director

(1) Member of the nomination committee.

(2) Member of the audit committee.

(3) Member of the compensation committee.

Executive Officers

Jack Yongfeng Zhang, Ph.D. co-founded our company in 1996 and has served as our Chief Executive Officer and a member of our board of directors since our inception and as our President from 1996 until June 2013. Dr. Zhang has also served as our Chief Science Officer since 2005. Dr. Zhang co-founded Applied Physics & Chemistry Laboratories, Inc., or APCL, a full service chemical analytical laboratory, in May 1989, where he held the position of President until October 2002. Dr. Zhang is named as the inventor on several U.S. and foreign patents. He received a Ph.D. in chemistry from the State University of New York at Stony Brook and was a Post Doctoral Research Associate at the California Institute of Technology. We believe Dr. Zhang's experience in the pharmaceutical industry and as one of our founders qualifies him to serve on our board of directors.

Mary Z. Luo, Ph.D. co-founded our company in 1996 and has served as our Chief Operating Officer and chairman of our board of directors since our inception and as Secretary from 1997 to April 2004. Dr. Luo has also served as our Chief Scientist since 2005. Dr. Luo co-founded APCL in May 1989 where she held the position of Chief Operating Officer. Dr. Luo is a professor emeritus of chemistry at California State Polytechnic University, Pomona and is named as the inventor on several U.S. and foreign patents. Dr. Luo received a Ph.D. in chemistry from Princeton University and was a Post Doctoral Research Associate at the California Institute of Technology. We believe Dr. Luo's experience in the pharmaceutical industry and as one of our founders qualifies her to serve on our board of directors.

Jason B. Shandell, J.D., M.B.A. has served as our President since June 2013. Mr. Shandell also served as our interim Chief Financial Officer from August 2013 to April 2014 and as our General Counsel and Secretary from December 2008 and our Senior Vice President of legal matters from 2012 until his promotion to President. Mr. Shandell has served as a member of our board of directors since 2010. Mr. Shandell also served as Corporate Counsel from March 2008 until his promotion to General Counsel and

122

Table of Contents

Secretary. From 2006 to 2008, Mr. Shandell was the Director of Technology at Move, Inc., an online real estate company. From 2004 to 2005, Mr. Shandell was Corporate Counsel at Amgen, Inc. From 2000 to 2004, Mr. Shandell was an Associate at the law firm of Shaw Pittman LLP. Mr. Shandell received a B.A. in psychology from the University of California, Santa Barbara in 1996 and a J.D. and an M.B.A. from the University of Southern California in 2000. Mr. Shandell was admitted to practice law in the state of California in December 2000. We believe that Mr. Shandell's experience as an executive in the pharmaceutical industry and legal training qualify him to serve on our board of directors.

William J. Peters has served as our Chief Financial Officer, Senior Vice President and Treasurer since April 2014. Mr. Peters previously served as Executive Vice President and Chief Financial Officer of Hi-Tech Pharmacal Co., Inc., or Hi-Tech, from August 2013 to April 2014 and Vice President and Chief Financial Officer at Hi-Tech from May 2004 to August 2013. From September 2003 to May 2004 he was Vice President of Corporate Development at Hi-Tech. From 2001 to 2003 Mr. Peters was the Director, Financial Evaluations for the Medco Health Solution subsidiary of Merck & Co., Inc., or Merck & Co., and Manager of Corporate Financial Analysis and Pharmaceutical Economics at Merck & Co. from 1998 to 2001. During his seven year career at Merck & Co., he also served as Manager of Treasury Planning and Analysis. He began his career in General Electric's Financial Management Program at its Aerospace division, where he later held positions in financial analysis and internal auditing. He earned an M.B.A. from Wharton School of Business, University of Pennsylvania in 1996 and a B.S. in Business Administration from Bucknell University in 1989.

Marilyn J. Purchase has served as our Corporate Executive Vice President of Operations since June 2007 and as President of International Medication Systems, Ltd. or IMS, since December 2013. Ms. Purchase previously held various management-level positions at IMS, our wholly-owned subsidiary, for more than 30 years and was appointed President in December 2013.

Diane G. Gerst has served as President of ANP since March 2014 and as our Corporate Senior Vice President of Quality Assurance since August 2012. Ms. Gerst also served as Corporate Vice President of Quality Assurance from August 2003 until her promotion to Senior Vice President. Prior to becoming the Vice President of Quality Assurance, she was our Vice President of Regulatory Affairs from June 2001 to July 2002. Ms. Gerst previously held various management level positions in regulatory and quality including eight years at Braun-McGaw and seven years at IMS. Ms. Gerst received a B.A. from the University of California, Berkeley in 1982.

Non-Employee Directors

Richard Koo, CPA has served as a member of our board of directors since August 2003 and also served as a member of our board of directors from January 1997 to February 2002. Mr. Koo has been the managing partner of Koo, Chow and Company, Certified Public Accountants since 1979, CEO and President of K.C. Group International Inc. since February 2003 and a Director of EverTrust Bank since January 2009. Prior to Koo, Chow and Company, Mr. Koo worked with PricewaterhouseCoopers LLP in various public offering audit assignments. Mr. Koo has worked as a finance and taxation expert for the United Nations. Mr. Koo received a B.S. in management from the National Taiwan University and an M.B.A. in accounting from San Jose State University. We believe that Mr. Koo's past experience and expertise in the field of finance and taxation qualify him to serve on our board of directors.

Richard Prins has served as a member of our board of directors since February 2002. Since 2008, Mr. Prins is a private investor and involved in various charitable organizations. Mr. Prins also volunteers as acting head of U.S. Operations for Advancing Native Missions and on the boards of directors of India Globalization Capital and Hilbert Technology. Mr. Prins was the Director of Investment Banking for Ferris, Baker Watts, Inc., or FBW, from 1996 until June 2008 when FBW was acquired by Royal Bank of Canada and served as a consultant to Royal Bank of Canada Capital Markets through December 2008. Prior to FBW, Mr. Prins was a Managing Director from July 1988 to April 1996 at Crestar Bank (now SunTrust Bank) in charge of mergers and acquisitions. Mr. Prins began his career in 1983 as the Assistant to the Chairman of

Table of Contents

the leverage buyout company, Tuscarora Corp., where he held various positions until July 1988. Mr. Prins received a B.A. in liberal arts from Colgate University and an M.B.A. from Oral Roberts University. We believe that Mr. Prins' experience in corporate finance and investment banking qualify him to serve on our board of directors.

Howard Lee, Ph.D. has served as a member of our board of directors since August 2007. He previously served as a member of the board of our subsidiary, IMS, from 1998 to 2002 and on our board of directors from 2002 to 2004. Dr. Lee is currently the partner at the CID Group, a prominent investment group in the greater China area, where he has worked since March 2012. From 2009 to 2010 he was the Chief Investment Officer at UniMed Venture Management Inc., a biotech venture capital firm. Prior to joining UniMed in July 2009, he was a Managing Director at Silver Biotech Management, Inc. from July 2006 to June 2009. Dr. Lee served as President and CEO of CDIB Biotech USA Investment Co. Ltd. from 2000 to 2006 and as Vice President of China Development Industrial Bank, an investment bank in Taiwan, from October 1995 to June 2006. He also serves as a director for the Development Center of Biotechnology in Taiwan. Dr. Lee earned his B.Sc. at Fu-Jen University (Taiwan), his M.Sc. and Ph.D. degrees in chemistry from the University of Southern California in Los Angeles in 1988 and 1990, respectively, and completed his postdoctoral research at the Loker Hydrocarbon Research Institute of the University of Southern California. We believe Dr. Lee's vast experience in biotech venture capital consulting qualify him to serve on our board of directors.

Michael A. Zasloff, M.D., Ph.D. has served as a member of our board of directors since October 2005. Dr. Zasloff has been the Professor of Surgery and Pediatrics at the Georgetown University School of Medicine since 2002, and was also the Dean of Research and Translational Science from 2002 until 2004. Between 2004 and 2007, Dr. Zasloff served as Vice President and Senior Analyst (Life Sciences) at Ferris, Baker Watts, Inc. From 1992 to 2001 Dr. Zasloff served as Executive Vice President and Vice Chairman of Magainin Pharmaceuticals Inc., a biopharmaceutical company which he founded. From 1988 until 1992, Dr. Zasloff served as the Charles E.H. Upham Professor in the Department of Pediatrics and Genetics at the University of Pennsylvania School of Medicine, and Chief, Division of Human Genetics and Molecular Biology at The Children's Hospital of Philadelphia. From 1982 until 1988, Dr. Zasloff was Chief of the Human Genetics Branch at the National Institutes of Child Health and Human Development, National Institutes of Health. Dr. Zasloff received a B.A. from Columbia College in biochemistry and holds an M.D., Ph.D. from the New York University School of Medicine. Dr. Zasloff is named the inventor on over 40 patents. We believe Dr. Zasloff's expertise and experience in the biopharmaceutical industry qualify him to serve on our board of directors.

Floyd F. Petersen, M.P.H. has served as a member of our board of directors since August 2004. From 1986 to the present, Mr. Petersen has been an Assistant Professor of Biostatistics at Loma Linda University Schools of Public Health, Medicine, and Nursing. From 1990 to 2010, Mr. Petersen served as Director of the Loma Linda University Health Research Consulting Group, which consults on health research study design and data analysis. Mr. Petersen was a member of the Loma Linda, California City Council from 1990 to 2010 and served as the Mayor of Loma Linda from 1996 to 2006. Mr. Petersen is currently the vice-chair and a board member of Vtrans, a non-profit, quasi-governmental agency. Mr. Petersen earned an M.P.H. from Loma Linda University with concentrations in Biostatistics and Health Administration. We believe that Mr. Petersen's years of experience in scientific academia and consulting qualify him to serve on our board of directors.

Stephen B. Shohet, M.D. has served as a member of our board of directors since December 2010. Dr. Shohet has been the Professor of Laboratory Medicine and Professor of Medicine at the University of California, San Francisco since 1976 and became an Emeritus Professor in 2004. In 1976, Dr. Shohet also became Director of the Cancer Research Institute at the University of California, San Francisco. Dr. Shohet received an A.B. from Harvard College in English literature and holds an M.D. from Harvard Medical School. He is Board Certified by the American Board of Internal Medicine. We believe that Dr. Shohet's medical

Table of Contents

background as well as his years of experience in scientific academia qualify him to serve on our board of directors.

Family Relationships

Dr. Zhang, our Chief Executive Officer, and Dr. Luo, our Chief Operating Officer, are husband and wife.

Board Composition and Independence

Our board of directors currently consists of nine members. All directors hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification, or removal. Our board of directors has determined that Mr. Koo, Mr. Prins, Dr. Lee, Dr. Zasloff, Mr. Petersen and Dr. Shohet are independent within the meaning of the NASDAQ Stock Market LLC listing standards.

Upon completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

The Class I directors will be Mr. Shandell, Mr. Petersen and Mr. Koo and their terms will expire at the annual general meeting of stockholders to be held in 2014;

The Class II directors will be Dr. Luo, Dr. Zasloff and Dr. Lee and their terms will expire at the annual general meeting of stockholders to be held in 2015; and

The Class III directors will be Dr. Zhang, Dr. Shohet and Mr. Prins and their terms will expire at the annual general meeting of stockholders to be held in 2016.

Risk Oversight

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through our committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to mitigate or manage them. The risk oversight process includes receiving regular reports from committees of our board of directors and members of senior management to enable our board of directors to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nomination committee manages risks associated with the independence of the board of directors, corporate disclosure practices and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board or directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board of directors as a whole.

Board Committees

Our board of directors includes an audit committee, a compensation committee and a nomination committee. Our audit, compensation and nomination committees are comprised of independent board members.

Table of Contents

Audit committee. Our audit committee currently consists of Mr. Koo, who is the chair of the committee, Dr. Shohet and Dr. Lee, each of whom are independent in accordance with the NASDAQ Stock Market LLC and SEC standards. Mr. Koo is an "audit committee financial expert" as the term is defined under SEC regulations. The audit committee operates under a written charter. The functions of the audit committee include:

- overseeing the engagement of our independent registered accounting firm;
- reviewing our audited financial statements and discussing them with the independent registered accounting firm and our management;
- meeting with the independent registered accounting firm and our management to consider the adequacy of our internal controls; and
- reviewing our financial plans, reporting recommendations to our full board of directors for approval and authorizing actions.

Both our independent registered accounting firm and internal financial personnel regularly meet with our audit committee and have unrestricted access to the audit committee.

Compensation committee. Our compensation committee currently consists of Mr. Prins, who is the chair of the committee, Mr. Petersen and Mr. Shohet, each of whom are independent in accordance with the NASDAQ Stock Market LLC standards. Each member of our compensation committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code. The compensation committee operates under a written charter. The functions of the compensation committee include:

- reviewing and, if deemed appropriate, recommending to our board of directors policies, practices and procedures relating to the compensation of our directors, officers and other managerial employees and the establishment and administration of our employee benefit plans;
- determining or recommending to the board of directors the compensation of our executive officers; and
- advising and consulting with our officers regarding managerial personnel and development.

Nomination committee. Our nomination committee consists of Dr. Zasloff, who is the chair of the committee, Mr. Petersen and Dr. Lee, each of whom are independent in accordance with the NASDAQ Stock Market LLC standards. The nomination committee operates under a written charter. The functions of the nomination committee include:

- establishing standards for service on our board of directors;
- identifying individuals qualified to become members of our board of directors and recommending director candidates for election or re-election to our board; and
- considering and making recommendations to our board of directors regarding the size and composition of the board of directors, committee composition and structure and procedures affecting directors.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is or has ever been one of our officers or employees. None of our executive officers serves, or in the past has served, as a member of the compensation committee or on the board of directors of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Table of Contents

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to our officers, directors and employees. Our code of business conduct and ethics is available on our website at www.amphastar.com. The contents of our website are not part of this prospectus and you should not consider the contents of our website in making an investment decision regarding our stock. We intend to disclose any amendments to our code of business conduct and ethics, or waivers of its requirements, on our website or in filings under the Exchange Act.

Table of Contents

EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

The following table sets forth total compensation paid to our named executive officers, who are comprised of (1) our principal executive officer and (2) our next two highest compensated executive officers other than the principal executive officer.

Name and principal position	Year	Salary	Bonus	Option Awards(1)	Stock Awards(1)	All Other Compensation(2)	Total
Jack Y. Zhang	2013	$ 847,800	$ 528,190	$ 2,400,000	$	$ 81,169(3)	$ 3,857,159
Chief Executive Officer	2012	798,000	184,152	1,333,000		75,891(4)	2,391,043
Mary Z. Luo	2013	671,943	273,780	1,400,000		34,126(5)	2,379,849
Chief Operating Officer	2012	648,001	149,540	958,000		31,833(6)	1,787,374
Jason B. Shandell	2013	453,443	245,190	593,000	394,000	23,256(7)	1,708,889
President	2012	377,885	59,664	260,000		*	697,549

* Indicates an amount less than $10,000.

(1) This amount reflects the aggregate grant date fair value computed in accordance with ASC Topic 718. The assumptions that we used to calculate these amounts are discussed in Note 8 to our consolidated financial statements appearing at the end of this prospectus.

(2) In accordance with SEC rules, this column discloses perquisites and other personal benefits for each named executive officer that received such perquisites and other personal benefits in an amount equal to or greater than $10,000.

(3) The amount is comprised of a $65,598 housing allowance, a $13,242 vehicle allowance, a $614 company contribution made under our 401(k) plan and a $1,715 group life insurance benefit in excess of the standard threshold granted to all other employees.

(4) The amount is comprised of a $58,895 housing allowance, an $11,881 vehicle allowance, a $3,400 company contribution made under our 401(k) plan and a $1,715 group life insurance benefit in excess of the standard threshold granted to all other employees.

(5) The amount is comprised of a $24,180 housing allowance, a $7,864 vehicle allowance, a $498 company contribution made under our 401(k) plan and a $1,584 group life insurance benefit in excess of the standard threshold granted to all other employees.

(6)

The amount is comprised of a $20,520 housing allowance, a $6,329 vehicle allowance, a $3,400 company contribution made under our 401(k) plan and a $1,584 group life insurance benefit in excess of the standard threshold granted to all other employees.

(7)

The amount is comprised of a $10,499 vehicle allowance, a $5,000 company contribution made under our 401(k) plan, a $216 group life insurance benefit in excess of the standard threshold to all other employees, a $6,110 reimbursement for medical expenses and a $1,431 reimbursement for travel expenses.

Employment Agreements

We entered into an employment agreement with William J. Peters effective March 11, 2014. We entered into substantially similar employment agreements with each of Jack Y. Zhang, Mary Z. Luo, Jason B. Shandell and Marilyn J. Purchase effective on the date of the closing of this offering that govern the terms of each executive officer's employment. The employment agreements provide for an initial term of three years and will be automatically extended for successive one-year periods, unless one of the parties provides the other 90 days' prior written notice before the expiration of the initial term or any annual renewal term

Table of Contents

that the term will not be extended. The employment agreements are terminable (a) by the executive officer at any time, provided the executive gives at least four weeks' prior notice of resignation; (b) by us at any time; or (c) due to the disability or death of the executive.

Pursuant to their respective employment agreements, if the executive's employment terminates for any reason, the executive officer is entitled to receive (a) any and all base salary and vacation pay earned through the date of termination and (b) any reimbursable expenses properly reported by the executive officer. Unless the executive officer resigns without "good reason" (as defined in the employment agreement) or the employment is terminated for "cause" (as defined in the employment agreements), the executive officer is also entitled to (a) any applicable prorated bonus, based on actual performance for the year of termination, as determined by the board of directors in its discretion when making bonus determinations for other senior executives and payable at such time as annual bonuses are otherwise determined for such other senior executives, and (b) any accrued but unpaid annual bonus for the fiscal year immediately preceding the year of termination.

If we do not renew an employment agreement at the end of the initial term or any renewal term, the executive's employment is terminated by us without "cause" (as defined in the employment agreements) or if the executive officer resigns with "good reason" (as defined in the employment agreements), such executive, conditioned upon execution of a release in form and substance satisfactory to us, is entitled to:

an amount equal to three, or two in the case of Mr. Peters, times the sum of (a) the highest base annual salary in effect (i) during the 12 months immediately prior to the date of termination or (ii) during the employment, if the employment has lasted less than 12 months, plus (b) the average annual bonus earned by the executive for the most recent three, or two in the case of Mr. Peters, fiscal years ending prior to the date of termination or the base salary for the remainder of the agreement, whichever is greater, such amount to be paid in cash or immediately-available funds in a lump sum thirty days following the date of termination;

continued payment of his or her health insurance premiums as may be necessary to allow the executive and his or her spouse and dependents to continue to receive health insurance coverage substantially similar to the coverage they received prior to the date of termination of the executive's employment, for a period of 12 months or the remainder of the agreement, whichever is greater commencing on the date of termination;

vesting of any restricted stock, stock option or other equity compensation awards granted by us, except to the extent that the provisions of the applicable restricted stock, stock option or other equity award are more favorable; and

coverage for the executive as a named insured on all directors' and officers' insurance maintained by us for the benefit of directors and officers on at least the same basis as all other covered individuals, and at least the same corporate indemnification we provide to other senior executives, through at least six years following the date of termination.

In addition, certain of our executive officers may be entitled to additional payments and benefits upon a "change of control" (as defined in the employment agreements). See " Potential Payments on Termination or Change of Control."

Table of Contents

Potential Payments on Termination or Change of Control

Under the employment agreements of Dr. Zhang, Dr. Luo, Mr. Shandell, Mr. Peters and Ms. Purchase, upon termination of employment resulting from a change in control (as defined in the employment agreements) and occurring as a result of the specific termination events and time periods set forth in the employment agreements, in addition to any severance payments as described above, the executives are entitled to:

- payment in an amount equal to three, or two in the case of Mr. Peters, times the sum of (a) the highest base salary in effect (i) during the 12 months immediately prior to the date of termination or (ii) during the period of employment, if the employment lasted less than 12 months, plus (b) the average annual bonus earned by the executive for the most recent three, or two in the case of Mr. Peters, fiscal years ending prior to the date of termination, such amount to be paid in cash or immediately-available funds in a lump sum sixty days following the date of termination;

- an additional 12-month extension of health insurance premium payments in addition to those payments to which he or she is otherwise entitled under his or her respective employment agreement; and

- full vesting of all restricted stock, stock options or other equity compensation awards granted by us that were unvested immediately prior to the change in control, except to the extent that the provisions of the applicable restricted stock, stock option or other equity award are more favorable.

Entitlement to the above benefits upon a change in control is conditioned upon execution of a release in form and substance satisfactory to us.

In the event of a change of control (as defined in the 2005 Plan) where the acquirer does not assume awards granted under the 2005 Plan, awards issued under the 2005 Plan will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable. In the event of a change of control where the acquirer assumes awards granted under the 2005 Plan, if the holder of any such award is terminated by the acquirer without cause (as defined in the 2005 Plan) or as a result of a constructive termination (as defined in the 2005 Plan) within one year after the change of control, such award will immediately vest in full and, if applicable, any remaining forfeiture, repurchase and other restrictions applicable to such award shall lapse on the date of termination.

Table of Contents

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth summary information regarding the outstanding equity awards for each of the named executive officers as of December 31, 2013.

	Option Awards(1)				Stock Awards	
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested(7)
Jack Y. Zhang	275,000		$ 22.29	8/2/14		
	275,000		12.97	9/28/15		
	174,937	87,494(2)	16.75	10/3/16		
	95,612	286,836(4)	11.51	7/13/17		
	44,247	132,740(4)	11.53	9/28/17		
		1,279,167(2)	12.02	7/5/18		
Mary Z. Luo	185,000		$ 22.29	8/2/14		
	185,000		12.97	9/28/15		
	121,167	60,601(2)	16.75	10/3/16		
	66,224	198,671(4)	11.51	7/13/17		
	34,658	103,974(4)	11.53	9/28/17		
		746,181(2)	12.02	7/5/18		
Jason B. Shandell	8,000		$ 33.49	5/9/18	666(5)	$ 9,769
	4,000		33.49	7/7/18	4,095(5)	60,027
	5,000		35.32	8/28/18	5,253(6)	77,009
	6,000	1,500(3)	20.26	8/2/19	36,121(6)	529,534
	3,600	2,400(3)	11.79	9/28/20		
	3,760	3,759(4)	14.81	10/3/21		
	14,249	42,747(4)	10.46	7/13/22		
	4,158	12,472(4)	10.48	9/28/22		
		151,988(4)	10.93	7/5/23		

(1) Information for this table is depicted on an award-by-award basis unless the exercise price and expiration date are identical.

(2) Options vest annually over a period of three years from the date of grant.

(3) Options vest annually over a period of five years from the date of grant.

(4)

Options vest annually over a period of four years from the date of grant.

(5)

DSU awards that vest annually over a period of five years from the date of grant.

(6)

DSU awards that vest annually over a period of four years from the date of grant.

(7)

The market value of DSU awards that have not vested are based on our per share value of $14.66 at December 31, 2013.

Employee Benefit Plans

Amended and Restated 2005 Equity Incentive Award Plan

Introduction. In September 2005, our board of directors adopted the 2005 Equity Incentive Award Plan, or the 2005 Plan, which was approved by our stockholders in October 2005 and is set to expire in September 2015. The 2005 Plan, which was to become effective after our initial public offering, was

Table of Contents

amended and restated and became effective in February 2009. We refer to the Amended and Restated Equity Incentive Award Plan as the 2005 Plan. Consequently, we no longer make grants of awards under plans that were in existence prior to the 2005 Plan. In general, the 2005 Plan is designed to meet the needs of a publicly traded company, including the requirements for granting "performance-based compensation" under Section 162(m) of the Code. The 2005 Plan provides for the grant of incentive stock options, or ISOs, nonqualified stock options, or NQSOs, restricted stock awards, restricted stock unit awards, stock appreciation rights, or SARs, dividend equivalents and stock payments to our employees, members of the board of directors and consultants.

Share Reserve. We have initially reserved 3,700,000 shares of our common stock for issuance under the 2005 Plan. This number will be increased by the number of shares of common stock related to options or other awards granted under our other equity incentive plans or arrangements that are repurchased, forfeited, expired or cancelled on or after the effective date of the 2005 Plan.

The 2005 Plan also contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance on January 1 of each year during the ten-year term of the 2005 Plan, beginning January 1, 2007. The annual increase in the number of shares shall be either 2% of our outstanding shares on the applicable January 1 or a lesser amount determined by our board of directors.

In addition, if at any time after the 2005 Plan became effective, our market capitalization exceeds by at least 200% our market capitalization on the date we become a public company for any 10 consecutive trading day period, then on the last day of such 10-day period, the number of shares available for issuance will be increased by 3% of our outstanding shares on that day. If, after this adjustment, for any subsequent 10 consecutive trading day period, our market capitalization exceeds by at least 200% our market capitalization at the last date of adjustment, then the number of shares available for issuance will again be increased by 2.5% of our outstanding shares.

In no event will the number of shares of our common stock that may be issued pursuant to awards under the 2005 Plan exceed an aggregate of 18,000,000 shares.

Administration. The compensation committee of our board of directors will administer the 2005 Plan. Our compensation committee must consist of at least two members of our board of directors, each of whom is a "non-employee director" for purposes of Rule 16b-3 under the Exchange Act and, with respect to awards that are intended to constitute performance-based compensation under Section 162(m), an "outside director" for purposes of Section 162(m) and an "independent director" under the rules of the NASDAQ Stock Market LLC. The 2005 Plan's administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject thereto and the terms and conditions thereof and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2005 Plan. The 2005 Plan's administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2005 Plan. Our board of directors may at any time exercise any and all rights and duties of the administrator of the 2005 Plan, except with respect to matters under Rule 16b-3 under the Exchange Act or Section 162(m) or any rules or regulations issued thereunder. The board of directors will administer the 2005 Plan with respect to awards to non-employee directors.

Eligibility. Options, SARs, restricted stock and other awards under the 2005 Plan may be granted to our officers or employees. Awards may also be granted to our non-employee directors and consultants, but only employees may be granted ISOs. The maximum number of shares that may be subject to awards granted under the 2005 Plan to any individual in any calendar year cannot exceed 2,000,000. This limit will not take effect until after we become a public company and the earliest of: (1) the first material modification of the 2005 Plan; (2) the issuance of all the shares reserved for issuance under the 2005 Plan; (3) the expiration of the 2005 Plan; (4) the first meeting of stockholders at which members of the board of directors are to be elected that occurs after the close of the third calendar year following the calendar year

Table of Contents

in which we registered an equity security under Section 12 of the Exchange Act; or (5) such other date required by Section 162(m) of the Code.

Awards. The 2005 Plan provides that our compensation committee (or the board of directors, in the case of awards to non-employee directors) may grant or issue stock options, SARs, restricted stock, restricted stock units, dividend equivalents and stock payments, or any combination thereof. The compensation committee (or the board of directors, in the case of awards to non-employee directors) will consider each award grant subjectively in light of the individual performance of the recipient and the anticipated contribution of the recipient to our long-term goals. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

Nonqualified Stock Options provide for the right to purchase shares of our common stock at a specified price which may not be less than the fair market value of a share of common stock on the date of grant and usually will become exercisable in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of performance targets established by our compensation committee (or the board of directors, in the case of awards to non-employee directors). NQSOs may be granted for any term up to ten years.

Incentive Stock Options are designed to comply with the provisions of, and be subject to specified restrictions contained in, the Code. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2005 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must expire upon the fifth anniversary of the date of its grant.

Restricted Stock may be made subject to such restrictions as determined by our compensation committee (or the board of directors, in the case of awards to non-employee directors). Typically, restricted stock may be forfeited for no consideration or repurchased by us at the original purchase price if the conditions or restrictions are not met, and they may not be sold or otherwise transferred to third parties until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will receive dividends, if any, prior to the time when the restrictions lapse.

Deferred Stock Units may be awarded to participants, typically without payment of consideration, but subject to vesting conditions based on continued employment or on performance criteria established by our compensation committee (or the board of directors, in the case of awards to non-employee directors). Deferred stock units, or DSUs, may not be sold or otherwise transferred or hypothecated until vesting conditions are removed or expire. Stock underlying deferred stock units will not be issued until the deferred stock units have vested, and recipients of deferred stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied. A deferred stock unit is a form of a restricted stock unit, whereby the issuance of the underlying stock is deferred for some stated period after the award has vested.

Stock Appreciation Rights typically will provide for payments to the holder based upon increases in the price of our common stock over the exercise price of the related option or other awards, but alternatively may be based upon criteria such as book value. Except as required by the Code, there are no restrictions specified in the 2005 Plan on the exercise of SARs or the amount of gain realizable therefrom. Our compensation committee or board of directors may elect to pay SARs in cash or in common stock or in a combination of both.

Dividend Equivalents represent the value of the dividends, if any, per share paid by us, calculated with reference to the number of shares covered by the stock options, SARs, or other awards held by the participant.

Stock Payments may be authorized by our compensation committee (or the board of directors, in the case of awards to non-employee directors) in the form of common stock or an option or other right to

Table of Contents

purchase common stock as part of a deferred compensation arrangement in lieu of all or any part of compensation, including bonuses, that would otherwise be payable in cash to the key employee or consultant.

Corporate Transactions. In the event of a change of control (as defined in the 2005 Plan) where the acquirer does not assume awards granted under the 2005 Plan, awards issued under the 2005 Plan will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable. In the event of a change of control where the acquirer assumes awards granted under the 2005 Plan, if the holder of any such award is terminated by the acquirer without cause or as a result of a constructive termination within one year after the change of control, such award will immediately vest in full and, if applicable, any remaining forfeiture, repurchase and other restrictions applicable to such award shall lapse on the date of termination.

Amendment and Termination of the 2005 Plan. Our board of directors may terminate, amend or modify the 2005 Plan. However, stockholder approval of any amendment to the 2005 Plan will be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the 2005 Plan that increases the number of shares available under the 2005 Plan. If not terminated earlier by the compensation committee or the board of directors, the 2005 Plan will terminate on the earlier of the tenth anniversary of the date of its adoption by our board of directors or the date of its approval by our stockholders.

As of March 31, 2014 options to purchase 9,795,127 shares of common stock were outstanding, 406,255 DSU grants were outstanding and 2,139,587 shares were available for future grants or awards under the 2005 Plan.

Amended and Restated 2002 Stock Option/Stock Issuance Plan

Introduction. The 2002 Stock Option/Stock Issuance Plan, or the 2002 Plan, was adopted by our board of directors in November 2002 and approved by our stockholders in August 2003. The board of directors approved an amendment and restatement of the 2002 Stock Option/Stock Issuance Plan in April 2004 increasing the number of options for grant under the Plan, which was approved by our stockholders in July 2004. We refer to the Amended and Restated 2002 Stock Option/Stock Issuance Plan as the 2002 Plan. Consequent to the 2005 Plan becoming effective, awards are no longer being made under the 2002 Plan.

Share Reserve. 6,400,000 shares of common stock were authorized for issuance under the 2002 Plan. In addition, no participant in the 2002 Plan may have been granted stock options, and/or stock awards for more than 400,000 shares of common stock per calendar year.

Structure. The 2002 Plan provided for two types of equity incentives:

option grants, pursuant to which eligible individuals in our employ or service may have been granted options to purchase shares of common stock at an exercise price not less than 85% of the fair market value of those shares on the grant date; and

stock awards, under which such individuals may have been issued shares of common stock directly or through the purchase of such shares at a price not less than 100% of their fair market value at the time of issuance; however, the purchase price for such shares may have been paid through the exchange of vested stock options, cancellation of indebtedness to our company or performance of services.

Eligibility. The individuals eligible to participate in the 2002 Plan included our employees, our non-employee Board members and any consultants we hired.

Administration. The 2002 Plan is administered by our compensation committee and/or our board of directors (for purposes of this description, the compensation committee and our Board will be referred to generally as the "plan administrator"). The plan administrator determined which eligible individuals were to receive option grants or stock awards under the 2002 Plan, the time or times when such option grants or

Table of Contents

stock awards were to be made, the number of shares subject to each such grant or award, the vesting schedule to be in effect for the option grant or stock award and the maximum term for which any granted option was to remain outstanding.

Plan Features. The 2002 Plan includes the following features:

The exercise or purchase price for the shares of common stock subject to awards made under the 2002 Plan may be paid in cash. If permitted in an optionee's option agreement, an option's exercise price may also be paid in shares of common stock valued at fair market value on the exercise date through a same-day sale program without any cash outlay by the optionee. In addition, if permitted in an option agreement, the plan administrator may provide financial assistance to an optionee in the exercise of his or her outstanding options or the purchase of his or her unvested shares by allowing such individual to deliver a full-recourse, interest-bearing promissory note in payment of the exercise price and any associated withholding taxes incurred in connection with such exercise or purchase.

In the event we merge or are acquired, options outstanding under the 2002 Plan shall be treated in one of the following ways:

the options shall continue (in the event we are the surviving corporation);

the options will be assumed by the acquirer;

the options will be substituted by the acquirer;

the options will become fully vested and exercisable, followed by the cancellation of such options; or

the options will be cashed out and then cancelled.

The Board may amend or modify the 2002 Plan at any time, subject to any required stockholder approval, but plan amendments will not affect any previously granted awards. The 2002 Plan would have terminated no later than November 2012. As of February 2009, subsequent to the 2005 Plan becoming effective, awards are no longer being made under the 2002 Plan.

As of March 31, 2014, options to purchase 1,920,450 shares of common stock were outstanding under the 2002 Plan.

Stock Options Granted Prior to 2002

From 1998 through 2001, our board of directors granted options to purchase shares of our common stock under the Key Employee Stock Incentive Plan, the 2001 Employee Incentive Plan, the 2000 Employee Incentive Plan and the 1999 Employee Incentive Plan. As of March 31, 2014, options to purchase 30,000 shares of common stock were outstanding from grants made prior to 2002. All of these outstanding options were granted to a former employee pursuant to option agreements between 1999 and 2001. Pursuant to a settlement agreement with this former employee, he may exercise 75% of these options within 90 days of our initial public offering.

2014 Employee Stock Purchase Plan

Introduction. Our board of directors approved and adopted the 2014 Employee Stock Purchase Plan, or the ESPP, on March 24, 2014. The ESPP will become effective on the date of the prospectus. 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 2,000,000 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

Administration. The ESPP will be administered by our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may

Table of Contents

specify offerings with durations of not more than 27 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 10% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our compensation committee, 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 and (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) employed for more than two years, (b) customarily employed for more than 20 hours per week, (c) customarily employed for more than five months per calendar year. 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. A participant may not purchase more than 5,000 shares of common stock during a purchase period.

Plan Amendments, Termination. Our compensation committee has the authority to amend or terminate our ESPP upon completion of an offering period.

401(k) Plan

We have a defined contribution 401(k) plan, whereby eligible employees can voluntarily contribute up to a defined percentage of their annual compensation up to the maximum statutory limit. We match contributions at a rate of 50% on the first 4% of employee contributions, or up to 2% of the employee's annual compensation, and we pay the administrative costs of the plan. Employer contributions vest ratably over four years.

Limitation of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws will contain provisions indemnifying our directors and officers to the fullest extent permitted by law. Prior to the completion of this offering, we intend to enter into indemnification agreements with each of our directors that may, in some cases, be broader than the specific indemnification provisions contained under Delaware law.

In addition, as permitted by Delaware law, our amended and restated certificate of incorporation will provide that no director will be liable to us or our stockholders for monetary damages due to breach of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director due to breach of certain fiduciary duties as a director, except that a director will be personally liable for:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- the payment of dividends or the redemption or purchase of stock in violation of Delaware law; or
- any transaction from which the director knowingly derived an improper personal benefit.

Table of Contents

To the extent that our directors, officers and controlling persons are indemnified under the provisions contained in our amended and restated certificate of incorporation, Delaware law, or contractual arrangements against liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, 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.

Director Compensation

We compensate non-employee members of the board of directors. Directors who are also employees do not receive cash or equity compensation for service on the board of directors in addition to compensation payable for their service as our employees. The non-employee members of our board of directors are reimbursed for travel, lodging and other reasonable expenses incurred in attending board of directors or committee meetings. Our directors received equity grants annually at the fair market value of our common stock at the time of grant under our 2005 Plan.

The cash and equity components of our compensation policy for non-employee directors are set forth below:

Position	Annual Cash Retainer	Meeting Fee	Teleconference Fee	Equity Grant
Base Fee	$ 40,000	$ 2,500	$ 500	$ 160,000
Chairperson Fee				
Audit committee	22,500			
Compensation committee	15,000			
Nomination committee	11,250			
Committee Member Fee				
Audit committee	10,000	1,375	500	
Compensation committee	7,500	1,375	500	
Nomination committee	5,000	1,375	500	

Under our director compensation program, our directors may choose to receive DSUs instead of options with the same aggregate fair value.

The following table sets forth summary information concerning the compensation awarded to, paid to, or earned by the non-employee members of our board of directors for the fiscal year ended December 31, 2013.

Name	Fees Earned or Paid in Cash	Stock Awards(1)	Option Awards(1)	Total
Richard Koo	$ 89,375	$ 80,000	$ 80,000	$ 249,375
Richard Prins	98,000	60,000	100,000	258,000
Howard Lee	73,875	80,000	80,000	233,875
Michael A. Zasloff	66,500	80,000	80,000	226,500
Floyd F. Petersen	80,064	80,000	80,000	240,064
Stephen B. Shohet	63,625		160,000	223,625

(1) This amount reflects the aggregate grant fair value computed in accordance with ASC Topic 718. The assumptions that we used to calculate these amounts are discussed in Note 8 to our consolidated financial statements appearing at the end of the prospectus.

Table of Contents

PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of May 30, 2014, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person known by us to own beneficially more than 5% of our common stock;
- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- the selling stockholder.

Applicable percentage ownership is based on 38,795,940 shares of common stock outstanding as of May 30, 2014. The percentage of beneficial ownership after this offering shown in the table is based on 42,795,940 shares of common stock outstanding after the closing of this offering, assuming no exercise of the underwriters' over-allotment option.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security, including options and DSUs that are currently exercisable or exercisable or deliverable within 60 days of May 30, 2014.

Except as otherwise noted, the address of each person or entity in the following table is c/o Amphastar Pharmaceuticals, Inc., 11570 Sixth Street, Rancho Cucamonga, California 91730.

	Beneficial Ownership Prior to Offering		Shares being Offered	Beneficial Ownership After the Offering	
Name and Address of Beneficial Owner	**Number of Shares**	**Percentage**	**Number of Shares**	**Number of Shares**	**Percentage**
5% Stockholders					
Applied Physics & Chemistry Laboratories, Inc.[2] 13760 Magnolia Avenue Chino, CA 91710	7,631,594	19.67%		7,631,594	17.83%
Coller International Partners IV Limited[3] PO Box 255 Trafalgar Court, Les Banques, St. Peter Port, Guernsey GY1 3QL Channel Islands	3,360,000	8.66%	3,360,000		*
Directors and Named Executive Officers					
Jack Y. Zhang[4][5].	11,150,953	27.14%		11,150,953	24.73%
Mary Z. Luo[4][5]	11,150,953	27.14%		11,150,953	24.73%
Jason B. Shandell[6]	119,114	*		119,114	*

Richard Koo[7]	214,365	*	214,365	*
Floyd F. Petersen[8]	110,729	*	110,729	*
Michael A. Zasloff[9]	174,143	*	174,143	*
Richard Prins[10]	121,903	*	121,903	*
Howard Lee[11]	176,595	*	176,595	*
Stephen B. Shohet[12]	165,461	*	165,461	*
All directors and executive officers as a group (12 persons)[13]	12,523,882	29.78%	12,523,882	27.20%

*

Represents beneficial ownership of less than 1% of the outstanding shares of common stock.

Table of Contents

(1) Unless otherwise indicated in the footnotes to this table and subject to applicable community property laws, we believe that the persons named in this table have sole voting and investment power with respect to all shares of common stock reflected in this table.

(2) Dr. Zhang and Dr. Luo are the sole owners of Applied Physics & Chemistry Laboratories, Inc.

(3) The board of directors of Coller International Partners IV Limited is comprised of Paul McDonald, John Marren, Cyril Mahon and Peter Hutton, each of whom may be deemed to share voting and investment power over the shares of common stock held by Coller International Partners IV Limited, but each disclaims beneficial ownership except to the extent of any indirect pecuniary interest therein. Admiral Nominees Limited and Nelson Representatives Limited are the shareholders of Coller International Partners IV Limited, each as nominee and trustee of Coller German Investors GmbH & Co. KG, Coller International Partners IV-D, L.P. and Coller International Partners IV-E, L.P. Coller International General Partner IV, L.P., or General Partner, is the general partner of Coller International Partners IV-D, L.P. and Coller International Partners IV-E, L.P. and the managing limited partner of Coller German Investors GmbH & Co. KG. Coller Investment Management Limited, or Investment Management, is the general partner of General Partner. The board of directors of Investment Management is comprised of Jeremy Coller, Roger Le Tissier, Paul McDonald, Andrew Hitchon, Cyril Mahon, Peter Hutton and John Loveless, each of whom may be deemed to share voting and investment power over the shares of common stock held by Coller International Partners IV Limited, but each disclaims beneficial ownership except to the extent of any indirect pecuniary interest therein.

(4) Dr. Zhang and Dr. Luo are spouses and the number and percentage of beneficial ownership of each represents their aggregate combined ownership of 27.14%, including their combined ownership in Applied Physics & Chemistry Laboratories, Inc., over which Drs. Zhang and Luo have shared voting and investment power.

(5) Includes (i) 7,631,594 shares held of record by Applied Physics & Chemistry Laboratories, Inc., the sole owners of which are Drs. Zhang and Luo, (ii) 1,368,754 shares of common stock subject to options exercisable within 60 days of May 30, 2014 and 649,108 shares held directly by Dr. Zhang, (iii) 906,974 shares of common stock subject to options exercisable within 60 days of May 30, 2014 and 547,823 shares held directly by Dr. Luo and (iv) 28,700 shares held in trust for which Drs. Zhang and Luo serve as custodians.

(6) Includes 12,102 shares owned by Mr. Shandell, 6,000 shares owned by Jason and Carolina Shandell, and 101,012 shares of common stock subject to options exercisable within 60 days of May 30, 2014 held by Mr. Shandell.

(7) Includes 204,365 shares owned by Mr. Koo and 10,000 shares owned by Richard Y. Koo, a sole proprietorship.

(8)

Includes 32,955 shares owned by Mr. Petersen and 77,774 shares of common stock subject to options exercisable within 60 days of May 30, 2014 held by Mr. Petersen.

(9)

Includes 8,682 shares owned by Dr. Zasloff and 165,461 shares of common stock subject to options exercisable within 60 days of May 30, 2014 held by Dr. Zasloff.

(10)

Includes 27,958 shares owned by Mr. Prins and 93,945 shares of common stock subject to options exercisable within 60 days of May 30, 2014 held by Mr. Prins.

(11)

Includes 89,758 shares owned by Dr. Lee and 86,837 shares of common stock subject to options exercisable within 60 days of May 30, 2014 held by Dr. Lee.

(12)

Consists of shares of common stock subject to options exercisable within 60 days of May 30, 2014 held by Dr. Shohet.

(13)

Includes 3,253,250 shares of common stock subject to options exercisable within 60 days of May 30, 2014 for all named directors and executive officers and directors as a group.

Table of Contents

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

As set forth in our audit committee charter, our audit committee is responsible for reviewing and approving all related-party transactions. Since January 1, 2011, we have entered into, and our audit committee has reviewed and approved, transactions described below with our directors, executive officers and holders of more than 5% of our voting securities and their respective affiliates. As used in this section, the terms "related person" and "transaction" have the meanings set forth in Item 404(a) of Regulation S-K under the Securities Act. In the course of its review and approval of transactions with related persons, the audit committee considers:

- the nature of the related person's interest in the transaction;
- the material terms of the transaction, including the amount involved and the type of the transaction;
- the importance of the transaction to the related person and to Amphastar;
- whether the transaction would impair the judgment of a director or executive officer to act in our best interest and the best interest of our stockholders; and
- any other matters the audit committee deems appropriate.

Any member of the audit committee who is a related person with respect to a transaction under review will not be able to participate in the discussions or vote on the approval or ratification of the transaction, other than to provide all material information regarding the transaction, including information regarding the extent of the member's interest in the transaction, to the audit committee. However, such a director may be counted in determining the presence of a quorum at a meeting of the committee that considers the transaction. Any material changes to the terms of, or any renewal of, any of these transactions will also require the same approval. If a related party transaction will be ongoing, the audit committee may establish guidelines or other parameters or conditions relating to our participation in the transaction. The audit committee may from time to time pre-approve types or categories of transactions by related persons but we have no such pre-approved types or categories of transactions at this time.

Agreements with Applied Physics & Chemistry Laboratories, Inc. and MicroScience Institute

In 2006, MicroScience Institute, or MSI, a related party which is also wholly-owned by Drs. Zhang and Luo, our director and Chief Executive Officer and our Chief Operating Officer and chairman of our board of directors, respectively, obtained the leasing rights to our New Drug Research Center, or NDRC, from Applied Physics & Chemistry Laboratories, Inc., or APCL, which is also owned by Drs. Zhang and Luo. Prior to this offering, APCL owned approximately 20% of our outstanding shares of common stock. APCL is owned 100% by Drs. Zhang and Luo. In April 2006, the audit committee approved a three year lease agreement between Amphastar and MSI for a facility previously leased from APCL and for additional office and laboratory space. The total annual rental under the lease is $1.0 million with an option to renew for an additional three years. In May 2009, we exercised our option to extend the lease with MSI for an additional three years under the same terms.

In September 2012, our audit committee approved a lease agreement with MSI for the NDRC facility. In October 2012, we signed a lease agreement for the NDRC facility with MSI pursuant to our board of director's approval. The effective term of the lease is three years commencing May 1, 2012 and terminating on the earlier of April 30, 2015 or the sale of the facility to us. The amount of lease payments were determined by reference to standard industry formulas for computing rent payments using the appraised fair market value of the facility and current market capitalization rates for the local area. The total annual rental under the lease is $0.6 million.

Concurrently with the execution of the new lease, in September 2012, the audit committee approved the purchase of the NDRC facility that was leased from MSI for a price of $7.4 million. The sales price was determined by obtaining three independent appraisals and selecting the lowest appraisal of the three. In

Table of Contents

October 2012, subsequent to the execution of the three-year lease agreement, a purchase agreement was signed by us and Drs. Zhang and Luo to complete the transaction approved by the board of directors.

Rent expense under the related-party leases discussed above was approximately $1.0 million and $0.6 million for the years ended December 31, 2011 and 2012, respectively, and is included in research and development expense.

Indemnification Agreements

We intend to enter into indemnification agreements with each of our directors and executive officers. The indemnification agreements, our amended and restated certificate of incorporation and our amended and restated bylaws will require us to indemnify our directors to the fullest extent permitted by Delaware law. For more information regarding these agreements, see "Executive and Director Compensation Limitation of Liability and Indemnification Matters."

Table of Contents

DESCRIPTION OF CAPITAL STOCK

General

Immediately upon completion of the offering and upon the filing of our amended and restated certificate of incorporation, we will be authorized to issue up to 320,000,000 shares, $0.0001 par value per share, of which 300,000,000 shares may be common stock and 20,000,000 shares may be preferred stock. The following description of our capital stock is subject to, and qualified in its entirety by, the provisions of our certificate of incorporation and amended and restated bylaws, which are included as exhibits to the registration statement of which this prospectus is a part, and by the provisions of applicable law.

Common Stock

As of May 30, 2014, there were 38,795,940 shares of our common stock outstanding that were held of record by 461 stockholders. There were no shares of preferred stock outstanding.

The holders of our common stock are entitled to one vote for each share held of record upon such matters and in such manner as may be provided by law. Under the Delaware General Corporation Law and our amended and restated bylaws, our board of directors may declare and pay dividends upon shares of our capital stock out of legally available funds, subject to any restrictions in our amended and restated certificate of incorporation. In the event we liquidate, dissolve, or wind up, the holders of our common stock are entitled under the Delaware General Corporation Law to share ratably in all assets remaining after payment of liabilities and liquidation preferences of any outstanding shares of the preferred stock. Holders of our common stock have no preemptive rights or rights to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of our common stock are fully paid and non-assessable.

Preferred Stock

Our board of directors has the authority to issue undesignated preferred stock in one or more series and to determine the powers, preferences and rights and the qualifications, limitations or restrictions granted to or imposed upon any wholly unissued series of undesignated preferred stock and to fix the number of shares constituting any series and the designation of the series, without any further vote or action by our stockholders. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, a majority of our outstanding voting stock. We have no present plans to issue any shares of preferred stock.

Registration Rights

After the closing of this offering, the holders of 799,676 shares of our common stock will be entitled to certain rights with respect to the registration of such shares under the Securities Act. The holders of these shares are entitled to certain piggyback registration rights. If we register any securities for public sale other than for our initial public offering, these holders will have the right to include their shares in the registration statement. In an underwritten offering, we have agreed to use our best efforts to cause the shares to be included in the underwriting on the same terms and conditions as the securities being sold through any such underwriters. We have agreed to indemnify the holders of this registration right against liabilities under the Securities Act, the Exchange Act, or other federal or state securities laws.

Table of Contents

Anti-Takeover Provision

Provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws could make our acquisition by means of a tender offer, a proxy contest or otherwise, and the removal of incumbent officers and directors, more difficult. These provisions are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweighs the disadvantages of discouraging proposals, including proposals that are priced above the then current market value of our common stock, because, among other things, negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. In general, Section 203 defines an "interested stockholder" as any entity or person who beneficially owns, or an affiliate or associate of the corporation that at any time within three years prior to the date of determination of interested stockholder status did beneficially own, 15% or more of the outstanding voting stock of the corporation, and affiliates and associates of such person. Under this provision, we may not engage in any business combination with any interested stockholder for a period of three years following the date the stockholder became an interested stockholder, unless:

- prior to that date our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock outstanding at the time the transaction began; or
- on or following that date the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, transfer, pledge, or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to some exceptions, any transaction that results in the issuance or transfer by the corporation or any of its direct or indirect subsidiaries of any stock of the corporation or of any such subsidiary to the interested stockholder;
- any transaction involving the corporation or any of its direct or indirect subsidiaries that has the effect of increasing the proportionate share of the stock of any class or series of the corporation or of any such subsidiary beneficially owned by the interested stockholder; or
- 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 or any direct or indirect majority-owned subsidiary.

Table of Contents

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our amended and restated certificate of incorporation and our amended and restated bylaws will contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of our company. In particular, our amended and restated certificate of incorporation and amended and restated bylaws, as applicable, among other things:

provide that our board will be classified into three classes of directors, which may discourage a third party from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors;

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

establish procedures with respect to stockholder proposals and stockholder nominations, including requiring that advance written notice of a stockholder proposal or director nomination generally must be received at our principal executive offices not less than 90 nor more than 120 days prior to the first anniversary of the previous year's annual meeting of stockholders;

do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in the board of directors and, as a result, may have the effect of deterring a hostile takeover or delaying or preventing changes in control or management of our company;

provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum, and not by the stockholders;

require that the vote of holders of $66^{2}/_{3}\%$ of the voting power of the outstanding shares entitled to vote generally in the election of directors is required to amend various provisions of our certificate of incorporation and amended and restated bylaws, including provisions relating to:

- the number of directors on our board of directors;
- the election, qualification and term of office of our directors;
- filling vacancies on our board of directors;
- the indemnification of our officers and directors;
- removal of members of our board of directors; and

certain other provisions of our certificate of incorporation and amended and restated bylaws;

provide that following this offering, no action may be effected by our stockholders by written consent, but must be effected at a duly-called annual or special meeting; and

allow us to issue without stockholder approval up to 20,000,000 shares of undesignated preferred stock with rights senior to those of the common stock and that otherwise could adversely affect the rights and powers, including voting rights, of the holders of common stock. In some circumstances, this issuance could have the effect of decreasing the market price of the common stock as well as having the anti-takeover effect discussed above.

These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by them and to discourage certain types of transactions that may involve an actual or threatened change of control of our company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in our management.

Table of Contents

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of 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; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amend and restated certificate or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Several lawsuits have been filed in Delaware challenging the enforceability of similar choice of forum provisions and it is possible that a court will determine that such provisions are not enforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

The Nasdaq Global Market

We have applied to list our common stock on the Nasdaq Global Market under the symbol "AMPH."

Table of Contents

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market following this offering or the possibility of sales of this kind occurring could cause the prevailing market price of our common stock to fall and impede our ability to raise capital through an offering of equity securities.

Upon the completion of this offering, we will have a total of 42,795,940 shares of common stock outstanding based upon 38,795,940 shares outstanding as of May 30, 2014, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options prior to completion of this offering. The shares offered by this prospectus will be freely tradable unless they are purchased by our "affiliates," as defined in Rule 144 under the Securities Act. Shares purchased by affiliates may generally only be sold pursuant to an effective registration statement under the Securities Act or in compliance with Rule 144.

The remaining 35,435,940 shares of our common stock are "restricted," which means they were originally sold in offerings that were not subject to a registration statement filed with the SEC. These restricted shares may generally be resold only through registration under the Securities Act or under an available exemption from registration, such as provided by Rule 144.

Lock-Up Agreements

All officers and directors and holders of substantially all of our outstanding common stock have entered into contractual "lock-up" agreements, and stockholders holding approximately 44% of our outstanding shares have entered into additional contractual "lock-up" agreements, each as described in "Underwriting." As a result of these contractual restrictions, notwithstanding possible earlier eligibility for sale under the provisions of Rules 144 and 701, 19,458,919 additional shares will be available for sale beginning 181 days after the date of this prospectus, 3,420,928 additional shares will be available for sale beginning 271 days after the date of this prospectus, 4,276,160 additional shares will be available for sale beginning 361 days after the date of this prospectus, 4,276,160 additional shares will be available for sale beginning 451 days after the date of this prospectus and 4,276,162 additional shares will be available for sale beginning 541 days after the date of this prospectus, subject in some cases to certain volume limitations.

Rule 144

In general, under Rule 144, as amended, a person (or persons whose shares are required to be aggregated) who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, 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 those shares, subject only to the availability of current public information about us.

A person (or persons whose shares are aggregated) who is deemed to be an affiliate of ours and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of common shares then outstanding, which will equal approximately 427,959 shares immediately after this offering (based upon shares outstanding as of May 30, 2014 and assuming no exercise of the underwriters' option to purchase additional shares and no outstanding options or warrants); or
- the average weekly trading volume of our common shares on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales are also subject to certain manner of sale provisions, notice requirements and the availability of current public information about us.

Table of Contents

Rule 701

Subject to certain limitations on the aggregate offering price of a transaction and other conditions, Rule 701 permits resales of shares issued prior to the date the issuer becomes subject to the reporting requirements of the Exchange Act, pursuant to certain compensatory benefit plans and contracts commencing 90 days after the issuer becomes subject to the reporting requirements of the Exchange Act, in reliance upon Rule 144 but without compliance with certain restrictions, including the holding period requirements. In addition, the SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of these options, including exercises after the date the issuer becomes so subject. Securities issued in reliance on Rule 701 are restricted securities and subject to the contractual restrictions described above, beginning 90 days after the date of this prospectus, may be sold by persons other than "affiliates" subject only to the manner of sale provisions of Rule 144 and by "affiliates" under Rule 144 without compliance with its one-year minimum holding period requirement.

S-8 Registration Statement

We intend to file a registration statement on Form S-8 under the Securities Act covering the shares of common stock subject to outstanding options or reserved for issuance under our various stock option plans. Upon the effectiveness of this registration statement, all of these shares will, subject to Rule 144 volume limitations applicable to affiliates, be available for sale in the open market, except to the extent that these shares are subject to vesting restrictions or the contractual restrictions described above.

Registration Rights

After the closing of this offering, the holders of 799,676 shares of our common stock will be entitled to certain rights with respect to the registration of such shares under the Securities Act. If we register any securities for public sale other than for our initial public offering, these holders will have the right to include their shares in the registration statement. In an underwritten offering, we have agreed to use our best efforts to cause the shares to be included in the underwriting on the same terms and conditions as the securities being sold through any such underwriters. We have agreed to indemnify the holders of this registration right against liabilities under the Securities Act, the Exchange Act, or other federal or state securities laws.

Table of Contents

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following is a summary of the material U.S. federal income tax consequences of the ownership and disposition of our common stock to non-U.S. holders, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. We have not sought any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance the IRS will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any foreign, state or local jurisdiction or any U.S. federal non-income tax laws other than U.S. federal estate tax laws to the limited extent described below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

banks, insurance companies, or other financial institutions;

persons subject to the alternative minimum or net investment income tax;

tax-exempt organizations;

controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;

dealers in securities or currencies;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;

persons that own, or are deemed to own, more than five percent of our common stock (except to the extent specifically set forth below);

certain former citizens or long-term residents of the U.S.;

persons who hold our common stock as a position in a "hedging transaction," "straddle" "conversion transaction" or other risk reduction transaction;

persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code; or

persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

YOU ARE URGED TO CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR SITUATION, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, FOREIGN, OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder if you are a holder other than a partnership or other entity classified as such for U.S. federal income tax purposes that, for U.S. federal income tax purposes, is not a U.S. person. For purposes of this discussion, you are a U.S. person if you are:

an individual citizen or resident of the U.S.;

Table of Contents

a corporation or other entity taxable as a corporation created or organized in the U.S. or under the laws of the U.S. or any political subdivision thereof or otherwise treated as such for U.S. federal income tax purposes;

an estate whose income is subject to U.S. federal income tax regardless of its source; or'

a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (y) which has made an election to continue to be treated as a U.S. person.

Distributions

We do not plan to make any distributions on our common stock in the foreseeable future. If we do make future distributions on our common stock (other than certain pro rata distributions of our common stock), however, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock.

Any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business (and, if an income tax treaty applies, that are attributable to a permanent establishment (or, if you are an individual, a fixed base) maintained by you in the U.S.) are exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

If you are eligible for a reduced rate of withholding tax pursuant to a tax treaty, you may generally obtain a refund of any excess amounts currently withheld if you timely file an appropriate claim for refund with the IRS. If you hold stock through a financial institution or other agent acting on your behalf, you will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dispositions

You generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

the gain is effectively connected with your conduct of a U.S. trade or business (and, if an income tax treaty applies, the gain is attributable to a permanent establishment (or, if you are an individual, a fixed base) maintained by you in the U.S.);

you are an individual who is present in the U.S. for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or

our common stock constitutes a U.S. real property interest by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or your holding period for our common stock.

Table of Contents

We believe that we are not currently and will not become a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, however, there can be no assurance we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and corporate non-U.S. holders described in the first bullet above may also be subject to the 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 the second bullet above, you will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by U.S. source capital losses (even though you are not considered a resident of the U.S.). You should consult any applicable income tax treaties that may provide for different rules.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address and the amount of tax withheld, if any, regardless of whether withholding was required. A similar report is sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence. Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding unless you establish an exemption, for example by properly certifying your non-U.S. status on an IRS Form W-8BEN or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

U.S. Federal Estate Taxes

Common stock owned or treated as owned by an individual who is a non-U.S. person (as specifically defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's 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.

Legislation Affecting Taxation of our Common Stock Held by or through Foreign Entities

Legislation enacted in 2010 generally will impose a U.S. federal withholding tax of 30% on dividends on and the gross proceeds of a disposition of our common stock, paid to a "foreign financial institution" (as specially defined under these rules), 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 the 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) or otherwise establishes an exemption. The legislation also generally will impose a U.S. federal withholding tax of 30% on dividends on and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. An intergovernmental agreement between the U.S. and an applicable non-U.S. country may modify the requirements discussed above. This withholding obligation under this

Table of Contents

legislation with respect to dividends on our common stock will not begin until July 1, 2014 and with respect to the gross proceeds of a sale or other disposition of our common stock will not begin until January 1, 2017. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and foreign tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

Table of Contents

UNDERWRITING

Jefferies LLC, BMO Capital Markets Corp. and Piper Jaffray & Co. 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, the selling stockholder and the underwriters, we and the selling stockholder have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us and the selling stockholder, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Jefferies LLC	
BMO Capital Markets Corp.	
Piper Jaffray & Co.	
Needham & Company, LLC	
Total	7,360,000

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 and the selling stockholder have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us and the selling stockholder 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 $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us and the selling stockholder. 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	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$
Proceeds, before expenses, to the selling stockholder	$	$	$

Table of Contents

Our portion of the expenses of the offering, which will include those incurred by the selling stockholder other than the underwriting discount, fees and disbursements of counsel for the selling stockholder and any transfer taxes, are estimated at $3,608,818, which includes an amount not to exceed $50,000 that we have agreed to reimburse the underwriters for certain FINRA-related expenses incurred by them in connection with this offering.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,104,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We and the selling stockholder, our executive officers and directors and substantially all of our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus, or the restricted period, without first obtaining the written consent of the underwriters. Stockholders holding approximately 44% of our outstanding shares have executed an additional lock-up agreement pursuant to which such security holders' securities are subject to a restricted period of 540 days, as follows: (i) 95% of such securities are restricted for 270 days, (ii) 75% of such securities are restricted for 360 days, (iii) 50% of such securities are restricted for 450 days and (iv) 25% of such securities are restricted for 540 days, each as measured from the date of this prospectus, and any sales or transfers during this restricted period require the written consent of each of Jefferies LLC and BMO Capital Markets Corp. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

offer, pledge, sell or contract to sell any common stock,

sell any option or contract to purchase any common stock,

purchase any option or contract to sell any common stock,

grant any option, right or warrant for the sale of any common stock,

lend or otherwise dispose of or transfer any common stock,

request or demand that we file a registration statement related to the common stock, or

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

These lock-up provisions apply to common stock and to securities convertible into or exchangeable or exercisable for common stock, whether owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The restrictions described in the second preceding paragraph shall not apply to:

the sale and transfer of shares of common stock to the underwriters pursuant to the terms of the underwriting agreement;

the issuance of shares of common stock by us upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof, *provided* that such securities will be subject to the lock-up restrictions described in the second preceding paragraph;

the disposition by us of shares of common stock or options to purchase common stock granted pursuant to existing employee benefit plans, *provided* that such securities will be subject to the lock-up restrictions described in the second preceding paragraph;

Table of Contents

the transfer of shares of common stock or any securities convertible into or exercisable or exchangeable for common stock (i) as a *bona fide* gift or gifts, (ii) to any immediate family of a security holder or to any trust for the direct or indirect benefit of the security holder or the immediate family of the security holder, (iii) if the security holder is a corporation, partnership or other business entity, as a distribution to limited partners, members or stockholders or other equity holders of the security holder (or their equivalents under the jurisdiction of organization of the security holder), (iv) if the security holder is a trust, to the beneficiaries of the security holder, (v) if the security holder is a corporation, partnership or other business entity, to the security holder's affiliates, (vi) pursuant to a qualified domestic order or in connection with a divorce settlement; or (vii) by will or intestate succession upon the death of the security holder, *provided* that in each case (1) the representatives receive a signed lock-up agreement for the balance of the restricted period from each donee, trustee, distributee, or transferee, as the case may be, (2) any such transfer shall not involve a disposition for value, (3) such transfers are not required to be reported on Form 4 in accordance with Section 16 of the Exchange Act during the restricted period and (4) the security holder does not otherwise voluntarily effect any public filing or report regarding such transfers during the restricted period;

the sale of shares of common stock purchased by a security holder on the open market following completion of the public offering if and only if (i) such sales are not required to be reported in any public report or filing during the restricted period and (ii) the security holder does not otherwise voluntarily effect any public filing or report regarding such sales during the restricted period;

the exercise of any rights to purchase (including by means of a "cashless exercise"), exchange or convert any stock options granted pursuant to our equity incentive plans, warrants or any other securities convertible into or exchangeable or exercisable for shares of common stock, *provided* that (i) the shares of common stock received upon such exercise, exchange or conversion shall remain subject to the terms of the lock-up and (ii) if the security holder is required to file a report under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of common stock during the restricted period, the security holder shall include a statement in such report to the effect that such transfer was not a disposition for value;

the establishment of a contract, instruction or trading plan, or a 10b5-1 Plan, that complies with the requirements of Rule 10b5-1(c)(1) under the Exchange Act at any time during the restricted period, *provided* that, during the restricted period, (i) the security holder shall not transfer any of the common stock or other securities under such 10b5-1 Plan and (ii) no public announcement or disclosure of entry into such 10b5-1 Plan is made or required to be made during the restricted period, including any filing under Section 16 of the Exchange Act;

the repurchase of securities by us in connection with the termination of a security holder's employment with us; and

the disposition of shares of common stock to us in a transaction exempt from Section 16(b) of the Exchange Act solely in connection with the payment of taxes due in connection with the current vesting of restricted stock (with such number of shares not to exceed that having a fair market value sufficient to fund the payment of such taxes), *provided* that if the security holder is required to file a report under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of common stock during the restricted period, the security holder shall include a statement in such report to the effect that such transfer was not a disposition for value.

Nasdaq Global Market Listing

We have applied to list our common stock on the Nasdaq Global Market under the symbol "AMPH."

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, the selling stockholder and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are

154

Table of Contents

- 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 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 may not develop. It is also possible that after the offering the shares 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

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

In connection with the offering, the underwriters may purchase and sell 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 the 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 their option to purchase additional shares 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 the option granted to them. "Naked" short sales are sales in excess of such 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 the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. 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

155

Table of Contents

engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

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

In addition, in the ordinary course of their business activities, the underwriters and their 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. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area, each, a Relevant Member State, no offer of shares may be made to the public in that Relevant Member State other than:

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; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require us, the selling stockholder or the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the selling stockholder, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a

Table of Contents

prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for us, the selling stockholder or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither we, the selling stockholder nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for us, the selling stockholder or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression "an offer to the public" in relation to any shares 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 the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or 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 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, us, or the 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 shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid

Table of Contents

and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, who we refer to as the Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The securities have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Table of Contents

Notice to Prospective Investors in 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 Non-CIS Securities may not be circulated or distributed, nor may the Non-CIS Securities 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, or 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.

Where the Non-CIS Securities 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,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the Non-CIS Securities pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Table of Contents

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by K&L Gates LLP, Irvine, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California.

EXPERTS

The consolidated financial statements of Amphastar Pharmaceuticals, Inc. at December 31, 2013 and December 31, 2012, and for each of the three years in the period ended December 31, 2013, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock offered in this prospectus. This prospectus, filed as part of the registration statement, does not contain all of the information set forth in the registration statement and its exhibits and schedules, portions of which have been omitted as permitted by the rules and regulations of the SEC. For further information about us and our common stock, we refer you to the registration statement and to its exhibits and schedules. Statements in this prospectus about the contents of any contract, agreement or other document are not necessarily complete and, in each instance, we refer you to the copy of such contract, agreement or document filed as an exhibit to the registration statement, with each such statement being qualified in all respects by reference to the document to which it refers. Anyone may inspect and copy the registration statement and its exhibits and schedules at the Public Reference Room the SEC maintains at 100 F Street, NE, Washington, D.C. 20549. You may obtain further information about the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. You may also inspect the registration statement and its exhibits and schedules and other information without charge at the website maintained by the SEC. The address of this site is http://www.sec.gov.

We do not presently file periodic reports with the SEC, however, upon completion of this offering, we will become subject to the informational requirements of the Exchange Act and will be required to file reports, proxy statements and other information with the SEC. You will be able to inspect and copy these reports, proxy statements and other information at the Public Reference Room maintained by the SEC at the address noted above, and at the SEC's website http://www.sec.gov. We intend to furnish our stockholders with annual reports containing audited financial statements and make available quarterly reports containing unaudited financial statements. Our website address is www.amphastar.com. The contents of our website are not part of this prospectus and you should not consider the contents of our website in making an investment decision regarding our common stock.

Table of Contents

Index to Consolidated Financial Statements

Amphastar Pharmaceuticals, Inc. Consolidated Financial Statements

Table of Contents

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Amphastar Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Amphastar Pharmaceuticals, Inc. (the Company) as of December 31, 2012 and 2013 and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Amphastar Pharmaceuticals, Inc. at December 31, 2012 and 2013 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Los Angeles, California
April 3, 2014