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

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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)

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650 Page Mill Road
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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.

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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.

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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.

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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

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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,

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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.

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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;

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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.

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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.

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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.

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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.

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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.

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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.

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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

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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

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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

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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.

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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

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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.

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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;

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- 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.

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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

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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

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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

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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.

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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.

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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.

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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

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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

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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

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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.

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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.

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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

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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.

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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

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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;

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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

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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.

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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.

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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.

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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.

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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

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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.

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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.

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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

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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

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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.

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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

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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.

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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

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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.

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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.

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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.

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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

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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.

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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.

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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.

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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.

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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.

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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

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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.

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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

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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