Amphastar Pharmaceuticals, Inc.
Form 10-K
March 26, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2014

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from ____ to _____

Commission File Number 001-36509

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

Delaware	33-0702205
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11570 6th Street,
Rancho Cucamonga, CA 91730
(Address of principal executive offices, including zip code)

(909) 980-9484
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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. (Check one):

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

Aggregate market value of registrant's common stock held by non-affiliates of the registrant on June 30, 2014, based upon the closing price of Common Stock on such date as reported by NASDAQ Global Select Market, was approximately $430,686,276. Shares of common stock known to be owned by directors and executive officers of the Registrant subject to Section 16 of the Securities Exchange Act of 1934 are not included in the computation. No determination has been made that such persons are "affiliates" within the meaning of Rule 12b-2 under the Exchange Act.

At March 18, 2015, there were 44,564,667, shares of the registrant's Common Stock outstanding.

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Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of its fiscal year to which this report relates in connection with its 2015 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" that involve substantial risks and uncertainties. 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," "c 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;
- our beliefs about and objectives for future operations;
- 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;
- future acquisitions or investments;
- our ability to expand internationally;

- economic and industry trends and trend analysis;

- 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; and

- our financial performance expectations, including our expectations regarding our revenue, cost of revenue, gross profit or gross margin, operating expenses, including changes in research and development, sales and marketing and general and administrative expenses, and our ability to achieve and maintain future profitability.

You should read this Annual Report and the documents that we reference elsewhere in this Annual Report 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 in this Annual Report, particularly in Part I. Item 1A. “Risk Factors.” These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report regardless of the time of delivery of this Annual Report. 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 Annual Report.

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Item 1. Business.

Overview

Amphastar Pharmaceuticals, together with its subsidiaries (collectively "Amphastar," "the Company," "we," "our," and "us"), is a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically-challenging generic and proprietary injectable and inhalation products. Additionally, in 2014, we commenced sales of insulin active pharmaceutical ingredient, or insulin API, products. We currently manufacture and sell 17 products and are developing a portfolio of 13 generic and eight proprietary injectable and inhalation product candidates. For the years ended December 31, 2014, 2013, and 2012, we recorded net revenues of $210.5 million, $229.7 million, and $204.3 million, respectively. We recorded a net loss of $10.7 million for the year ended December 31, 2014 and recorded net income of $11.9 million and $18.1 million for the years ended December 31, 2013 and 2012, respectively.

Our largest product by net revenues is currently enoxaparin sodium injection, the generic equivalent of Sanofi S.A.'s Lovenox®. Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant and is indicated for multiple indications including the prevention and treatment of deep vein thrombosis. We commenced sales of our enoxaparin product in January 2012, and for the years ended December 31, 2014, 2013, and 2012, we recognized net revenues from the sale of our enoxaparin product of $107.5 million, $145.9 million, and $127.7 million, respectively. We believe that our enoxaparin product demonstrates our capabilities in characterizing complex molecules (which is a process that involves a determination of physiochemical properties, biological activity, immunochemical properties and purity), developing therapeutically equivalent generic versions of drugs with large, complex molecules and meeting regulatory requirements.

In addition to our currently marketed products, we have a pipeline of 21 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. In 2013, we filed an NDA for Primatene® Mist HFA. In May 2014, we received a complete response letter, or CRL, from the FDA, which required 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, the CRL 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 and accordingly, we believe this condition for approval has been satisfied. We met with the FDA in October 2014 to discuss preliminary data results and to clarify the FDA requirements for further studies. We are in the process of generating the remaining data required by the CRL and plan to 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 candidate or approval at all.

Our Amphadase® product candidate is a bovine-sourced hyaluronidase injection. We received approval of our NDA for Amphadase® from the FDA in 2004, but we 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 can be no assurance that we will receive approval for this or any of our other product candidates.

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

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

leverage our research and development capabilities;

require raw materials or an API for which we believe we have a competitive advantage in sourcing, synthesizing or manufacturing; and/or

improve upon an existing drug's formulation with respect to drug delivery, safety and/or efficacy.

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

To complement our internal growth and expertise, we have made several strategic acquisitions of companies, products and technologies. We believe that 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.

Our Markets

We primarily target products with high technical barriers to market entry, with a particular focus on the injectable and inhalation markets. We also target the manufacture and sale of certain APIs.

Injectable market. Based on an IMS Health National Sales Perspective Report, the U.S. generic injectable drug market in 2014 was approximately $8.0 billion, of which our generic development portfolio is targeting over $5.0 billion. The injectable market requires highly technical manufacturing capabilities and compliance with strict cGMP requirements, which create high barriers to market entry. Due to these high barriers to market entry, there are a limited number of companies with the technology and experience needed to manufacture injectable products. There have also been a number of quality issues over the past several years that have disrupted the ability of certain injectable manufacturers to produce sufficient product quantity to meet market demand. As such, the supply of injectables has been constrained, even as demand for injectable products has continued to increase.

Inhalation market. Based on an IMS Health National Sales Perspective Report, the U.S. inhalation drug market in 2014 was approximately $21.9 billion, of which our generic development portfolio is targeting over $9.0 billion. Inhalation drug therapy is used extensively to treat respiratory conditions such as asthma and chronic obstructive pulmonary disease. The MDI is the most widely used device to deliver inhalation therapies. It uses pressurized gas, historically chlorofluorocarbons, or CFCs, and more recently hydrofluoroalkanes, or HFAs, to release its dose when the device is activated by the patient. The DPI, which does not rely on a propellant, is also widely used. As in the case of injectables, there are significant technical barriers to manufacturing inhalation products. The evolution of inhalation delivery technologies from nebulizers and CFCs to HFAs and DPIs has required manufacturers of inhalation products to re-formulate their products, which in many cases may require technical engineering capabilities, additional regulatory approvals and modified delivery devices. Additionally, the development of generic HFA and DPI products will require bioequivalence studies for FDA approval.

Our Strengths

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

Robust portfolio of products and product candidates. Including our enoxaparin product, we have 17 commercial products and 21 product candidates at different stages of development. We also continue to develop our product candidates, which represent our longer-term growth opportunities.

Advanced technical capabilities and multiple delivery technologies. We have developed several advanced technical capabilities that we incorporate into the development of our products and product candidates, including characterization of complex molecules, peptide and protein analysis, immunogenicity studies, particle engineering and sustained-release technology. In addition, we apply these capabilities across our injectable and inhalation

delivery technologies. Our injectable delivery technologies enable us to develop and manufacture generic and proprietary injectables in normal solution, lyophilized, suspension, jelly and emulsion forms, as well as in pre-filled syringes. Our inhalation technologies cover a variety of delivery methods, including DPIs and HFA formulations of MDIs. These technical capabilities form the foundation for our strategy to develop products with high barriers to market entry targeting a wide range of indications.

Vertically integrated infrastructure. We are a vertically integrated company with the demonstrated ability to advance a product candidate from the research stage through commercialization. Our capabilities include strong research and development expertise, sophisticated pharmaceutical engineering capabilities, comprehensive manufacturing capabilities, including the ability to synthesize and manufacture our own API, a strict quality assurance system, extensive regulatory and clinical experience and established marketing and distribution relationships. We believe our vertical integration allows us to achieve better operating efficiencies, accelerated product development and internal control over product quality.

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

Our Strategy

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

Diversify our revenues by commercializing our product candidates. Assuming we are successful in developing and obtaining regulatory approvals, we plan to commercialize our product candidates and thereby diversify our sources of revenues. We have 21 product candidates in various stages of development, including 13 generic product candidates and eight proprietary product candidates. We also expect to expand our internal sales and marketing capabilities and, in some cases, enter into strategic alliances with other pharmaceutical companies, to drive market penetration for our product candidates.

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

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

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

Target and integrate acquisitions of pharmaceutical companies, products and technologies. We have a demonstrated ability to identify, acquire and integrate pharmaceutical companies, products and technologies to complement our internal product development capabilities. We have acquired International Medication Systems, Limited, or IMS, Armstrong Pharmaceuticals, Inc., or Armstrong, Nanjing Puyan Pharmaceutical Technology Co., Ltd. (which we renamed Amphastar Nanjing Pharmaceuticals Co., Ltd.), or ANP, and Merck's API Manufacturing Business in Éragny-sur-Epte, France, in connection with which, we established our French subsidiary, Amphastar France Pharmaceuticals, S.A.S., or AFP. Products we have acquired include Cortrosyn® and Epinephrine Mist, and trade names such as Primatene® Mist. We believe that our scientific and managerial expertise and our integration

experience have improved the quality of the product lines and companies that we have acquired, which has had, and we believe will continue to have, a positive effect on our results of operations. For example, if approval is received from the FDA, we plan to have our acquired subsidiary ANP provide us with access to certain raw materials for the manufacture of the API for our enoxaparin product and eventually to manufacture API for our other products and product candidates.

Our Technical Capabilities

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

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

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

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

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

Immunogenicity. The ability of an antigen to elicit immune responses is called immunogenicity. Unwanted immunogenicity, which is strongly linked with protein drug products, occurs when a patient mounts an undesired immune response against a drug therapy. As a result, the FDA has signaled that they may require immunogenicity studies as part of the new pathway for biosimilars and biogenerics, and in the past the FDA has required these studies in connection with the approval of products with complex molecules. We gained expertise in immunogenicity by performing immunogenicity studies in connection with the FDA approval process for our enoxaparin product. We believe that our experience in conducting these difficult immunogenicity studies will be of primary importance in our future efforts to develop complex molecules, biosimilar and biogeneric product candidates.

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

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

Sustained-release. We have developed technology aimed at improving drug delivery through sustained-release injectable products. The purpose of our sustained-release technology is to create products that require less dosing

frequency and that we believe can diminish the fluctuations of drug concentrations in a patient's blood stream that otherwise require more frequent dosing. We plan to use our sustained-release technology to develop both generic and proprietary products.

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Business Segments

Our performance will be assessed and resources will be allocated based on the following two reportable segments: (1) finished pharmaceutical products and (2) active pharmaceutical ingredients, or API products. The finished pharmaceutical products segment currently manufactures, markets and distributes enoxaparin, Cortrosyn®, naloxone, lidocaine jelly, as well as, various other critical and non-critical care drugs. The API segment currently manufactures and distributes recombinant human insulin and porcine insulin. Information reported herein is consistent with how it is reviewed and evaluated by our chief operating decision maker. Factors used to identify our segments include markets, customers and products.

For more information regarding our segments, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Segment Information."

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Finished Pharmaceutical Product Segment

Our Marketed Products

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

Enoxaparin

Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant which is indicated for multiple indications, including the prevention and treatment of deep vein thrombosis. Enoxaparin is difficult to produce in part because the API is not easily obtained or manufactured. We manufacture the API for our enoxaparin product and perform all subsequent manufacturing of the finished product in-house. We believe that it will be difficult for other companies to obtain or manufacture the API and prove "sameness." In January 2012, we commenced sales of our enoxaparin product. For the years ended December 31, 2014, 2013, and 2012, we recorded net revenues from enoxaparin of $107.5 million, $145.9 million, and $127.7 million, respectively.

Other Marketed Products

We have 14 other products that we currently market. Other marketed products include Cortrosyn® (cosyntropin for injection), a lyophilized powder that is indicated for use as a diagnostic agent in the screening of patients with adrenocortical insufficiency, lidocaine jelly, a local anesthetic product used primarily for urological procedures and our portfolio of emergency syringe products, which include critical care drugs, such as atropine, calcium chloride, dextrose, epinephrine, lidocaine, naloxone and sodium bicarbonate, which are provided in pre-filled syringes and are designed for emergency use in hospital settings. We also manufacture and sell phytonadione injection for newborn use, lidocaine topical solution for use as a local anesthetic, morphine, epinephrine in vial form and a lorazepam injection. For the years ended December 31, 2014, 2013, and 2012, we recorded net revenues from these other marketed products of $103.0 million, $83.8 million, and $76.6 million, respectively.

Our Product Candidates

We seek to develop product candidates with high technical barriers to market entry that leverage our technical capabilities and competitive advantages. We are focused on both generics and proprietary product candidates in the injectable and inhalable markets. The product candidates in our pipeline are in various stages of development, with a number of these candidates still in early stages of development. We currently have 21 product candidates in our pipeline, including 13 generic product candidates and eight proprietary product candidates.

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

Generic Product Candidates

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

injectable technologies, which include various delivery methods and sizes of pre-filled syringes, vials in solution, jelly, suspension and lyophilized forms;

inhalation technologies, which include MDIs, nasal and DPIs; and

sophisticated analytical technologies, which include characterization and immunogenicity studies for complex molecules, particle engineering, sustained-release technology and peptide, protein and DNA analysis.

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

			Applied Technical Capability				
Delivery Technology	Number of Candidates	Therapeutic Area	Characterization	Immunogenicity	Particle Engineering	Sustained-Release	Peptide and Protein Technology
Injectable	5	Endocrinology	P	P		P	P
Injectable	1	Hematology	P				
Injectable	1	Reproductive System	P			P	
Inhalation	6	Respiratory	P		P		

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

Proprietary Product Candidates

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

With respect to our proprietary pipeline strategy, we currently have eight proprietary drug candidates at various development stages that leverage our various technical capabilities. The following table summarizes our proprietary product candidates for which NDAs have been filed with the FDA.

			Applied Technical Capability				
Delivery Technology	Candidates	Therapeutic Indication	Characterization	Immunogenicity	Particle Engineering	Sustained-Release	Peptide and Protein Technology
Inhalation	Primatene® Mist HFA	Asthma			P		
Injectable	Amphadase®	Anesthetic Adjuvant	P				P

Primatene® Mist HFA

Primatene® Mist HFA, an over-the-counter epinephrine inhalation product candidate, is intended to be used for the temporary relief of mild symptoms of intermittent asthma. We developed Primatene® Mist HFA to replace the over-the-counter CFC formulation of our Primatene® Mist product which was withdrawn for environmental reasons under the Montreal Protocol. We acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene® Mist, and the associated CFC inventory, from Wyeth Consumer Healthcare Division in 2008 for $33.1 million. At the time of the transaction the Environmental Protection Agency was reviewing a possible ban on all CFC formulated products. In our first full year of sales of the CFC formulation of Primatene® Mist, we generated cash flows from sales of the product in excess of the purchase price. We filed an investigational new drug application, or IND, for Primatene® Mist HFA for mild symptoms of intermittent asthma in October 2009.

We filed an NDA for Primatene® Mist HFA in 2013. In February 2014, the FDA held a joint meeting of the Nonprescription Drugs Advisory Committee and its Pulmonary Allergy Drugs Advisory Committee, which we refer to as the Committee, to discuss the NDA for Primatene® Mist HFA. The Committee voted 14 to 10 that the data in the NDA supported efficacy, but voted 17 to 7 that safety had not been established for the intended over-the-counter use. The Committee also voted 18 to 6 that the product did not have a favorable risk-benefit profile for the intended over-the-counter use, and individual Committee members provided recommendations for resolving their concerns. On May 22, 2014, we received a CRL from the FDA, which required 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 and accordingly, we believe this condition for approval has been satisfied. We met with the FDA in October 2014 to discuss preliminary data results and to clarify the FDA requirements for further studies. We are in the process of generating the remaining data required by the CRL and plan to 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 candidate or approval at all.

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Amphadase® (Hyaluronidase Injection)

Amphadase® is a bovine-sourced hyaluronidase injection. Other formulations of hyaluronidase injection include Vitrase and Hylenex which are marketed by Bausch & Lomb and Halozyme, respectively. We received our NDA approval for Amphadase® in 2004, but we discontinued the product in 2009 due to a lack of API supply. We filed an IND in February 2004 for Amphadase® as an adjuvant in subcutaneous fluid administration for achieving hydration, to increase absorption and dispersion of other injected drugs, and in subcutaneous urography for improving absorption of radiopaque agents. We reactivated this IND in April 2012 to allow studies of the new API, which is to be supplied by us. We filed an NDA supplement in December 2013 to qualify such API. In April 2014, our China facility was subject to an inspection by the FDA. The inspection resulted in multiple observations on Form 483, an FDA form on which deficiencies are noted after an FDA inspection. We believe we have addressed the FDA's concerns in our initial response in May 2014 and with data provided in October 2014. We are currently awaiting approval from the FDA.

Other Proprietary Product Candidates

In addition to Primatene® Mist HFA and Amphadase®, we have six other proprietary product candidates in development, which include two new chemical entity drug candidates. These proprietary product candidates target indications including diabetes, asthma, anticoagulants, osteoporosis and Alzheimer's disease. These product candidates incorporate a wide variety of our technical capabilities, such as particle engineering, sustained-release technology and peptide and protein analysis and utilize our inhalation and injectable delivery technologies.

API Segment

We began to manufacture and sell two products recombinant human insulin, or RHI, API and porcine insulin API as a result of our acquisition of Merck Sharpe & Dohme's, or Merck's, API manufacturing business in Éragny-sur-Epte, France, or the Merck API Transaction, in April 2014. In July 2014, we entered into a supply agreement with MannKind Corporation, or MannKind to supply them with RHI for use in their product Afrezza®, and in January 2015 we entered to a supply option agreement to supply additional quantities, as needed.

Acquisition of Merck's API Manufacturing Business

On April 30, 2014, we completed our acquisition of the Merck API Transaction, which manufactures porcine insulin API and recombinant human insulin API. The purchase price of the transaction totaled €24.8 million, or $34.4 million on April 30, 2014, subject to certain customary post-closing adjustments and currency exchange fluctuations. The terms of the purchase include multiple payments over four years as follows:

	Euros	U.S. Dollars
	(in thousands)	
At Closing, April 2014	€ 13,252	$ 18,352
December 2014	4,899	5,989
December 2015	3,186	3,873
December 2016	3,186	3,873
December 2017	500	607
	€ 25,023	$ 32,694

In order to facilitate the acquisition, we established a subsidiary in France, AFP. We will continue the current site manufacturing activities, which consist of the manufacturing 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 under which Merck was operating at this facility. In addition, certain existing customer agreements have been assigned to AFP.

Supply Agreement with MannKind Corporation

On July 31, 2014, we entered into a supply agreement with MannKind, pursuant to which we will manufacture for and supply to MannKind certain quantities of recombinant human insulin, or RHI, for use in MannKind's product Afrezza®. Under the terms of the supply agreement, we will be responsible for manufacturing the RHI in accordance with MannKind's specifications and agreed-upon quality standards. MannKind has agreed to purchase annual minimum quantities of RHI under the supply agreement of an aggregate amount of approximately €120.1 million, or approximately $146.0 million, in calendar years 2015 through 2019. MannKind paid a non-refundable reservation fee to us in the amount of €11.0 million, or approximately $14.0 million. Under the agreement, the non-refundable reservation fee is considered as partial payment for the purchase commitment quantity for 2015. We classified the amount as deferred revenue.

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Unless earlier terminated, the term of the supply agreement expires on December 31, 2019 and can be renewed for additional, successive two-year terms upon 12 months' written notice given prior to the end of the initial term or any additional two-year term. MannKind and we each have customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy, or insolvency of the other party. In addition, MannKind may terminate the supply agreement upon two years' prior written notice to us without cause or upon 30 days prior written notice to us if a controlling regulatory authority withdraws approval for Afrezza®; provided, however, in the event of a termination pursuant to either of these scenarios, the provisions of the supply agreement require MannKind to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

In January 2015, we entered into a supply option agreement with MannKind, pursuant to which MannKind will have the option to purchase RHI, for use in MannKind's product Afrezza®, in addition to the amounts specified in the July 2014 supply agreement. Under the agreement, MannKind has the option to purchase additional RHI in calendar years 2016 through 2019. In the event MannKind elects not to exercise its minimum annual purchase option for any year, MannKind shall pay us a capacity cancellation fee.

Research and Development

We have approximately 217 employees dedicated to research and development with expertise in areas such as pharmaceutical formulation, process development, toxicity studies, analytical, synthetic and physical chemistry, drug delivery, device development, equipment and engineering, clinical research statistical analysis, etc. Our focus on developing products with high barriers to market entry requires a significant investment in research and development, including clinical development. In particular, developing proprietary products that are reformulations of existing proprietary compounds often requires clinical trials to gain regulatory approval, and we have a team dedicated to designing and managing clinical trials. We have successfully completed several clinical trials for some of our product candidates and are in the process of planning clinical trials for other product candidates under development.

We have made, and will continue to make, substantial investments in research and development. Research and development costs for the years ended December 31, 2014, 2013 and 2012 were $28.4 million, $33.0 million, and $31.2 million, respectively, which represent 14%, 14% and 15% of our net revenues for that period, respectively.

Backlog

A significant portion of our customer shipments in any fiscal year relate to orders received and shipped in that fiscal year, resulting in low product backlog relative to total shipments. Backlog is not material and not a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

Manufacturing and Facilities

Our manufacturing facilities are located in Rancho Cucamonga and South El Monte, California; Canton, Massachusetts; Éragny-sur-Epte, France; and Nanjing, China. We own or lease a total of 60 buildings at six locations in the U.S., France and China, that comprise 1.44 million square feet of manufacturing, research and development, distribution, packaging, laboratory, office and warehouse space. Our facilities are regularly inspected by the FDA in connection with our product approvals, and we believe that all of our facilities are being operated in material compliance with the FDA's cGMP regulations.

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

We acquired Merck's API manufacturing business in Éragny-sur-Epte, France in April 2014, which manufactures porcine insulin API and RHI API, and we expect to continue the current site activities.

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

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Raw Material and Other Suppliers

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

If our suppliers encounter problems during manufacturing, establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Further, a significant portion of our raw materials may be available only from foreign sources, which are subject to the special risks of doing business abroad. For example, heparin USP is the starting material for the production of the API in our enoxaparin product. We have established a supply chain for heparin that originates in China and have implemented validated technology processes designed to screen and test incoming starting material, which includes methods currently required by the FDA. However, the FDA has required companies importing heparin to test imported heparin using specific screening methods to detect certain contaminants and it has increased its scrutiny of Chinese facilities that produce heparin for the U.S. market. For example, in August 2008, the FDA inspected two facilities in China belonging to suppliers in our heparin supply chain and issued warning letters, one of which needed to be resolved as a precondition to approving the ANDA for our enoxaparin product candidate in September 2011. If the facility owned by our ANP subsidiary is qualified by the FDA, we plan to have ANP provide us with starting materials for the manufacture of API for enoxaparin. We also plan to have our subsidiary eventually manufacture APIs for not only enoxaparin, but also our other products and product candidates.

Sales and Marketing

Our products are primarily marketed and sold to hospitals, long-term care facilities, alternate care sites, clinics and doctors' offices. Most of these facilities are members of one or more group purchasing organizations, which negotiate collective purchasing agreements on behalf of their members. These facilities purchase products through specialty distributors and wholesalers. We have relationships with the major group purchasing organizations in the U.S. We also have relationships with major specialty distributors, wholesalers and retailers who distribute pharmaceutical products nationwide.

The following table provides information regarding the percentage of our net revenues that is derived from each of our major customers and partners:

	% of Net Revenues Year Ended December 31,		
	2014	2013	2012
Actavis, Inc.	30 %	35 %	35 %
AmerisourceBergen Corporation	15 %	15 %	14 %
Cardinal Health, Inc.	14 %	13 %	13 %

McKesson Corporation	22	%	26	%	27	%

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

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

For the years ended December 31, 2014, 2013, and 2012, we generated 4%, 1% and 1% of our total revenue, respectively, from customers located outside of the United States. Other financial information about our segment and geographic areas is incorporated herein by reference to Note 6 of the Notes to Consolidated Financial Statements included elsewhere in this report.

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Competition

The majority of our marketed products are generic products. We face and will face significant competition for our products and product candidates from pharmaceutical companies that focus on the generic injectable and inhalation markets such as Hospira, Inc., Sagent Pharmaceuticals, Inc., Akorn, Inc., Sandoz Inc., Mylan Inc. and Teva Pharmaceutical Industries Ltd. Competition in the generic pharmaceutical industry has increased as producers of branded products have entered the business by creating generic drug subsidiaries, purchasing generic drug companies, or licensing their products to generic manufacturers prior to patent expiration and/or as their patents expire. Therefore, our competitors also include the innovator companies of our generic drug products. For example, enoxaparin is currently marketed by Sanofi S.A., or Sanofi, under the brand name Lovenox®. Sanofi also markets their authorized generic enoxaparin product through their subsidiary, Winthrop. Sandoz also markets a generic version of enoxaparin. Teva Pharmaceuticals Industries Ltd. has received approval from the FDA of its ANDA for its generic enoxaparin product, and Hospira has filed an ANDA with the FDA for its generic version of enoxaparin. 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.

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

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

Government Regulation and Price Constraints

In the United States

General

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

pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control. These applications must also contain data and information related to safety, effectiveness, bioavailability and/or bioequivalence.

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

FDA Approval and Regulatory Considerations

Prescription generic and branded pharmaceutical products are subject to extensive regulation by the FDA under the FFDCA and PHSA and regulations implementing those statutes, with regard to the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of such products, and regulation by other state, federal and foreign agencies under the laws that they enforce. For many drugs (drugs falling within the definition of "new drug" in the FFDCA), including the drugs in our current drug portfolio, FDA approval is required before marketing in the U.S. Applications for FDA drug approval must generally contain, among other things, information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, quality control and either safety and effectiveness or bioequivalence. There are two drug approval processes under the FFDCA — an ANDA approval process for generic drugs and an NDA approval process for new drugs that cannot be approved in ANDAs. For drugs that are "biological products" within the meaning of the PHSA, there are two different approval processes — a biological license application, or BLA, approval process for original biological products and a biosimilar application approval process for biosimilar products that are approved based on their similarity to biologicals that were previously approved in BLAs.

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The ANDA Approval Process

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

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

Generally, if an ANDA applicant (1) files a substantially complete ANDA with a Paragraph IV certification on the first day that any ANDA applicant files an application with such a certification based on the same reference drug and (2) provides appropriate notice to the NDA holder, and all patent owner(s) for a particular generic product, the applicant may be awarded a delay in the approval of other subsequently filed ANDAs with Paragraph IV certifications based on the same reference drug. This statutory delay is commonly referred to as 180-day exclusivity. A substantially complete ANDA is one that contains all the information required by the statute and the FDA's regulations, including the results of any required bioequivalence studies. The FDA may refuse to accept the filing of an ANDA that is not substantially complete or may determine during substantive review of the ANDA that additional information, such as an additional bioequivalence study, is required to support approval. Such a determination may affect an applicant's first to file status and eligibility for 180-day exclusivity. The MMA provides that the 180-day exclusivity delay ends 180 days after the first commercial marketing of the ANDA product. This exclusivity may be forfeited under a number of different circumstances, including: (1) failure to market within certain prescribed periods of time following certain events related to submission of the application, approval of the application, court decisions and settlements and patent withdrawals from the Orange Book; (2) an amendment or withdrawal of the Paragraph IV certification or

certifications upon which the exclusivity was based; (3) failure to obtain tentative approval within certain prescribed time periods (30, 36, or 40 months after submission of the ANDA); (4) an agreement with the NDA holder, patent owner or another ANDA applicant that is determined by a court or the FTC to violate provisions of antitrust laws; (5) withdrawal of the ANDA; or (6) expiration of patent or patents upon which exclusivity is based.

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

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

ANDA approvals can also be delayed by orphan drug exclusivity, pediatric exclusivity and exclusivity for certain new antibiotic drugs. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug, for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or an ANDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued written request for such a study. The FFDCA also provides exclusivity for certain antibiotic drugs for serious or life-threatening infections that FDA designates as “qualified infectious disease products.” This exclusivity extends other exclusivities for the same drug by five years, but does not extend patent-related delays in approval.

The NDA Approval Process

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

The “Full NDA”

The approval process for a full NDA generally involves:

completion of preclinical laboratory and animal testing in compliance with the FDA’s good laboratory practice, or GLP, regulations;

submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must satisfy the FDA and become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the efficacy of the proposed drug product for each intended use;

satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's cGMP regulations; and

submission to and approval by the FDA of an NDA.

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

Phase 1, during which the drug is introduced into healthy human subjects or, on occasion, patients and is tested for safety, stability, dose tolerance and metabolism;

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Phase 2, during which the drug is introduced into a limited patient population to determine the efficacy of the product in specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks; and

Phase 3, during which the clinical trial is expanded to a larger and more diverse patient group at geographically dispersed clinical trial sites to further evaluate the drug and ultimately to demonstrate effectiveness.

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

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

The Section 505(b)(2) NDA

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

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

The Biosimilar Application Approval Process

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

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

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The PHSA provides a number of exclusivity protections for reference products that may delay submission and approval of biosimilar applications. The PHSA delays submission of a biosimilar application until four years after the date on which the reference product was first licensed and delays final approval of a biosimilar application until twelve years after the first licensure of the reference product. The first-licensure requirement precludes an additional period of exclusivity for a supplement to the original application for the reference product. It also precludes exclusivity for an entirely new BLA in certain circumstances. A new BLA submitted by a sponsor or manufacturer of a previously approved biologic would not be protected by exclusivity for (1) a non-structural change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or (2) a structural change that does not result in a change in safety, purity or potency. As in the case of NDAs approved under the FFDCA, BLAs may be entitled to orphan exclusivity and to pediatric exclusivity.

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

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

The BLA Approval Process

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

completion of preclinical laboratory and animal testing in compliance with the FDA’s GLP regulations;

submission to the FDA of an IND for human clinical testing, which must satisfy FDA and become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the efficacy of the proposed drug product for each intended use;

satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA’s cGMP regulations; and

submission to and approval by the FDA of a BLA.

FDA Action on an Application for Approval

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

product based on the results of those studies.

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

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Manufacturing (cGMP) Requirements

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

Other Regulatory Requirements

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

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

record-keeping requirements;

reporting of adverse experiences with the drug;

providing the FDA with updated safety and efficacy information;

reporting on advertisements and promotional labeling;

drug sampling and distribution requirements; and

complying with electronic record and signature requirements.

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

FDA Enforcement Authority

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions (which may in some circumstances involve restitution, disgorgement or profits, recalls and/or total or partial suspension of production or distribution), seizure of products, withdrawal of approvals, refusal to approve pending applications and criminal prosecution of the company and company officials that may result in fines and

incarceration. FDA has authority to inspect manufacturing facilities as well as other facilities in which drug products are held, packaged or stored, to determine compliance with cGMP and other requirements under the FDCA. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals, any one or more of which could have a materially adverse effect on us.

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On February 27 through March 3, 2014, our facility in Rancho Cucamonga, CA was subject to an inspection by the FDA under the Bioresearch Monitoring Program, or BIMO. The inspection covered a clinical trial for one of our pipeline products to establish that Good Clinical Practices were followed during the execution of the trial. The inspection did not result in any observations on Form 483.

On March 31, 2014 through April 4, 2014, our facility in Nanjing, China was subject to an inspection by the FDA. The inspection resulted in multiple observations on Form 483. We responded to those observations on April 25, 2014 providing our corrective action plan as well as corrective actions already implemented. We believe that we have addressed all of the observations and the final follow up response to the FDA was submitted with data supporting our actions in October 2014.

On March 31, 2014 through April 3, 2014, our facility in Canton, MA was subject to a preapproval inspection by the FDA relating to our NDA for Primatene® Mist HFA. The inspection did not result in any observations on Form 483.

From July 9, 2014 through August 8, 2014, our facility in Rancho Cucamonga, CA was subject to an inspection by the FDA. The inspection included a review of current Good Manufacturing Practices, preapproval inspections for two ANDAs currently being reviewed by the FDA, and a review of post-market adverse drug events. The inspections resulted in multiple observations on Form 483. We responded to those observations on September 3, 2014. We believe that our responses to the Form 483 will satisfy the FDA and that no significant further actions will be necessary.

From August 27, 2014 through September 12, 2014, our facility in South El Monte, CA was subject to a current Good Manufacturing Practices inspection by the FDA. The inspections resulted in multiple observations on Form 483. We responded to those observations on October 3, 2014. We believe that our responses to the Form 483 will satisfy the FDA and that no significant further actions will be necessary.

Foreign Regulatory Requirements

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

Prescription Drug Wrap-Up

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

Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA did not challenge the marketing of these drugs without approval. In 1984, however, spurred by serious adverse reactions to one of these products and concerns expressed by Congress, FDA undertook an assessment of the products under an initiative known as the “Prescription Drug Wrap-Up.” Most of these drugs contain

active ingredients that were first marketed prior to the enactment of the FFDCA. Several of our marketed pharmaceutical products fall within this category.

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

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

Fraud and Abuse Laws

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

Federal False Claims Act

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

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

The Sunshine Act

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

Environmental Considerations

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

which could be material.

The costs of complying with various applicable 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.

Prior to the Merck API Transaction, Merck notified us of several items it had identified as part of its own internal auditing that relate to potential minor environmental issues. Merck identified certain issues that did not meet their internal policies and procedures but did not violate any French environmental law or regulation. Merck has agreed to pay for the remediation costs up to a certain dollar amount, after which we will be responsible for any additional costs; however, we expect that remediation costs will remain below that threshold.

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

Other Regulations

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.

Intellectual Property

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

We primarily rely on trade secrets, unpatented proprietary know-how and continuing technological innovation to protect our products and technologies, especially where we do not believe patent protection is appropriate or obtainable. Although in some cases we seek patent protection to preserve our competitive position, our current patent portfolio does not cover the majority of our existing products and product candidates. We own several U.S. and foreign patents covering processes and equipment used in the manufacture of a few of our products. The expiration dates of these patents range from 2020 to 2027.

In addition, we own a United States patent covering Primatene® Mist HFA: United States Patent Number 8,367,734, or the "'734 patent," which was issued on February 5, 2013, and expires in January 2026. Additionally, we have several patent applications that are currently pending in the U.S. and other countries, including China, but which have not yet issued as patents. Accordingly, other than the '734 patent covering Primatene® Mist HFA, none of our significant products or product candidates are covered by any United States or foreign patents related to formulations or compositions. Indeed, many of our products and product candidates are generic products, and therefore may not be eligible for patent protection. For example, our enoxaparin product is a generic product, and as such, it is not covered by any United States or foreign patents. Other of our products, including Amphadase®, are based on compounds for which any applicable patents have expired, or which were not patented by Amphastar in the first instance because they are older compounds. As for the remainder of our product candidates that are not intended to be generic products, these are early stage product candidates currently under development, for which we intend to seek to obtain patent rights or rely on trade secret protection (but in any case, are not currently covered by any United States or foreign patents). In addition, with respect to such product candidates, we may seek patent rights for various potential technology platforms (or rely on trade secret protection), which could apply across multiple product candidates (but again, such potential technology platforms currently are not covered by any United States or foreign patents).

We may not be able to obtain patent or other forms of protection for inventions or other intellectual property developed by our officers, employees, or consultants because we might not have been the first to file or to invent the patentable technology or others may have independently developed similar or alternative technology. We also own several trademarks registered with the USPTO and one trademark registered with the Canadian Intellectual Property Office.

Despite our efforts to protect our proprietary information through the use of confidentiality and non-disclosure agreements, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary. Other parties may also independently develop know-how or obtain unauthorized access to our technologies.

Intellectual property protection is highly uncertain and involves complex legal and factual questions. Our patents and those for which we have or will license rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if a patent application is filed, some or all of the patent claims may not be allowed, the patent itself may not issue, or in the event of issuance, the issued claims may not be sufficient to protect the technology owned by or licensed to us.

Third-party patent applications and patents could reduce the coverage of the patents licensed, or that may be licensed to, or owned by us. If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from the commercialization of products or be required to obtain licenses to these patents or to develop or obtain alternative technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or those of our licensors.

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Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. USPTO interference proceedings may be necessary if we and another party both claim to have invented the same subject matter. Even if we ultimately prevail, we could incur substantial costs and our management's attention would be diverted if:

litigation is required to defend against patent suits brought by third parties;

we participate in patent suits brought against or initiated by our licensors;

we initiate suits against third parties who are infringing on our patents; or

we participate in an interference or other similar USPTO proceeding.

However, even if we pursue litigation or other action to protect our intellectual property rights, we may not prevail in any of these actions or proceedings.

Employees

As of December 31, 2014, we had a total of 1,361 full-time employees.

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 corporate offices are located at 11570 6th Street, Rancho Cucamonga, CA 91730. Our telephone number is (909) 980-9484. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. You can access our filings with the SEC by visiting www.amphastar.com. The information that is contained on, or can be accessed through our website is not incorporated into this Annual Report on Form 10-K, and the inclusion of our website address is an inactive textual reference only.

We use our website as a channel of distribution for important company information. Important information, including press releases, analyst presentations and financial information regarding us, as well as corporate governance information, is routinely posted and accessible on the "Investors" section of the website, which is accessible by clicking on the tab labeled "Investors" on our website home page. Information on or that can be accessed through our website is not part of this Annual Report on Form 10-K, and the inclusion of our website address is an inactive textual reference only.

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Item 1A. 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 Annual Report, including our consolidated financial statements and the related notes thereto. 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 common 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 51%, 64%, and 63% of our total net revenues for the years ended December 31, 2014, 2013, and 2012, 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. Our enoxaparin product could be rendered obsolete or negatively impacted 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.

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 U.S. Food and Drug Administration, or 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 hydrofluoroalkane, or 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.”

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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 abbreviated new drug application, or 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 S.A., or 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.

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 active pharmaceutical ingredient, or 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 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.

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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 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, Teva Pharmaceutical Industries Ltd. has received approval from the FDA of its ANDA for its generic enoxaparin product and Hospira, Inc. has filed an ANDA with the FDA for approval of its generic version. 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.

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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 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 prod