Amphastar Pharmaceuticals, Inc.
Form 10-K
March 15, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016

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

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

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 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 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 (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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2016, based upon the closing price of Common Stock on such date as reported by NASDAQ Global Select Market, was approximately $570,095,519. Shares of common stock known to be held by directors, executive officers and holders of 5% or more of the outstanding common stock of the registrant are not included in the computation. No determination has been made that such persons are "affiliates" of the registrant for any other purpose.

At March 8, 2017, there were 45,910,116, shares of the registrant's common stock outstanding.

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 2017 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," "might," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project" "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements relate to future events or future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by the 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 following termination of our profit sharing agreement with Actavis;
- our expectations regarding our manufacturing and production and the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- the timing and likelihood of FDA approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- our ability to compete in the development and marketing of our products and product candidates;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies, as well as those of our API customers;
- 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 protection for our products and our ability to successfully defend our intellectual property in cases of alleged infringement;
- the implementation of our business strategies, product development strategies and technology utilization;
- the potential for exposure to product liability claims;
- future acquisitions, divestitures or investments, including the anticipated benefits of such acquisitions, divestitures 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;
- our remediation efforts for a material weakness in our internal control over financial reporting; 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

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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 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, and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. 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.

Unless expressly indicated or the context requires otherwise, references in this Annual Report to “Amphastar,” “the Company,” “we,” “our,” and “us” refer to Amphastar Pharmaceuticals, Inc. and our subsidiaries.

Item 1. Business.

Overview

We are a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically challenging generic and proprietary injectable, inhalation, and intranasal products. Additionally, we sell insulin active pharmaceutical ingredient, or insulin API, products. We currently manufacture and sell 19 products including Amphadase®, which we re-launched in the fourth quarter of 2015. Additionally, we are developing a portfolio of 15 generic abbreviated new drug applications, or ANDAs, three generic biosimilar product candidates and six proprietary injectable and inhalation product candidates. For the years ended December 31, 2016, 2015, and 2014, we recorded net revenues of $255.2 million, $251.5 million, and $210.5 million, respectively. We recorded net income of $10.5 million for the year ended December 31, 2016 and recorded a net loss of $2.8 million and $10.7 million for the years ended December 31, 2015 and 2014, 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 has 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, 2016, 2015, and 2014, we recognized net revenues from the sale of our enoxaparin product of $59.3 million, $84.5 million, and $107.5 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), performing sophisticated immunogenicity studies, developing therapeutically equivalent generic versions of drugs with large, complex molecules and meeting regulatory requirements.

We have agreements with established group purchasing organizations and wholesaler networks to distribute enoxaparin, which is marketed under our own label for the hospital and clinic market. For the U.S. retail market, we had an agreement with Actavis Inc., or Actavis, to distribute enoxaparin, which is marketed under Actavis' label. On June 30, 2016, Actavis and Amphastar amended the distribution agreement to, among other things, amend the termination date of such agreement. In December 2016, our distribution agreement was terminated pursuant to such amendment.

In June 2015, we received approval of our new drug application, or NDA, supplement for Amphadase®. This approval marked the first approved starting material from Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP, and signified that our facility located in Nanjing, China had been qualified by the U.S. Food and Drug Administration, or FDA. We re-launched Amphadase® in the fourth quarter of 2015. Amphadase® is competing in the hyaluronidase market and is used for the dispersion and absorption of other injected drugs.

Our pipeline has over 20 generic and proprietary product candidates in various stages of development and targets variety of indications. With respect to these product candidates, we have five ANDAs and two NDAs currently on file with the FDA.

Our product candidate, Primatene® Mist, an over-the-counter epinephrine inhalation product candidate, is intended to be

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used for the temporary relief of mild asthma symptoms. In 2013, we filed an NDA for Primatene® Mist. 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/human factors and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. We submitted a responsive NDA amendment in June 2016 and received another CRL from the FDA in December 2016, which requires additional packaging and label revisions and follow-up studies to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. We intend to continue to work with the FDA during the post-action phase to address their concerns in the CRL and to bring Primatene® Mist back to the over-the-counter market as soon as possible. However, there can be no guarantee that any future amendment to our NDA will result in timely approval of Primatene® Mist or approval at all.

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 pre-filled syringes, vials, 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 proprietary research and development capabilities;

- require raw materials or APIs 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.

Not all of our products will include all of these characteristics. Moreover, we may 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 acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing, and research and development capabilities including the ability to manufacture raw materials, APIs and other components for our products.

Included in these acquisitions are marketing authorizations for 33 products in the UK, Ireland, Australia, and New Zealand, representing 11 different injectable chemical entities, from UCB Pharma GmbH. We plan to transfer the manufacturing of these products to our facilities in California, which will require approvals from the UK Medicines and Healthcare products Regulatory Agency before the product candidates can be re-launched by us.

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 manufacture and sell certain APIs.

· Injectable market. Based on an IMS Health National Sales Perspective Report, the U.S. generic injectable drug market in 2016 was approximately $9.5 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 current Good Manufacturing Practice, or 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

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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 2016 was approximately $25.2 billion, of which our generic development portfolio is targeting over $10.0 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 patient activates the device. 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 19 commercial products and over 20 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 of 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.
- 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.

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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 over 20 product candidates in various stages of development, including 15 generic ANDAs, three generic biosimilar product candidates and six 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 six 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 (1) International Medication Systems, Limited or IMS, (2) Armstrong Pharmaceuticals, Inc. or Armstrong, (3) Nanjing Puyan Pharmaceutical Technology Co., Ltd. (which we renamed as Amphastar Nanjing Pharmaceuticals Co., Ltd.), or ANP, (4) Nanjing Letop Medical Technology Co. Ltd. (which we renamed as Nanjing Letop Fine Chemistry Co. Ltd., or Letop, (5) 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, and (6) International Medication Systems (UK) Limited, or IMS UK. Products we have acquired include Cortrosyn® and Epinephrine Mist, and trade names such as Primatene®. 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 we receive approval 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.

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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.

- 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.

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- 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.

Business Segments

Our performance is assessed and resources are 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®, Amphadase®, 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."

Finished Pharmaceutical Product Segment

Our Marketed Products

We currently manufacture and sell 19 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. In January 2012, we commenced sales of our enoxaparin product. For the years ended December 31, 2016, 2015, and 2014, we recorded net revenues from enoxaparin of $59.3 million, $84.5 million, and $107.5 million, respectively.

Naloxone

We sell two versions of naloxone injections indicated for the emergency treatment of known or suspected opioid overdose. Sales of naloxone for the years ended December 31, 2016, 2015, and 2014 were $47.5 million, $38.6 million, and $19.2 million, respectively.

Other Marketed Products

We have 15 other products that we currently market. Other marketed products include the following:

- Cortrosyn® (cosyntropin for injection), which is a lyophilized powder that is indicated for use as a diagnostic agent in the screening of patients with adrenocortical insufficiency;

- Amphadase®, which is a bovine-sourced hyaluronidase injection and is used 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;
- Lidocaine jelly, which is a local anesthetic product used primarily for urological procedures;

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- Lidocaine topical solution, which is used as a local anesthetic for a variety of procedures;
- Phytonadione injection, which is Vitamin K that is used for newborn babies;
- our portfolio of emergency syringe products, which include critical care drugs, such as morphine, atropine, calcium chloride, dextrose, epinephrine, lidocaine, and sodium bicarbonate, which are provided in pre-filled syringes and are designed for emergency use in hospital settings;
- Lorazepam injection, which is a sedative used prior to surgery and medical procedures;
- Ketorolac, which is used for acute pain management, usually in a postoperative setting; and
- Procainamide, which is indicated for the treatment of documented ventricular arrhythmias.

For the years ended December 31, 2016, 2015, and 2014, we recorded net revenues from these other marketed products of $133.4 million, $101.8 million, and $71.8 million, respectively.

Our Product Candidates

We seek to develop product candidates with high technical barriers to competitive market entry that leverage our technical capabilities and other competitive advantages. We are focused on both generic 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 over 20 product candidates in our pipeline, including 15 generic ANDAs, three generic biosimilar product candidates and six 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 to competition, including difficult formulations, which require complex characterizations, difficult manufacturing requirements and/or limited availability of raw materials. We believe that such factors will make these product candidates less susceptible to competition and pricing pressure. We currently have 15 generic ANDAs and three generic biosimilar 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, and DPIs;
- nasal delivery systems; 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 the 15 generic ANDAs and three generic biosimilar product candidates in development.

		Applied Technical Capability				
Delivery Technology	Therapeutic Area	Characterization	Immunogenicity	Particle Engineering	Sustained-Release	Peptide and Protein Technology
		ü	ü		ü	ü
Injectable	Endocrinology	ü				
Injectable	Hematology	ü			ü	
Injectable	Reproductive System	ü				
Injectable	Neurology	ü		ü		
Inhalation	Respiratory					

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

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 six proprietary drug candidates at various development stages that leverage our various technical capabilities. The following paragaph summarizes our proprietary product candidates for which NDAs have been filed with the FDA.

Primatene® Mist

Primatene® Mist, 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 an HFA version of Primatene® Mist 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®, 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 for mild symptoms

of intermittent asthma in October 2009.

We filed an NDA for Primatene® Mist 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. 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. In May 2014, we received a CRL from the FDA, which required additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral/human factors and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. We met with the FDA in October 2014 to discuss preliminary data results and to clarify the FDA requirements for further studies. We received further advice regarding our ongoing studies from the FDA in January 2016 and subsequently completed the human factor studies accordingly. We submitted a responsive NDA amendment in June 2016 and received another CRL from the FDA in December 2016, which requires additional packaging and label revisions and follow-up studies to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. We intend to continue to work with the FDA during the post-action phase to address their concerns in the CRL and bring Primatene® Mist back to the over-the-counter market as soon as possible. However, there can be no guarantee that any future amendment to our NDA will result in timely approval of Primatene® Mist or approval at all.

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Intranasal naloxone

Intranasal naloxone, a prescription naloxone nasal spray product candidate, is intended to be used for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

We filed an NDA for Naloxone Hydrochloride 2mg/0.5mL Nasal Spray in April 2016. In February 2017, we received a CRL from the FDA, which identifies four primary issues that need to be addressed prior to approval of our NDA. The four issues are comprised of (1) improving on our human factors validation study, (2) modifying the delivery accuracy verification method, (3) improving our standards of device reliability, and (4) adjusting the volume per actuation to account for pediatric use down to birth. We intend to continue to work with the FDA to address their concerns in the CRL. However, there can be no guarantee that any future amendment to our NDA will result in timely approval of intranasal naloxone or approval at all.

Other Proprietary Product Candidates

In addition to Primatene® Mist and intranasal naloxone, we have four other proprietary product candidates in development. These product candidates incorporate multiple indications utilizing a wide variety of our technical capabilities.

API Segment

We began to manufacture and sell two API 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. The purpose for the acquisition was to enhance our vertical integration strategy as we target certain finished products for the injectable insulin market. However, we continue to sell RHI API to third parties, which helps fund our vertical integration strategy, including the ongoing technology transfer and supply arrangement between Merck and AFP.

For the years ended December 31, 2016, 2015 and 2014, we recorded net revenues of $14.9 million, $26.6 million and $12.0 million, respectively, from our API products.

Acquisition of Merck's API Manufacturing Business

On April 30, 2014, we completed our acquisition of the Merck's API manufacturing business in Éragny-sur-Epte, France, which manufactures porcine insulin API and RHI 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	3,483
December 2016	3,186	3,427
December 2017	500	526
	€ 25,023	$ 31,777

In order to facilitate the acquisition, we established AFP in France. We will continue the current site manufacturing activities, which consist of the manufacturing of porcine insulin API and RHI API. As part of the transaction, we have entered into various additional agreements, including various supply agreements, as well as the assignment and/or licensing of patents under which Merck was operating at this facility. In addition, certain existing customer agreements have been assigned to AFP. Currently, we are in the process of transferring the manufacturing of starting material for RHI API from Merck to AFP. This process will require capital expenditures at AFP and is expected to take two or more years to complete.

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Supply Agreement with MannKind Corporation

On July 31, 2014, we entered into a supply agreement with MannKind, or the Supply Agreement, pursuant to which we agreed to manufacture for and supply to MannKind certain quantities of RHI API, for use in MannKind's product Afrezza®. Under the Supply Agreement, MannKind agreed to purchase annual minimum quantities of RHI API in an aggregate amount of approximately €120.1 million, or approximately $146.0 million, over five years from calendar years 2015 through 2019. Specifically, the minimum annual purchase commitment was approximately €27.1 million in 2015, and approximately €23.3 million each year from 2016 through 2019.

On July 31, 2014, upon entering into the Supply Agreement, MannKind paid a non-refundable prepayment to us in the amount of €11.0 million, or approximately $14.0 million. Under the Supply Agreement, the non-refundable prepayment was applied towards the 2015 annual commitment. We recorded the amount as deferred revenue in 2014, and it was recognized as net revenue in 2015 at the time the product was shipped.

In January 2015, we entered into a supply option agreement with MannKind, or the Option Agreement, pursuant to which MannKind will have the option to purchase RHI API in excess of the minimum amounts specified in the Supply Agreement in calendar years 2016 through 2019. In the event MannKind elects not to exercise its minimum annual purchase option for any year under the Option Agreement, MannKind is obligated to pay us a specified capacity cancellation fee.

In 2015, the sales of RHI API to MannKind were €17.1 million, or approximately $20.8 million, and the unfulfilled 2015 commitment under the Supply Agreement was €6.0 million as of December 31, 2015. The Company and MannKind mutually, verbally agreed that MannKind could delay a portion of the minimum contractually obligated quantities of RHI API for 2015 and purchase the remaining unfulfilled 2015 commitment in 2016. No other aspects of the Supply Agreement were modified at that time.

In October 2015, MannKind informed the Company that it was not exercising the option to purchase additional quantities of RHI API for 2016 under the Option Agreement and paid the Company the specified capacity cancellation fee of $0.8 million. Such capacity cancellation fee was recorded as net revenue in the Company's consolidated statement of operations for the year ended December 31, 2015.

In 2016, sales of RHI API to MannKind totaled $6.8 million, which fulfilled the remaining unfulfilled 2015 commitment of RHI API under the Supply Agreement.

In November 2016, we amended the Supply Agreement, or Supply Agreement Amendment, with MannKind, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement has not been reduced; however, the annual minimum purchase commitments of RHI API under the Supply Agreement have been modified and extended through 2023, which timeframe had previously lapsed after calendar year 2019. Specifically, the minimum annual purchase commitment in calendar year 2016 has been cancelled, and the minimum annual purchase commitments in calendar years 2017 through 2023 have been modified to be €2.7 million of insulin in the fourth quarter of 2017, €8.9 million in 2018, €11.6 million in 2019, €15.5 million in 2020 and in 2021, and €19.4 million in 2022 and in 2023. MannKind may request to purchase additional quantities of RHI API in excess of its annual minimum purchase commitments. The Supply Agreement Amendment also (i) shortened the required expiry dates for RHI API delivered

to MannKind pursuant to the Supply Agreement, (ii) modified the timing of MannKind's payment for the minimum annual purchase commitment in calendar year 2017, and (iii) added a pre-payment requirement for purchases of RHI API by MannKind in calendar years 2017 and 2018. The Supply Agreement Amendment 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.

Concurrently with the amendment of the Supply Agreement, we amended the Option Agreement, or the Option Agreement Amendment, with MannKind, which extends the timing for payment of the capacity cancellation fee for 2017 and decreases the amounts payable as capacity cancellation fees for 2018 and 2019 in the event MannKind fails to exercise its minimum annual purchase option for any given year. We recognized the cancellation fee for 2017 of $1.5 million in net revenue in our consolidated statement of operations for the year ended December 31, 2016.

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In addition the Supply Agreement Amendment provided us the right of first refusal to participate in the development and commercialization of Afrezza® in China through a collaborative arrangement.

Research and Development

As of December 31, 2016, we had 277 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, 2016, 2015 and 2014 were $41.2 million, $37.3 million, and $28.9 million, respectively, which represent 16%, 15% and 14% 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, generally resulting in low product backlog relative to total shipments at any time. Our 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 71 buildings at six locations in the United States, France and China, that comprise 1.6 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 are currently in the process of modifying our current facility in France to increase our internal manufacturing capabilities so that we can take over the manufacturing of inclusion bodies, which are the starting material for our RHI API, from Merck. We anticipate the projct will take another two years to complete. We expect that this project will cost a total of $10.0 million and will take another two years to complete.

We believe that our current manufacturing capacity is adequate for the near term. We have approached capacity at our IMS facilities. As a result of this capacity issue, we began a significant project that will cost approximately $11.0 million over two years in order to increase capacity and modernize these facilities. The sterile filling area of the facility was shut down for the month of December 2016 for construction and for the installation of equipment in a new sterile suite. During 2017, we expect to complete construction, finish installing new equipment and undergo a validation process which needs to be completed before the new sterile area can be used in production.

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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 APIs 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 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 include 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 subsidiaries eventually manufacture APIs for not only enoxaparin, but also for 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 United States. 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,		
	2016	2015	2014
Actavis(1)	14 %	21 %	30 %
AmerisourceBergen Corporation	21 %	17 %	15 %

Cardinal Health, Inc.	22	%	17	%	14	%
McKesson Corporation	21	%	22	%	22	%

(1) The agreement with Actavis was terminated in December 2016.

Our marketing department is responsible for establishing and maintaining contracts and relationships with the group purchasing organizations, distributors, retailers, wholesalers and, occasionally, directly with hospitals or long-term care

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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 Inc., or Actavis, we were 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. The agreement with Actavis was terminated in December 2016.

For the years ended December 31, 2016, 2015, and 2014, we generated 3%, 2% and 4% 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.

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 Pfizer, Inc., Sagent Pharmaceuticals, Inc., Akorn, Inc., Sandoz Inc., Mylan Inc., Fresenius Kabi USA 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 its authorized generic enoxaparin product through its subsidiary, Winthrop, and also through Fresenius Kabi USA. Sandoz and Teva Pharmaceuticals Industries Ltd. also market a generic version of enoxaparin. Other companies may have 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.

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Government Regulation

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 United States. 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 over-the-counter 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.

The ANDA Approval Process

Our pipeline 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

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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 Medicare Prescription Drug Improvement and Modernization Act of 2003, or 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 MMA, and do not apply where the first ANDA with a Paragraph IV certification submitted for the reference drug was filed before December 8, 2003. In this circumstance, the pre-MMA exclusivity provisions apply. Under these provisions, the 180-day exclusivity delay ends 180 days after the first commercial marketing of the ANDA product or a court decision holding the patent invalid, unenforceable or not infringed, whichever comes first. In addition, under the pre-MMA exclusivity provisions, exclusivity is awarded separately to the first applicant or applicants submitting an ANDA with a paragraph IV certification for each patent, resulting in the possibility that different ANDA applicants will hold different

exclusivities on different patents, resulting in situations in which an applicant that holds an exclusivity on one patent is subject to another applicant's exclusivity on a different patent. The FDA has addressed these situations through policies involving exclusivity sharing. The pre-MMA exclusivity provisions do not provide for exclusivity forfeiture.

ANDA approvals can be delayed by exclusivities awarded to the holder of the NDA for the reference drug. The FFDCA provides five-year exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE,

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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 to demonstrate safety, 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

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Review Board, or IRB. Human clinical trials are typically conducted in three sequential phases that may overlap. These phases generally include:

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

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

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

The Section 505(b)(2) NDA

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

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

The PHSA provides a number of exclusivity protections for reference products that may delay submission and approval of biosimilar applications. The PHSA delays submission of a biosimilar application until four years after the date on which the reference product was first licensed and delays final approval of a biosimilar application until 12 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;

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- 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.

Combination Products

- A combination product is a product comprising of two or more regulated components (e.g., a drug and device) that are combined into a single product, co-packaged, or sold separately but intended for co-administration, as evidenced by the labeling for the products. A drug that is administered using an inhaler is an example of a combination drug/device product.
- The FDA is divided into various Centers, which each have authority over a specific type of product. NDAs are reviewed by personnel within the Center for Drug Evaluation and Research, or CDER, while device applications and premarket notifications are reviewed by the Center for Devices and Radiological Health, or CDRH. When reviewing a drug/device combination product, the FDA must assign a lead Center to review the product, based on the combination product's primary mode of action, or PMOA, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product.
- When evaluating an application, a lead Center may consult other Centers and apply the standards that would be applicable but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. One reason to submit multiple applications is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each may be evaluated by a different lead Center.
- Our inhalers and prefilled syringes, which deliver a specific drug, are regulated by the FDA as combination product. We believe the combination product will be regulated by the FDA as a drug (and not a device) because the primary mode of action of the combination will be a drug action. As such, we will need to submit a marketing application to the CDER for our inhalers that deliver a specific drug. CDRH will provide input to CDER on the device aspects of the combination. We can provide no assurance that any of our combination products will be approved by FDA in a timely fashion, if at all.
- Like their constituent products—e.g., drugs and devices—combination products are highly regulated and subject to a broad range of post marketing requirements including cGMPs, adverse event reporting, periodic reports, labeling and advertising and promotion requirements and restrictions, market withdrawal and recall.

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

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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.

Manufacturing (cGMP) Requirements

We and our 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 the FDA will approve our products and we must continue to meet these requirements after our products are approved. We and our 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.

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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.

From February 29, 2016 through March 4, 2016, our facility in Éragny-sur-Epte, France was subject to an inspection by the FDA. The inspection included a review of Quality Systems, Production Controls, Laboratory Controls, Material Management, and Facilities and Equipment Maintenance. The inspection resulted in multiple observations on Form 483, an FDA form on which deficiencies are noted after an FDA inspection. We responded to those observations on March 24, 2016. We believe that our response to the Form 483 will satisfy the requirements of the FDA and that no further actions will be necessary. We received a correspondence from the FDA on June 3, 2016, stating that the inspection was considered closed.

From April 25, 2016 through April 28, 2016, our facility in Nanjing, China was subject to an inspection by the FDA. The inspection included a review of Quality Systems, Production Controls, Laboratory Controls, Material Management, and Facilities and Equipment Maintenance. The inspection resulted in no observations on Form 483. We received a correspondence from the FDA on July 26, 2016, stating that the inspection was considered closed.

From August 22, 2016 through August 26, 2016, our facility in Rancho Cucamonga, California was subject to an inspection of the bioanalytical data and operations for the conduct of the bioequivalence studies conducted by us. The inspection resulted in multiple observations on Form 483. We responded to those observations on September 16, 2016. The same day, we received an e-mail confirmation of receipt of our response to the FDA. We believe that our response to the Form 483 will satisfy the requirements of the FDA and that no further actions will be necessary. No further correspondence has been received from the FDA to date in this regard.

From October 6, 2016 through October 14, 2016, our third party contract clinical study site was subject to a biomedical inspection by the FDA covering pharmacokinetic (PK) clinical studies, executed per our in-house designed

protocols. There were no Form 483 observations issued at the end of the inspection.

From October 17, 2016 through October 21, 2016, our facility in Chino, California was subject to inspection of the facility's compliance with Good Laboratory Practices regulations, and associated operations for the conduct of the non-clinical safety/toxicity studies conducted by us. The inspection resulted in multiple observations on Form 483. We responded to those observations on November 11, 2016, in accordance with FDA requirements. A confirmation of receipt was recived on November 14, 2016. A follow up letter was received from the FDA on November 29, 2016, and our follow up response was sent on December 12, 2016. We received a correspondence dated January 9, 2017 that our responses appear to be adequate. Additional correspondence from the FDA District Office dated January 14 ,2017, confirmed that the FDA considered the inpection closed.

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From November 29, 2016 through December 7, 2016, our IMS facility in South El Monte, California was subject to an inspection by the FDA. The inspection included a review of our compliance with cGMP regulations and verification of corrective actions implemented from a previous inspection in July 2015. The inspection resulted in multiple observations on Form 483, an FDA form on which deficiencies are noted after an FDA inspection. We responded to those observations on December 29, 2016, within the required 15-working day window of the issuance of the Form 483. A follow up letter to the FDA District Office was additionally sent on January 31, 2017, outlining additional progress on our corrective action plan submitted in December. We believe that our responses to the Form 483 will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From January 30, 2017 through February 09, 2017, our IMS facility in South El Monte, California was subject to a preapproval inspection by the FDA. The inspection included a review of our corrective actions taken from the recent cGMP inspection as well as review of data to support our pending application. The inspections resulted in multiple observations on Form 483. We responded to those observations on February 14, 2017.

Foreign Regulatory Requirements

Outside the United States, 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 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 recently requested us to discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which has been marketed under the “grandfather” exception to the FDA’s “Prescription Drug Wrap-Up” program. We are currently in discussions with the FDA regarding the timing of the discontinuation of this product. For the year ended December 31, 2016, we recognized $18.6 million in net revenues for the sale of this product. The charge of $3.3 million was included in the cost of revenues in our consolidated statements of operations for the year ended December 31, 2016 to adjust the related inventory items and firm purchase commitment to their net realizable value due to the anticipated discontinuation of the product.

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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 United States. 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.

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 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

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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.

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 2035.

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We own a U.S. patent covering the HFA version of Primatene® Mist: U.S. Patent Number 8,367,734, or the "'734 patent," which was issued on February 5, 2013, and expires in January 2026. We have several patent applications that are currently pending. The majority of our significant products or product candidates are not covered by any U.S. 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 U.S. 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, we may seek to obtain patent rights or rely on trade secret protection (but, in any case, the majority of our products and product candidates are not currently covered by any U.S. or foreign patents).

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

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

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

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

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

- litigation is required to defend against patent suits brought by third parties;
- we participate in patent suits brought against or initiated by our licensors;
- we initiate suits against third parties who are infringing on our patents; or
- we participate in an interference or other similar USPTO proceeding.

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

Employees

As of December 31, 2016, we had 1,541 full-time employees.

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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.

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 on Form 10-K, 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 and naloxone products collectively represent a majority of our net revenues. If the sales volume or pricing of our enoxaparin product continues to decline, if the sales volume or pricing of our naloxone product declines, or if we are unable to satisfy market demand for these products, they could have a material adverse effect on our business, financial position and results of operations.

Sales from our enoxaparin product represented 23%, 34%, and 51% of our total net revenues for the years ended December 31, 2016, 2015, and 2014, respectively, and sales of our naloxone products represented 19%, 15%, and 9% of our total net revenues for the years ended December 31, 2016, 2015, and 2014, respectively. We are currently experiencing declining revenue from enoxaparin and some of our other existing products and 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, if the sales volume or pricing of naloxone declines, or if we are unable to satisfy market demand for these products, 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. Our enoxaparin and naloxone products 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;

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- 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 these products may cause our revenues to decline, and we may not be able to achieve and maintain profitability. In addition, our distribution agreement with Actavis was terminated effective December 2016 pursuant to an amendment we entered into on June 30, 2016. If we are unable to engage another marketing and distribution partner, or if we are unable to market and distribute our enoxaparin product ourselves, revenues could further decrease or be delayed from this product, and our business, financial position and results of operations would be materially and adversely affected.

We incurred losses for fiscal 2014 and fiscal 2015 and we may operate at a loss in the near term while continuing to invest in developing new products.

We recorded a net loss of $10.7 million for the year ended December 31, 2014, and a net loss of $2.8 million for the year ended December 31, 2015. These losses resulted principally from a decrease in profits from enoxaparin. We may continue to incur operating and net losses and negative cash flow from operations in the future. Our business may generate operating losses if we do not successfully commercialize our product candidates, maintain sales of and profits from existing products, and generate sufficient revenues to support our level of operating expenses, especially as we continue our investment in developing new products. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict whether we will 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 attempting to seek 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. For example, on December 27, 2016, we received a complete response letter from the FDA informing us that our NDA for Primatene® Mist cannot be approved in its present form. Additionally, we may lose FDA approval of our approved products and/or our products may become subject to foreign regulations.”

The development and commercialization process, particularly with respect to our proprietary products, is time-consuming, costly and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to produce and market such products successfully and profitably. For example, we filed an abbreviated new drug application, or ANDA, for our enoxaparin product in March 2003, but

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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 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, or may discontinue production of raw materials, components or APIs used in our products or product candidates, 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, may discontinue production, 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.

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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.

Underutilization of our manufacturing capacity could negatively impact our gross margins.

We have invested significantly in our manufacturing capacity in order to vertically integrate our business, contain the costs of raw materials and reduce the risks imposed by relying on third-party single source suppliers. We currently own and operate facilities that manufacture raw materials and APIs for our products and product candidates and those of our customers and partners, including insulin API for MannKind. However, if market demand decreases or if market supply surpasses demand, whether because of macroeconomic factors, pharmaceutical industry volatility, or deficiencies specific to our customers, we may not be able to reduce manufacturing expenses or overhead costs proportionately. For example, a significant portion of our manufacturing capacity in our facility in Éragny-sur-Epte, France is utilized for the manufacture of insulin API for MannKind, and a significant portion of our manufacturing capacity in Rancho Cucamonga is utilized for the manufacture of enoxaparin. On November 9, 2016, we amended our supply agreement with MannKind, or the Supply Agreement and our option purchase agreement with MannKind, or the Option Agreement, to modify and extend the annual minimum purchase commitments under the Supply Agreement and the Option Agreement to cover calendar years 2014 through 2023, which timeframe had previously lapsed after calendar year 2019. While the aggregate total purchase commitment remains unchanged, the amendments to the Supply Agreement and the Option Agreement will result in reduced sales of API for MannKind on an annual basis.

If an increase in supply outpaces the increase in market demand, or if demand decreases, such as a reduction in sales of insulin API for MannKind, the resulting oversupply could adversely impact our sales and result in the underutilization of our manufacturing capacity, high inventory levels, changes in revenue mix and rapid price erosion, which would lower our margins and adversely impact our financial results. In addition, in order to offset fixed manufacturing overhead costs and utilize our current facilities and personnel, it may at times be in our best interest to continue to produce and sell products that are not profitable in the near term, although this would negatively impact our gross margins.

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. For example, a competitor has received FDA approval for their intranasal naloxone product in the markets for which we are currently seeking approval. 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.

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 large entities 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

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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, enoxaparin is currently marketed by Sanofi, under the brand name Lovenox®. Sanofi also markets its authorized

generic enoxaparin product through its subsidiary, Winthrop, and also through Fresenius Kabi USA. Sandoz and Teva Pharmaceuticals Industries Ltd., also market a generic version of enoxaparin. Other companies may have filed an ANDA with the FDA for approval of enoxaparin. The presence of these current and prospective competitive products has had, and may continue to 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 sales volume, per unit pricing and gross margins attributable to this product. 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

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significant generic products in the future, as the number and size of proprietary products that are subject to patent challenges is expected to decrease in the next several years compared to historical levels. Additionally, as new competitors enter the market, there may be increased pricing pressure on certain products, which may result in lower gross margins. In addition to our enoxaparin product, we have experienced significant pricing pressure on many of our other products, including Cortrosyn®, and we expect this trend to continue in the future.

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

Such competition can also result from the entry of generic versions of another product in the same therapeutic class as one of our drugs, or in another competing therapeutic class, or from the compulsory licensing of our products by governments, or from a general weakening of intellectual property laws in certain countries around the world.

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

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

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

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

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

· the relative therapeutic advantages and disadvantages of our products compared to competitive products;

- the relative timing of commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products and for competing products;

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- the willingness of third party payers to reimburse for our prescription products;
- the willingness of pharmacy chains to stock our new products; and
- the willingness of consumers to pay for our products.

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

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

Many of the existing and potential customers for our products have combined to form group purchasing organizations in an effort to lower costs. Group purchasing organizations negotiate pricing arrangements with medical supply manufacturers and distributors, and these negotiated prices are made available to a group purchasing organization's affiliated hospitals and other members. Group purchasing organizations provide end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the group purchasing organization of their choice for their purchasing needs. We currently derive, and expect to continue to derive, our revenue from end-user customers that are members of group purchasing organizations. Maintaining our strong relationships with these group purchasing organizations will require us to continue to be a reliable supplier, offer a broad product line, remain price competitive, comply with FDA regulations and provide high-quality products. Although our group purchasing organization pricing agreements are typically multi-year in duration, most of them may be terminated by either party with 60 or 90 days' notice. The group purchasing organizations with which we have relationships may have relationships with manufacturers that sell competing products, and such group purchasing organizations may earn higher margins from these competing products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our group purchasing organization relationships, sales of our products and revenue could decline.

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

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

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

A significant proportion of our sales are made to relatively few U.S. wholesalers and group purchasing organizations. These customers are continuing to undergo significant consolidation. Sales to three of these customers for the years ended December 31, 2016, 2015, and 2014, respectively, accounted for approximately 64%, 56%, and 51% of our total net revenues, respectively. Such consolidation has provided and may continue to provide them with additional

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purchasing leverage, and consequently may increase the pricing pressures that we face. Additionally, the emergence of large buying groups representing independent retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to extract price discounts on our products.

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

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

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

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

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

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

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

Because a portion of our manufacturing takes place in China, a significant disruption in the construction or operation of our manufacturing facility in China, political unrest in China, tariffs or changes in social, political and economic

conditions or in laws, regulations and policies governing foreign trade could materially and adversely affect our business, financial condition and results of operations.

We currently manufacture the starting material for Amphadase® at our manufacturing facility in China, and we plan to use this facility to manufacture several of the APIs for products in our pipeline. Additionally, we intend to continue to invest in the expansion of this manufacturing facility. Any disruption in construction of the facility or the inability of our

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

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

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

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

- requirements or preferences for domestic products or solutions, which could reduce demand for our products;
- differing existing or future regulatory and certification requirements;
- management communication and integration problems resulting from cultural and geographic dispersion;
- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties in enforcing contracts;
- difficulties and costs of staffing and managing non-U.S. operations;
- the uncertainty of protection for intellectual property rights in some countries;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products;
- changes in social, political, and economic conditions or in laws, regulations and policies governing foreign trade, manufacturing, development and investment both domestically as well as in other countries and jurisdictions into which we manufacture or sell our products;
- greater risk of a failure of foreign employees to comply with both U.S. and foreign laws, including export and antitrust regulations, the U.S. Foreign Corrupt Practices Act and any trade regulations ensuring fair trade practices;
- uneven electricity supply that can negatively impact manufacturing;
- heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;

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- potentially adverse tax consequences, including multiple and possibly overlapping tax structures; and
- political and economic instability, political unrest and terrorism.

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

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

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

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

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

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

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We

are currently expanding our operation abroad, including expanding our facilities in China, a country which has experienced governmental and private sector corruption to some degree, and in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. Our internal control policies and procedures may not always protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of complex foreign and U.S. laws and regulations could result in fines and penalties, criminal sanctions against us, our officers, or our employees, prohibitions on the conduct of our business and on our ability to offer our products in

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one or more countries, and could also materially affect our brand, our international growth efforts, our ability to attract and retain employees, our business, and our operating results. There can be no assurance that our partners, our employees, contractors, or agents will not subject us to potential claims or penalties. Any violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Movements in foreign currency exchange rates could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

The United Kingdom’s vote to leave the European Union will have uncertain effects and could adversely affect us.

On June 23, 2016, a referendum was held on the UK’s membership in the European Union, or the EU, the outcome of which was a vote in favor of leaving the EU, or the Brexit. Negotiations are expected to commence shortly to determine the future terms of the UK’s relationship with the EU, including the terms of trade between the UK and the EU and the rest of the world.

Article 50 of the Treaty of the European Union, or Article 50, allows a member state to decide to withdraw from the European Union in accordance with its own constitutional requirements. The formal process for leaving the European Union will be triggered only when the United Kingdom delivers an Article 50 notice to the European Council, although informal negotiations around the terms of any exit may be held before such notice is given. On February 1, 2017, the UK Parliament voted in favor of allowing the UK to start the process of leaving the European Union and authorized the filing an Article 50 notice to that end. The UK Prime Minister has stated that the UK will deliver an Article 50 notice by the end of March 2017. While it is unclear whether it will be possible for the UK Government to meet the desired timeline, the Prime Minister has indicated that it remains her intention to do so.

Delivery of the Article 50 notice will start a two-year period for the United Kingdom to exit from the European Union, although this period can be extended with the unanimous agreement of the European Council. Without any such extension (and assuming that the terms of withdrawal have not already been agreed), the United Kingdom’s membership in the European Union would end automatically on the expiration of that two-year period.

The effects of Brexit will depend on agreements the UK makes to retain access to EU markets either during a transitional period or more permanently. Brexit creates an uncertain political and economic environment in the UK and potentially across other EU member states for the foreseeable future, including during any period while the terms of Brexit are being negotiated and such uncertainties could impair or limit our ability to transact business in the member EU states.

Further, Brexit could adversely affect European and worldwide economic or market conditions and could contribute to instability in global financial markets, and the value of the Pound Sterling currency or other currencies, including the

Euro. We are exposed to the economic, market and fiscal conditions in the UK and the EU and to changes in any of these conditions. Depending on the terms reached regarding Brexit, it is possible that there may be adverse practical and/or operational implications on our business.

A significant amount of the regulatory regime that applies to us in the UK is derived from EU directives and regulations. For so long as the UK remains a member of the EU, those sources of legislation will (unless otherwise repealed or amended) remain in effect. However, Brexit could change the legal and regulatory framework within the UK where we operate and is likely to lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. Consequently, no assurance can be given as to the impact of Brexit and, in particular, no assurance can be given that our operating results, financial condition and prospects would not be adversely impacted by the result.

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

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

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

We currently maintain a $10.0 million product liability insurance policy, which covers Amphastar, International Medication Systems, Ltd., or IMS, and Amphastar France Pharmaceuticals S.A.S., or AFP products, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer from any product liability claims. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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

We plan to regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on

our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, customer or employee base, including diversion of management's attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies that we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. If we are unable to successfully integrate technologies, products, businesses or personnel that we acquire, we

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could incur significant impairment charges or other adverse financial consequences.

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

We intend to conduct an extensive due diligence investigation for any business we consider acquiring. Intensive due diligence is often time consuming and expensive due to the operations, finance and legal professionals who may be involved in the due diligence process. Even if we conduct extensive due diligence on a target business which we acquire, we may not identify all material issues that are present inside a particular target business. If our due diligence fails to discover or identify material issues relating to a target business, industry or the environment in which the target business operates, we may be forced to later write-down or write-off assets, restructure the target business's operations or incur impairment or other charges that could result in losses to us.

Charges to earnings resulting from acquisitions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

A significant portion of these adjustments could be accounted for as expenses that will decrease our net income and

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earnings per share for the periods in which those costs are incurred. Such charges could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of the common stock to decline.

We may evaluate asset dispositions and other transactions that may impact our results of operations, and we may not achieve the expected results from these transactions.

From time to time, we may enter into agreements to dispose of certain assets. However, we cannot assure you that we will be able to dispose of any such assets at any anticipated prices, or at all, or that any such sale will occur during any anticipated time frame. In addition, we may engage in business combinations, purchases of assets or contractual arrangements or joint ventures. Subject to the agreements governing our existing debt or otherwise, some of these transactions may be financed with our additional borrowings. We may suffer a loss of key employees, customers or suppliers, loss of revenues, increases in costs or other difficulties in connection with these transactions. Other transactions may advance future cash flows from some of our businesses, thereby yielding increased short-term liquidity, but consequently resulting in lower cash flows from these operations over the longer term. The failure to realize the expected long-term benefits of any one or more of these transactions could have a material adverse effect on our financial condition or results of operations.

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

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

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. As a result of the failure of the Joint Select Committee to propose, and of Congress to enact, deficit reduction measures of at least $1.2 trillion for the years 2013 through 2021, the Budget Control Act provides for automatic cuts to be made to most federal government programs, which, with respect to Medicare, would include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Pursuant to the American Taxpayer Relief Act of 2012, which was enacted by Congress on January 1, 2013, the imposition of these automatic cuts began April 1, 2013. In addition, the new law, among other things, reduces Medicare inpatient payment amounts to hospitals and increases the statute of limitations for recovering overpayments from three years to five years. The full impact on our business of this new law, assuming it is implemented, is uncertain.

The current presidential administration and Congress are also expected to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the pharmaceutical industry as a whole is currently unknown. But, any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and

regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For example, in November 2013, Congress passed the Drug Quality and Security Act, or the DQSA. The DQSA establishes federal pedigree tracking standards requiring drugs to be labeled and tracked at the lot level, preempts state drug pedigree requirements, and will eventually require all supply-chain stakeholders to participate in an electronic,

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interoperable prescription drug track and trace system. The DQSA also establishes new requirements for drug wholesale distributors and third party logistics providers, including licensing requirements in states that had not previously licensed such entities. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

Our business is sensitive to general economic conditions, both inside and outside the U.S. Slower global economic growth, credit market crises, high levels of unemployment, reduced levels of capital expenditures, government deficit reduction, sequestration and other austerity measures and other challenges affecting the global economy adversely affect us and our distributors, customers and suppliers. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. Such uncertain economic times may have a material adverse effect on our

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revenues, results of operations, financial condition and, if circumstances worsen, our ability to raise capital at reasonable rates. If slower growth in the global economy or in any of the markets we serve continues for a significant period, if there is significant deterioration in the global economy or such markets or if improvements in the global economy don't benefit the markets we serve, our business and financial statements could be adversely affected.

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

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

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

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

A significant amount of our total assets is related to goodwill and intangible assets. As of December 31, 2016, the value of our goodwill and intangible assets net of accumulated amortization was $50.3 million. Goodwill and other intangible assets are tested for impairment annually when events occur or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. Any future goodwill or other intangible asset impairment, if any, would be recorded in operating income and could have a material adverse effect on our results of operations and financial condition.

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

Our loan agreements are collateralized by substantially all of our presently existing and subsequently acquired personal property assets, and subject us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We are also subject to certain covenants that require us to maintain certain financial ratios and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants and ratios, we have certain limitations on the

manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of our lenders, which we may not be able to obtain. We may not be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and interest on our debt, and in the past we have not been in compliance with certain financial covenants. In addition, upon the occurrence of an event of default, our lenders, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of

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default includes our failure to pay any amount due and payable under the loan agreements, the occurrence of a material adverse change in our business as defined in the loan agreements, our breach of any covenant in the loan agreements, subject to a grace period in some cases, or an involuntary insolvency proceeding. Additionally, a lender could exercise its lien on substantially all of our assets and our future working capital, borrowings or equity financing may not be available to repay or refinance any such debt.

As a public company, we are obligated to develop and maintain adequate internal controls and be able, on an annual basis, to provide an assertion as to the effectiveness of such controls. Failure to maintain adequate internal controls or to implement new or improved controls could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. For the year ended December 31, 2015, we identified a material weakness in our internal control over financial reporting, which was remediated in 2016. However, we cannot be certain that any control remediation efforts undertaken during 2016 will enable us to avoid a material weakness in the future. Ensuring that we have adequate internal financial and accounting controls and procedures in place to help produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently.

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

In the event that our Chief Executive Officer, Chief Financial Officer, or independent registered public accounting firm determines in the future that our internal control over financial reporting is not effective as defined under Section 404, we could be subject to one or more investigations or enforcement actions by state or federal regulatory agencies, stockholder lawsuits or other adverse actions requiring us to incur defense costs, pay fines, make settlements or seek judgments, which may adversely affect investor perceptions and potentially result in a decline in our stock price.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions or changes in accounting standards could lead to a restatement or revision to previously consolidated financial statements, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in greater detail in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” the results of which form the basis for making judgments about the

carrying values of assets and liabilities that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition, provision for wholesaler chargebacks, accruals for product returns, valuation of inventory, impairment of intangibles and long-lived assets, accounting for income taxes and share-based compensation.

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Furthermore, although we have recorded reserves for litigation related contingencies based on estimates of probable future costs, such litigation related contingencies could result in substantial further costs. Also, any new or revised accounting standards may require adjustments to previously issued financial statements. Any such changes could result in corresponding changes to the amounts of liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Changes in financial accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our business and financial results.

Changes in income tax laws, tax rulings and other factors may have a significantly adverse impact on our effective tax rate and tax expense, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

Additionally, increases in our effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by various taxing authorities and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

counterfeits, we could incur substantial reputational and financial harm in the longer term.

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material

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disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

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

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

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

Risks Relating to Regulatory Matters

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

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

We may encounter delays or agency rejections during any stage of the regulatory review and approval process based upon a variety of factors, including without limitation the failure to provide clinical data demonstrating compliance with the FDA's requirements for safety, efficacy and quality. Those requirements may become more stringent prior to submission of our applications for approval or during the review of our applications due to changes in the law or changes in FDA policy or the adoption of new regulations. After submission of an application, the FDA may refuse to file the application, deny approval of the application or require additional testing or data. The FDA can convene an Advisory Committee to assist the FDA in examining specific issues related to the application. In February 2014, the FDA held a

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joint meeting of its Nonprescription Drugs Advisory Committee and its Pulmonary Allergy Drugs Advisory Committee, which we refer to as the Committee, to discuss the NDA for Primatene® Mist. The Committee voted 14 to 10 that the data in the NDA supported efficacy, but voted 17 to 7 that safety had not been established for the intended over-the-counter use. The Committee also voted 18 to 6 that the product did not have a favorable risk-benefit profile for the intended over-the-counter use, and individual Committee members provided recommendations for resolving their concerns. Although the FDA is not required to follow the recommendations of its advisory committees, it usually does. In May 2014, we received a CRL from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral/human factors and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. We met with the FDA in October 2014 to discuss preliminary data results and to clarify the FDA requirements for further studies. We received further advice regarding our ongoing studies from the FDA in January 2016 and subsequently completed the human factor studies accordingly. We submitted a responsive NDA amendment in June 2016 and received another CRL from the FDA in December 2016, which requires additional packaging and label revisions and follow-up studies to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. We intend to continue to work with the FDA during the post-action phase to address their concerns in the CRL and bring Primatene® Mist back to the over-the-counter market as soon as possible. However, there can be no guarantee that any future amendment to our NDA will result in timely approval of the product or approval at all.

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

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

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

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. Further, clinical trials

of potential products often reveal that it is not practical or feasible to continue development efforts. If any of our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Our clinical trials may not demonstrate consistent or adequate efficacy and safety to obtain regulatory

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approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

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

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

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

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

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

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

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

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

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

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

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

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

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

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulations by the FDA in the U.S. and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of an NDA from the FDA. NDA approvals may require extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. Any submissions may not be accepted for filing and review by the FDA. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require additional expensive and time-consuming post-approval clinical trials or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions. Obtaining regulatory approval for marketing of a product

candidate in one country does not necessarily ensure that we will be able to obtain regulatory approval in any other country.

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

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regulatory approval for any of our product candidates may be withdrawn.

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

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

A fast track designation by the regulatory agencies, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have fast track designation for any of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional procedures adopted by the FDA. In addition, the FDA may withdraw fast track designation if they believe that the designation is no longer supported by data from our clinical development program or if a competitor's product candidate is approved. For example, we were granted a fast track designation for our intranasal naloxone product, but this designation was withdrawn after a competitor's intranasal naloxone was approved. Many drugs that have received fast track designation have failed to obtain FDA approval.

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

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

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

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

Although the FDA may determine that a generic product is therapeutically equivalent to a brand product and indicate this therapeutic equivalence by providing it with an "A" rating in the FDA's Orange Book, this designation is not binding

on state pharmacy boards or state agencies. As a result, in states that do not deem our product candidates substitutable at the pharmacy level, physicians may be required to specifically prescribe our product or a generic product alternative in order for our product to be dispensed. Should this occur with respect to one of our generic product candidates, it could materially reduce sales in those states, which would substantially harm our business.

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

We plan to build on our existing platforms to produce biosimilar products in the future. In 2010, Congress amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to previously approved biologics notwithstanding minor

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differences in inactive components. The process for bringing a biosimilar product to market is uncertain and may be drawn out for an extended period of time. The FDA has not yet promulgated regulations governing this process and only four biosimilar applications have been approved as of September 30, 2016. Approval of biosimilar applications may be delayed by exclusivity on the BLA for the reference product for up to 12 years. Biosimilar applicants are also subjected to a patent resolution process that will require biosimilar applicants to share the contents of their application and information concerning its manufacturing processes with counsel for the company holding the BLA for the reference drug and to engage in a patent litigation process that could delay or prevent the commercial launch of a product for many years.

Biosimilar products are not presumed to be substitutable for the reference drug under the Biologics Price Competition and Innovation Act, or BPCIA. Biosimilar applicants must seek a separate FDA determination that they are "interchangeable" with the reference drug, meaning that they can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. None of the four biosimilar products that have been approved by the FDA have been approved as "interchangeable" and therefore, are not substitutable for the referenced drug. The statutory standards for determining biosimilarity and interchangeability are broad and uncertain, and the FDA has broad discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis.

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

Our competitive advantage in this area will depend on our success in demonstrating to the FDA that platform technology provides a level of scientific assurance that facilitates determinations of interchangeability, reduces the need for expensive clinical or other testing and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a brand product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach as the FDA begins to implement the new law. BLA holders will develop strategies and precedents for delaying or impeding approvals of biosimilar products and determinations of interchangeability. For example, the lengthy 12-year exclusivity protection provides the BLA holder for the reference drug with an opportunity to develop and replace its original product with a modified product that may avoid a determination of interchangeability and that may qualify for an additional 12-year marketing exclusivity period, reducing the potential opportunity for substitution at the retail pharmacy level for interchangeable biosimilars. As brand and biosimilar companies gain greater understanding of and experience with the new regulatory pathway, we expect to see new and unexpected company strategies, FDA decisions and court decisions that will pose unexpected challenges that will prevent, delay or make more difficult biosimilar approvals. As an example, there is a currently pending Citizen Petition filed with the FDA that argues that approving a biosimilar that relies on a reference product approved under a BLA submitted prior to passage of the BPCIA would constitute a taking under the Fifth Amendment to the U.S. Constitution that requires just compensation. The Citizen Petition requests that the FDA not accept for filing, file, approve, discuss or otherwise take any action with regard to any investigational new drug application or BLA for a product for which the reference product BLA was submitted prior to passage of the BPCIA. Should this petition be granted, there would be far fewer approved biologics that could serve as reference products for biosimilar applications, which could have a significant adverse impact on our business.

In addition, the BPCIA was passed as part of the Affordable Care Act. The Trump administration has stated that repeal and replacement of the Affordable Care Act is a priority for the administration. If the Affordable Care Act is amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected.

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

Some of our products or product candidates may be used in combination with a drug delivery device, such as an injector, inhaler or other delivery system. Although the drug delivery devices we currently use in our products and product candidates are provided by third parties, we recently entered into a collaboration agreement with a medical device manufacturer to develop a drug delivery system to be used for one of our pipeline products. These drug-device combination products are particularly complex, expensive and time-consuming to develop due to the number of variables involved in the final product design, including ease of patient and doctor use, establishing clinical efficacy, reliability and cost of manufacturing, regulatory approval requirements and standards and other important factors. We will be responsible for any regulatory filings arising from this collaboration and, although we have significant in-house and external regulatory expertise, we have never prepared or submitted an NDA to the FDA for a drug-device combination product. Our product candidates intended for use with such drug delivery, or expanded indications that we may seek for our products used with such devices, may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval.

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

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

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

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

- making changes to the formulation of their product and arguing that potential generic competitors must demonstrate bioequivalence and/or comparable abuse-resistance to the reformulated brand product;
- pursuing new patents for existing products which may be granted immediately prior to the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;

- selling the brand product as an authorized generic, either by the brand company directly, through an affiliate or by a marketing partner;
- using the FDA's Citizen Petition process to request amendments to FDA standards or otherwise delay generic drug approvals;

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- challenging FDA denials of Citizen Petitions in court and seeking injunctive relief to reverse approval of generic drug applications;
- seeking changes to standards in the U.S. Pharmacopeia/National Formulary, which are compendial drug standards that are recognized by industry and, in some instances, are enforceable under the FFDCA;
- attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled by the DEA;
- using the legislative and regulatory process to set standards and requirements for abuse deterrent formulations that are patented or that will otherwise impede or prevent generic competition;
- seeking special patent-term extensions through amendments to non-related federal legislation;
- engaging in initiatives to enact state legislation that would restrict the substitution of certain generic drugs, including products that we are developing;
- entering into agreements with pharmacy benefit management companies that block the dispensing of generic products;
- seeking patents on methods of manufacturing certain API;
- settling patent lawsuits with generic companies in a manner that leaves the patent as an obstacle for approval of other companies' generic drugs;
- settling patent litigation with generic companies in a manner that avoids forfeiture of or otherwise protects or extends the exclusivity period;
- providing medical education or other information to physicians, third-party payers and federal and state regulators that take the position that certain generic products are inappropriate for approval or for substitution after approval;
- seeking state law restrictions on the substitution of generic and biosimilar products at the pharmacy level without the instruction or permission of a physician; and
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic.

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

Our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers and administrators.

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

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

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

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

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

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

Our business, products and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous

substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations. For example, as a result of environmental concerns about the use of CFCs, the FDA issued a final rule on January 16, 2009 that required the phase-out of the CFC version of our Primatene® Mist product by December 31, 2011. This phase out caused us to halt sales of the CFC version of our Primatene® Mist product subsequent to

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December 31, 2011 and write off our inventory for the product, which had an adverse effect on our financial results.

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

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

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

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

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

alleging unfair competition or related claims.

As a result of our meetings with the FDA in 2009, we decided to discontinue all of our products that were subject to the Prescription Drug Wrap-Up program, with the exception of epinephrine in vial form. These products were all produced at our subsidiary, IMS. During the third quarter of 2010, the FDA requested that we reintroduce several of the withdrawn products to cope with a drug shortage, while we prepared and filed applications for approval of the products. Between

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August and October, 2010, we reintroduced atropine, calcium chloride, morphine, dextrose, epinephrine, and sodium bicarbonate injections, and continue to market these products without FDA approval. For the years ended December 31, 2016, 2015, and 2014, we recorded net revenues of $52.1 million, $40.2 million, and $27.0 million, respectively, from unapproved products. The FDA recently requested us to discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which has been marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. We are currently in discussions with the FDA regarding the timing of the discontinuation of this product. For the year ended December 31, 2016, we recognized $18.6 million in net revenues for the sale of this product. The charge of $3.3 million was included in the cost of revenues in our consolidated statements of operations for the year ended December 31, 2016 to adjust the related inventory items and firm purchase commitment to their net realizable value due to the anticipated discontinuation of the product. We have filed five ANDAs and are preparing additional applications with respect to other products in order to finally mitigate all risk associated with the marketing of unapproved drug products. In the interim, we continue to operate within the FDA Compliance Policy Guide, CPG Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs.

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

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

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

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

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

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

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

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

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

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

- the federal healthcare programs' anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FFDCA and similar laws regulating advertisement and labeling;
- the U.S. Foreign Corrupt Practices Act, which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials; and
- non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

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

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Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

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

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if a healthcare provider settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

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

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

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

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

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Any state or federal regulatory review of us or the third parties with whom we contract, regardless of the outcome, would be costly and time-consuming.

Risks Relating to our Intellectual Property

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

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

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

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

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

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

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

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As a generic pharmaceutical company, we also expect to file ANDAs, Paragraph IV certifications and to attempt to invalidate patents of third party reference drugs for which we seek to develop generic versions.

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

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

For example, we have been involved in litigation related to our sales of enoxaparin. A preliminary injunction was issued on October 28, 2011 that barred us from selling our generic enoxaparin until the injunction was stayed on January 25, 2012. After appeal, the U.S. Supreme Court denied certiorari and on July 19, 2013, the District Court granted our motion for summary judgment in accordance with the Federal Circuit opinion and denied Momenta and Sandoz's motion for leave to amend infringement contentions. However, on November 10, 2015, the Federal Circuit reversed the District Court's granting of summary judgment. For further details, see the section titled Litigation in Note 18 in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report on Form 10-K. The protracted litigation involved – and may continue to involve – large legal expenses and the diversion of management's time and effort away from the business. Any future adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses – whether in this litigation or in other litigation – could result in substantial monetary damage awards and could prevent us from manufacturing and selling our products, which could have a material and adverse effect on our financial condition.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which situation is commonly referred to as an at-risk launch. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer as well as injunctive relief, which would halt our ability to market and sell such products altogether. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with generic products, patented proprietary products generally realize a substantially higher profit margin than generic products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

With respect to our proprietary products, if we fail to adequately protect or enforce our intellectual property rights, we could lose sales to generic versions of our proprietary products which could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The success of our proprietary products depends in part on our ability to obtain, maintain and enforce patents and trademarks, and to protect trade secrets, know-how and other proprietary information. Our ability to commercialize

any proprietary product successfully will largely depend upon our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our proprietary products business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

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

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

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

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

If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secret protections against them, which could have a material adverse effect on our business.

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

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

profitability, financial condition and operations.

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- the commercial success of our key products and those of our customers;
- results of clinical trials of our product candidates or those of our competitors;
- pricing actions by competitors;
- the timing of orders or any cancellation of orders from our customers;
- manufacturing or supply interruptions;
- actions by regulatory bodies, such as the FDA, that have the effect of delaying or rejecting approvals of our product candidates;
- changes in the prescription practices of physicians;
- changes or developments in laws or regulations applicable to our product candidates;
- introduction of competitive products or technologies;
- failure to meet or exceed financial projections we provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of securities analysts or investors;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments or achievement of significant milestones;

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- changes in, or termination of our agreements with our business partners;
- developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents or other proprietary rights;
- litigation or investigations involving us, our industry, or both;
- additions or departures of key scientific or management personnel;
- announcements or issuances of debt, equity or convertible securities;
- sales of our common stock by our stockholders;
- changes in the market valuations of similar companies;
- major catastrophic events;
- major changes in our Board of Directors or management or departures of key personnel;
- general economic and market conditions and overall fluctuations in U.S. equity markets; or
- the other factors described in this “Item 1.A Risk Factors” section.

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

In addition, if the market for pharmaceutical company stocks or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. Our stock price may also be affected by sales of large blocks of our stock or an interruption or change in our stock buyback program.

In the past, following periods of volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management’s attention and resources from our business, and this could have a material adverse effect on our business, operating results and financial condition.

Sales of substantial amounts of our common stock, or indications of an intent to sell, may cause our stock price to decline.

If we or our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of $250 million of our common stock, preferred stock, depositary shares, warrants, units, or debt securities. We may also issue shares of common stock or securities convertible into our common stock from time to time in connection with financings, acquisitions, investments or otherwise. Any such issuances would result in dilution to our existing stockholders and could cause our stock price to fall.

In addition, we have registered approximately 19.7 million shares subject to options and RSUs outstanding or reserved for future issuance under our equity compensation plans. If these additional shares are sold, or if it is perceived that they

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will be sold, in the public market, the trading price of our common stock could decline.

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

As of March 8, 2017, Jack Y. Zhang and Mary Z. Luo, each of whom serves as one of our directors and executive officers, and their affiliates beneficially own approximately 27.7% of our outstanding common stock, including shares of common stock subject to options exercisable within 60 days of March 8, 2017. Our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, own approximately 31.0% of the outstanding, including shares of our common stock, based on the number of shares outstanding and shares of our common stock subject to options exercisable within 60 days of March 8, 2017. As a result, these stockholders, if acting together, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

Jack Yongfeng Zhang and Mary Ziping Luo have pledged shares of our common stock to secure certain borrowed funds. The forced sale of these shares pursuant to a margin call could cause our stock price to decline and negatively impact our business.

Since September 30, 2015, UBS Bank USA, has made extensions of credit in the aggregate amount of $4.8 million to Applied Physics & Chemistry Laboratories, Inc., which is owned solely by Jack Yongfeng Zhang and Mary Ziping Luo. The loan is pledged by 1,907,898 shares of our common stock currently held by Dr. Zhang and Dr. Luo. Interest on the loan accrues at market rates. UBS Bank USA received customary fees and expense reimbursements in connection with these loans.

We are not a party to these loans, which are full recourse against Applied Physics & Chemistry Laboratories, Inc. and are secured by pledges of a portion of our common stock currently beneficially owned by Dr. Zhang and Dr. Luo.

If the price of our common stock declines, Dr. Zhang and Dr. Luo may be forced by UBS Bank USA to provide additional collateral for the loans or to sell shares of our common stock held by them in order to remain within the margin limitations imposed under the terms of their loans. The loans between these banking institutions on the one hand, and Dr. Zhang and Dr. Luo on the other hand, prohibit the non-pledged shares currently owned by Dr. Zhang and Dr. Luo from being pledged to secure any other loans. These factors may limit Dr. Zhang and Dr. Luo’s ability to either pledge additional shares of our common stock or sell shares of our common stock held by them as a means to avoid or satisfy a margin call with respect to their pledged common stock in the event of a decline in our stock price that is large enough to trigger a margin call. Any sales of common stock following a margin call that is not satisfied may cause the price of our common stock to decline further.

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

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

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the

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Dodd-Frank Act, the listing requirements of the NASDAQ Stock Market LLC and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company," as defined in the JOBS Act. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. Although we have already hired additional employees to comply with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our costs and expenses.

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

We also believe that being a public company and these new rules and regulations make it more expensive for us to obtain director and officer liability insurance.

As a result of disclosure of information in this Annual Report on Form 10-K and in filings required of a public company, our business and financial condition are more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be adversely affected. Even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

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

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

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

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

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less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

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

As an emerging growth company, we have also chosen to take advantage of certain provisions of the JOBS Act that allow us to provide less information in our public reports than would otherwise be required if we are not an emerging growth company. As a result, this Annual Report on Form 10-K includes less information about us than would otherwise be required if we were not an emerging growth company within the meaning of the JOBS Act, which may make it more difficult to evaluate an investment in our company.

We would cease to be an emerging growth company upon the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, which occurred on June 25, 2014, (ii) the last day of the fiscal year during which we have annual gross revenue of at least $1.0 billion, (iii) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act (we will qualify as a large accelerated filer as of the first day of the first fiscal year after we have (a) more than $700.0 million in outstanding common equity held by our non-affiliates and (b) been public for at least 12 months; the value of our outstanding common equity will be measured each year on the last business day of our second fiscal quarter); or (iv) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of the Delaware General Corporation Law, or the DGCL, could depress the trading price of our common stock by making it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- establishing advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon at stockholder meetings; and
- establishing a classified Board of Directors, whereby only one-third of the members of our Board of Directors are elected at one time.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL,

which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with

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an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could delay or prevent a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our common stock.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

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 71 buildings at six locations in the U.S., France and China, that comprise 1.6 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.

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

The following table provides a summary of our owned properties as of December 31, 2016:

Location	Aggregate Facility Size (in square feet)	Primary Use	Segment
Rancho Cucamonga, CA	267,674	Headquarters, research and development, laboratories, manufacturing, packaging, warehousing and administration offices	Finished pharmaceutical products
Éragny-sur-Epte, France	251,983	Manufacturing, laboratories, warehousing and administration offices	API
Canton, MA	251,750	Manufacturing, packaging, warehousing, distribution and administration offices	Finished pharmaceutical products
Nanjing, China	353,231	Manufacturing, procurement, research and development, warehousing, and administration office	Finished pharmaceutical products
Chino, CA	57,968	Research and development, and laboratories	

			Finished pharmaceutical products
South El Monte, CA	10,000	Manufacturing	Finished pharmaceutical products

The properties leased by us have expiration dates ranging from 2017 to 2025 (including certain renewal options). The following table provides a summary of our leased properties:

Location	Aggregate Facility Size (in square feet)	Primary Use	Segment
Nanjing, China	32,674	Manufacturing, laboratories and administration offices	Finished pharmaceutical products
Rancho Cucamonga, CA	94,545	Warehousing, distribution and administration offices	Finished pharmaceutical products
South El Monte, CA	323,358	Manufacturing, packaging, warehousing, distribution and administration offices	Finished pharmaceutical products

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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.

Item 3. Legal Proceedings.

The disclosure under Note 17 of the Notes to the Consolidated Financial Statements included elsewhere in this report is incorporated by reference in this Part I, Item 3.

Item 4. Mine Safety Disclosures.

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is listed on the NASDAQ Global Select Market and has traded under the symbol "AMPH" since our initial public offering on June 25, 2014. Prior to this date, there was no public market for our common stock. The following table sets forth the high and low market price for our common stock during each of the quarterly periods indicated, as reported on the NASDAQ Global Select Market:

	Market Price	
	High	Low
2015		
First Quarter	$ 15.51	$ 11.31
Second Quarter	$ 18.19	$ 13.80
Third Quarter	$ 17.93	$ 10.78
Fourth Quarter	$ 15.49	$ 11.02
2016		
First Quarter	$ 13.89	$ 10.53
Second Quarter	$ 16.63	$ 11.72
Third Quarter	$ 21.26	$ 15.97
Fourth Quarter	$ 21.55	$ 16.99

Dividend Policy

We have not declared or paid any dividends on our common stock since our initial public offering. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future. Additionally, our ability to pay dividends on our common stock is limited by restrictions under the terms of our existing credit facilities. Any future determinations related to dividend policy will be made at the discretion of our Board of Directors.

Holders of Record

At March 8, 2017, we had 45,910,116 shares of common stock outstanding held by approximately 206 stockholders of record of our common stock. We believe the actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in "street" name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Stock Performance Graph

This graph shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Amphastar Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since June 25, 2014, which is the date our common stock first began trading on the NASDAQ Global Select Market, with the cumulative stockholder return since May 31, 2014, on two indices: the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index. The graph assumes an initial investment of $100 on June 25, 2014, in our common stock and on May 31, 2014, in the stocks comprising each index. It also assumes reinvestment of dividends, if any. Historical stockholder return shown is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

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Issuer Purchases of Equity Securities During the Quarter Ended December 31, 2016

The table below provides information with respect to repurchases of our common stock.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 – October 31, 2016	14,124	$ 18.46	14,124	—
November 1 – November 30, 2016	10,700	17.82	10,700	—
December 1 – December 31, 2016	23,410	20.03	23,410	—

(1) During the fourth quarter of 2016, we repurchased shares of our common stock as part of the share buyback programs authorized by our Board of Directors on November 10, 2015 and November 7, 2016. As of December 31, 2016, $19.9 million remained available under such programs.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during fiscal 2016 other than transactions previously reported in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12, “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” for information regarding securities authorized for issuance.

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Item 6. Selected Financial Data.

The following table sets forth selected financial data as of and for the periods indicated. The selected consolidated statements of operations data for fiscal 2016, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016 and 2015, are derived from our audited financial statements appearing in Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K. The selected consolidated statements of operations data for fiscal 2013 and 2012 and the consolidated balance sheet data as of December 31, 2014, 2013, and 2012, are derived from audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results to be expected in the future.

The data presented below should be read in conjunction with our consolidated financial statements, the notes to our consolidated financial statements and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net revenues	$ 255,165	$ 251,519	$ 210,461	$ 229,681	$ 204,323
Cost of revenues	150,976	174,172	159,205	142,725	114,020
Gross profit	104,189	77,347	51,256	86,956	90,303
Operating expenses:					
Selling, distribution and marketing	5,466	5,470	5,564	5,349	4,426
General and administrative	41,832	41,504	34,809	30,972	27,223
Research and development	41,199	37,271	28,866	33,145	33,257
Total operating expenses	88,497	84,245	69,239	69,466	64,906
Income (loss) from operations	15,692	(6,898)	(17,983)	17,490	25,397
Non-operating income (expense):					
Interest income	270	315	243	187	242
Interest expense	(1,024)	(987)	(609)	(958)	(784)
Other income (expense), net	8	(2,794)	201	508	1,023
Total non-operating income (expense)	(746)	(3,466)	(165)	(263)	481
Income (loss) before income taxes	14,946	(10,364)	(18,148)	17,227	25,878
Income tax expense (benefit)	4,414	(7,577)	(7,449)	5,365	7,784
Net income (loss)	$ 10,532	$ (2,787)	$ (10,699)	$ 11,862	$ 18,094
Net income (loss) per common share:					
Basic	$ 0.23	$ (0.06)	$ (0.25)	$ 0.31	$ 0.47
Diluted	$ 0.22	$ (0.06)	$ (0.25)	$ 0.31	$ 0.46
Weighted-average shares used to compute net income (loss) per common share:					
Basic	45,375	44,961	41,957	38,712	38,580
Diluted	47,504	44,961	41,957	38,883	38,940

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	December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$ 74,271	$ 67,359	$ 69,323	$ 54,912	$ 52,101
Working capital	123,479	115,979	135,401	107,569	105,615
Total assets	427,738	390,136	389,370	338,748	317,477
Long-term debt and capital leases, including current portion	37,722	41,099	43,700	32,173	38,002
Retained earnings	70,855	60,323	63,110	73,809	61,947
Total stockholders' equity	329,255	295,510	281,860	251,545	233,439

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following is a discussion and analysis of the consolidated operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in Item 8 under the heading "Financial Statements and Supplementary Data." This discussion contains forward-looking statements that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in the section entitled "Risk Factors."

Overview

We are a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically challenging generic and proprietary injectable, inhalation, and intranasal products. Additionally, we sell insulin API products. We currently manufacture and sell 19 products including Amphadase®, which we re-launched in the fourth quarter of 2015. Additionally, we are developing a portfolio of 15 generic abbreviated new drug applications, or ANDAs, three generic biosimilar product candidates and six proprietary injectable and inhalation product candidates.

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 has multiple indications, including the prevention and treatment of deep vein thrombosis.

We have agreements with established group purchasing organizations and wholesaler networks to distribute enoxaparin, which is marketed under our own label for the hospital and clinic market. For the U.S. retail market, we had a distribution agreement with Actavis Inc., or Actavis, to distribute enoxaparin, which is marketed under Actavis' label. On June 30, 2016, we amended the distribution agreement with Actavis, to, among other things, amend the termination date of such agreement. In December 2016, our distribution agreement was terminated pursuant to such amendment.

In June 2015, we received approval of our new drug application, or NDA, supplement for Amphadase®. This marks the first approved starting material from ANP and signifies that our facility located in Nanjing, China has been qualified by the U.S. Food and Drug Administration, or FDA. We re-launched Amphadase® in the fourth quarter of 2015. Amphadase® is competing in the hyaluronidase market and is used for the dispersion and absorption of other injected drugs.

Our pipeline of over 20 generic and proprietary product candidates is in various stages of development and targets a variety of indications. With respect to these product candidates, we have five abbreviated new drug applications, or ANDAs, and two NDAs on file with the FDA.

To complement our internal growth and expertise, we have made several acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology

infrastructure by providing additional manufacturing, marketing, and research and development capabilities including the ability to manufacture raw materials, APIs and other components for our products.

Included in these acquisitions are marketing authorizations for 33 products in the UK, Ireland, Australia, and New Zealand, representing 11 different injectable chemical entities, from UCB Pharma GmbH. We plan to transfer the manufacturing of these products to our facilities in California, which will require approvals from the UK Medicines and Healthcare products Regulatory Agency before the product candidates can be re-launched by us.

Business Segments

Our performance is assessed and resources are 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®, Amphadase®, naloxone,

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lidocaine jelly as well as various other critical and non-critical care drugs. The API segment currently manufactures and distributes recombinant human insulin, or RHI API and porcine insulin API. 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 Reporting Information.”

Results of Operations

Year ended December 31, 2016 compared to year ended December 31, 2015

Net revenues

	Year Ended December 31, 2016 (in thousands)	2015	Change Dollars	%
Net revenues				
Finished pharmaceutical products	$ 240,221	$ 224,941	$ 15,280	7 %
API	14,944	26,578	(11,634)	(44)%
Total net revenues	$ 255,165	$ 251,519	$ 3,646	1 %
Cost of revenues				
Finished pharmaceutical products	$ 134,121	$ 150,795	$ (16,674)	(11)%
API	16,855	23,377	(6,522)	(28)%
Total cost of revenues	$ 150,976	$ 174,172	$ (23,196)	(13)%
Gross profit	$ 104,189	$ 77,347	$ 26,842	35 %
as % of net revenues	41 %	31 %		

The increase of net revenues of the finished pharmaceutical products for 2016 was primarily due to the following changes:

	Year Ended December 31, 2016 (in thousands)	2015	Change Dollars	%
Finished pharmaceutical products net revenues				
Enoxaparin	$ 59,320	$ 84,502	$ (25,182)	(30)%
Naloxone	47,532	38,602	8,930	23 %
Lidocaine	36,600	30,260	6,340	21 %
Phytonadione	33,315	19,804	13,511	68 %
Epinephrine	25,661	14,936	10,725	72 %
Other finished pharmaceutical products	37,793	36,837	956	3 %
Total finished pharmaceutical products net revenues	$ 240,221	$ 224,941	$ 15,280	7 %

Lower average selling prices of enoxaparin caused a decrease of approximately $6.4 million compared to 2015, while lower unit volumes in the retail market, primarily as a result of the termination agreement with Actavis, led to a decrease in sales of enoxaparin of approximately $18.8 million compared to 2015. On June 30, 2016, we amended the distribution agreement with Actavis, which terminated the agreement in December 2016. We completed shipments to Actavis under our supply agreement in August 2016 and did not begin selling to retail customers until the end of December 2016. As result of the termination of the Actavis agreement, the timing of sales into the retail channel may be adversely affected in the near term. We expect that the average selling price and unit volumes of enoxaparin will continue to decline in the near term as a result of competition.

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The increase of sales of naloxone in 2016 was primarily a result of an increase in unit volumes that were partially offset by a decrease in average selling price of $1.4 million, primarily due to increased rebates. Sales of this product may decline due to future competitor launches.

An increase in the average selling price of Lidocaine caused an increase of approximately $2.6 million in net revenues, while higher unit volumes led to an increase in sales of approximately $3.8 million compared to 2015. The increases in phytonadione and epinephrine were primarily the result of higher average selling prices. The FDA recently requested us to discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which has been marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. We are currently in discussions with the FDA regarding the timing of the discontinuation of this product. For the year ended December 31, 2016, we recognized $18.6 million in net revenues for the sale of this product.

Our insulin API business had an overall decrease in sales of RHI API and porcine insulin API to $14.9 million in 2016 from $26.6 million in 2015, as MannKind purchased the remaining unfulfilled 2015 commitments, but did not purchase any of its 2016 commitments under the supply agreement entered into in 2014.

We anticipate that sales of insulin API will continue to fluctuate and will likely decrease due to the inherent uncertainties related to sales of RHI API to MannKind. In November 2016, we amended the Supply Agreement, or Supply Agreement Amendment, with MannKind, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement has not been reduced; however, the annual minimum purchase commitments of RHI API under the Supply Agreement have been modified and extended through 2023, which timeframe had previously lapsed after calendar year 2019. Specifically, the minimum annual purchase commitment in calendar year 2016 has been cancelled, and the minimum annual purchase commitments in calendar years 2017 through 2023 have been modified to be €2.7 million of insulin in the fourth quarter of 2017, €8.9 million in 2018, €11.6 million in 2019, €15.5 million in 2020 and in 2021, and €19.4 million in 2022 and in 2023. MannKind may request to purchase additional quantities of RHI API in excess of its annual minimum purchase commitments. The Supply Agreement Amendment also (i) modified, and shortened, the required expiry dates for RHI API delivered to MannKind pursuant to the Supply Agreement, (ii) modified the timing of MannKind's payment for the minimum annual purchase commitment in calendar year 2017, and (iii) added a pre-payment requirement for purchases of RHI API by MannKind in calendar years 2017 and 2018. The Supply Agreement Amendment 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.

Concurrently with the amendment of the Supply Agreement, we amended the Option Agreement, or the Option Supply Agreement, with MannKind, which extends the timing for payment of the capacity cancellation fee for 2017 and decreases the amounts payable as capacity cancellation fees for 2018 and 2019 in the event MannKind fails to exercise its minimum annual purchase option for any given year. We recognized the cancellation fee for 2017 of $1.5 million in net revenues in our consolidated statement of operations for the year ended December 31, 2016, and subsequently collected on this receivable.

In addition, most of our API sales are denominated in Euros, and the fluctuation in the value of the Euro versus the dollar compared to 2015 has had, and will continue to have, an impact on API sales revenues in the near term.

Cost of revenues

Cost of revenue of enoxaparin decreased by $22.6 million compared to 2015, primarily due to a decrease of $6.7 million in average cost per unit as a result of lower heparin input costs and a decrease of $16.0 million in unit volume as a result of lower sales volume. In addition, cost of revenue for insulin API decreased $7.4 million compared to 2015, primarily due to a decrease in unit volume of $7.1 million. These decreases were partially offset by an increase in personnel costs at our U.S. manufacturing sites. In December 2016, we recorded a charge of $7.3 million to adjust certain inventory items to their net realizable value, including $3.1 million for enoxaparin inventory items due to a decrease in the forecasted average selling price and $3.3 million for epinephrine injection, USP vial inventory items and related firm inventory purchase commitment due to the anticipated discontinuation of the product.

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The increase in gross margin in 2016 was driven by increased pricing on epinephrine, phytonadione and lidocaine. Partially offsetting the increases were pricing decreases of enoxaparin and naloxone and increased personnel costs at our U.S. facilities.

Declining average selling prices and unit volume of enoxaparin, and one of our epinephrine products, will put downward pressure on gross margins, but we believe this trend will be partially offset by increases in prices of several other finished pharmaceutical products. As a result, gross margin is expected to be variable depending on revenue mix.

Selling, distribution, and marketing, and general and administrative

	Year Ended December 31,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 5,466	$ 5,470	$ (4)	(0)%
General and administrative	41,832	41,504	328	1 %

The increase in general and administrative expenses in 2016 was primarily due to an increase in personnel cost and legal fees, which was partially offset by the effect of a one-time $3.3 million settlement charge in 2015 relating to our California employment litigation.

We expect that general and administrative expenses will increase on an annual basis due to increased costs associated with ongoing compliance with public company reporting obligations as well as legal fees associated with our enoxaparin patent litigation.

Research and development

	Year Ended December 31,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 15,157	$ 14,380	$ 777	5 %
Pre-launch inventory	1,096	822	274	33 %
Clinical trials	1,599	5,441	(3,842)	(71)%
FDA fees	2,764	313	2,451	783 %
Testing, operating and lab supplies	12,310	9,577	2,733	29 %
Depreciation	4,736	3,795	941	25 %

Other expenses	3,537	2,943	594	20 %
Total research and development expenses	$ 41,199	$ 37,271	$ 3,928	11 %

The increase of pre-launch inventory expense compared to 2015 was due to a $1.1 million expense related to Primatene® Mist in 2016. Clinical trial expense decreased due to higher spending in 2015 on Primatene® Mist and intranasal naloxone. FDA fees increased in 2016 due to the NDA filing fee for intranasal naloxone. Testing, operating and lab supplies increased due to expenditures on materials for our ANDA pipeline.

Research and development costs consist primarily of costs associated with the research and development of our product candidates, such as salaries and other personnel related expenses for employees involved with research and development activities, manufacturing pre launch inventory, clinical trials, FDA fees, testing, operating and lab supplies, depreciation and other related expenses. We expense research and development costs as incurred.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. These costs will fluctuate significantly from quarter to quarter based on the timing of various clinical trials, the pre-launch costs associated with new products, and FDA filing fees. As we undertake new and challenging research and development projects, we anticipate that the associated annual costs will increase significantly over the next several quarters and years.

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Provision for income tax expense (benefit)

	Year Ended December 31,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Income tax expense (benefit)	$ 4,414	$ (7,577)	$ (11,991)	(158)%
Effective tax rate	30 %	73 %		

The difference in income tax expense (benefit) in 2016 compared to 2015 was due to a pre-tax income in 2016 compared to a pre-tax loss in 2015.

Year ended December 31, 2015 compared to year ended December 31, 2014

Net revenues

	Year Ended December 31,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 224,941	$ 198,480	$ 26,461	13 %
API	26,578	11,981	14,597	122%
as % of net revenues	$ 251,519	$ 210,461	$ 41,058	20 %
Cost of revenues				
Finished pharmaceutical products	$ 150,795	$ 145,757	$ 5,038	3 %
API	23,377	13,448	9,929	74 %
Total cost of revenues	$ 174,172	$ 159,205	$ 14,967	9 %
Gross profit	$ 77,347	$ 51,256	$ 26,091	51 %
as % of net revenues	31 %	24 %		

Net revenues were $251.5 million and $210.5 million for the years ended December 31, 2015 and 2014, respectively, representing an increase of $41.1 million, or 20%. The increase was primarily due to an increase in sales of other finished pharmaceutical products largely due to an increase in sales of naloxone to $38.6 million from $19.2 million, as a result of increased unit volumes at higher average prices. Additionally, we increased sales of phytonadione, epinephrine, lidocaine, and atropine, as a result of higher average prices. Our insulin API business, which we acquired from Merck in April 2014, had increased sales of recombinant human insulin, or RHI API and porcine insulin API by $14.6 million due to sales of RHI to MannKind. The increase in net revenues was partially offset by a decrease in sales of enoxaparin, which decreased $23.0 million to $84.5 million on higher unit volumes at lower average selling prices.

Cost of revenues

Cost of revenues was $174.2 million and $159.2 million for the years ended December 31, 2015 and 2014, respectively, representing an increase of $15.0 million, or 9%. The increase was primarily due to an increase in the overall cost of revenue for the API business, which we acquired in April 2014, as a result of a full year of sales. This was partially offset by a decrease in average cost per unit of enoxaparin. Additionally, lower average heparin material costs contributed to the improvement in gross margins. Overall, the cost of revenues as a percentage of revenues decreased to 69% from 76% due to higher average prices of several finished pharmaceutical products.

Selling, distribution, and marketing, general and administrative, and impairment of long-lived assets

	Year Ended December 31,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 5,470	$ 5,564	$ (94)	(2)%
General and administrative	41,504	34,809	6,695	19 %

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Selling, distribution, and marketing expenses were $5.5 million and $5.6 million for the years ended December 31, 2015 and 2014, respectively. General and administrative expenses were $41.5 million and $34.8 million for the years ended December 31, 2015 and 2014, respectively, representing an increase of $6.7 million, or 19%. The increase was primarily due to a $3.3 million settlement of our California employment litigation as well as an increase of $1.3 million, primarily related to costs associated with our compliance with public company reporting obligations. Additionally, the inclusion of a full year of expenses generated at our French subsidiary, AFP, which we acquired in April 2014 contributed to the increase.

Research and development

	Year Ended December 31,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Research and development	$ 37,271	$ 28,866	$ 8,405	29 %

Research and development expenses were $37.3 million and $28.9 million for the years ended December 31, 2015 and 2014, respectively, representing an increase of $8.4 million, or 29%. This increase was primarily due to an increase of $3.5 million in clinical trial expense, related to our intranasal naloxone product candidate and to our generic pipeline, as well as an increase of $2.9 million for pre-launch inventory and purchases of materials and other research and development supplies, relating to the approval of Amphadase®, which we re-launched in October 2015, as well as other costs relating to the development of our intranasal naloxone product candidate.

The following table sets forth our research and development expenses for the years ended December 31, 2015 and 2014:

	Year Ended December 31,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 14,380	$ 11,283	$ 3,097	27 %
Pre-launch inventory	822	1,018	(196)	(19) %
Clinical trials	5,441	1,915	3,526	184 %
FDA fees	313	—	313	N/A
Testing, operating and lab supplies	9,577	6,511	3,066	47 %
Depreciation	3,795	3,725	70	2 %
Other expenses	2,943	4,414	(1,471)	(33) %
Total research and development expenses	$ 37,271	$ 28,866	$ 8,405	29 %

Provision for income tax benefit

	Year Ended December 31,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Income tax benefit	$ (7,577)	$ (7,449)	$ (128)	2 %
Effective tax rate	73 %	41 %		

Provision for income tax benefit was $7.6 million and $7.4 million for the years ended December 31, 2015 and 2014, respectively, representing an increase in income tax benefit of $0.2 million, or 2%.

Liquidity and Capital Resources

Cash Requirements and Sources

We need capital resources to maintain and expand our business. We expect our cash requirements to increase significantly in the foreseeable future as we sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our current development stage product candidates and pursue strategic acquisitions of businesses or assets. Our future capital expenditures include projects to upgrade, expand and improve our manufacturing

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facilities in the United States, China, and France. Our cash obligations include the principal and interest payments due on our existing loans and lease payments, as described below and throughout this Annual Report on Form 10-K. As of December 31, 2016, our foreign subsidiaries collectively held $18.3 million in cash and cash equivalents. We do not plan to repatriate foreign earnings to the U.S. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the U.S. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for the next 12 months. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the receipt of regulatory approval for any product candidates that we are developing or the timing of any product introductions, which could be lengthy or ultimately unsuccessful.

We maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of $250 million of our common stock, preferred stock, depositary shares, warrants, units, or debt securities. If we require or elect to seek additional capital through debt or equity financing in the future, we may not be able to raise capital on terms acceptable to us or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. If we are required and unable to raise additional capital when desired, our business, operating results and financial condition may be adversely affected.

Working capital increased $7.5 million to $123.5 million at December 31, 2016, compared to $116.0 million at December 31, 2015.

Cash Flows from Operations

The following table summarizes our cash flows used in operating, investing, and financing activities for the years ended December 31, 2016, 2015 and 2014.

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Statement of Cash Flow Data:			
Net cash provided by (used in)			
Operating activities	$ 38,560	$ 10,681	$ 21,052
Investing activities	(39,501)	(16,925)	(39,773)
Financing activities	7,140	2,237	32,117
Effect of exchange rate changes on cash	81	2,253	845
Net increase (decrease) in cash and cash equivalents	$ 6,280	$ (1,754)	$ 14,241

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $38.6 million for the year ended December 31, 2016, which included net income of $10.5 million. Non-cash items were comprised of $14.6 million of depreciation and amortization, and

$15.1 million of share-based compensation expense. This was partially offset by a change of $3.0 million in operating assets and liabilities, which was primarily due to the decrease of accounts receivable and an increase in inventory.

Accounts receivable declined by approximately $6.4 million as of December 31, 2016, as compared to December 31, 2015, primarily due to a decrease of sales of $13.4 million to $63.5 million in the fourth quarter of 2016 as compared to $76.9 million in the fourth quarter of 2015.

Inventories increased by approximately $9.7 million as of December 31, 2016, as compared to December 31, 2015. Enoxaparin related inventory increased by $8.5 million as a result of the timing of component and raw material purchases. Inventory relating to other finished pharmaceutical products increased by $1.5 million due to higher forecasted future demands.

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Investing Activities

Net cash used in investing activities was $39.5 million for the year ended December 31, 2016, primarily as a result of $7.7 million for the purchase of IMS UK, $4.0 million for the purchase of the 14 ANDAs from Hikma Pharmaceuticals PLC, $0.8 million relating to the acquisition of Nanjing Letop Medical Technology Co. Ltd., or Letop, and $21.4 million in purchases of property, machinery, and equipment, including the associated capitalized labor and interest on self-constructed assets. Additionally, $5.0 million in deposits were paid for machinery and equipment in 2016.

Financing Activities

Net cash provided by financing activities was $7.1 million for the year ended December 31, 2016. This cash inflow was primarily a result of $20.6 million of proceeds received from our equity plans. These inflows were offset by payments of $9.9 million relating to the repurchase of our common stock. Additionally, we refinanced two existing mortgages, which led to the receipts of $10.2 million, and these inflows were offset by $14.7 million of principal repayments, primarily related to these mortgage loans.

Debt and Borrowing Capacity

Our outstanding debt obligations are summarized as follows:

	December 31,		
	2016	2015	Change
	(in thousands)		
Short-term debt and current portion of long-term debt	$ 5,366	$ 10,934	$ (5,568)
Long-term debt	32,356	30,165	2,191
Total debt	$ 37,722	$ 41,099	$ (3,377)

As of December 31, 2016, we had $37.1 million in unused borrowing capacity under revolving lines of credit with Cathay Bank and East West Bank. At December 31, 2016, we were in compliance with our debt covenants, which include a minimum current ratio, minimum debt service coverage, minimum tangible net worth, and maximum debt-to-effective-tangible-net-worth ratio, computed on a consolidated basis.

Lines of credit bear variable interest rates and are secured by inventory, accounts receivable, intangible assets, and equipment. The weighted average interest rates on lines of credit as of December 31, 2016 and 2015, were 3.5% and 3.8%, respectively. We have also entered into or refinanced certain mortgage and equipment loans with Cathay Bank and East West Bank, which bear variable or fixed interest rates and are secured by buildings and equipment. On certain loans with East West Bank, we have entered into fixed interest rate swap contracts to exchange the variable interests for fixed interest rates without the exchange of underlying notional debt amounts.

For more information regarding our outstanding indebtedness, see “Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Debt.”

Critical Accounting Policies

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

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accounting policies are more fully described in Note 2 to our audited consolidated financial statements, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our audited consolidated financial statements.

Revenue Recognition

Our net revenues consist principally of revenues generated from the sale of our pharmaceutical products. We also generate a small amount of revenues from contract manufacturing services. Generally, we recognize revenues at the time of product delivery to our customers. In some cases, revenues are recognized at the time of shipment when stipulated by the terms of the sale agreements. Revenues derived from contract manufacturing services are recognized when third party products are shipped to customers, after the customer has accepted test samples of the products to be shipped.

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

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

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

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

Provision for Wholesaler Chargebacks

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

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

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Beginning balance	$ 15,217	$ 11,872
Provision related to sales made in the current period	166,987	162,238
Credits issued to third parties	(144,384)	(158,893)
Ending balance	$ 37,820	$ 15,217

Changes in the chargeback provision from period to period are primarily dependent on our sales to wholesalers, the level of inventory held at the wholesalers and the wholesalers' customer mix. The approach that we use to estimate chargebacks has been consistently applied for all periods presented. Variations in estimates have been historically small. We continually monitor the provision for chargebacks and make adjustments when we believe that the actual chargebacks may differ from the estimates. The settlement of chargebacks generally occurs within 30 days after the sale to wholesalers.

Accrual for Product Returns

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

When we do not have specific historical experience with actual returns for a product, we consider other available information to record a reasonable product return reserve. If we already sell products that are similar to a newly launched product, we estimate the new product return rate using historical experience of similar products. If there are similar products on the market produced by other companies, we may also consider the additional relevant industry data in calculating our estimate. The criteria used to make the determination of whether a new product is similar to existing products includes whether it: (i) is used for the treatment of a similar type of disease or indication, (ii) has a comparable shelf life, (iii) has similar frequency of dosing, (iv) has similar types of customers, (v) is distributed in a similar manner and (vi) has similar rights of return and other comparable sales incentives. We also consider whether we have the ability to monitor inventory levels in our distribution channels to determine the underlying patient demand for a new product. We analyze the product's sell through cycle based on wholesaler chargeback claims and customers' re ordering patterns to determine whether the estimated product return rate is reasonable. Additionally, we consider factors such as size and maturity of the market prior to launch and the introduction of additional competition. If the available information is not sufficient to estimate a reasonable product return accrual, revenues from the sales of the new product would not be recognized until the product is consumed by the end customer or rights of return granted under the return policy have expired. As of December 31, 2016, sales of approximately $0.5 million for one of our products were not recognized in revenues, due to insufficient information available to estimate a reasonable

product return accrual.

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

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

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Beginning balance	$ 2,621	$ 2,408
Provision for product returns	1,753	1,675
Credits issued to third parties	(1,231)	(1,462)
Ending balance	$ 3,143	$ 2,621

For the years ended December 31, 2016 and 2015, our aggregate product return rate was 1.1% and 1.1% of qualified sales, respectively.

Inventory

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

Impairment of Intangible and Long Lived Assets

We review long lived assets and definite-lived identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Such events and circumstances include decisions by the FDA regarding evidence of effectiveness of proprietary drug candidates or bioequivalence (sameness) of our generic product candidates as compared to the reference drug, communication with the regulatory agencies regarding the safety and efficacy of our products under review, the use of the asset in current research and development projects, any potential alternative uses of the asset in other research and development projects in the short to medium term, clinical trial results and research and development portfolio management options. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount exceeds the fair value of the assets (assets to be held and used) or fair value less cost to sell (assets to be disposed of). All of our impairments relate primarily to the isolated write off of certain manufacturing equipment related to abandoned projects. Since we periodically assess our product candidates and make changes to product development plans, we incur impairment charges from time to time. These charges are recorded in the impairment of long-lived assets line item on our consolidated statement of operations and can fluctuate significantly from period to period.

The only indefinite lived intangible asset, the Primatene® trademark acquired in June 2008, and goodwill are tested for impairment annually in the fourth quarter or more frequently if indicators of impairment are present. An impairment

loss is recorded if the asset's fair value is less than its carrying value. We also periodically review the Primatene® trademark to determine if events and circumstances continue to support an indefinite useful life. When we choose to perform a qualitative assessment, we evaluate economic, industry and company-specific factors as an initial step. If we determine it is more likely than not that the Primatene® trademark is impaired or the fair value of a reporting unit is less than its carrying amount, further quantitative impairment process is then performed; otherwise, no further testing is required. If the life is no longer indefinite, the asset is tested for impairment, and the carrying value, after recognition of any impairment loss, is amortized over its remaining useful life. No impairment of indefinite-lived intangible asset and goodwill was recorded during the years ended December 31, 2016, 2015, or 2014, respectively.

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Since December 31, 2011, we are no longer allowed to distribute the CFC formulation of our Primatene® Mist product related to this intangible asset. However, we have developed a hydrofluoroalkane, or HFA, version of this product, which we plan to market under the same trade name. In 2013, we filed a new drug application, or NDA, for Primatene® Mist. In May 2014, we received a complete response letter, or CRL, from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral/human factors and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. We submitted a responsive NDA amendment in June 2016 and received another CRL from the FDA in December 2016, which required additional packaging and label revisions and follow-up studies to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. We intend to continue to work with the FDA during the post-action phase to address their concerns in the CRL and bring Primatene® Mist back to the over-the-counter market as soon as possible. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the Primatene® Mist or approval at all.

Deferred Income Taxes

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

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

Share-Based Compensation

Options issued under our 2015 Equity Incentive Award Plan, or the 2015 Plan, and our Amended and Restated 2005 Equity Incentive Award Plan, or 2005 Plan are granted at exercise prices equal to or greater than the fair value of the underlying common shares on the date of grant and vest based on continuous service. There have been no awards with performance conditions and no awards with market conditions. The options have a contractual term of five to ten years and generally vest over a three to five year period. We use the Black Scholes option pricing model to determine the fair value of options awards. The Black Scholes option pricing model has various inputs such as the common share price on the date of grant, exercise price, the risk free interest rate, volatility, expected life and dividend yield, all of which are estimates. We used the risk free rate on U.S. Treasury securities at the time of grant for instruments with maturities commensurate with the expected term of the stock option. Our volatility estimate was based on a set of peer companies, since our shares do not have sufficient trading history. Management considers factors such as stage of life cycle, competitors, size, market capitalization and financial leverage in the selection of similar entities. Our dividend yield was assumed to be 0%, because we have no plans to pay dividends. We estimate the expected term of options with consideration of vesting date, contractual term, and historical experience for employee exercise and post-vesting employment termination behavior after our common stock has been publicly traded. The expected term of "plain vanilla" options is estimated based on the midpoint between the vesting date and the end of the contractual term under the simplified method.

The fair value of each share-based compensation award is amortized into compensation expense on a straight line basis between the grant date for the option and the vesting date net of expected forfeitures. We estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual numbers differ from such estimates. The change of any of these inputs could significantly impact the determination of the fair value of our options as well as significantly impact our results of operations.

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Common Stock Valuation Prior to Our Initial Public Offering

For all equity grants prior to our initial public offering on June 25, 2014, we were required to estimate the fair value of the common stock underlying our share based awards when performing the fair value calculations with the Black Scholes option pricing model. The fair values of the common stock underlying our share based awards were determined by our Board of Directors, with input from management and contemporaneous third party valuations. We believe that our Board of Directors had the relevant experience and expertise to determine the fair value of our common stock. As described below, the exercise price of our share based awards was determined by our Board of Directors based on a number of factors, including the most recent third party valuation report as of the grant date.

Given the absence of a public trading market of our common stock prior to our initial public offering, and in accordance with the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately Held Company Equity Securities Issued as Compensation, our Board of Directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock.

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

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

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

Once an enterprise value was determined, we utilized the option pricing method, or OPM, to allocate the equity value to our common stock. The OPM values each equity class by creating a series of call options on our equity value, with exercise prices based on the strike prices of derivatives. This method is generally preferred when future outcomes are difficult to predict and dissolution or liquidation is not imminent. The inability to readily sell shares of a company increases the owner’s exposure to changing market conditions and increases the risk of ownership. Because of the lack of marketability and the resulting increased risk associated with ownership of a privately held stock, an investor typically demands a higher return or yield in comparison to a similar but publicly traded stock. An indication of the discount for lack of marketability can be developed using a put option model. A put option model values what the illiquid security holder lacks, the ability to sell his or her shares. Theoretically, a holder of an illiquid security and a put option, and a holder of an identical, but liquid security, are in the same financial position. The put option model has the benefit of being company specific (through the use of a company specific volatility rate), verifiable and has relatively few inputs (risk free rate, term and volatility).

Business Combinations

If an acquired set of activities and assets is capable of being operated as a business consisting of inputs and processes from the viewpoint of a market participant, the assets acquired and liabilities assumed are a business. Business combinations are accounted for using the acquisition method of accounting. The fair value of the assets acquired and liabilities assumed are determinations based on discounted cash flow analyses or other valuation techniques. In determining the fair value of the assets acquired and liabilities assumed in a material acquisition, we may utilize appraisals from third party valuation firms to determine fair values of some or all of the assets acquired and liabilities assumed, or may complete some or all of the valuations internally. In either case, we take full responsibility for the

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determination of the fair value of the assets acquired and liabilities assumed. The fair value determination involves various inputs such as prospective financial information, discount rate, and other assumptions, all of which are estimates. The value of goodwill reflects the excess of the fair value of the consideration conveyed to the seller over the fair value of the net assets received.

Acquisition-related costs that we incur to effect a business combination are expensed in the periods in which the costs are incurred.

JOBS Act Accounting Election

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued an accounting standards update that creates a single source of revenue guidance for companies in all industries. The new standard provides guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers, unless the contracts are within the scope of other accounting standards. It also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required regarding customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. This guidance permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method). Based on the related accounting standards update issued in August 2015, this guidance will be effective for us in 2018, including interim periods within the year. While we are still in the process of evaluating the effect of adoption on our consolidated financial statements and are currently assessing our contracts with customers and sale of nonfinancial assets. We anticipate expanding our consolidated financial statement disclosures in order to comply with the new guidance. We expect to select the modified retrospective transition method upon the adoption. In addition, in February 2017, the FASB issued an accounting standards update to clarify the scope of the model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets and to add guidance for partial sales of nonfinancial assets. This guidance is to be applied using a full retrospective method or a modified retrospective method as outlined in the guidance and is effective at the same time as discussed above. We are currently evaluating the provisions of this guidance and assessing its potential impact on our financial statements and disclosures.

In July 2015, the FASB issued an accounting standards update which requires entities to measure most inventories at the lower of cost or net realizable value, or NRV, thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market. Under the new guidance, inventory is measured at the lower of cost

or net realizable value, which eliminates the need to determine replacement cost and evaluate whether it is above the ceiling (NRV) or below the floor (NRV less a normal profit margin). The guidance defines NRV as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. We have elected to adopt the guidance early and apply the guidance prospectively in our interim quarter beginning October 1, 2016. The adoption of this accounting guidance did not have a material impact on our consolidated financial statements and related disclosures.

In November 2015, the FASB issued an accounting standards update to the balance sheet classification of deferred taxes. Under existing standards, deferred taxes for each tax-paying jurisdiction are presented as a net current asset or liability and net long-term asset or liability. To simplify presentation, the new guidance will require that all deferred tax assets and liabilities, along with related valuation allowances, be classified as long-term on the balance sheet. As a result, each

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tax-paying jurisdiction will now only have one net long-term deferred tax asset or liability. The new guidance does not change the existing requirement that prohibits offsetting deferred tax liabilities from one jurisdiction against deferred tax assets of another jurisdiction. The guidance is effective for annual periods beginning after December 15, 2016, and interim reporting periods therein. Early adoption is permitted. The new guidance may be applied prospectively or retrospectively. We have elected to adopt the guidance early and apply the guidance prospectively. Therefore, prior periods were not retrospectively adjusted. The reclassification of our deferred tax assets and liabilities does not have any impact on our net income or cash flow; thus, the adoption of the guidance does not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued an accounting standards update that is aimed at making leasing activities more transparent and comparable, and which requires substantially all leases to be recognized by lessees on their balance sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This guidance will become effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements for the reporting periods in which the guidance is adopted. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued an accounting standards update that is aimed at improving the employee share-based payment accounting. The standard update simplifies the accounting for employee share-based payments and involves several aspects of the accounting for share-based transactions, including the potential timing of expenses, the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The guidance is effective for annual periods during the year ended December 15, 2017, and interim reporting periods therein. Early adoption is permitted. The adoption of the guidance is not expected to have a material impact on our consolidated financial statements and related disclosures.

In June 2016, the FASB issued an accounting standards update that is aimed at providing financial statement users with more useful information about the expected credit losses on financial instruments and other commitments to extend credit. The standard update changes the impairment model for financial assets measured at amortized cost, requiring presentation at the net amount expected to be collected. The measurement of expected credit losses requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Available-for-sale debt securities with unrealized losses will be recorded through an allowance for credit losses. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted for annual periods after 2019. We will be required to apply the standard’s provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued an accounting standards update that is aimed at addressing certain issues regarding classifications of certain cash receipt and cash payment on the statement of cash flows where diversity in practice was

identified. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted. We will be required to apply the guidance retrospectively in the first interim and annual periods in which the guidance is adopted. We do not believe that the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In October 2016, the FASB issued an accounting standards update that requires an entity to recognize the income tax consequences of intra-entity transfer of an asset other than inventory when the transfer occurs. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted as of the beginning of an annual reporting period for which financial statements, interim or annual, have not been issued. The amendments will be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

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In November 2016, the FASB issued an accounting standards update that will require entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, we will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted, including adoption in an interim period. The amendments will be applied using a retrospective transition method to each period presented. We will be required to apply the guidance retrospectively when adopted. We do not believe that the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued an accounting standards update that provides guidance to assist entities with evaluating when a set of transferred assets and activities is a business. Under the updated guidance, a set is not a business if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar assets. If the threshold is not met, the update requires that, to be a business, the set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. The definition of outputs was also aligned with ASC 606 by focusing on revenue-generating activities. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2018, and prospectively applicable to any transactions occurring within the period of adoption. Early adoption is permitted. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued an accounting standards update that eliminates the requirement to calculate the implied fair value of goodwill. An entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The FASB also eliminated the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020, and applied on a prospective basis. Early adoption is permitted for interim and annual goodwill impairment testing dates after January 1, 2017. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

Non-GAAP Financial Measures

We report our financial results in accordance with accounting principles generally accepted in the United States, or GAAP.

Collaboration Agreement with a Medical Device Manufacturer

We have entered into a collaboration agreement with a medical device manufacturer to develop a drug delivery system to be used by us for one of our pipeline products. As of December 31, 2016, we have paid an upfront payment of $0.5 million and $1.2 million in milestone payments under this agreement, which were classified as research and development expense. We are obligated to pay up to an additional $0.8 million if certain milestones are met. As of December 31, 2016, no such obligation existed. Pursuant to the collaboration agreement, if the medical device manufacturer is successful in the development of this drug delivery system and our pipeline products receive appropriate regulatory approval, we intend to enter into a commercial supply agreement with such medical device manufacturer for a minimum purchase of 1.0 million units during the first 12 months.

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Contractual Obligations

Set forth below are our contractual payment obligations (including interest obligations but excluding intercompany obligations) as of December 31, 2016:

Contractual Obligations(1)	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
	(in thousands)				
Long-term debt(2)	$ 41,049	$ 6,452	$ 20,900	$ 9,890	$ 3,807
Operating leases	7,817	3,038	3,962	817	—
Capital leases	1,864	429	860	575	—
Facility construction in Nanjing, China(3)	15,000	—	15,000	—	—
Purchase obligations(4)	41,879	27,547	14,332	—	—
	$ 107,609	$ 37,466	$ 55,054	$ 11,282	$ 3,807

(1) The table above excludes (i) our liability for uncertain tax position of $6.7 million because the timing of any related payments cannot be reasonably estimated.

(2) Long term debt includes accrued and unpaid interest. As of December 31, 2016, the principal amount of long-term debt with variable interest exposure was $20.4 million. As of December 31, 2016, the weighted average variable interest rate on our long term debt was 4.0%.

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

(4) The purchase obligations principally relate to inventory and pharmaceutical manufacturing and laboratory equipment. We anticipate meeting these purchase obligations through a combination of cash on hand, future cash flows from operations and debt and lease facilities.

Off Balance Sheet Arrangements

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

Investment in China

We entered into agreements with a Chinese governmental entity to acquire land use rights to real property in Nanjing, China. Under the terms of these agreements, we are committed to invest capital in our wholly owned subsidiary, Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP, and to develop these properties as an API manufacturing facility for our pipeline products. In conjunction with these agreements, ANP modified its business license on July 3, 2012, to increase its authorized capital. As of December 31, 2016, we have invested the total registered capital commitment of $61.0 million to ANP. This investment in ANP resulted in cash being transferred from the U.S. parent company to ANP.

Per these agreements, in January 2010 we acquired certain land use rights with a carrying value of $1.2 million. In addition, we purchased additional land use rights in November 2012 for $1.3 million. We are committed to spend approximately $15.0 million in land development. The agreements require the construction of fixed assets on the property and specified a timetable for the construction of these fixed assets. The current pace of development of the property is behind the schedule described in the purchase agreement and, per the purchase agreement, potential monetary penalties could result if the development is delayed or not completed in accordance with the guidelines

stated in the purchase agreements. We are in discussions with the Chinese government regarding the development and believe that the likelihood of incurring any penalty is remote.

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies. The Food and Drug Administration, or FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The Drug Enforcement Administration, or DEA, maintains oversight over our products that are considered controlled substances.

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From February 29, 2016 through March 4, 2016, our facility in Éragny-sur-Epte, France was subject to an inspection by the FDA. The inspection included a review of Quality Systems, Production Controls, Laboratory Controls, Material Management, and Facilities and Equipment Maintenance. The inspection resulted in multiple observations on Form 483, an FDA form on which dificiencies are noted after an FDA inspection. We responded to those observations on March 24, 2016. We believe that our response to the Form 483 will satisfy the requirements of the FDA and that no further actions will be necessary. We received a correspondence from the FDA on June 3, 2016, stating that the inspection was considered closed.

From April 25, 2016 through April 28, 2016, our facility in Nanjing, China was subject to an inspection by the FDA. The inspection included a review of Quality Systems, Production Controls, Laboratory Controls, Material Management, and Facilities and Equipment Maintenance. The inspection resulted in no observations on Form 483. We received a correspondence from the FDA on July 27, 2016, stating that the inspection was considered closed.

From August 22, 2016 through August 26, 2016, our facility in Rancho Cucamonga, California was subject to an inspection of the bioanalytical data and operations for the conduct of the bioequivalence studies conducted by us. The inspection resulted in multiple observations on Form 483. We responded to those observations on September 16, 2016. That same day, we received an e-mail confirmation of receipt of our response to the FDA. We believe that our response to the Form 483 will satisfy the requirements of the FDA and that no further actions will be necessary. No further correspondence has been received from the FDA to date in this regard.

From October 6, 2016 through October 14, 2016, our third party contract clinical study site was subject to a biomedical inspection by the FDA covering pharmacokinetic (PK) clinical studies, executed per our in-house designed protocols. There were no Form 483 observations issued at the end of the inspection.

From October 17, 2016 through October 21, 2016, our facility in Chino, California was subject to inspection of the facility’s compliance with Good Laboratory Practices regulations, and associated operations for the conduct of the non-clinical safety/toxicity studies conducted by us. The inspection resulted in multiple observations on Form 483. We responded to those observations on November 11, 2016, in accordance with FDA requirements. A confirmation of receipt was received on November 14, 2016. A follow up letter was received from the FDA on November 29, 2016, and our follow up response was sent on December 12, 2016. We received a correspondence dated January 9, 2017 that our responses appear to be adequate. Additional correspondence from the FDA District Office dated January 14, 2017, confirmed that the FDA considered the inspection closed.

From November 29, 2016 through December 7, 2016, our IMS facility in South El Monte, California was subject to an inspection by the FDA. The inspection included a review of our compliance with cGMP regulations and verification of corrective actions implemented from a previous inspection in July 2015. The inspection resulted in multiple observations on Form 483, an FDA form on which deficiencies are noted after an FDA inspection. We responded to those observations on December 29, 2016, within the required 15-working day window of the issuance of the Form 483. A follow up letter to the FDA District Office was additionally sent on January 31, 2017, outlining

additional progress on our corrective action plan submitted in December. We believe that our responses to Form 483 will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From January 30, 2017 through February 09, 2017, our IMS facility in South El Monte, California was subject to a preapproval inspection by the FDA. The inspection included a review of our corrective actions taken from the recent cGMP inspection as well as review of data to support our pending application. The inspections resulted in multiple observations on Form 483. We responded to those observations on February 14, 2017.

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Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The following discussion provides forward-looking quantitative and qualitative information about our potential exposure to market risk. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings. We are exposed to market risk for changes in the market values of our investments (Investment Risk), the impact of interest rate changes (Interest Rate Risk), and the impact of foreign currency exchange changes (Foreign Currency Exchange Risk).

Investment Risk

We regularly review the carrying value of our investments and identify and recognize losses, for income statement purposes, when events and circumstances indicate that any declines in the fair values of such investments below our accounting basis are other than temporary. As of December 31, 2016, we did not have any such investments.

As of December 31, 2016, we had $15.3 million deposited in four banks located in China, $2.8 million deposited in one bank located in France, and $0.2 million deposited in one bank located in the United Kingdom. We also maintained $36.1 million in cash equivalents that include money market accounts, money market funds, Money Market Insured Deposit Account Service, or MMIDAS, and Insured Cash Sweep, or ICS, accounts as of December 31, 2016. The remaining amounts of our cash equivalent as of December 31, 2016, are in non-interest bearing accounts.

As of December 31, 2015, we had $6.0 million deposited in three banks located in China and $1.6 million deposited in one bank located in France. We also maintained $42.5 million in Money Market, MMIDAS, and ICS, accounts as of December 31, 2015. The remaining amounts of our cash equivalent as of December 31, 2015, are in non-interest bearing accounts.

The MMIDAS accounts and ICS accounts allow us to distribute our funds among a network of depository institutions that are re allocated such that each deposit account is below the $250.0 thousand Federal Deposit Insurance Corporation, or FDIC, limit, thus providing greater FDIC insurance coverage for our overall cash balances. We have not experienced any losses in such accounts, nor do we believe we are exposed to any significant credit risk on our bank account balances.

Interest Rate Risk

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

As of December 31, 2016, we had $37.7 million in long-term debts and capital leases outstanding. Of this amount, $20.4 million had variable interest rates which were not locked-in through fixed interest rate swap contracts. The debt with variable interest rate exposure had a weighted-average interest rate of 4.0% at December 31, 2016. An increase in the index underlying these rates of 1% (100 basis points) would increase our annual interest expense on the debts with variable interest rate exposure by approximately $0.2 million per year. As of December 31, 2015, we had $41.1 million in long-term debts and capital leases outstanding. Of this amount, $26.6 million had variable interest rates which were not locked-in through fixed interest rate swap contracts. The debts with variable interest rate exposure had a weighted-average interest rate of 4.0% at December 31, 2015. An increase in the index underlying these rates of 1%

(100 basis points) would increase our annual interest expense on the debts with variable interest rate exposure by approximately $0.3 million per year.

Foreign Currency Rate Risk

Our products are primarily sold in the U.S. domestic market, and for the years ended December 31, 2016, 2015, and 2014, foreign sales were minimal. Therefore, we have little exposure to foreign currency price fluctuations. However, as a result of our acquisition of the API manufacturing business in Éragny-sur-Epte, France, we are exposed to market risk

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related to changes in foreign currency exchange rates. Specifically, our insulin sales contracts are primarily denominated in Euros, which are subject to fluctuations relative to the U.S. dollar, or USD. We do not currently hedge our foreign currency exchange rate risk. At this time, an immediate 10% change in currency exchange rates would not have a material effect on our financial position, results of operations or cash flows.

Our Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Limited, or ANP, maintains their books of record in Chinese Yuan. These books are remeasured into the functional currency of USD using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign exchange gains and losses are reflected in our statement of operations.

Our French subsidiary, Amphastar France Pharmaceuticals, S.A.S., or AFP, maintains their books of record in Euros. Our U.K. subsidiary, International Medication Systems (UK) Limited, or IMS UK, maintains its books of record in Great Britain Pounds. These books are translated to USD at the average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing exchange rate at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other comprehensive income (loss). We do not undertake hedging transactions to cover our foreign currency exposure.

As of December 31, 2016 and 2015, our foreign subsidiaries had cash balances denominated in foreign currencies in the amount of $3.5 million and $3.9 million, respectively.

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Item 8. Financial Statements and Supplementary Data.

Index to Amphastar Pharmaceuticals, Inc. Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Amphastar Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Amphastar Pharmaceuticals, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Amphastar Pharmaceuticals, Inc. at December 31, 2016 and 2015, and the consolidated results of its operations, and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Los Angeles, California

March 15, 2017

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AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 72,354	$ 66,074
Short-term investments	527	—
Restricted short-term investments	1,390	1,285
Accounts receivable, net	26,777	33,233
Inventories	79,754	70,665
Income tax refunds and deposits	22	238
Prepaid expenses and other assets	3,272	4,439
Total current assets	184,096	175,934
Property, plant, and equipment, net	152,944	142,161
Goodwill and intangible assets, net	50,307	39,901
Other assets	9,390	4,696
Deferred tax assets	31,001	27,444
Total assets	$ 427,738	$ 390,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 16,196	$ 13,872
Accrued liabilities	15,703	16,732
Income taxes payable	7,705	3,076
Accrued payroll and related benefits	13,847	12,840
Current portion of product return accrual	1,800	1,858
Current portion of deferred revenue	—	643
Current portion of long-term debt and capital leases	5,366	10,934
Total current liabilities	60,617	59,955
Long-term product return accrual	1,343	763
Long-term reserve for income tax liabilities	845	497
Long-term deferred revenue	97	1,339
Long-term debt and capital leases, net of current portion	32,356	30,165
Deferred tax liabilities	1,455	—
Other long-term liabilities	1,770	1,907
Total liabilities	98,483	94,626
Commitments and contingencies:		
Stockholders’ equity:		
	—	—

Preferred stock: par value $0.0001; 20,000,000 shares authorized; no shares issued and outstanding		
Common stock: par value $0.0001; 300,000,000 shares authorized; 47,765,149 and 46,248,622 shares issued and outstanding as of December 31, 2016 and 45,960,206 and 45,198,491 shares issued and outstanding as of December 31, 2015, respectively	5	5
Additional paid-in capital	283,123	247,829
Retained earnings	70,855	60,323
Accumulated other comprehensive loss	(4,696)	(2,475)
Treasury stock	(20,032)	(10,172)
Total stockholders' equity	329,255	295,510
Total liabilities and stockholders' equity	$ 427,738	$ 390,136

See accompanying notes to consolidated financial statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2016	2015	2014
Net revenues	$ 255,165	$ 251,519	$ 210,461
Cost of revenues	150,976	174,172	159,205
Gross profit	104,189	77,347	51,256
Operating expenses:			
Selling, distribution, and marketing	5,466	5,470	5,564
General and administrative	41,832	41,504	34,809
Research and development	41,199	37,271	28,866
Total operating expenses	88,497	84,245	69,239
Income (loss) from operations	15,692	(6,898)	(17,983)
Non-operating income (expense):			
Interest income	270	315	243
Interest expense	(1,024)	(987)	(609)
Other income (expense), net	8	(2,794)	201
Total non-operating expense, net	(746)	(3,466)	(165)
Income (loss) before income taxes	14,946	(10,364)	(18,148)
Income tax expense (benefit)	4,414	(7,577)	(7,449)
Net income (loss)	$ 10,532	$ (2,787)	$ (10,699)
Net income (loss) per share:			
Basic	$ 0.23	$ (0.06)	$ (0.25)
Diluted	$ 0.22	$ (0.06)	$ (0.25)
Weighted-average shares used to compute net income (loss) per share:			
Basic	45,375	44,961	41,957
Diluted	47,504	44,961	41,957

See accompanying notes to consolidated financial statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

	Year Ended December 31,		
	2016	2015	2014
Net income (loss)	$ 10,532	$ (2,787)	$ (10,699)
Other comprehensive income (loss), net of income taxes			
Foreign currency translation adjustment	(1,800)	(805)	(1,810)
Change in pension obligations	(421)	(16)	156
Total other comprehensive loss	(2,221)	(821)	(1,654)
Total comprehensive income (loss)	$ 8,311	$ (3,608)	$ (12,353)

See accompanying notes to consolidated financial statements.

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Amphastar Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

	Common Stock		Additional Paid-in	Retained	Accumulated Other Comprehensive Income	Treasury Stock		
	Shares	Amount	Capital	Earnings	(loss)	Shares	Amount	Total
Balance as of December 31, 2013	38,765,940	$ 4	$ 177,732	$ 73,809	$ —	—	$ —	$ 251,545
Net loss	—	—	—	(10,699)	—	—	—	(10,699)
Accumulated other comprehensive loss	—	—	—	—	(1,654)	—	—	(1,654)
Common stock issued through initial public offering	5,840,000	—	38,018	—	—	—	—	38,018
Cost related to public offering	—	—	(3,358)	—	—	—	—	(3,358)
Treasury stock acquired	—	—	—	—	—	(29,400)	(345)	(345)
Issuance of common stock in connection with the Company's equity plans	70,227	—	182	—	—	—	—	182
Share-based compensation expense	—	—	9,280	—	—	—	—	9,280
Tax effect of share-based compensation	—	—	(1,109)	—	—	—	—	(1,109)
Balance as of December 31, 2014	44,676,167	4	220,745	63,110	(1,654)	(29,400)	(345)	281,860
Net loss	—	—	—	(2,787)	—	—	—	(2,787)
Accumulated other comprehensive loss	—	—	—	—	(821)	—	—	(821)
Treasury stock acquired	—	—	—	—	—	(735,679)	(9,865)	(9,865)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(38)	—	—	3,364	38	—
	1,284,039	1	14,200	—	—	—	—	14,201

Issuance of common stock in connection with the Company's equity plans								
Share-based compensation expense	—	—	12,815	—	—	—	—	12,815
Tax effect of share-based compensation	—	—	107	—	—	—	—	107
Balance as of December 31, 2015	45,960,206	5	$ 247,829	60,323	(2,475)	(761,715)	(10,172)	295,510
Net income	—	—	—	10,532	—	—	—	10,532
Accumulated other comprehensive loss	—	—	—	—	(2,221)	—	—	(2,221)
Treasury stock acquired	—	—	—	—	—	(759,067)	(9,908)	(9,908)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(48)	—	—	4,255	48	—
Issuance of common stock in connection with the Company's equity plans	1,804,943	—	20,639	—	—	—	—	20,639
Share-based compensation expense	—	—	15,124	—	—	—	—	15,124
Tax effect of share-based compensation	—	—	(421)	—	—	—	—	(421)
Balance as of December 31, 2016	47,765,149	$ 5	$ 283,123	$ 70,855	$ (4,696)	(1,516,527)	$ (20,032)	$ 329,255

See accompanying notes to consolidated financial statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash Flows From Operating Activities:			
Net income (loss)	$ 10,532	$ (2,787)	$ (10,699)
Reconciliation to net cash provided by operating activities:			
Loss on disposal and impairment of property, plant, and equipment	1,242	310	485
Depreciation of property, plant, and equipment	12,047	11,314	12,528
Amortization of product rights, trademarks, and patents	2,517	1,938	1,920
Imputed interest accretion	72	110	163
Share-based compensation	15,124	12,815	9,280
Reserve for uncertain tax positions	347	(1)	499
Changes in deferred taxes	(3,618)	(7,880)	(8,743)
Changes in operating assets and liabilities:			
Accounts receivable, net	6,377	(11,012)	1,210
Inventories	(9,715)	9,775	6,565
Prepaid expenses and other assets	1,129	(699)	(88)
Income tax refund, deposits, and payable	3,329	(71)	2,432
Accounts payable and accrued liabilities	(823)	(3,131)	5,500
Net cash provided by operating activities	38,560	10,681	21,052
Cash Flows From Investing Activities:			
Business Acquisitions	(12,461)	—	(18,352)
Purchases and construction of property, plant, and equipment	(21,382)	(16,047)	(20,499)
Proceeds from the sale of property, plant and equipment	—	51	—
Purchase of short-term investments	(3,602)	—	—
Maturity of short-term investments	3,075	—	—
Changes in restricted short-term investments	(105)	210	(170)
Payment of deposits and other assets	(5,026)	(1,139)	(752)
Net cash used in investing activities	(39,501)	(16,925)	(39,773)
Cash Flows From Financing Activities:			
Net proceeds from equity plans	20,639	14,201	38,200
Excess tax benefit related to share-based compensation	863	107	(1,109)
Cost related to public offering	—	—	(1,920)
Purchase of treasury stock	(9,908)	(9,865)	(345)
Proceeds from borrowing under lines of credit	—	—	25,000
Repayments under lines of credit	—	—	(40,000)
Proceeds from issuance of long-term debt	10,198	6,785	26,505
Principal payments on long-term debt	(14,652)	(8,991)	(8,216)
Principal payments on short-term debt	—	—	(5,998)

Net cash provided by financing activities	7,140	2,237	32,117
Effect of exchange rate changes on cash	81	2,253	845
Net increase (decrease) in cash and cash equivalents	6,280	(1,754)	14,241
Cash and cash equivalents at beginning of period	66,074	67,828	53,587
Cash and cash equivalents at end of period	$ 72,354	$ 66,074	$ 67,828
Noncash Investing and Financing Activities:			
Equipment acquired under capital leases	$ 1,238	$ 150	$ 78

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	Year Ended December 31,		
	2016	2015	2014
Supplemental Disclosures of Cash Flow Information:			
Interest paid, net of capitalized interest	$ 1,722	$ 1,941	$ 2,607
Income taxes paid	$ 3,397	$ 146	$ 436

See accompanying notes to consolidated financial statements

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. General

Amphastar Pharmaceuticals, Inc., a California corporation, was incorporated on February 29, 1996 and merged with and into Amphastar Pharmaceuticals, Inc., a Delaware corporation, in July 2004 (together with its subsidiaries, hereinafter referred to as “the Company”). The Company is a specialty pharmaceutical company that primarily develops, manufactures, markets, and sells generic and proprietary injectable, inhalation, and intranasal products, including products with high technical barriers to market entry. Additionally, the Company sells insulin active pharmaceutical ingredient, or API products. Most of the Company’s products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. The Company’s insulin API products are sold to other pharmaceutical companies for use in their own products and are being used by the Company in the development of injectable finished pharmaceutical products. The Company’s inhalation products will be primarily distributed through drug retailers once they are brought to market.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, and are prepared in accordance with accounting principles generally accepted in the United States, or GAAP. Certain amounts in the prior years’ consolidated statements of operations have been reclassified to conform to the current year presentation. This reclassification has no impact on net income or cash flows. All significant intercompany activity has been eliminated in the preparation of the consolidated financial statements. The Company’s subsidiaries include: (1) International Medication Systems, Limited, or IMS; (2) Armstrong Pharmaceuticals, Inc., or Armstrong; (3) Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP; (4) Nanjing Letop Fine Chemistry Co., Ltd., or Letop, (5) Amphastar France Pharmaceuticals, S.A.S., or AFP, (6) Amphastar UK Ltd., or AUK, and (7) International Medication Systems (UK) Limited, or IMS UK.

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying

notes. Actual results could differ from those estimates. The principal accounting estimates include: determination of allowances for doubtful accounts and discounts, provision for chargebacks, liabilities for product returns, adjustment to cost for excess or unsellable inventory, impairment of long-lived and intangible assets and goodwill, self-insured claims, workers' compensation liabilities, litigation reserves, stock price volatilities for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

The functional currency of the Company, its domestic subsidiaries, its Chinese subsidiary, ANP, and its U.K. subsidiary, AUK, is the U.S. dollar, or USD. ANP maintains its books of record in Chinese Yuan. These books are remeasured into the functional currency of USD using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign currency exchange gains and losses are reflected in the Company's statements of operations.

The Company's French subsidiary, AFP, Chinese subsidiary, Letop, and U.K. subsidiary, IMS UK, maintain their books of record in Euros, Chinese Yuan, and Great Britain Pounds, respectively, which are the local currencies and have been determined to be their respective functional currencies. These books are translated into USD using average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other accumulated comprehensive income (loss). The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

are reported in other accumulated comprehensive income (loss). The unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature for the years ended December 31, 2016, 2015, and 2014 were a $1.5 million loss, $2.0 million loss, and a $2.7 million loss, respectively.

Additionally, the Company does not undertake hedging transactions to cover its foreign currency exposure.

Comprehensive Income (Loss)

For the years ended December 31, 2016, 2015 and 2014, the Company included its foreign currency translation gain or loss and change in pension obligation of its defined benefit pension plan as part of its comprehensive income (loss).

Shipping and Handling Costs

For the years ended December 31, 2016, 2015, and 2014, the Company included shipping and handling costs of approximately $2.4 million, $2.6 million, and $2.5 million, respectively, in selling, distribution and marketing expenses in the accompanying consolidated statements of operations.

Research and Development Costs

Research and development costs are charged to expense as incurred and consist of costs incurred to further the Company’s research and development activities including salaries and related employee benefits, costs associated with clinical trials, nonclinical research and development activities, regulatory activities, research related overhead expenses and fees paid to external service providers.

The Company may produce inventories prior to or with the expectation of receiving marketing authorization in the near term, based on operational decisions about the most effective use of existing resources. This inventory is referred

to as pre launch inventory. It is the Company's accounting policy that the pre-launch inventory is capitalized if it has a probable future economic benefit. If marketing authorization is received and previously expensed pre launch inventory is sold, such sales may contribute up to a 100% margin to the Company's operating results. Pre launch inventory costs include cost of work in process, materials, and finished drug products. As of December 31, 2016, 2015, and 2014, the Company did not have any capitalized pre-launch inventory.

Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, restricted short-term investments, accounts receivable, accounts payable, accrued expenses, and short-term borrowings approximate fair value due to the short maturity of these items. A majority of the Company's long-term obligations consist of variable rate debt and their carrying value approximates fair value as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities. However, the Company has one fixed-rate, long-term mortgage for which the carrying value differs from the fair value and is not remeasured on a recurring basis (see Note 12). The Company at times enters into fixed interest rate swap contracts to exchange the variable interest rates for fixed interest rates without the exchange of the underlying notional debt amounts. Such interest rate swap contracts are recorded at their fair values.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash, money market accounts, money market funds, certificates of deposit and highly liquid investments purchased with original maturities of three months or less.

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Restricted Short Term Investments and Short-Term Investments

Restricted short term investments as of December 31, 2016 and 2015 included $1.4 million and $1.3 million, respectively, in certificates of deposit, which are the collateral required for the Company to qualify for workers' compensation self insurance and are available to meet the Company's workers' compensation obligations on a current basis, as needed. These funds are classified as current assets. The Company's short term investments include municipal bonds with original maturities greater than three months and are classified as held-to-maturity. The municipal bonds are carried at amortized cost in the Company's consolidated balance sheet, which approximates their fair value determined based on Level 2 inputs. The Company does not intend to and will not be required to sell the investments before recovery of their amortized cost basis.

Allowance for Doubtful Accounts Receivable

The Company evaluates the collectability of accounts receivable based on a combination of factors. When the Company is aware of circumstances that may impair a customer's ability to pay subsequent to the original sale, the Company records a specific allowance to reduce the amounts receivable to the amount that the Company reasonably believes to be collectable. For all other customers, the Company recognizes an allowance for doubtful accounts based on factors that include the length of time the receivables are past due, industry and geographic concentrations, the current business environment and historical collection experience. As of December 31, 2016 and 2015, the Company's allowance for doubtful accounts was $0.3 million and $0.7 million, respectively.

Inventories

Inventories consist of currently marketed products and products manufactured under contract. Inventories are stated at the lower of cost or net realizable value, using the first in, first out method. Provisions are made for slow moving, unsellable, or obsolete items. Net realizable value is the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose. The charge of $7.3 million was included in the cost of revenues in the Company's consolidated statements of operations for the year ended December 31, 2016 to adjust the Company's inventory items to their net realizable value, including $3.1 million related to enoxaparin inventory items due to a decrease in the forecasted average selling price and $3.3 million related to Epinephrine Injection, USP vial inventory items and firm purchase commitments due to the anticipated discontinuation of the product.

Property, Plant and Equipment

Property, plant and equipment are stated at cost or, in the case of assets acquired in a business combination, at fair value on the purchase date. Depreciation and amortization expense is computed using the straight line method over the estimated useful lives of the related assets as follows:

Buildings	20 - 31 years
Machinery and equipment	2 - 12 years
Furniture and fixtures	3 - 7 years
Automobiles	4 - 5 years
Leasehold improvements	Lesser of remaining lease term or useful life

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Intangible Assets

Intangible assets with finite lives are amortized using the straight-line method over the period the asset is expected to contribute directly or indirectly to the future cash flows of the Company as follows:

Product rights	5 - 15 years
Patents	10 - 20 years
Land-use rights	37 - 50 years

Impairment of Long Lived Assets, including Identifiable Definite-Lived Intangible Assets

The Company reviews long-term assets and identifiable definite-lived intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset or an asset group, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount of the asset exceeds the fair value of the assets (assets to be held and used) or fair value less cost to sell (assets to be disposed of). The Company also reviews the useful lives of its assets periodically to determine whether events and circumstances warrant a revision to the remaining useful life. Changes in the useful life are adjusted prospectively by revising the remaining period over which the asset is amortized.

Deferred Income Taxes

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

Impairment of Indefinite-Lived Intangible Asset and Goodwill

The Company reviews indefinite lived intangible asset and goodwill for impairment in the fourth quarter of each year or more frequently if indicators of impairment are present. When the Company chooses to perform a qualitative assessment, it evaluates economic, industry and company-specific factors as an initial step. If the Company determines it is more likely than not that the indefinite-lived intangible asset is impaired or the fair value of a reporting unit is less than its carrying amount, further quantitative impairment process is then performed; otherwise, no further testing is required. An impairment loss is recorded if the asset's fair value is less than its carrying value. The Company also periodically reviews the indefinite-lived intangible asset to determine if events and circumstances continue to support an indefinite useful life. If the life is no longer indefinite, the asset is tested for impairment. The carrying value, after recognition of any impairment loss, is amortized over its remaining useful life.

Self-Insured Claims

The Company is primarily self-insured, up to certain limits, for workers' compensation claims. The Company has purchased stop-loss insurance, which will reimburse the Company for individual claims in excess of $350,000 annually or aggregate claims exceeding $1.9 million annually. Operations are charged with the cost of claims reported and an estimate of claims incurred but not reported. A liability for unpaid claims and the associated claim expenses, including incurred but not reported losses, is actuarially determined and reflected in accrued liabilities in the accompanying consolidated balance sheets. Total expense under the program was approximately $1.6 million, $1.2 million, and $1.0 million, for the years ended December 31, 2016, 2015 and 2014, respectively. The self-insured claims liability was

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

$3.5 million and $2.7 million at December 31, 2016 and 2015, respectively. The determination of such claims and expenses and the appropriateness of the related liability is reviewed periodically and updated, as necessary. Changes in estimates are recorded in the period identified.

Business Combinations

If an acquired set of activities and assets is capable of being operated as a business consisting of inputs and processes from the viewpoint of a market participant, the asset acquired and liabilities assumed are a business. Business combinations are accounted for using the acquisition method of accounting, which requires an acquirer to recognize the assets acquired and the liabilities assumed at the acquisition date measured at their fair values as of that date. Fair value determinations are based on discounted cash flow analyses or other valuation techniques. In determining the fair value of the assets acquired and liabilities assumed in a material acquisition, the Company may utilize appraisals from third party valuation firms to determine fair values of some or all of the assets acquired and liabilities assumed, or may complete some or all of the valuations internally. In either case, the Company takes full responsibility for the determination of the fair value of the assets acquired and liabilities assumed. The value of goodwill reflects the excess of the fair value of the consideration conveyed to the seller over the fair value of the net assets received.

Acquisition-related costs that the Company incurs to effect a business combination are expensed in the periods in which the costs are incurred. When the operations of the acquired businesses were not material to the Company’s consolidated financial statements, no pro forma presentation is disclosed.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued an accounting standards update that creates a single source of revenue guidance for companies in all industries. The new standard provides guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers, unless the contracts are within the scope of other accounting standards. It also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required regarding customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. This guidance permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the

guidance recognized at the date of initial application (the cumulative catch-up transition method). Based on the related accounting standards update issued in August 2015, this guidance will be effective for the Company in 2018, including interim periods within the year. While the Company is still in the process of evaluating the effect of adoption on its consolidated financial statements and is currently assessing its contracts with customers and sale of nonfinancial assets. The Company anticipates it will expand its consolidated financial statement disclosures in order to comply with the new guidance. The Company expects to select the modified retrospective transition method upon the adoption. In addition, in February 2017, the FASB issued an accounting standards update to clarify the scope of the model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets and to add guidance for partial sales of nonfinancial assets. This guidance is to be applied using a full retrospective method or a modified retrospective method as outlined in the guidance and is effective at the same time as discussed above. The Company is currently evaluating the provisions of this guidance and assessing its potential impact on the Company’s financial statements and disclosures.

In July 2015, the FASB issued an accounting standards update which requires entities to measure most inventories at the lower of cost or net realizable value, or NRV, thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market. Under the new guidance, inventory is measured at the lower of cost or net realizable value, which eliminates the need to determine replacement cost and evaluate whether it is above the ceiling (NRV) or below the floor (NRV less a normal profit margin). The guidance defines NRV as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The Company has elected to adopt the guidance early and apply the guidance prospectively in its interim quarter beginning

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

October 1, 2016. The adoption of this accounting guidance did not have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2015, the FASB issued an accounting standards update to the balance sheet classification of deferred taxes. Under existing standards, deferred taxes for each tax-paying jurisdiction are presented as a net current asset or liability and net long-term asset or liability. To simplify presentation, the new guidance will require that all deferred tax assets and liabilities, along with related valuation allowances, be classified as long-term on the balance sheet. As a result, each tax-paying jurisdiction will now only have one net long-term deferred tax asset or liability. The new guidance does not change the existing requirement that prohibits offsetting deferred tax liabilities from one jurisdiction against deferred tax assets of another jurisdiction. The guidance is effective for annual periods beginning after December 15, 2016, and interim reporting periods therein. Early adoption is permitted. The new guidance may be applied prospectively or retrospectively. The Company has elected to adopt the guidance early and apply the guidance prospectively. Therefore, prior periods were not retrospectively adjusted. The reclassification of the Company's deferred tax assets and liabilities does not have any impact on the Company's net income or cash flow; thus, the adoption of the guidance does not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued an accounting standards update that is aimed at making leasing activities more transparent and comparable, and which requires substantially all leases to be recognized by lessees on their balance sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This guidance will become effective for the Company's interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements for the reporting periods in which the guidance is adopted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued an accounting standards update that is aimed at improving the employee share-based payment accounting. The standard update simplifies the accounting for employee share-based payments and involves several aspects of the accounting for share-based transactions, including the potential timing of expenses, the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The guidance is effective for annual periods during the year ended December 15, 2017, and interim reporting periods therein. Early adoption is permitted. The adoption of the guidance is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In June 2016, the FASB issued an accounting standards update that is aimed at providing financial statement users with more useful information about the expected credit losses on financial instruments and other commitments to extend credit. The standard update changes the impairment model for financial assets measured at amortized cost, requiring presentation at the net amount expected to be collected. The measurement of expected credit losses requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Available-for-sale debt securities with unrealized losses will be recorded through an allowance for credit losses. The guidance is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted for annual periods after 2019. The Company will be required to apply the standard’s provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued an accounting standards update that is aimed at addressing certain issues regarding classifications of certain cash receipt and cash payment on the statement of cash flows where diversity in practice was identified. The guidance is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted. The Company will be required to apply the guidance retrospectively in the first interim and annual periods in which the guidance is adopted. The Company does not believe that the adoption of this accounting guidance will have a material impact on the Company’s consolidated financial statements and related

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

disclosures.

In October 2016, the FASB issued an accounting standards update that requires an entity to recognize the income tax consequences of intra-entity transfer of an asset other than inventory when the transfer occurs. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted as of the beginning of an annual reporting period for which financial statements, interim or annual, have not been issued. The amendments will be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In November 2016, the FASB issued an accounting standards update that will require entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, the Company will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted, including adoption in an interim period.

The amendments will be applied using a retrospective transition method to each period presented. The Company will be required to apply the guidance retrospectively when adopted. The Company does not believe that the adoption of this accounting guidance will have a material impact on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued an accounting standards update that provides guidance to assist entities with evaluating when a set of transferred assets and activities is a business. Under the updated guidance, a set is not a business if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar assets. If the threshold is not met, the update requires that, to be a business, the set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. The definition of outputs was also aligned with ASC 606 by focusing on revenue-generating activities. The guidance is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2018, and prospectively applicable to any transactions occurring within the period of adoption. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued an accounting standards update that eliminates the requirement to calculate the implied fair value of goodwill. An entity should perform its annual, or interim, goodwill impairment test by

comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The FASB also eliminated the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and applied on a prospective basis. Early adoption is permitted for interim and annual goodwill impairment testing dates after January 1, 2017. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

3. Business Acquisitions

Acquisition of International Medication Systems (UK) Limited from UCB PHARMA GmbH

In August 2016, the Company's newly established UK subsidiary, AUK, acquired IMS UK, a UK-based subsidiary of UCB PHARMA GmbH, including its trademarks, assets related to the products, as well as marketing authorizations for 33 products in the UK, Ireland, Australia, and New Zealand, representing 11 different injectable chemical entities. The Company paid $7.7 million in cash as consideration for the transaction. The Company plans to transfer the

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manufacturing of the purchased products to its facilities in California. The transfer will require approval of the UK Medicines and Healthcare products Regulatory Agency and other related regulatory agencies before the products can be sold by the Company. The transaction is accounted for as a business combination in accordance with ASC 805.

The fair values of the assets acquired and liabilities assumed include marketing authorizations of $9.2 million, manufacturing equipment of $0.1 million, and deferred tax liability of $1.6 million. The acquired marketing authorizations intangible assets are subject to a straight-line amortization over a useful life of approximately 10 years.

Acquisition of fourteen injectable products from Hikma Pharmaceuticals PLC

In March 2016, the Company acquired 14 abbreviated new drug applications, or ANDAs, representing 11 different injectable chemical entities from Hikma Pharmaceuticals PLC, or Hikma, for $4.0 million. The Company has concluded that this transaction will be accounted for as a business combination in accordance with ASC 805.

The ANDAs are estimated to have a fair value of $4.0 million, which is subject to a straight-line amortization over a useful life of approximately 15 years.

In February 2017, the Company sold these products to an unrelated party. (See note 18)

Acquisition of Nanjing Letop Medical Technology Co. Ltd.

In January 2016, the Company’s Chinese subsidiary, ANP, acquired Nanjing Letop Medical Technology Co. Ltd. for $1.7 million consisting of $0.8 million in cash and a deposit of $0.9 million that ANP had previously paid to Letop and which was effectively eliminated upon the consummation of the transaction. The Company accounted for this transaction as a business combination in accordance with ASC 805. The Company recognized $1.4 million of acquired assets, $0.1 million of assumed liabilities, and $0.4 million of goodwill. Letop had previously supplied ANP with intermediates used in making various active pharmaceutical ingredients. In March 2016, the acquired subsidiary was renamed Nanjing Letop Fine Chemistry Co., Ltd.

Acquisition of Merck's API Manufacturing Business

On April 30, 2014, the Company completed the acquisition of the Merck Sharpe & Dohme's API manufacturing business in Éragny-sur-Epte, France, or the Merck API Transaction, which manufactures porcine insulin API and recombinant human insulin API, or RHI 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 rate fluctuations. The terms of the purchase include multiple payments over four years as follows (see Note 12):

	Euros	U.S. Dollars
	(in thousands)	
At Closing, April 2014	€ 13,252	$ 18,352
December 2014	4,899	5,989
December 2015	3,186	3,483
December 2016	3,186	3,427
December 2017	500	526
	€ 25,023	$ 31,777

In order to facilitate the acquisition, the Company established AFP in France. The Company is continuing the current site manufacturing activities, which consist of the manufacturing of porcine insulin API and RHI API. As part of the transaction, the Company has entered into various additional agreements, including various supply agreements, as well as the assignment and/or licensing of patents under which Merck was operating at this facility. In addition, certain existing customer agreements have been assigned to AFP. Currently, the Company is in the process of transferring the

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manufacturing of starting material for RHI API from Merck to AFP. This process will require capital expenditures at AFP and is expected to take two or more years to complete.

The transaction is accounted for as a business combination in accordance with ASC 805. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

	Fair Value	
	Euros	U.S. Dollars
	(in thousands)	
Inventory	€ 15,565	$ 21,554
Real property	4,800	6,647
Machinery and equipment	6,800	9,417
Intangibles	80	111
Goodwill	3,155	4,369
Total assets acquired	€ 30,400	$ 42,098
Accrued liabilities	€ 2,425	$ 3,358
Deferred tax liabilities	3,155	4,369
Total liabilities assumed	5,580	7,727
Total fair value of consideration transferred	€ 24,820	$ 34,371

The operations of the acquired business have been included in the Company’s consolidated financial statements commencing on the acquisition date. The results of operations for this acquisition have not been separately presented because this acquisition is not material to the Company’s consolidated results of operations.

The following unaudited pro forma financial information for the years ended December 31, 2014 and 2013 gives effect to the transaction as if it had occurred on January 1, 2013. Such unaudited pro forma information is based on historical financial information prior to the transaction as well as actual results subsequent to the acquisition with respect to the transaction and does not reflect estimated operational and administrative cost savings, or synergies, for periods prior to the transaction, that management of the combined company estimates may be achieved as a result of the transaction.

The unaudited pro forma information primarily reflects the additional depreciation related to the fair value adjustment to property, plant and equipment acquired, valuation step up related to the fair value of inventory and additional interest expense associated with the financing obtained by the Company in connection with the acquisition.

	Year Ended December 31,	
	2014	2013
	(in thousands, except per share data)	
Net revenues	$ 212,745	$ 243,786
Net loss	(11,928)	12,969
Diluted net loss per share	$ (0.28)	$ 0.33

4. Revenue Recognition

Generally, revenue is recognized at the time of product delivery to the Company’s customers. In some cases, revenue is recognized at the time of shipment when stipulated by the terms of the sale agreements. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, after the customer has accepted test samples of the products to be shipped. On June 30, 2016, the Company and Actavis amended the distribution agreement, which terminated the agreement in December 2016. Profit-sharing revenue under this agreement was recognized at the time Actavis sold the products to its customers.

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The Company does not recognize product revenue unless the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) transfer of title has occurred, (iii) the price to the customer is fixed or determinable, and (iv) collection is reasonably assured. Furthermore, the Company does not recognize revenue until all customer acceptance requirements have been met. The Company estimates and records reductions to revenue for discounts, product returns, and pricing adjustments, such as wholesaler chargebacks, in the same period that the related revenue is recorded.

The Company's accounting policy is to review each agreement involving contract development and manufacturing services to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenues are recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. The Company does not have any revenue arrangements with multiple deliverables.

Provision for Wholesaler Chargebacks

The provision for chargebacks is a significant estimate used in the recognition of revenue. As part of its sales terms with wholesale customers, the Company agrees to reimburse wholesalers for differences between the gross sales prices at which the Company sells its products to wholesalers and the actual prices of such products at the time wholesalers resell them under the Company's various contractual arrangements with third parties such as hospitals and group purchasing organizations. The Company estimates chargebacks at the time of sale to wholesalers based on wholesaler inventory stocking levels, historic chargeback rates, and current contract pricing.

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

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Beginning balance	$ 15,217	$ 11,872
Provision related to sales made in the current period	166,987	162,238
Credits issued to third parties	(144,384)	(158,893)
Ending balance	$ 37,820	$ 15,217

Changes in chargeback provision from period to period are primarily dependent on the Company's sales to its wholesalers, the level of inventory held by the wholesalers, and on the wholesaler's customer mix. The approach that the Company uses to estimate chargebacks has been consistently applied for all periods presented. Variations in estimates have been historically small. The Company continually monitors the provision for chargebacks and makes adjustments when it believes that the actual chargebacks may differ from the estimates. The settlement of chargebacks generally occurs within 30 days after the sale to wholesalers.

Accrual for Product Returns

The Company offers most customers the right to return qualified excess or expired inventory for partial credit; however, products sold to Actavis were and API product sales are non-returnable. The Company's product returns primarily consist of the returns of expired products from sales made in prior periods. Returned products cannot be resold. At the time product revenue is recognized, the Company records an accrual for estimated returns. The accrual is based, in part, upon the historical relationship of product returns to sales and customer contract terms. The Company also assesses other factors that could affect product returns including market conditions, product obsolescence, and the introduction of new competition. Although these factors do not normally give the Company's customers the right to return products outside of the regular return policy, the Company realizes that such factors could ultimately lead to increased returns. The Company analyzes these situations on a case-by-case basis and makes adjustments to the product return reserve as appropriate. If the available information is not sufficient to estimate a reasonable product return accrual, revenues from the sales of the new product would not be recognized until the product is consumed by the end customer or rights of

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return granted under the return policy have expired. As of December 31, 2016, sales of approximately $0.5 million for one of the Company's products were not recognized in revenues, due to insufficient information available to estimate a reasonable product return accrual.

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

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Beginning balance	$ 2,621	$ 2,408
Provision for product returns	1,753	1,675
Credits issued to third parties	(1,231)	(1,462)
Ending balance	$ 3,143	$ 2,621

For the years ended December 31, 2016 and 2015, the Company's aggregate product return rate was 1.1% and 1.1% of qualified sales, respectively.

5. Income (Loss) per Share

Basic income (loss) per share is calculated based upon the weighted-average number of shares outstanding during the period. Diluted income per share gives effect to all potential dilutive shares outstanding during the period, such as stock options, nonvested deferred stock units and restricted stock units (collectively referred to herein as "RSUs"), and shares issuable under the Company's Employee Stock Purchase Plan, or the ESPP.

For the year ended December 31, 2016, options to purchase 2,379,984 shares of stock with a weighted-average exercise price of $22.46 per share, were excluded in the computation of diluted net income per share because the effect from the assumed exercise of these options would be anti-dilutive.

As the Company reported a net loss for the years ended December 31, 2015 and 2014, the diluted net loss per share, as reported, equals the basic net loss per share since the effect of the assumed exercise of stock options, vesting of nonvested RSUs, and issuance of common shares under the Company's ESPP are anti-dilutive. Total stock options, nonvested RSUs, and shares issuable under the Company's ESPP excluded from the year ended December 31, 2015 net loss per share were 12,240,467 stock options; 866,540 nonvested RSUs, and 61,766 shares issuable under the ESPP. Total stock options and nonvested RSUs excluded from the year ended December 31, 2014 net loss per share were 11,371,891 stock options and 503,010 nonvested RSUs.

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The following table provides the calculation of basic and diluted net income (loss) per share for each of the periods presented:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands, except per share data)		
Basic and dilutive numerator:			
Net income (loss)	$ 10,532	$ (2,787)	$ (10,699)
Denominator:			
Weighted-average shares outstanding — basic	45,375	44,961	41,957
Net effect of dilutive securities:			
Incremental shares from equity awards	2,129	—	—
Weighted-average shares outstanding — diluted	47,504	44,961	41,957
Net income (loss) per share — basic	$ 0.23	$ (0.06)	$ (0.25)
Net income (loss) per share — diluted	$ 0.22	$ (0.06)	$ (0.25)

6. Segment Reporting

The Company’s business is the development, manufacture, and marketing of pharmaceutical products. The Company has established two reporting segments that each report to the Chief Operating Decision Maker, or CODM, as defined in ASC 280, Segment Reporting. The Company’s performance is assessed and resources are allocated by the CODM based on the following two reportable segments:

- Finished pharmaceutical products
- Active pharmaceutical ingredients, or API

The finished pharmaceutical products segment manufactures, markets and distributes enoxaparin, Cortrosyn®, Amphadase®, naloxone, lidocaine, as well as various other critical and non-critical care drugs. The API segment manufactures and distributes recombinant human insulin API and porcine insulin API for external customers and internal product development.

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Selected financial information by reporting segment is presented below:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Net revenues:			
Finished pharmaceutical products	$ 240,221	$ 224,941	$ 198,480
API	14,944	26,578	11,981
Total net revenues	255,165	251,519	210,461
Gross profit:			
Finished pharmaceutical products	106,100	74,146	52,724
API	(1,911)	3,201	(1,468)
Total gross profit	104,189	77,347	51,256
Operating expenses	88,497	84,245	69,239
Income (loss) from operations	15,692	(6,898)	(17,983)
Non-operating expenses	(746)	(3,466)	(165)
Income (loss) before income taxes	$ 14,946	$ (10,364)	$ (18,148)

The Company manages its business segments to the gross profit level and manages its operating and other costs on a company-wide basis. The Company does not identify total assets by segment for internal purposes, as the Company's CODM does not assess performance, make strategic decisions, or allocate resources based on assets.

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The amount of net revenues in the finished pharmaceutical products segment is presented below:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Finished pharmaceutical products net revenues:			
Enoxaparin	$ 59,320	$ 84,502	$ 107,456
Naloxone	47,532	38,602	19,236
Lidocaine	36,600	30,260	23,195
Phytonadione	33,315	19,804	9,512
Epinephrine	25,661	14,936	8,853
Other finished pharmaceutical products	37,793	36,837	30,228
Total finished pharmaceutical products net revenues	$ 240,221	$ 224,941	$ 198,480

Net revenues and carrying values of long-lived assets of enterprises by geographic regions are as follows:

	Net Revenue			Long-Lived Assets	
	Year Ended December 31,			December 31,	
	2016	2015	2014	2016	2015
	(in thousands)				
United States	$ 249,007	$ 243,295	$ 198,480	$ 104,110	$ 100,404
China	—	—	—	35,085	28,547
France	6,158	8,224	11,981	13,659	13,210
United Kingdom	—	—	—	90	—
Total	$ 255,165	$ 251,519	$ 210,461	$ 152,944	$ 142,161

7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc. or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. Actavis had exclusive marketing rights of the Company's enoxaparin product to the U.S. retail pharmacy market (see Note 16). MannKind Corporation began buying RHI API from the Company in December 2014. The Company considers these five customers to be its major customers, as each individually and these customers collectively, represented a significant percentage of the Company's net revenue for the years ended December 31, 2016, 2015, and 2014, and accounts receivable as of December 31, 2016 and 2015. The following table provides accounts receivable and net revenues information for these major customers:

	% of Total Accounts Receivable		% of Net Revenue		
	December 31,	December 31,	Year Ended December 31,		
	2016	2015	2016	2015	2014
Actavis(1)	1 %	12 %	14 %	21 %	30 %
AmerisourceBergen	30 %	12 %	21 %	17 %	15 %
Cardinal Health	28 %	20 %	22 %	17 %	14 %
MannKind Corporation	2 %	13 %	3 %	8 %	2 %
McKesson	19 %	21 %	21 %	22 %	22 %

(1) The Agreement with Actavis was terminated in December 2016.

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Supplier Concentrations

The Company depends on suppliers for raw materials, active pharmaceutical ingredients, and other components that are subject to stringent U.S. Food and Drug Administration, or FDA, requirements. Some of these materials may only be available from one or a limited number of sources. Establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Furthermore, a significant portion of raw materials may only be available from foreign sources. If the Company is unable to secure, on a timely basis, sufficient quantities of the materials it depends on to manufacture and market its products, it could have a materially adverse effect on the Company's business, financial condition, and results of operations.

8. Fair Value Measurements

The accounting standards of the FASB, define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal or most advantageous market for the asset or liability at the measurement date (an exit price). These standards also establish a hierarchy that prioritizes observable and unobservable inputs used in measuring fair value of an asset or liability, as described below:

- Level 1 – Inputs to measure fair value are based on quoted prices (unadjusted) in active markets on identical assets or liabilities;

- Level 2 – Inputs to measure fair value are based on the following: a) quoted prices in active markets on similar assets or liabilities, b) quoted prices for identical or similar instruments in inactive markets, or c) observable (other than quoted prices) or collaborated observable market data used in a pricing model from which the fair value is derived; and

- Level 3 – Inputs to measure fair value are unobservable and the assets or liabilities have little, if any, market activity; these inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on best information available in the circumstances.

The Company measures fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The Company classifies its cash equivalents and restricted short-term investments as Level 1 assets, as they are valued on a recurring basis using quoted market prices with no valuation adjustments applied. The Company does not hold any Level 3 instruments that are measured for fair value on a recurring basis.

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The fair values of the Company's financial assets and liabilities measured on a recurring basis, as of December 31, 2016 and 2015, are as follows:

	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
	(in thousands)			
Cash equivalents	$ 36,082	$ 36,082	$ —	$ —
Restricted short-term investments	1,390	1,390	—	—
Fair value measurement as of December 31, 2016	$ 37,472	$ 37,472	$ —	$ —
Cash equivalents	$ 42,486	$ 42,486	$ —	$ —
Restricted short-term investments	1,285	1,285	—	—
Fair value measurement as of December 31, 2015	$ 43,771	$ 43,771	$ —	$ —

The fair value of the Company's cash equivalents includes money market accounts, money market funds, Money Market Insured Deposit Account Service and Insured Cash Sweep accounts. Restricted short-term investments consist of certificate of deposit accounts that expire within 12 months for which market prices are readily available. The restrictions placed on the certificate of deposit accounts have a negligible effect on the fair value of these financial assets; these funds are restricted to meet the Company's obligation for workers' compensation claims.

Short-term investments primarily consist of held-to-maturity municipal bonds with original maturities greater than three months. The municipal bonds are carried at amortized cost in the Company's consolidated balance sheet, which approximates their fair value determined based on Level 2 inputs. The Company does not intend to and will not be required to sell the investments before recovery of their amortized cost basis.

The Company adopted the required fair value measurements and disclosures provisions related to nonfinancial assets and liabilities. These assets and liabilities are not measured at fair value on a recurring basis but are subject to fair value adjustments in certain circumstances. These items primarily include long-lived assets, goodwill, and intangible assets for which the fair value of assets is determined as part of the related impairment test. As of December 31, 2016

and 2015, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

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9. Goodwill and Intangible Assets

The table below shows the weighted-average life, original cost, accumulated amortization, and net book value by major intangible asset classification:

	Weighted-Average Life (Years) (in thousands)	Original Cost	Accumulated Amortization	Net Book Value
Definite-lived intangible assets				
Cortrosyn® product rights	12	$ 27,134	$ 24,461	$ 2,673
IMS (UK) international product rights(1)	10	8,632	359	8,273
Acquired ANDAs(2)	15	4,000	222	3,778
Patents	10	293	137	156
Land-use rights	39	2,540	354	2,186
Other intangible assets	1	574	534	40
Subtotal	12	43,173	26,067	17,106
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,976	—	3,976
Subtotal	*	33,201	—	33,201
As of December 31, 2016	*	$ 76,374	$ 26,067	$ 50,307

	Weighted-Average Life (Years) (in thousands)	Original Cost	Accumulated Amortization	Net Book Value
Definite-lived intangible assets				
Cortrosyn® product rights	12	$ 27,134	$ 22,679	$ 4,455
Patents	10	293	107	186
Land-use rights	39	2,540	288	2,252
Other intangible assets	1	590	533	57

Subtotal	12	30,557	23,607	6,950
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,726	—	3,726
Subtotal	*	32,951	—	32,951
As of December 31, 2015	*	$ 63,508	$ 23,607	$ 39,901

*Intangible assets with indefinite lives have an indeterminable average life.

(1)In August 2016, the Company acquired International Medication Systems (UK) Limited from UCB PHARMA GmbH for $7.7 million. The fair value of the marketing authorization was $9.2 million as of the acquisition date (see Note 3).

(2)In March 2016, the Company acquired 14 ANDAs representing 11 different injectable chemical entities from Hikma Pharmaceuticals PLC for $4.0 million (see Note 3). In February 2017, the Company sold the 14 ANDAs to an unrelated party purchaser for $6.4 million (see note 18).

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Goodwill

The changes in the carrying amounts of goodwill were as follows:

	December 31,	
	2016	2015
	(in thousands)	
Beginning balance	$ 3,726	$ 4,467
Goodwill related to acquisition of business	391	—
Currency translation and other adjustments	(141)	(741)
Ending balance	$ 3,976	$ 3,726

Primatene® Trademark

In January 2009, the Company acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene® Mist, an over-the-counter bronchodilator product, which are recorded at the allocated fair value of $29.2 million, which is its carrying value as of December 31, 2016.

The trademark was determined to have an indefinite life. In determining its indefinite life, the Company considered the following: the expected use of the intangible; the longevity of the brand; the legal, regulatory and contractual provisions that affect their maximum useful life; the Company’s ability to renew or extend the asset’s legal or contractual life without substantial costs; effects of the regulatory environment; expected changes in distribution channels; maintenance expenditures required to obtain the expected future cash flows from the asset; and considerations for obsolescence, demand, competition and other economic factors.

As a result of environmental concerns about Chlorofluorocarbons, or CFCs, the FDA issued a final ruling on January 16, 2009 that required the CFC formulation of its Primatene® Mist product to be phased out by December 31, 2011. The former formulation of Primatene® Mist contained CFCs as a propellant; however, the Company intends to use the trademark for a future version of Primatene® that utilizes hydrofluoroalkane, or HFA, as a propellant.

In 2013, the Company filed a new drug application, or NDA, for Primatene® Mist and received a Prescription Drug User Fee Act date set for May 2014. In May 2014, the Company received a complete response letter, or CRL, from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral/human factors and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. The Company met with the FDA in October 2014 to discuss preliminary data results and to clarify the FDA requirements for further studies. The Company received further advice regarding its ongoing studies from the FDA in January 2016 and subsequently completed the human factor studies accordingly. The Company submitted a responsive NDA amendment in June 2016 and received another CRL from the FDA in December 2016, which requires additional packaging and label revisions and follow-up studies to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. The Company intends to continue to work with the FDA during the post-action phase to address their concerns in the CRL and bring Primatene® Mist back to the over-the-counter market. However, there can be no guarantee that any future amendment to the Company's NDA will result in timely approval of Primatene® Mist or approval at all.

Based on the Company's filed version of Primatene® Mist, the long history of the Primatene trademark (marketed since 1963), the Company's perpetual rights to the trademark, the nature of the CRL received in December 2016, the plan that the HFA version will be marketed under the same trademark if approved by the FDA, and other factors previously considered, the trademark continues to have an indefinite useful life, and an impairment charge is not required based on the Company's qualitative assessment as of December 31, 2016.

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Amortization

Included in cost of revenues for the years ended December 31, 2016, 2015 and 2014 is product rights amortization expense of $2.4 million, $1.8 million, and $1.8 million, respectively, primarily related to Cortrosyn®.

As of December 31, 2016, the expected amortization expense for all amortizable intangible assets during the next five fiscal years ended December 31 and thereafter is as follows:

	(in thousands)
2017	$ 2,650
2018	1,759
2019	857
2020	851
2021	851
Thereafter	10,138
Total amortizable intangible assets	17,106
Indefinite-lived intangibles	33,201
Total intangibles (net of accumulated amortization)	$ 50,307

10. Inventories

Inventories consist of the following:

	December 31,	
	2016	2015
	(in thousands)	
Raw materials and supplies	$ 36,209	$ 29,904
Work in process	22,266	26,081

Finished goods	21,279	14,680
Total inventories	$ 79,754	$ 70,665

11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	December 31, 2016	2015
	(in thousands)	
Buildings	$ 85,283	$ 82,309
Leasehold improvements	24,619	23,392
Land	6,857	6,895
Machinery and equipment	111,041	108,442
Furniture, fixtures, and automobiles	15,113	13,439
Construction in progress	32,044	19,942
Total property, plant, and equipment	274,957	254,419
Less accumulated depreciation	(122,013)	(112,258)
Total property, plant, and equipment, net	$ 152,944	$ 142,161

The Company incurred depreciation expense of $12.0 million, $11.3 million, and $12.5 million for the years ended December 31, 2016, 2015, and 2014, respectively.

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Interest expense capitalized was approximately $0.8 million, $1.1 million, and $1.2 million, for the years ended December 31, 2016, 2015, and 2014, respectively. The interest expense capitalized is primarily related to certain foreign construction projects during the year.

As of December 31, 2016 and 2015, the Company had $2.6 million and $2.9 million, respectively, in capitalized manufacturing equipment that is intended to be used specifically for the manufacture of Primatene® Mist. The Company will continue to monitor developments with the FDA as it relates to its Primatene® indefinite lived intangible assets in determining if there is an impairment of these related fixed assets (see Note 9).

12. Debt

Debt consists of the following:

	December 31,	
	2016	2015
	(in thousands)	
Loans with East West Bank		
Mortgage payable matured January 2016	$ —	$ 3,725
Mortgage payable matured September 2016	—	2,211
Equipment loan due April 2017	433	1,700
Line of credit facility due September 2017	—	—
Equipment loan due January 2019	3,208	4,748
Mortgage payable due February 2021	3,660	—
Equipment credit line due September 2021	2,882	—
Mortgage payable due October 2026	3,582	—
Loans with Cathay Bank		
Line of credit facility due May 2018	—	—
Acquisition loan due April 2019	17,079	19,012
Mortgage payable due April 2021	4,367	4,460

Loans with Seine-Normandie Water Agency		
French government loan 1 due March 2018	30	46
French government loan 2 due June 2020	99	128
French government loan 3 due July 2021	262	325
Payment Obligation to Merck	506	3,942
Equipment under Capital Leases	1,614	802
Total debt and capital leases	37,722	41,099
Less current portion of long-term debt and capital leases	5,366	10,934
Long-term debt and capital leases, net of current portion	$ 32,356	$ 30,165

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Loans with East West Bank

Equipment Loan—Due April 2017

In March 2012, the Company entered into an $8.0 million revolving credit facility. In March 2013, the Company converted the outstanding principal balance of $4.9 million into an equipment loan, which matures in April 2017. Borrowings under the facility are secured by equipment. Borrowings under the facility bear a variable interest rate at the prime rate as published by The Wall Street Journal plus 0.25%, with a minimum interest rate of 3.50%. As of December 31, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

Line of Credit Facility—Due September 2017

In March 2012, the Company entered into a $10.0 million line of credit facility. Borrowings under the facility are secured by inventory and accounts receivable. Borrowings under the facility bear a variable interest rate at the prime rate as published by The Wall Street Journal. This facility matured in March 2016.

In March 2016, the Company amended the facility to increase the line of credit to $15.0 million and extended the maturity date to September 2017. As of December 31, 2016, the Company did not have any amounts outstanding under this facility.

Equipment Loan—Due January 2019

In July 2013, the Company entered into an $8.0 million line of credit facility. Borrowings under the facility were secured by equipment. The facility bore a variable interest rate at the prime rate as published in The Wall Street Journal plus 0.25% and was to mature in January 2019.

In January 2015, the Company drew down $6.2 million from the line of credit facility. Subsequently, the facility was converted into an equipment loan with an outstanding principal balance of $6.2 million and a maturity date of January 2019. Borrowings under the facility are secured by equipment purchased with the debt proceeds. As of December 31, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. The Company entered into a fixed interest rate swap contract on this facility to exchange the variable interest rate for a fixed interest rate of 4.48% over the life of the facility without the exchange of the underlying notional debt amount. The interest rate swap contract does not qualify for hedge accounting, and is recorded at fair value for an immaterial amount based on Level 2 inputs.

Mortgage Payable—Due February 2021

In December 2010, the Company refinanced an existing mortgage term loan, which had an outstanding principal balance of $4.5 million at December 31, 2010. The loan was payable in monthly installments with a final balloon payment of $3.8 million. The loan was secured by one of the buildings at the Company’s Rancho Cucamonga, California, headquarters complex, as well as one of its buildings at its Chino, California, complex. The loan had a variable interest rate at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 5.00%, and matured in January 2016.

The Company refinanced the mortgage term loan in January 2016, which had an outstanding principal balance of $3.7 million at December 31, 2015, and a maturity date of February 2021. The refinanced loan is payable in monthly installments with a final balloon payment of $3.3 million. The refinanced loan is secured by one of the buildings at the Company’s Rancho Cucamonga, California, headquarters complex. The refinanced loan has a variable interest rate at the prime rate as published by The Wall Street Journal. As of December 31, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. The Company entered into a fixed interest rate swap contract on this loan to exchange the variable interest rate for a fixed interest rate

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of 4.39% over the life of the loan without the exchange of the underlying notional debt amount. The interest rate swap contract does not qualify for hedge accounting, and is recorded at fair value for an immaterial amount based on Level 2 inputs.

Equipment Credit Line–Due September 2021

In March 2016, the Company entered into a $5.0 million equipment credit line with an 18-month draw down period and interest payments due monthly through September 2017 at the prime rate as published by The Wall Street Journal. After the draw down period, the outstanding principal balance converts into a 48-month loan with principal and interest payments due monthly. Borrowings under the facility are secured by equipment, and bear a variable interest rate at the prime rate as published by The Wall Street Journal. This facility matures in September 2021. As of December 31, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. As of December 31, 2016, the Company has drawn $2.9 million from the equipment line of credit.

Mortgage Payable—Due October 2026

In September 2006, the Company entered into a mortgage term loan in the principal amount of $2.8 million, which matured in September 2016. The loan was payable in monthly installments with a final balloon payment of $2.2 million plus interest. The loan was secured by one of the buildings at the Company’s Rancho Cucamonga, California, headquarters complex. The variable interest rate was equal to the three-month LIBOR plus 2.50%.

The Company refinanced the mortgage term loan in September 2016, which increased the principal amount to $3.6 million and extended the maturity date to October 2026. The refinanced loan is payable in monthly installments with a final balloon payment of $2.9 million. The refinanced loan has a variable interest rate at the one-month LIBOR rate plus 2.75%. Subsequently, the Company entered into a fixed interest rate swap contract on this loan to exchange the variable interest rate for a fixed interest rate of 4.15% until October 2021 without the exchange of the underlying notional debt amount. As of December 31, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. The interest rate swap contract does not qualify for hedge accounting, and is recorded at fair value for an immaterial amount based on Level 2 inputs.

Loans with Cathay Bank

Line of Credit Facility—Due May 2018

In April 2012, the Company entered into a $20.0 million revolving line of credit facility. Borrowings under the facility are secured by inventory, accounts receivable, and intangibles held by the Company. The facility bears a variable interest rate at the prime rate as published by The Wall Street Journal with a minimum interest rate of 4.00%. This revolving line of credit was to mature in May 2016. In June 2016, the Company modified the facility to extend the maturity date to May 2018. As of December 31, 2016, the Company did not have any amounts outstanding under this facility.

Acquisition Loan with Cathay Bank—Due April 2019

On April 22, 2014, in conjunction with the Merck API Transaction, the Company entered into a secured term loan with Cathay Bank as lender. The principal amount of the loan is $21.9 million and bears a variable interest rate at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 4.00%. Beginning on June 1, 2014, and through the maturity date April 22, 2019, the Company must make monthly payments of principal and interest based on the then outstanding amount of the loan amortized over a 120-month period. On April 22, 2019, all amounts outstanding under the loan become due and payable, which would be approximately $12.0 million based upon an interest rate of 4.00%. The loan is secured by 65% of the issued and outstanding shares of stock in AFP and certain assets of the Company, including accounts receivable, inventory, certain investment property, goods, deposit accounts, and general

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intangibles but not including the Company's equipment and real property. As of December 31, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

The loan includes customary restrictions on, among other things, the Company's ability to incur additional indebtedness, pay dividends in cash or make other distributions in cash, make certain investments, create liens, sell assets, and make loans. The loan also includes customary events of defaults, the occurrence and continuation of any of which provide Cathay Bank the right to exercise remedies against the Company and the collateral securing the loan. These events of default include, among other things, the Company's failure to pay any amounts due under the loan, the Company's insolvency, the occurrence of any default under certain other indebtedness or material agreements, and a final judgment against the Company that is not discharged in 30 days.

Mortgage Payable—Due April 2021

In March 2007, the Company entered into a mortgage term loan in the principal amount of $5.3 million, which matured in March 2014. In April 2014, the Company refinanced the mortgage term loan, which had a principal balance outstanding of $4.6 million. The loan is payable in monthly installments with a final balloon payment of $3.9 million. The loan is secured by the building at the Company's Canton, Massachusetts location and bears interest at a fixed rate of 5.42% and matures in April 2021. As of December 31, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

Loans with Seine-Normandie Water Agency

In January 2015, the Company entered into three French government loans with the Seine-Normandie water agency in the aggregate amount of €0.6 million, or $0.7 million, subject to currency exchange fluctuations. The life of the loans range between three to six years, and includes annual equal payments and bears no interest over the life of the loans.

As of December 31, 2016, the payment obligation had an aggregate book value of €0.4 million, or $0.4 million, subject to currency exchange rate fluctuations, which approximates fair value. The fair value of the payment obligation was determined by using the interest rate associated with the Company's acquisition loan with Cathay Bank that bears a variable interest rate at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 4.00%.

Such interest rate is deemed to be a Level 2 input for measuring fair value.

Payment Obligation to Merck

Merck—Due December 2017

On April 30, 2014, in conjunction with the Merck API Transaction, the Company entered into a commitment obligation with Merck, in the principal amount of €11.6 million, or $16.0 million, subject to currency exchange rate fluctuations. The terms of the purchase price include annual payments over four years and bear a fixed interest rate of 3.00%. The final payment to Merck relating to this obligation is due December 2017. In December 2016 and 2015, the Company made a principal payment of €3.2 million, or $3.4 million and €3.2 million, or $3.5 million, respectively.

As of December 31, 2016, the payment obligation had a book value of €0.5 million, or $0.5 million, which approximates fair value. The fair value of the payment obligation was determined by using the interest rate associated with the Company’s acquisition loan with Cathay Bank that bears a variable interest rate at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 4.00%. Such interest rate is deemed to be a Level 2 input for measuring fair value.

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Covenants

At December 31, 2016 and 2015, the Company was in compliance with its debt covenants, which include a minimum current ratio, minimum debt service coverage, minimum tangible net worth, and maximum debt-to-effective-tangible-net-worth ratio, computed on a consolidated basis.

Equipment under Capital Leases

The Company entered into leases for certain equipment under capital leasing arrangements, which will expire at various times through 2021. The cost of equipment under capital leases was $2.0 million and $1.5 million at December 31, 2016 and 2015, respectively.

The accumulated depreciation of equipment under capital leases was $0.2 million and $0.7 million at December 31, 2016 and 2015, respectively. Depreciation of assets recorded under capital leases is included in depreciation expense in the accompanying consolidated financial statements.

Long-Term Debt Maturities

As of December 31, 2016, the principal amounts of long-term debt maturities during each of the next five fiscal years ending December 31 are as follows:

	Debt	Capital Leases	Total
	(in thousands)		
2017	$ 5,004	$ 362	
2018	4,702	379	
2019	14,155	396	
2020	1,075	388	
2021	7,906	167	
Thereafter	3,188	—	
	$ 36,030	$ 1,692	$ 37,722

13. Income Taxes

The Company's income (loss) before income taxes generated from its United States and foreign operations were:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Income (loss) before income taxes:			
United States	$ 20,888	$ (4,344)	$ (12,946)
Foreign	(5,942)	(6,020)	(5,202)
Total income (loss) before taxes	$ 14,946	$ (10,364)	$ (18,148)

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The Company's provision (benefit) for income taxes consisted of the following:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Current provision (benefit):			
Federal	$ 7,279	$ 82	$ (131)
State	344	73	193
Foreign	787	(112)	1,388
Total current provision	8,410	43	1,450
Deferred provision (benefit):			
Federal	(2,491)	(5,222)	(4,309)
State	(1,066)	(1,250)	(1,699)
Foreign	(439)	(1,148)	(2,891)
Total deferred benefit	(3,996)	(7,620)	(8,899)
Total provision (benefit) for income taxes	$ 4,414	$ (7,577)	$ (7,449)

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,		
	2016	2015	2014
Statutory federal income tax (benefit)	35.0 %	(35.0)%	(35.0)%
State tax expense, net of federal tax benefit	(3.1)	(7.4)	(5.4)
Foreign tax rate differences	1.8	(1.1)	1.8
Foreign valuation allowance	14.4	(23.3)	—
Qualified production activities deduction	(8.7)	—	—
Research and development credits	(11.7)	(15.4)	(6.4)
Share-based compensation	3.0	7.7	4.0
Other	(1.2)	1.4	—
Effective tax rate (benefit)	29.5 %	(73.1)%	(41.0)%

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Deferred Tax Assets and Liabilities

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards, and the tax effects of net operating loss carryforwards. The significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2016	2015
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforward	$ 4,698	$ 8,616
State income taxes	393	300
Inventory capitalization and reserve	7,368	5,365
Deferred revenue	—	584
Accrued payroll and benefits	1,813	1,793
Share-based compensation	10,545	10,125
Research and development credits	9,668	13,071
Alternative minimum tax	895	529
Accrued professional fees	1,333	987
Product return allowance	1,758	1,545
Accrued chargebacks	15,158	5,910
Bad debt reserve	95	253
Intangibles	3,370	3,370
Accrued for workers' compensation insurance	1,409	1,035
Total deferred tax assets	58,503	53,483
Deferred tax liabilities:		
Depreciation/amortization	13,763	15,065
Intangibles	8,208	5,430
Federal impact of state deferred taxes	3,784	3,380
Other	158	1,241
Total deferred tax liabilities	25,913	25,116
Valuation allowance	(3,044)	(923)
Net deferred tax assets	$ 29,546	$ 27,444

Net Operating Loss Carryforwards and Tax Credits

At December 31, 2016, the Company had no material U.S. federal, California, or other State net operating loss, or NOL carryforwards. The Company had foreign NOL carryforwards of approximately $16.7 million which can be used annually with certain limitations and have an indefinite carryforward period.

At December 31, 2016, the Company had federal and California research and development tax credit carryforwards of approximately $2.6 million and $11.7 million, respectively. The federal research and development tax credit begins to expire in 2035. The California research and development tax credit has an indefinite carryforward period. The Company also had a U.S. federal alternative minimum tax credit carryforward of $0.5 million which can be used to offset future regular tax to the extent of the current AMT; the credit has an indefinite carryforward period.

The utilization of NOL and credit carryforwards and other tax attributes could be subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 (the “Code”), whereby they could be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period, as defined in the Code.

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Valuation Allowance

In assessing the need for a valuation allowance, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. Ultimately, the realization of deferred tax assets depends on the existence of future taxable income. Management considers sources of taxable income such as income in prior carryback periods, future reversal of existing deferred taxable temporary differences, tax-planning strategies, and projected future taxable income.

The Company recorded a valuation allowance against a deferred tax asset with the AFP purchase accounting in 2014 of €3.2 million, or $4.4 million, subject to currency exchange rate fluctuations, with an offsetting increase to goodwill. In March 2015, the Company reversed the €3.2 million, or $3.3 million, subject to currency exchange rate fluctuations, deferred tax valuation allowance in conjunction with the transfer of AFPs intangible assets from France to the United States. In addition, in 2015, the Company assessed the realizability of the deferred tax assets of AFP and determined that it was not more likely than not that the net deferred tax assets of AFP would be realized. Therefore, the Company established a full valuation allowance of $0.9 million as of December 31, 2015. The Company has discontinued recognizing AFP income tax benefits until it is determined that it is more likely than not that AFP will generate sufficient taxable income to realize its deferred income tax assets. As of December 31, 2016, the Company had a full valuation allowance against the deferred tax assets of AFP, which totaled $3.0 million.

Undistributed Losses from Foreign Operations

As of December 31, 2016 and 2015, deferred income taxes have not been provided on the accumulated undistributed losses of the Company’s foreign subsidiaries of approximately $14.9 million and $7.1 million, respectively. It is the Company’s plan not to repatriate future foreign earnings to the U.S.

Uncertain Income Tax Positions

A reconciliation of the beginning and ending balances of unrecognized tax benefits is as follows:

	December 31,		
	2016	2015	2014
	(in thousands)		
Balance at the beginning of the year	$ 5,595	$ 4,783	$ 4,186
Additions based on tax positions related to prior years	188	—	—
Additions based on tax positions related to the current year	903	812	655
Deductions based on statute of limitations	—	—	(58)
Balance at the end of the year	$ 6,686	$ 5,595	$ 4,783

Included in the balance of unrecognized tax benefits as of December 31, 2016, was $5.9 million that represents the portion that would impact the effective income tax rate if recognized. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefit as of December 31, 2016, will decline by $1.9 million in the next 12 months as a result of the expected resolution of a current U.S. state audit.

The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax provision. For the years ended December 31, 2016 and 2015, the Company recognized accrued interest of approximately $0.3 million and $0.1 million, respectively, related to its uncertain tax position.

The Company and/or one or more of its subsidiaries filed income tax returns in the U.S. federal jurisdiction and various U.S. states and foreign jurisdictions. As of December 31, 2016, the Company is not subject to U.S. federal, state, and foreign income tax examinations for years before 2007. In August 2011, the California Franchise Tax Board commenced an audit of the Company’s 2007, 2008, and 2009 tax returns; this audit is currently ongoing. The Company is subject to income tax audit by tax authorities for tax years 2013, 2014 and 2015 for federal and 2007 to 2015 for states.

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14. Stockholders' Equity

Common and Preferred Stock

In June 2014, the Company completed an initial public offering in which the Company sold 5,840,000 shares of its common stock, which included 1,200,000 shares of the Company's common stock pursuant to the underwriters' exercise of their over-allotment option, at a price to the public of $7.00 per share, resulting in gross proceeds of $40.9 million. In connection with the offering, the Company paid $6.2 million in underwriting discounts, commissions, and offering costs, resulting in net proceeds of $34.7 million.

The Company's Certificate of Incorporation, as amended and restated in June 2014 in connection with the closing of its initial public offering, authorizes the Company to issue 300,000,000 shares of common stock, $0.0001 par value per share, and 20,000,000 shares of preferred stock, $0.0001 par value per share. As of December 31, 2016 and 2015, there were no shares of preferred stock issued or outstanding.

Equity Plans

As of December 31, 2016, the Company has two equity plans: the 2015 Equity Incentive Award Plan, or 2015 Plan, and the 2014 Employee Stock Purchase Plan or ESPP. Prior to the adoption of these plans, the Company granted options pursuant to the Amended and Restated 2005 Equity Incentive Award Plan and the 2002 Amended and Restated Stock Option/Stock Issuance Plan. Upon termination of the predecessor plans, the shares available for grant at the time of termination, and shares subsequently returned to the plans upon forfeiture or option termination, were transferred to the successor plan in effect at the time of share return. The Company issues new shares of common stock upon exercise of stock options, vesting of restricted stock units, or RSU, and settlement of ESPP, with the exception of the awards granted to employees at AFP, which are settled through re-issuance of the Company's treasury shares.

The 2015 Equity Incentive Plan

In March 2015, the Board of Directors adopted the Company's 2015 Equity Incentive Plan, or the 2015 Plan, which was approved by the Company's stockholders in May 2015 and is set to expire in March 2025. The 2015 Plan is designed to meet the needs of a publicly traded company, including the requirements for granting "performance based compensation" under Section 162(m) of the Internal Revenue Code. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units, performance shares, and other stock or cash awards to employees of the Company and its subsidiaries, members of the Board of Directors and consultants.

The Company initially reserved 5,000,000 shares of common stock for issuance under the 2015 Plan. This number will be increased by the number of shares available for issuance under the Company's prior equity incentive plans or arrangements that are not subject to options or other awards, plus the number of shares of common stock related to options or other awards granted under the Company's prior equity incentive plans or arrangements that are repurchased, forfeited, expired, or cancelled on or after the effective date of the 2015 Plan. The 2015 Plan also contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance on January 1 of each year during the 10 year term of the 2015 Plan, beginning January 1, 2016. The annual increase in the number of shares shall be the lessor of (i) 3,000,000 shares, (ii) two and one-half percent (2.5%) of the outstanding shares on the last day of the immediately preceding fiscal year, or (iii) such number of shares as determined by the Board of Directors. As of the effective date, there were 5,300,296 shares available for grant under the 2015 Plan.

As of December 31, 2016, the Company reserved an aggregate of 4,164,625 shares of common stock for future issuance under the 2015 Plan. In January 2017, an additional 1,156,216 shares were reserved under the 2015 Plan pursuant to the evergreen provision.

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Amended and Restated 2005 Equity Incentive Award Plan

The Amended and Restated 2005 Equity Incentive Award Plan, or 2005 Plan provided for the grant of incentive stock options, or ISOs, nonqualified stock options, or NQSOs, restricted stock awards, restricted stock unit awards, stock appreciation rights, or SARs, dividend equivalents and stock payments to the Company's employees, members of the Board of Directors and consultants. Stock options under the 2005 Plan were granted with a term of up to ten years and at prices no less than the fair market value of the Company's common stock on the date of grant. To date, stock options granted to existing employees generally vest over three to five years and stock options granted to new employees vest over four years.

As of March 2015, consequent to the 2015 Plan becoming effective, awards were no longer being made under the 2005 Plan.

2014 Employee Stock Purchase Plan

In June 2014, the Company adopted the ESPP in connection with its initial public offering. A total of 2,000,000 shares of common stock are reserved for issuance under this plan. The Company's ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Under the ESPP, the Company may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of its common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances. The price at which the stock is purchased is equal 85% of the lower of the fair market value of the common stock at the beginning of an offering period or on the date of purchase.

As of December 31, 2016, the Company has issued 248,587 shares of common stock under the ESPP and 1,751,413 shares of its common stock remained available for issuance under the ESPP.

For the year ended December 31, 2016 and 2015, the Company recorded ESPP expense of $0.5 million and $0.4 million, respectively.

Share Buyback Program

On November 6, 2014, the Company's Board of Directors authorized a $10.0 million share buyback program, which was completed in December 2015. On November 10, 2015, the Company's Board of Directors authorized an additional $10.0 million to the Company's share buyback program. The primary goal of the program is to offset dilution created by the Company's equity compensation programs. On November 7, 2016, the Company's Board of Directors authorized an increase of $20.0 million to the Company's share buyback program, which is expected to continue for an indefinite period of time.

Purchases are being made through the open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions or other means as determined by the Company's management and in accordance with the requirements of the Securities and Exchange Commission. The timing and actual number of shares repurchased will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions. These repurchased shares are accounted for under the cost method and are included as a component of treasury stock in the Company's Consolidated Balance Sheets.

Pursuant to the Company's share repurchase program, the Company purchased 759,067 and 735,679 shares of its common stock during the years ended December 31, 2016 and 2015, totaling $9.9 million and $9.9 million, respectively.

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Share-Based Award Activity and Balances

The Company accounts for share based compensation payments in accordance with ASC 718, which requires measurement and recognition of compensation expense at fair value for all share based payment awards made to employees, directors, and nonemployees. Under these standards, the fair value of option awards and the option components of the ESPP awards are estimated at the grant date using the Black-Scholes option-pricing model. The fair value of RSUs is estimated at the grant date using the Company's common share price. Non vested stock options held by non-employees are revalued using the Company's estimate of fair value at each balance sheet date. The portion that is ultimately expected to vest is amortized and recognized in the compensation expenses on a straight-line basis over the requisite service period, generally from the grant date to the vesting date.

Options issued under the Company's 2015 Plan and 2005 Plan, are granted at exercise prices equal to or greater than the fair value of the underlying common shares on the date of grant and vest based on continuous service. There have been no awards with performance conditions and no awards with market conditions. The options have a contractual term of five to ten years and generally vest over a three- to five year period. The Black Scholes option pricing model has various inputs such as the common share price on the date of grant, exercise price, the risk free interest rate, volatility, expected life and dividend yield, all of which are estimates. The Company records share based compensation expense net of expected forfeitures. The change of any of these inputs could significantly impact the determination of the fair value of the Company's options as well as significantly impact its results of operations.

The significant assumptions used in the Black-Scholes option-pricing are as follows:

- Determining Fair Value of the underlying common stock. For options and ESPP awards granted after the completion of the Company's initial public offering, the fair value for its underlying common stock is determined using the closing price on the date of grant as reported on the NASDAQ Global Select Market.

Since the Company's common stock was not traded in a public stock market exchange prior to June 25, 2014, prior to such date the Board of Directors considered numerous factors including recent cash sales of the Company's common stock to third-party investors, new business and economic developments affecting the Company and independent appraisals, when appropriate, to determine the fair value of the Company's common stock. Independent appraisal reports were prepared using conventional valuation techniques, such as discounted cash flow analyses and the guideline company method using revenue and earnings multiples for comparable publicly traded companies, and a calculation of total option proceeds, from which a discount factor for lack of marketability was applied. This determination of the fair value of the common stock was performed on a contemporaneous basis. Prior to the Company's initial public offering, the Board of Directors determined the Company's common stock fair market value on a quarterly basis and in some cases more frequently when appropriate.

· Expected Volatility. The Company has limited data regarding company specific historical or implied volatility of its share price. Consequently, the Company estimates its volatility based on the average of the historical volatilities of peer group companies from publicly available data for sequential periods approximately equal to the expected terms of its option grants. Management considers factors such as stage of life cycle, competitors, size, market capitalization and financial leverage in the selection of similar entities.

· Expected Term. The expected term represents the period of time in which the options granted are expected to be outstanding. The Company estimates the expected term of options with consideration of vesting date, contractual term, and historical experience for employee exercise and post-vesting employment termination behavior after its common stock has been publicly traded. The expected term of “plain vanilla” options is estimated based on the midpoint between the vesting date and the end of the

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contractual term under the simplified method permitted by the SEC implementation guidance. The weighted average expected term of the Company's options is approximately five years.

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

- Dividends. The Company does not anticipate paying cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield rate of zero.

The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual experience differs from those estimates. For the years ended December 31, 2016, 2015 and 2014, the Company estimated an average overall forfeiture rate of 7%, 8%, and 8%, respectively, based on historical experience. Forfeiture rates are separately estimated for its (1) directors and officers, (2) management personnel and (3) other employees. Share based compensation is recorded net of expected forfeitures. The Company periodically assesses the forfeiture rate and the amount of expense recognized based on estimated historical forfeitures as compared to actual forfeitures. Changes in estimates are recorded in the period they are identified.

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

The weighted-averages for key assumptions used in determining the fair value of options granted during the years ended December 31, 2016, 2015, and 2014 are as follows:

	Year Ended December 31,		
	2016	2015	2014
Average volatility	30.4 %	27.1 %	29.9 %
Risk-free interest rate	1.5 %	1.3 %	1.7 %
Weighted-average expected life in years	5.5	4.5	5.0
Dividend yield rate	— %	— %	— %

Stock Options

A summary of option activity under all plans for the year ended December 31, 2016, is presented below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1) (in thousands)
Outstanding as of December 31, 2015	12,240,467	$ 15.41		
Options granted	2,395,789	12.19		
Options exercised	(1,465,539)	13.88		
Options cancelled	(178,932)	13.50		
Options expired	(461,488)	26.99		
Outstanding as of December 31, 2016	12,530,297	$ 14.57	4.32	$ 60,292
Exercisable as of December 31, 2016	7,938,110	$ 15.15	2.86	$ 38,041

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the Company's common stock for those awards that have an exercise price below the estimated fair value at December 31, 2016.

During the years ended December 31, 2016, 2015, and 2014, the Company recorded expense of $8.0 million, $7.9 million, and $6.7 million, respectively, related to stock options granted to employees under all plans, and expenses of

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$0.7 million, $0.5 million, and $0.6 million, respectively, related to stock options granted to the Board of Directors under all plans.

Information relating to option grants and exercises is as follows:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands, except per share data)		
Weighted-average grant date fair value	$ 3.42	$ 3.45	$ 4.02
Intrinsic value of options exercised	7,446	3,247	144
Cash received	20,338	13,502	571
Total fair value of the options vested during the year	8,654	6,634	6,407

A summary of the status of the Company's nonvested options as of December 31, 2016, and changes during the year ended December 31, 2016, are presented below:

	Options	Weighted-Average Grant Date Fair Value
Nonvested as of December 31, 2015	5,202,095	$ 3.44
Options granted	2,395,789	3.42
Options vested	(2,826,765)	3.06
Options forfeited	(178,932)	4.68
Nonvested as of December 31, 2016	4,592,187	3.61

As of December 31, 2016, there was $10.9 million of total unrecognized compensation cost, net of forfeitures, related to nonvested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.1 years and will be adjusted for future changes in estimated forfeitures.

Deferred Stock Units/Restricted Stock Units

Beginning in 2007, the Company granted deferred stock units, or DSUs, to certain employees and members of the Board of Directors with a vesting period of up to five years, and commencing in 2015, such equity was issued as restricted stock units, or RSUs (such RSUs and DSUs are collectively referred to herein as RSUs). The grantee receives one share of common stock at a specified future date for each RSU awarded. The RSUs may not be sold or otherwise transferred until certificates of common stock have been issued, recorded, and delivered to the participant. The RSUs do not have any voting or dividend rights prior to the issuance of certificates of the underlying common stock. The share-based expense associated with these grants was based on the Company's common stock fair value at the time of grant and is amortized over the requisite service period, which generally is the vesting period, using the straight-line method. During the years ended December 31, 2016, 2015, and 2014, the Company recorded expenses of $5.2 million, $3.4 million, and $1.6 million, respectively, related to RSU awards granted to employees under all plans, and expenses of $0.7 million, $0.5 million, and $0.4 million, respectively, related to RSU awards granted to the Board of Directors.

As of December 31, 2016, there was $10.1 million of total unrecognized compensation cost, net of forfeitures, related to nonvested RSU-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.3 years and will be adjusted for future changes in estimated forfeitures.

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Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued as Compensation(1) (in thousands)
RSUs outstanding at December 31, 2015	866,540	
RSUs granted	732,021	$ 8,646
RSUs forfeited	(54,381)	
Common stock delivered	(108,817)	
RSUs surrendered for taxes	(219,577)	
RSUs outstanding at December 31, 2016	1,215,786	

(1) The total FMV is derived from the number of RSUs granted times the current stock price on the date of grant.

Equity Awards to Consultants

The Company has entered into various consulting agreements with Company stockholders and third-party consultants. Consulting expenses are accrued as services are rendered. Consulting services are paid in cash and/or in common stock or stock options. Share-based compensation expense is recorded over the service period based on the estimated fair market value of the equity award at the date services are performed or upon completion of all services under the agreement. During the year ended December 31, 2016, the Company recorded $0.1 million in share-based compensation related to the issuance of equity awards for services rendered by consultants. During the year ended December 31, 2015, the Company recorded $0.2 million in share-based compensation related to the issuance of equity awards for service rendered by consultants. During the year ended December 31, 2014, the Company recorded an immaterial amount of share-based compensation related to the issuance of equity awards for services rendered by consultants.

The Company recorded share-based compensation expense under all plans and is included in the Company’s consolidated statement of operations as follows:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Cost of revenues	$ 2,967	$ 2,526	$ 1,678
Operating expenses:			
Selling, distribution, and marketing	220	192	137
General and administrative	10,865	9,185	6,800
Research and development	1,072	912	665
Total share-based compensation	$ 15,124	$ 12,815	$ 9,280

15. Employee Benefits

401(k) Plan

The Company has a defined contribution 401(k) plan, or the Plan, whereby eligible employees voluntarily contribute up to a defined percentage of their annual compensation. The Company matches contributions at a rate of 50% on the first 6% of employee contributions, and pays the administrative costs of the Plan. Employer contributions vest over four years. Total employer contributions for the years ended December 31, 2016, 2015, and 2014 were approximately $1.0 million, $0.7 million, and $0.7 million, respectively.

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Defined Benefit Pension Plan

In connection with the Merck API Transaction, the Company assumed an obligation associated with a defined-benefit plan for eligible employees of AFP. This plan provides benefits to the employees from the date of retirement and is based on the employee's length of time employed by the Company. The calculation is based on a statistical calculation combining a number of factors that include the employee's age, length of service, and AFPs turnover rate.

The liability under the plan is based on a discount rate of 1.75% as of December 31, 2016 and 2015, respectively. The liability is included in accrued liabilities in the accompanying consolidated balance sheets. The plan is currently unfunded, and the benefit obligation under the plan was $1.7 million and $1.6 million at December 31, 2016 and 2015, respectively. Expense under the plan was $0.2 million, $0.1 million, and $0.2 million for the years ended December 31, 2016, 2015, and 2014, respectively. For the year ended December 31, 2016, the Company recorded an unrecognized gain of $0.4 million in its accumulated other comprehensive income related to the change in actuarial valuation of the Company's defined benefit pension plan. For the year ended December 31, 2015, the Company recorded an immaterial amount of unrecognized loss in its accumulated other comprehensive loss related to the change in actuarial valuation of the Company's defined benefit pension plan. The Company recorded an unrecognized gain of $0.2 million in its accumulated other comprehensive loss during the year ended December 31, 2014, related to the change in actuarial valuation of the Company's defined benefit pension plan.

16. Commitments and Contingencies

Distribution Agreement with Actavis Inc.

In May 2005, the Company entered into an agreement to grant certain exclusive marketing rights for its enoxaparin product to Andrx Pharmaceuticals, Inc., or Andrx, which generally extends to the U.S. retail pharmacy market. To obtain such rights, Andrx made a non-refundable, upfront payment of $4.5 million to the Company upon execution of the agreement which was classified as deferred revenues. Under the agreement, the Company is paid a fixed cost per unit sold to Andrx and also shares in the gross profits (as defined) from Andrx's sales of the product in the U.S. retail pharmacy market. In November 2006, Watson Pharmaceuticals, Inc., or Watson, acquired Andrx and all of the rights and obligations associated with the agreement. In January 2013, Watson adopted Actavis, Inc. as its new global name. In March 2015, Actavis acquired Allergan plc and adopted Allergan plc as its new global name in June 2015.

In January 2012, the Company launched enoxaparin, beginning the seven-year period in which Actavis has the exclusive marketing rights for the Company's enoxaparin product in the U.S. retail pharmacy market and the start of the Company's recognition of the $4.5 million deferred revenue over this period on a straight-line basis. On June 30, 2016, the Company and Actavis amended the distribution agreement, which terminated the agreement in December 2016. The Company recognized the remaining balance of the deferred revenue over the period from July 1, 2016 through December 31, 2016, on a straight-line basis as a result of the revised estimate of the contractual period. As of December 31, 2016, the balance of the deferred revenue has been fully recognized.

The Company manufactured its enoxaparin product for the retail market according to demand specifications of Actavis. Upon shipment of enoxaparin to Actavis, the Company recognized product sales at an agreed transfer price and records the related cost of products sold. Based on the terms of the Company's distribution agreement with Actavis, the Company was entitled to a share of the ultimate profits based on the eventual net revenue from enoxaparin sales by Actavis to the end user less the agreed transfer price originally paid by Actavis to the Company. Actavis provided the Company with a quarterly sales report that calculated the Company's share of Actavis enoxaparin gross profit. The Company recorded its share of Actavis gross profit as a component of net revenue.

Supply Agreement with MannKind Corporation

On July 31, 2014, the Company entered in a supply agreement with MannKind Corporation, or MannKind, or the Supply Agreement, pursuant to which the Company agreed to manufacture for and supply to MannKind certain quantities of

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RHI API for use in MannKind's product Afrezza®. Under the Supply Agreement, MannKind agreed to purchase annual minimum quantities of RHI API in an aggregate amount of approximately €120.1 million, or approximately $146.0 million, over five years from calendar years 2015 through 2019. Specifically, the minimum annual purchase commitment was approximately €27.1 million in 2015, and approximately €23.3 million each year from 2016 through 2019.

On July 31, 2014, upon entering into the Supply Agreement, MannKind paid a non-refundable prepayment to the Company in the amount of €11.0 million, or approximately $14.0 million. Under the Supply Agreement, the non-refundable prepayment was applied towards the 2015 annual commitment. The Company recorded the amount as deferred revenue in 2014, and it was recognized as net revenue in 2015 at the time the product was shipped.

In January 2015, the Company entered into a supply option agreement with MannKind, or the Option Agreement, pursuant to which MannKind will have the option to purchase RHI API in excess of the minimum amounts specified in the Supply Agreement in calendar years 2016 through 2019. In the event MannKind elects not to exercise its minimum annual purchase option for any year under the Option Agreement, MannKind is obligated to pay the Company a specified capacity cancellation fee.

In October 2015, MannKind informed the Company that it was not exercising the option to purchase additional quantities of RHI API for 2016 under the Option Agreement and paid the Company the specified capacity cancellation fee of $0.8 million. Such capacity cancellation fee was recorded as net revenue in the Company's consolidated statement of operations for the year ended December 31, 2015.

For the year ended December 31, 2016, sales of RHI API to MannKind totaled $6.8 million, which fulfilled the remaining unfulfilled 2015 commitment of RHI under the Supply Agreement.

In November 2016, the Company amended the Supply Agreement with MannKind, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement has not been reduced; however, the annual minimum purchase commitments of RHI API under the Supply Agreement have been modified and extended through 2023, which timeframe had previously lapsed after calendar year 2019. Specifically, the minimum annual purchase commitment in calendar year 2016 has been cancelled, and the minimum annual purchase commitments in calendar years 2017 through 2023 have been modified to be €2.7 million of insulin in the fourth quarter of 2017, €8.9 million in 2018, €11.6 million in 2019, €15.5 million in 2020 and in 2021, and €19.4 million in 2022 and in 2023. MannKind may request to purchase additional quantities of RHI API in excess of its annual minimum purchase commitments. The

Supply Agreement Amendment also (i) shortened the required expiry dates for RHI API delivered to MannKind pursuant to the Supply Agreement, (ii) modified the timing of MannKind's payment for the minimum annual purchase commitment in calendar year 2017, and (iii) added a pre-payment requirement for purchases of RHI API by MannKind in calendar years 2017 and 2018. The amendment 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.

Concurrently with the amendment of the Supply Agreement, the Company amended the Option Agreement with MannKind, whereby the amendment to the Option Agreement extends the timing for payment of the capacity cancellation fee for 2017 and decreases the amounts payable as capacity cancellation fees for 2018 and 2019 in the event MannKind fails to exercise its minimum annual purchase option for any given year. The Company recognized the cancellation fee for 2017 of $1.5 million in net revenues in its consolidated statement of operations for the year ended December 31, 2016, and subsequently collected on this receivable.

In addition to, and in consideration of the amended timeframe and other amendments contained in the amendment to the Supply Agreement in the amendment to the Option Agreement, the Supply Agreement Amendment provided the Company right of first refusal to participate in the development and commercialization of Afrezza® in China through a collaborative arrangement.

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Collaboration Agreement with a Medical Device Manufacturer

The Company has entered into a collaboration agreement with a medical device manufacturer to develop a drug delivery system to be used by the Company for one of its pipeline products. As of December 31, 2016, the Company has paid an upfront payment of $0.5 million and $1.2 million in milestone payments under this agreement, which were classified as research and development expense. The Company is obligated to pay up to an additional $0.8 million if certain milestones are met. As of December 31, 2016, no such obligation existed. Pursuant to the collaboration agreement, if the medical device manufacturer is successful in the development of this drug delivery system and the Company's pipeline products receive appropriate regulatory approval, the Company is obligated to enter into a commercial supply agreement with such medical device manufacturer for a minimum purchase of 1.0 million units during the first 12 months.

Operating Lease Agreements

The Company leases real and personal property, in the normal course of business, under various non-cancelable operating leases. The Company, at its option, can renew a substantial portion of its leases, at the market rate, for various renewal periods ranging from one to six years. Rental expense under these leases for the years ended December 31, 2016, 2015, and 2014, was approximately $3.4 million, $3.3 million, and $3.1 million, respectively.

Future minimum rental payments under operating leases that have initial or remaining non-cancelable lease terms in excess of 12 months for fiscal years ending December 31 are as follows:

	Operating Leases (in thousands)
2017	$ 3,038
2018	2,366
2019	1,596
2020	764

2021	53
	$ 7,817

Purchase Commitments

As of December 31, 2016, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $41.9 million. The Company anticipates that most of these commitments with remaining term in excess of one year will be fulfilled by 2018.

The Company entered into agreements with a Chinese governmental entity to acquire land-use rights to real property in Nanjing, China. Under the terms of these agreements, the Company committed to invest capital in its wholly-owned subsidiary, ANP, and to develop these properties as an API manufacturing facility for the Company's pipeline products. In conjunction with these agreements, ANP modified its business license on July 3, 2012, to increase its authorized capital. As of December 31, 2016, the Company had invested its total registered capital commitment of $61.0 million to ANP. This investment in ANP resulted in cash being transferred from the U.S. parent company to ANP.

Per these agreements, in January 2010, the Company acquired certain land-use rights with a carrying value of $1.2 million. In addition, the Company purchased additional land-use rights in November 2012 for $1.3 million. The Company committed to spend approximately $15.0 million in land development. The agreements require the construction of fixed assets on the property and specified a timetable for the construction of these fixed assets. The current pace of development of the property is behind the schedules described in the purchase agreements and, per the purchase agreement, potential monetary penalties could result if the development is delayed or not completed in

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accordance with the guidelines stated in the purchase agreements. The Company is in discussions with the Chinese government regarding the development and believes that the likelihood of incurring any penalty is remote.

17. Litigation

Enoxaparin Patent Litigation

In September 2011, Momenta Pharmaceuticals, Inc., or Momenta, a Boston based pharmaceutical company, and Sandoz Inc., or Sandoz, the generic division of Novartis, initiated litigation against the Company for alleged patent infringement of two patents related to testing methods for batch release of enoxaparin, which the Company refers to as the "'886 patent" and the "'466 patent." The lawsuit was filed in the United States District Court for the District of Massachusetts, or the Massachusetts District Court. In October 2011, the Massachusetts District Court issued a preliminary injunction barring the Company from selling its generic enoxaparin product and also requiring Momenta and Sandoz to post a $100.1 million bond. The preliminary injunction was stayed by the United States Court of Appeals for the Federal Circuit, or the Federal Circuit, in January 2012, and reversed by the Federal Circuit in August 2012.

In January 2013, the Company moved for summary judgment of non infringement of both patents. Momenta and Sandoz withdrew their allegations as to the '466 patent, and in July 2013, the Massachusetts District Court granted the Company's motion for summary judgment of non infringement of the '886 patent and denied Momenta and Sandoz's motion for leave to amend their infringement contentions. On January 24, 2014, the Massachusetts District Court judge entered final judgment in the Company's favor on both patents. Momenta and Sandoz also filed a motion to collect attorneys' fees and costs relating to a discovery motion which the Massachusetts District Court granted. On May 9, 2016, the Massachusetts District Court issued an order imposing fees and costs of approximately $0.4 million in relation to this discovery motion. This amount has been accrued in the general and administrative expense for the quarter ended March 31, 2016. On January 30, 2014, Momenta and Sandoz filed a notice of appeal to the Federal Circuit appealing the court's final judgment including summary judgment denying Momenta and Sandoz's motion for leave to amend their infringement contentions.

Following appeal briefing filed by the parties, the Federal Circuit held oral argument on May 4, 2015. On November 10, 2015, the Federal Circuit panel affirmed-in-part and vacated-in-part the decision of the Massachusetts District Court granting summary judgment of non-infringement as to the Company, and it remanded the case to the Massachusetts District Court for further proceedings consistent with its opinion. The Federal Circuit panel affirmed

the Massachusetts District Court's holding in the Company's favor that the Company does not infringe under 35 U.S.C. 271(g), and the panel vacated the grant of summary judgment to the extent it was based on the determination that the Company's activities fall within the 35 U.S.C. 271(e)(1) safe harbor. The Federal Circuit panel also left to the Massachusetts District Court's discretion whether to reconsider on remand its denial of leave for Momenta and Sandoz to amend their infringement contentions. On January 11, 2016, the Company filed a Petition for Rehearing En Banc with the Federal Circuit. On February 17, 2016, the Federal Circuit denied the Company's Petition, and the Federal Circuit issued its mandate on February 24, 2016, whereby the case returned to the Massachusetts District Court for further proceedings.

On March 18, 2016, the parties filed a joint status report with the Massachusetts District Court. On June 21, 2016, the Massachusetts District Court granted Momenta and Sandoz's Motion for Leave to Amend its Infringement Contentions. In light of Momenta and Sandoz's Amended Infringement Contentions and recent changes in Supreme Court precedent since the case was stayed in 2012, the Company sought to amend its Non-Infringement and Invalidity Contentions. The Massachusetts District Court then held a status conference on July 6, 2016 and referred the issue of the Company's amended contentions to the Magistrate Judge for briefing and further informed the parties that replies to any Summary Judgment motion are due in May 2017 and that trial is set to begin on July 10, 2017. On July 15, 2016, the Massachusetts District Court entered the Amended Scheduling Order setting the end of any remaining fact discovery for November 22, 2016 and the end of expert discovery for March 24, 2017. Fact discovery closed on November 22, 2016. The parties have exchanged opening and rebuttal expert reports.

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On July 18, 2016, the Company submitted its Motion for Leave to Amend Its Non-Infringement and Invalidity Contentions and Momenta and Sandoz responded on July 25, 2016. In light of the new arguments made in their response, the Company further filed a Motion For Leave to Reply in Further Support of Defendants' Motion for Leave to Amend Non-Infringement and Invalidity Contentions, which was granted. A hearing was held on August 23, 2016, where the Magistrate Judge ordered the Company to file its proposed amended contentions, which it filed on August 31, 2016. On February 4, 2017, the Magistrate Judge issued an order denying the Company leave to amend its contentions. The Company filed objections to this order with the District Court on February 21, 2017. The Massachusetts District Court has not yet ruled on the Company's pending motion regarding its amended contentions.

In parallel with the Massachusetts District Court proceedings, the Company appealed the Federal Circuit's decision to vacate the grant of the Company's summary judgment to the extent it was based on the determination that the Company's activities are protected under the Safe Harbor. The Company filed a Petition for a Writ of Certiorari with the Supreme Court on May 17, 2016. Momenta and Sandoz initially waived their right to respond to the petition; however, on May 31, 2016, the Supreme Court requested a response from Momenta and Sandoz. The response from Momenta and Sandoz was initially due on June 30, 2016, but they requested an extension. Momenta and Sandoz filed their response on August 1, 2016. On October 3, 2016, the Supreme Court declined the Petition for a Writ of Certiorari.

The Company will continue to vigorously defend this case in the Massachusetts District Court. The Company intends to attempt to collect the $100.1 million bond posted by Momenta and Sandoz following a decision on the merits, provided that the Company prevails in Massachusetts District Court.

False Claims Act Litigation

In January 2009, the Company filed a qui tam complaint in the U.S. District Court for the Central District of California, or the California District Court, alleging that Aventis Pharma S.A., or Aventis, through its acquisition of a patent through false and misleading statements to the U.S. Patent and Trademark Office, as well as through false and misleading statements to the FDA, overcharged the federal and state governments for its Lovenox® product. If the Company is successful in this litigation, it could be entitled to a portion of any damage award that the government ultimately may recover from Aventis. In October 2011, the California District Court unsealed the Company's complaint.

On February 28, 2014, Aventis filed a motion for summary judgment on the issue of the adequacy of the Company's notice letter to the government, and the California District Court denied Aventis' motion for summary judgment in a final order it issued on May 12, 2014. On June 9, 2014, at Aventis' request, the California District Court issued an order certifying for appeal its order denying Aventis' motion for summary judgment. On June 9, 2014, Aventis filed with the United States Court of Appeals for the Ninth Circuit, or the Ninth Circuit, a petition for permission to appeal the California District Court's denial of Aventis' motion for summary judgment, and the Company filed an opposition to Aventis' petition on June 19, 2014. On August 22, 2014, the Ninth Circuit granted Aventis' petition. The parties have completed and filed their respective appeal briefs with the Ninth Circuit. On November 10, 2016, the Ninth Circuit heard oral argument on the pending appeal and took the matter under submission.

The California District Court set an evidentiary hearing for July 7, 2014 on the "original source" issue, a key element under the False Claims Act. The evidentiary hearing was conducted as scheduled, from July 7, 2014 through July 10, 2014. On July 13, 2015, the California District Court issued a ruling concluding that the Company is not an original source under the False Claims Act and entered final judgment dismissing the case for lack of subject matter jurisdiction.

On July 20, 2015, the Company filed with the Ninth Circuit a notice of appeal of the California District Court's dismissal of the case, and Aventis filed a notice of cross-appeal on August 5, 2015. On November 12, 2015, Aventis filed a pleading asking that the California District Court impose various monetary penalties and fines against the Company, including disgorgement of enoxaparin revenues and attorneys' fees expended by Aventis in this action, based on Aventis's allegations that the Company engaged in sanctionable conduct. On November 23, 2015, the California District Court issued an order setting forth a procedure for sanctions proceedings as to the Company as well as its outside counsel. On December 24, 2015, the Company filed a pleading with the California District Court opposing the

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imposition of sanctions, and on January 20, 2016, Aventis filed a response pleading further pressing for the imposition of sanctions. On May 4, 2016, the California District Court issued three orders requesting that the Company and its outside counsel file a document showing cause as to why sanctions should not be imposed and to set up a conference call with the partiers and the court to discuss whether any discovery and/or a hearing is necessary. On June 13, 2016, the Company and its outside counsel each filed responses to the court's order to show cause as to why sanctions should not be imposed. On July 21, 2016, Aventis filed a response contending that the court should impose sanctions. On February 10, 2017, the Court held a show cause hearing regarding the potential imposition of sanctions and took the matter under submission. The Company intends to continue to vigorously defend against any such imposition of sanctions.

On March 28, 2016, the Company filed its opening brief with the Ninth Circuit Court of Appeals setting forth detailed arguments as to why the False Claims Act litigation should not have been dismissed by the California District Court. On June 20, 2016, Aventis filed its principal brief in the appeal, responding to the Company's arguments regarding dismissal of the False Claims Act litigation, and setting forth Aventis's argument that it should be awarded attorneys' fees and expenses. On September 19, 2016, the Company filed its reply brief to Aventis's principal brief. On October 3, 2016, Aventis filed its reply brief in support of its cross-appeal of the District Court's denial of attorneys' fees. The Ninth Circuit has scheduled oral arguments to be heard on November 10, 2016. On November 10, 2016, the Ninth Circuit heard oral argument on the pending appeals and took them under submission.

California Employment Litigation

On January 6, 2015, the Company received a formal demand from Plaintiff's counsel in an employment related lawsuit captioned Eva Hernandez v. International Medication Systems Limited, in connection with a complaint originally filed on February 4, 2013, in the Superior Court of California County of Los Angeles, or the Court, by plaintiff Eva Hernandez on behalf of herself and others similarly situated. Plaintiff's complaint included alleged violations of the California Labor Code stemming from the Company's alleged timekeeping practices, as well as other similar and related claims brought under California law. In the complaint, Plaintiff sought damages and related remedies under California law, as well as various penalty payments under the California Labor Code, on behalf of herself and others similarly situated. On April 7, 2015, solely to resolve the dispute, minimize disruption to the Company due to ongoing litigation, and other similar and related factors (but unrelated to the alleged merits of Plaintiff's claims), the Company reached an agreement in principle to settle this matter on a class-wide basis for a total amount of $3.2 million, plus applicable payroll taxes. The Joint Stipulation of Settlement as executed by the parties was filed with the Court on June 2, 2015. On July 1, 2015, the Court preliminarily approved the settlement, and on November 5, 2015, the Court entered an order granting final approval of the settlement. On May 13, 2016, the court reviewed and approved the final distribution report. The case was removed from the Court's Civil Active Case List.

Momenta/Sandoz Antitrust Litigation

On September 17, 2015, the Company initiated a lawsuit by filing a complaint in the California District Court against Momenta and Sandoz, or Defendants. The Company's complaint generally asserts that Defendants have engaged in certain types of illegal, monopolistic, and anticompetitive conduct giving rise to various causes of action against them. On December 9, 2015, Defendants filed a motion to dismiss and a motion to transfer the case to the District of Massachusetts. On January 4, 2016, the Company filed oppositions to both motions. On January 26, 2016, the California District Court granted Defendants' motion to transfer and did not rule on Defendants' motion to dismiss. Accordingly, the case was transferred to the District of Massachusetts. On February 9, 2016, the Company filed a writ of mandamus with the Ninth Circuit to attempt to appeal the California District Court's granting of Defendants' motion to transfer to the District of Massachusetts. The Ninth Circuit denied this petition on May 20, 2016, and as such the case will remain before the District of Massachusetts. On July 27, 2016, the Massachusetts District Court granted Defendants' motion to dismiss based upon an antitrust immunity doctrine, without addressing the substantive merits of the claims.

On August 25, 2016, the Company filed with the First Circuit Court of Appeals a notice of appeal of the Massachusetts District Court's dismissal of the antitrust case. On October 31, 2016, the Company filed its appeal brief with the First Circuit. On December 5, 2016, Defendants' filed their response brief with the First Circuit Court of Appeals. On

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December 19, 2016, the Company filed its rely brief with the First Circuit Court of Appeals, which concluded the briefing on this appeal. On February 9, 2017, the First Circuit Court of Appeals heard oral arguments. On March 6, 2017, the First Circuit Court of Appeals issued its decision, in which it held 3 to 0 that the District Court of Massachusetts erred in dismissing the Company's antitrust case and sent the case back to the District Court to consider additional arguments.

Other Litigation

The Company is also subject to various other claims and lawsuits from time-to-time arising in the ordinary course of business. The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. In the opinion of management, the ultimate resolution of any such matters is not expected to have a material adverse effect on its financial position, results of operations, or cash flows; however, the results of litigation and claims are inherently unpredictable and the Company's view of these matters may change in the future. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

18. Subsequent Events

Sale of Fourteen Injectable ANDAs

In February 2017, the Company sold the 14 ANDAs it acquired in March 2016 from Hikma to an unrelated party. The consideration included a purchase price of $6.4 million of which (i) the amount of $1.0 million was received upon closing, and the remaining $5.4 million will be paid upon certain milestones. If the purchaser is not able to achieve these milestones by December 31, 2017, the purchaser will pay the remaining payments within 30 days of December 31, 2017. In addition to the purchase price, the purchaser agrees to pay the Company a royalty fee equal to 2% of net sales, which are derived from purchaser's sales of the products for a period from February 2017 through February 2027. The Company is also subject to certain indemnification liability payable to the purchaser, which is limited up to $0.6 million. As of December 31, 2016, the 14 ANDAs had a carrying amount of $3.8 million.

Discontinuation of epinephrine injection, USP vial product

In March 2017, the FDA has requested the Company to discontinue the manufacturing and distribution of its epinephrine injection, USP vial product, which has been marketed under the “grandfather” exception to the FDA’s “Prescription Drug Wrap-Up” program. The Company is currently in discussions with the FDA regarding the timing of the discontinuation of this product. For the year ended December 31, 2016, the Company recognized $18.6 million in net revenues for the sale of this product. The charge of $3.3 million was included in the cost of revenues in its consolidated statements of operations for the year ended December 31, 2016 to adjust the related inventory items and firm purchase commitment to their net realizable value due to the anticipated discontinuation of the product.

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

19. Quarterly Financial Data (Unaudited)

	2016 Quarters			
	First	Second	Third	Fourth
	(in thousands, except per share data)			
Net revenues				
Finished pharmaceutical products	$ 58,554	$ 63,756	$ 59,058	$ 58,853
API	812	4,277	5,165	4,690
Total net revenues	$ 59,366	$ 68,033	$ 64,223	$ 63,543
Gross profit				
Finished pharmaceutical products	$ 25,824	$ 30,598	$ 28,621	$ 21,057
API	(922)	1,116	(1,009)	(1,096)
Total gross profit	$ 24,902	$ 31,714	$ 27,612	$ 19,961
Net income (loss)	$ 2,489	$ 6,895	$ 3,890	$ (2,742)
Weighted-average shares used to compute net income (loss) per share				
Basic	45,041	44,957	45,398	46,104
Diluted	46,810	45,968	47,953	46,104
Net income (loss) per share				
Basic	$ 0.06	$ 0.15	$ 0.09	$ (0.06)
Diluted	$ 0.05	$ 0.15	$ 0.08	$ (0.06)

	2015 Quarters			
	First	Second	Third	Fourth
	(in thousands, except per share data)			
Net revenue				
Finished pharmaceutical products	$ 50,872	$ 50,075	$ 57,902	$ 66,092
API	6,014	3,778	5,966	10,820
Total net revenues	$ 56,886	$ 53,853	$ 63,868	$ 76,912
Gross profit				
Finished pharmaceutical products	$ 12,853	$ 12,634	$ 19,302	$ 29,357
API	427	684	(1,724)	3,814
Total gross profit	$ 13,280	$ 13,318	$ 17,578	$ 33,171

Net income (loss)	$ (665)	$ (6,647)	$ (3,008)	$ 7,533
Weighted-average shares used to compute net income (loss) per share				
Basic	44,601	44,849	45,310	45,085
Diluted	44,601	44,849	45,310	46,709
Net income (loss) per share				
Basic	$ (0.01)	$ (0.15)	$ (0.07)	$ 0.17
Diluted	$ (0.01)	$ (0.15)	$ (0.07)	$ 0.16

Net income (loss) per share amounts for the fiscal quarters have been calculated independently and may not in the aggregate equal the amount for the full year.

During the fourth quarter of 2015, the Company identified an immaterial error in each of its previously reported quarters of 2015, primarily pertaining to the result of not recognizing non-operating expense for certain foreign currency transactions. The Company corrected the immaterial error in the fourth quarter of 2015, resulting in a decrease to net income of $1.1 million. Based on management's evaluation of the materiality of the error from a qualitative and quantitative perspective as required by authoritative guidance, the Company concluded that correcting the error had no material impact on any of the Company's previously issued interim financial statements and had no effect on the trend of financial results.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of senior management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on the evaluation under that framework and applicable SEC rules, our management concluded that our internal control over financial reporting was effective as of December 31, 2016.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm on our internal control over financial reporting due to an exemption established pursuant to the JOBS Act for “emerging growth companies.”

Changes in Internal Control Over Financial Reporting

For the year ended December 31, 2015, we identified a material weakness in our internal control over financial reporting in the area of non-standard and complex transactions. The accounting for certain non-standard and complex transactions were not analyzed and/or reviewed in sufficient detail by knowledgeable personnel to reach the appropriate accounting conclusion to properly record the transaction. The number of errors identified and the commonality of the root cause of the adjustments (namely, inadequate resources to provide for a more thorough and precise review in these areas), led us to conclude that there is a material weakness in internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Recognizing this material weakness and the resulting errors identified, management performed additional analyses and supplementary review procedures and has concluded that the effects of these errors were not material to any prior year or prior quarters’ previously reported amounts. During the quarter ended December 31, 2016, we remediated the material weakness in our internal control over financial reporting described above. The remediation efforts were focused on addressing the underlying causes of the material weakness

and included hiring additional accounting and finance personnel with technical accounting and financial reporting experience, enhancing and segregating duties within our accounting and finance department, and enhancing our internal review procedures during the financial statements close process. We believe these additional resources, processes and procedures have enabled us to broaden the scope and quality of our controls relating to the oversight and review of financial statements and our application of relevant accounting policies.

Except for the remediation efforts described above, there have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting means a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management overriding the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be included in our Proxy Statement for our 2017 Annual Meeting of Stockholders to be filed within 120 days after our fiscal year end of December 31, 2016, or 2017 Proxy Statement, and is incorporated by reference into this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information required by this item will be included in our 2017 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be included in our 2017 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be included in our 2017 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services.

Information required by this item will be included in our 2017 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements filed as part of this report are listed in Part II, Item 8 of this report.

(2) No other financial schedules have been included because they are not applicable, not required or because required information is included in the consolidated financial statements or notes thereto.

(b)The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

HIDDEN_ROW

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on July 1, 2014)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.1+	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.2+	2002 Stock Option/Stock Issuance Plan (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.3+	Form of Notice of Stock Option Grant under the Amended 2002 Stock Option/Stock Issuance Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.4+	Amended and Restated 2005 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.5+	Form of Stock Option Grant Notice and Stock Option Agreement under the Amended and Restated 2005 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.6+	Form of Deferred Stock Unit Notice of Grant and Deferred Stock Unit Agreement under the Amended and Restated 2005 Equity Incentive Award Plan (incorporated by reference to

	Exhibit 10.6 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.7†	Distribution Agreement, dated May 2, 2005, between Amphastar Pharmaceuticals, Inc. and Andrx Pharmaceuticals, Inc., as amended (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.8	Business Loan Agreement, dated December 31, 2010, between International Medication Systems, Limited and East West Bank, as amended (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.9	Revolving Loan and Security Agreement, dated April 10, 2012, between Amphastar Pharmaceuticals, Inc. and Cathay Bank (incorporated by reference to Exhibit 10.9 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.10	Business Loan Agreement, dated July 5, 2013, between International Medication Systems, Limited, Amphastar Pharmaceuticals, Inc. and East West Bank (incorporated by reference to Exhibit 10.10 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)

10.11	Registration Rights Agreement, dated February 4, 2005, between Amphastar Pharmaceuticals, Inc. and Lotus China Fund, L.P. (incorporated by reference to Exhibit 10.11 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.12	Standard offer, Agreement and Escrow Instructions for Purchase of Real Estate, dated October 2, 2012, among Amphastar Pharmaceuticals, Inc., Jack Y. Zhang and Mary Z. Luo (incorporated by reference to Exhibit 10.12 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.13◊	Transfer Contract for the Right to the Use of State-owned Land, dated December 29, 2009, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and Nanjing Xingang Hi-Tech Company Limited (incorporated by reference to Exhibit 10.13 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.14◊	Investment Agreement, dated July 5, 2010, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and the Management Committee of the Nanjing Economic and Technological Development Zone (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.15◊	Transfer Contract for the Right to the Use of State-owned Land, dated December 31, 2010, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and Nanjing Xingang Hi-Tech Company Limited. (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.16†	Long-Term Supply Agreement, dated November 30, 2008, between Qingdao Jiulong Biopharmaceutical Co., Ltd. and International Medication Systems, Limited (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.17+	2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.18	Asset Purchase Agreement, dated April 30, 2014, among Diosynth France, Amphastar France Pharmaceuticals SAS and Schering-Plough (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.19	Loan Agreement, dated April 22, 2014, between Amphastar Pharmaceuticals, Inc. and Cathay Bank (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.20	Promissory Note, dated April 22, 2014, by Amphastar Pharmaceuticals, Inc. payable to Cathay Bank in the original principal sum of $21,900,000 (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.21+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Jack Zhang (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.22+	

	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Mary Luo (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.23+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Jason Shandell (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.24+	Employment Agreement, dated March 11, 2014, between Amphastar Pharmaceuticals, Inc. and William Peters (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.25†	Supply Agreement, dated July 31, 2014, between MannKind Corporation and Amphastar France Pharmaceuticals, S.A.S. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014)

10.26	First Amendment to Supply Agreement, dated October 31, 2014, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014)
10.27+	2015 Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 1, 2015)
10.28	Business Loan Agreement, dated January 28, 2016, between Amphastar Pharmaceuticals, Inc. and East West Bank in the original principal sum of $3,724,841. (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2016)
10.29	Equipment Line of Credit Agreement, dated March 7, 2016, between International Medication Systems, Limited and East West Bank in the principal sum of $5,000,000. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2016)
10.30	Fifth Modification to the Revolving Line of Credit Agreement, dated March 7, 2016, between International Medication Systems, Limited and East West Bank in the principal sum of $15,000,000. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2016)
10.31	Seventh Amendment and Termination Agreement by and between the Company and Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc. – Florida and as Andrx Pharmaceuticals, Inc.) dated June 30, 2016. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 7, 2016)
10.32	Fourth Modification to the Revolving Line of Credit Agreement, dated June 23, 2016, between Amphastar Pharmaceuticals, Inc. and Armstrong Pharmaceuticals, Inc. and Cathay Bank in the principal sum of $20,000,000. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2016)
10.33	Business Loan Agreement, dated September 8, 2016, between Amphastar Pharmaceuticals, Inc. and East West Bank in the original principal sum of $3,591,250. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2016)
10.34†	Second Amendment to Supply Agreement, dated November 9, 2016, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc.
12.1	Computation of Ratio of Earnings to Combined Fixed Charges and preferred stock dividends
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document

101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definitions Linkbase Document

#The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act (including this Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

+Indicates a management contract or compensatory plan or arrangement.

◊English translation of original Chinese document.

†Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and file separately with the SEC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: /s/ JACK Y. ZHANG
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

Date: March 15, 2017

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: /s/ WILLIAM J. PETERS
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 15, 2017

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Jack Y. Zhang and William J. Peters, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated:

Signature	Title	Date
/s/ JACK Y. ZHANG Jack Yongfeng Zhang	Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2017
/s/ MARY Z. LUO Mary Z. Luo	Chairman, Chief Operating Officer and Director	March 15, 2017
/s/ WILLIAM J. PETERS William J. Peters	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2017
/s/ JASON B. SHANDELL Jason B. Shandell	President and Director	March 15, 2017
/s/ RICHARD KOO Richard Koo	Director	March 15, 2017
/s/ HOWARD LEE Howard Lee	Director	March 15, 2017
/s/ FLOYD PETERSEN Floyd Petersen	Director	March 15, 2017
/s/ RICHARD PRINS Richard Prins	Director	March 15, 2017
/s/ STEPHEN SHOHET Stephen Shohet	Director	March 15, 2017
/s/ MICHAEL A. ZASLOFF Michael A. Zasloff	Director	March 15, 2017

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