Amphastar Pharmaceuticals, Inc.
Form 10-K
March 14, 2018

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, 2017

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2017, based upon the closing price of Common Stock on such date as reported by Nasdaq Global Select Market, was approximately $638,082,059. 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 6, 2018, there were 46,350,595, 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 2018 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

Table of Contents

Amphastar Pharmaceuticals, Inc.

Table of Contents

Table of Contents

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 the impact of global and domestic tax reform, including the Tax Cuts and Jobs Act of 2017;
- the timing for completion of construction and validation at our IMS facility; and
- our financial performance expectations, including our expectations regarding our backlog, 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.

Table of Contents

You should read this Annual Report and the documents that we reference elsewhere in this Annual Report completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. We discuss many of these risks and uncertainties in greater detail in this Annual Report, particularly in 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, as well as insulin active pharmaceutical ingredient, or insulin API, products. We currently manufacture and sell over 20 products. Additionally, we are currently developing a portfolio of 15 generic abbreviated new drug applications, or ANDAs, three generic biosimilar product candidates and six proprietary product candidates.

For the years ended December 31, 2017, 2016, and 2015, we recorded net revenues of $240.2 million, $255.2 million, and $251.5 million, respectively. We recorded net income of $4.5 million and $10.5 million for the years ended December 31, 2017 and 2016, respectively, and recorded a net loss of $2.8 million for the year ended December 31, 2015. Our largest products by net revenues currently include naloxone hydrochloride injection, lidocaine jelly and sterile solution, phytonadione injection, and enoxaparin sodium injection.

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 three ANDAs and two NDAs currently on file with the FDA.

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, nasal sprays, 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.

Table of Contents

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

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 are in the process of transferring the manufacturing of these products to our facilities in California, which will require approvals from the UK Medicines and Healthcare products Regulatory Agency before we can relaunch the product candidates.

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 IQVIA National Sales Perspective Report, the U.S. generic injectable drug market in 2017 was approximately $9.9 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 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 IQVIA National Sales Perspective Report, the U.S. inhalation drug market in 2017 was approximately $25.6 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 requires 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 over 20 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.

Table of Contents

- 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.

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.

Table of Contents

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

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.

Table of Contents

- Immunogenicity. The ability of an antigen to elicit immune responses is called immunogenicity. Unwanted immunogenicity, which is strongly linked with protein drug products, occurs when a patient mounts an undesired immune response against a drug therapy. As a result, the FDA has signaled that they may require immunogenicity studies as part of the new pathway for biosimilars and biogenerics, and in the past, the FDA has required these studies in connection with the approval of products with complex molecules. We gained expertise in immunogenicity by performing immunogenicity studies in connection with the FDA approval process for our enoxaparin product. We believe that our experience in conducting these difficult immunogenicity studies will be of primary importance in our future efforts to develop complex molecules, biosimilar and biogeneric product candidates.
- Peptide and protein product development and production. The development of peptide and protein drug products utilizes characterization technology and immunogenicity studies as well as recombinant DNA, or rDNA, API manufacturing technology. We have experience in the use of rDNA manufacturing technology which includes the genetic engineering of host cells, fermentation to promote cell culture growth and isolation and purification of the desired protein from the cell culture. Through each step, testing is required to ensure that only the desired protein is included in the finished product. We believe that this technology will allow us to develop protein and peptide drug products.
- Particle engineering. Particle engineering is important in the field of pulmonary drug delivery as there is a direct relationship between the properties of a particle and its absorption by the lungs. We believe our expertise and technology applicable to particle engineering and physical chemistry allows us to engineer the size, shape, surface smoothness and distribution of particles to develop inhalation products that are more easily dispersed through targeted areas. We believe this expertise will allow us to formulate difficult to disperse inhalation products.
- Sustained-release. We have developed technology aimed at improving drug delivery through sustained-release injectable products. The purpose of our sustained-release technology is to create products that require less dosing frequency and that we believe can diminish the fluctuations of drug concentrations in a patient's blood stream that otherwise require more frequent dosing. We plan to use our sustained-release technology to develop both generic and proprietary products.

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, 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 Information."

Finished Pharmaceutical Product Segment

Our Marketed Products

We currently manufacture and sell 20 products in our finished pharmaceutical product segment. The following is a description of products in our existing portfolio.

Table of Contents

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, 2017, 2016, and 2015, we recorded net revenues from enoxaparin of $36.6 million, $59.3 million, and $84.5 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, 2017, 2016, and 2015 were $42.3 million, $47.5 million, and $38.6 million, respectively.

Other Marketed Products

We have 18 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;
- 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;
- Procainamide, which is indicated for the treatment of documented ventricular arrhythmias;
- Neostigmine Methylsulfate Injection, which a cholinesterase inhibitor used in the treatment of myasthenia gravis and to reverse the effects of muscle relaxants such as gallamine and tubocurarine;
- Medroxyprogesterone Acetate Injectable Suspension, indicated for the prevention of pregnancy; and
- Sodium Nitroprusside Injection, which is indicated for the immediate reduction of blood pressure of adults and pediatric patients in hypertensive crisis, and for producing controlled hypotension in order to reduce bleeding during surgery and for the treatment of acute congestive heart failure. The launch of this product is planned for the second quarter of 2018.

Table of Contents

For the years ended December 31, 2017, 2016, and 2015, we recorded net revenues from these other marketed products of $151.2 million, $133.4 million, and $101.8 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.

The following table summarizes our technical capabilities needed for the generic ANDAs and generic biosimilar product candidates in development.

Delivery Technology	Characterization	Immunogenicity	Particle Engineering	Sustained-Release	Peptide and Protein Technology
Injectable	ü	ü	ü	ü	ü
Inhalation					

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.

Table of Contents

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 paragraph 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 submitted a responsive NDA amendment in June 2016 and received a second 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 product correctly to support approval in the over-the-counter setting. After several meetings with the FDA in 2017, we further revised our packaging and label and plan to perform another human factors study based on such revisions. On November 2017, we submitted our proposed protocol to the FDA. In March 2018, we received an Advice Letter from the FDA regarding our proposed protocol. Based on that feedback we plan to conduct an additional human factors study. Once we receive acceptable results from the study, we will resubmit the NDA. We intend to continue to work with the FDA 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 our NDA will result in timely approval of Primatene® Mist or approval at all.

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.

Table of Contents

API Segment

We began to manufacture and sell two API products, 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, 2017, 2016 and 2015, we recorded net revenues of $10.0 million, $14.9 million and $26.6 million, respectively, from our API products.

Supply Agreement with MannKind Corporation

On July 31, 2014, we entered into a supply agreement with MannKind Corporation, or 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.

In January 2015, we entered into a supply option agreement with MannKind, or the Option Agreement, pursuant to which MannKind has 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 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 API under the Supply Agreement.

In November 2016, we 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. For the year ended December 31, 2017, sales of RHI API to MannKind totaled $3.2 million, which fulfilled the 2017 commitment of RHI API under the amended Supply Agreement.

Concurrent with the amendment of the Supply Agreement, we 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

Table of Contents

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. In August 2017, MannKind notified us that it would not exercise its minimum annual purchase option of RHI API for 2018. We recognized the cancellation fee for 2018 of $0.9 million in net revenues in our consolidated statements of operations for the year ended December 31, 2017.

In addition to, and in consideration for the updated timeframe and other changes contained in the amendment to the Supply Agreement and the amendment to the Option Agreement, 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, 2017, we had 290 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, 2017, 2016 and 2015 were $43.4 million, $41.2 million, and $37.3 million, respectively, which represent 18%, 16% and 15% of our net revenues for that period, respectively.

Backlog

A significant portion of our customer shipments in any fiscal year relate to orders received and shipped in that fiscal year, generally resulting in low product backlog relative to total shipments at any time. Our backlog is not material and not a meaningful indicator 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 75 buildings at six locations in the United States, France and China, that comprise 1.8 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 continue to expand our facility in Nanjing, China, and expect further significant investment.

Our API manufacturing business in Éragny-sur-Epte, France which we acquired in April 2014 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 our RHI API's starting material. We expect that this project will cost approximately $27.0 million. As of December 31, 2017, we have spent $18.1 million, and expect to complete this project by the end of 2019.

We believe that our current manufacturing capacity is adequate for the near term. Our South El Monte, California facility was nearing capacity, so we began a significant project to increase production and modernize the facilities. The project cost to date is $14.4 million. In 2017, we completed construction, finished installing new equipment and started the validation process which needs to be completed before the new sterile area can be used in production. We expect to begin using the new production lines by the end of 2018.

Table of Contents

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 our manufacturing facility in China is qualified by the FDA, we plan to have it 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, doctors' offices, and retail pharmacies. 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,		
	2017	2016	2015
Actavis(1)	—	14 %	21 %
AmerisourceBergen Corporation	28 %	21 %	17 %

Cardinal Health, Inc.	23	%	22	%	17	%
McKesson Corporation	27	%	21	%	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

Table of Contents

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, 2017, 2016, and 2015, we generated 3%, 3% and 2% 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.

Table of Contents

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

Table of Contents

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,

Table of Contents

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

18

Table of Contents

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.

Table of Contents

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;

Table of Contents

- 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

Table of Contents

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.

Table of Contents

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 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. We believe that our responses to the observations will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From March 13, 2017 through March 31, 2017, our Amphastar facility in Rancho Cucamonga, California was subject to a preapproval inspection by the FDA. The inspection included a review of our corrective actions taken from the previous cGMP inspection in July 2014 as well as review of data to support our pending applications. The inspections resulted in multiple observations on Form 483. We fully responded to those observations on April 22, 2017. We believe that our responses to the observations will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From April 24, 2017 through April 28, 2017, our facility in Nanjing, China was subject to an inspection by the FDA. The purpose was a pre-approval inspection for the manufacture of API. The inspection resulted in several observations on Form 483. We responded to those observations on May 19, 2017, and believe that our responses to the observations satisfied the requirements of the FDA and the inspection is considered closed.

On October 20, 2017, a representative from the U.S. Department of Agriculture, or USDA, inspected our facility in Chino, California. The inspection covered compliance with USDA regulations regarding laboratory animal handling and well-being. No citations were made.

From October 23, 2017 through October 26, 2017, our facility in Nanjing, China was subject to an inspection by the FDA. The purpose was a general cGMP inspection to cover the facility for FDA's fiscal year 2018. The inspection included a review of Quality Systems, Production Controls, Laboratory Controls, Material Management, and Facilities and Equipment Maintenance. The inspection also included a review of our corrective actions taken from the previous inspection in April 2017. There were no Form 483 observations issued.

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

Table of Contents

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 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 discontinued selling this product in the second quarter of 2017. For the years ended December 31, 2017, 2016, and 2015 we recognized $17.8 million, $18.6 million, and $7.8 million, in net revenues for the sale of this product, respectively. 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 and firm purchase commitment to their net realizable value due to the anticipated discontinuation of the product. Additionally, in September 2017, the FDA granted approval of our ANDA for Sodium Bicarbonate injection.

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.

Table of Contents

Federal False Claims Act

Another development affecting the health care industry is the increased use of the federal False Claims Act, and in particular, 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 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

Table of Contents

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.

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.

Table of Contents

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, 2017, we had 1,644 full-time employees.

Corporate Information

We incorporated in California under the name Amphastar Pharmaceuticals, Inc. in 1996 and merged our California corporation into Amphastar Pharmaceuticals, Inc., a newly formed Delaware corporation, in 2004. Our corporate offices are located at 11570 6th Street, Rancho Cucamonga, CA 91730. Our telephone number is (909) 980-9484. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. You can access our filings with the SEC by visiting www.amphastar.com. The information that is contained on, or can be accessed through our website is not incorporated into this Annual Report on Form 10-K, and the inclusion of our website address is an inactive textual reference only.

We use our website as a channel of distribution for important company information. Important information, including press releases, analyst presentations and financial information regarding us, as well as corporate governance information, is routinely posted and accessible on the "Investors" section of the website, which is accessible by clicking

on the tab labeled “Investors” on our website home page. Information on or that can be accessed through our website is not part of this Annual Report on Form 10-K, and the inclusion of our website address is an inactive textual reference only.

Table of Contents

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 15%, 23%, and 34% of our total net revenues for the years ended December 31, 2017, 2016, and 2015, respectively, and sales of our naloxone products represented 18%, 19%, and 15% of our total net revenues for the years ended December 31, 2017, 2016, and 2015, 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;
- loss of key relationships with suppliers, group purchasing organizations or end-user customers;
- manufacturing or supply interruptions;
- increase in material input costs;
- 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.

Table of Contents

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

Generally accepted accounting principles, or U.S. GAAP in the United States are subject to interpretation by the Financial Accounting Standards Board, or FASB, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change. For example, in May 2014, the FASB issued ASU No. 2014-09, Revenue From Contracts With Customers (Topic 606), as subsequently amended, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP and became effective for us beginning the first quarter of fiscal 2018. In addition, were we to change our critical accounting estimates, our results of operations could be significantly impacted. These or other changes in accounting principles could adversely affect our financial results. See Note 2 of the Notes to Financial Statements in Part II - Item 8 of this Annual Report on Form 10-K for information regarding the effect of new accounting pronouncements on our financial statements. Any difficulties in implementing these pronouncements could cause us to fail to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us.

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. 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. See the risk factor entitled, "The FDA approval process is time-consuming and complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all. Additionally, we may lose FDA approval 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 FDA approval was not granted until September 2011 due to delays caused largely by our inclusion in lengthy litigation with Sanofi S.A., or Sanofi, the FDA's requirement that we perform immunogenicity studies and the receipt of an FDA Warning Letter by the supplier of the starting material for our enoxaparin product, who also became the subject of an FDA Import Alert. Following FDA approval, we became involved in litigation with Momenta Pharmaceuticals, Inc. and Sandoz, Inc., which further delayed the commercial launch of our enoxaparin product until January 2012. Delays in any part of the process, or our inability to obtain regulatory approval of our products, could

adversely affect our operating results by restricting or delaying our introduction of new products, which could cause the market value of our products to decline. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially and adversely affected, and the market value of our common stock could decline.

Our ability to introduce new generic products also depends upon our success in challenging patent rights held by third parties or in developing non-infringing products. Due to the emergence and development of competing products over time, our overall profitability depends on, among other things, our ability to introduce new products in a timely manner, to continue to manufacture products cost-effectively and to manage the life cycle of our product portfolio. If we are

Table of Contents

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.

We incurred losses for 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 $2.8 million for the year ended December 31, 2015. These losses resulted principally from a decrease in profits from enoxaparin. Although we achieved net income in the years ended 2016 and 2017, we may 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 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.

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.

Table of Contents

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 have resulted and will continue to 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 further 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.

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.

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

Table of Contents

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 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

Table of Contents

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 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;

Table of Contents

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

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

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

Many of the existing and potential customers for our products have combined to form group purchasing organizations in an effort to lower costs. Group purchasing organizations negotiate pricing arrangements with medical supply manufacturers and distributors, and these negotiated prices are made available to a group purchasing organization's affiliated hospitals and other members. Group purchasing organizations provide end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. 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.

34

Table of Contents

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, 2017, 2016, and 2015, respectively, accounted for approximately 78%, 64%, and 56% of our total net revenues, respectively. Such consolidation has provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face.

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; 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® and the API for Nitroprusside at our manufacturing

Table of Contents

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 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

Table of Contents

sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;

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

In addition, the expansion of our existing international operations, including our facility expansion in Nanjing, China, and entry into additional international markets, including our 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.

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 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 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

Table of Contents

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.

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

On June 23, 2016, the electorate in the United Kingdom, or UK, voted in favor of leaving the European Union, or EU, (commonly referred to as the “Brexit”). Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the UK from the EU will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the UK provides a notice of withdrawal pursuant to the EU Treaty.

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.

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

Table of Contents

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 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

Table of Contents

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; and
- charges to our operating results resulting from expenses incurred to effect the acquisition.

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

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

40

Table of Contents

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 made extensive changes to the delivery of health care in the United States. 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect that there will be additional challenges and amendments to the Affordable Care Act in the future. The Trump administration and members of the U.S. Congress have indicated that they may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Most recently, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. We do not currently know the extent to which any such changes may impact our business or financial condition, as well as the pharmaceutical industry as a whole. 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, 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;

Table of Contents

- 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.

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, 2017, the value of our goodwill and intangible assets net of accumulated amortization was $45.1 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 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

Table of Contents

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.

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

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

Additionally, as a result of any 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.

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.

Table of Contents

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

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

The U.S. government has recently enacted the Tax Act, which includes significant changes to the taxation of business entities. These changes include, among others, a federal statutory rate reduction from 35% to 21% effective January 1, 2018, the elimination or reduction of certain domestic deductions and credits, limitations on the deductibility of executive compensation, and a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain and is subject to developing interpretations of the provisions of the legislation, changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries, and the filing of our tax returns. The final analysis of

Table of Contents

the transition tax and the remeasurement of our deferred tax assets and liabilities will be completed as additional information becomes available, but no later than one year from the date of enactment.

In addition to income taxes in the United States, 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.

In addition, tax laws are dynamic and subject to change as evidenced by the Tax Act. As new laws are passed and new interpretations of the law are issued or applied, our provision for income taxes may be affected. Recent changes to U.S. tax laws, including taxation of earnings outside of the U.S., the introduction of a base erosion anti-abuse tax and the disallowance of tax deductions for certain book expense, as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of our earnings, as well as cash and cash equivalent balances we currently maintain. Furthermore, due to shifting economic and political conditions, tax policies or rates in various jurisdictions may be subject to significant change. Additionally, increases in our effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by various taxing authorities and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

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

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

Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, third-party providers, distributors or other contractors, could result in information theft, data corruption and significant disruption of our business operations.

We, our collaborators, third-party providers, distributors and other contractors utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As

Table of Contents

use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our collaborators', third-party providers', distributors' and other contractors' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects despite our security measures. Similarly, there can be no assurance that our collaborators, third-party providers, distributors and other contractors will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

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

Table of Contents

Committee to assist the FDA in examining specific issues related to the application. In February 2014, the FDA held a joint meeting of its Nonprescription Drugs Advisory Committee and its Pulmonary Allergy Drugs Advisory Committee, which we refer to as the Committee, to discuss the NDA for Primatene® Mist. 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 submitted a responsive NDA amendment in June 2016 and received a second 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 product correctly to support approval in the over-the-counter setting. After several meetings with the FDA in 2017, we further revised our packaging and label and plan to perform another human factors study based on such revisions. In November 2017, we submitted our proposed protocol to the FDA. In March 2018, we received an Advice Letter from the FDA regarding our proposed protocol. Based on that feedback we plan to conduct an additional human factors study. Once we receive acceptable results from the study, we will resubmit the NDA. We intend to continue to work with the FDA 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 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

Table of Contents

populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Our clinical trials may not demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

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

Table of Contents

product candidate.

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

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

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

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

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

We are engaging in particle engineering for certain product candidates, including 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,

Table of Contents

regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

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

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

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

Table of Contents

PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to previously approved biologics notwithstanding minor differences in inactive components. The process for bringing a biosimilar product to market is uncertain and may be drawn out for an extended period of time. The FDA has not yet promulgated regulations governing this process and only nine biosimilar applications have been approved as of December 31, 2017. 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 nine 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. 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.

Table of Contents

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 have entered into collaboration agreements with various medical device manufacturers to develop drug delivery systems to be used for 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;

Table of Contents

- 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.

Table of Contents

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

Table of Contents

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

Table of Contents

August and October, 2010, we reintroduced atropine, calcium chloride, morphine, dextrose, epinephrine prefilled syringes, epinephrine injection, USP vial, and sodium bicarbonate injections.

In February 2017, the FDA requested that we discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which had been marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. We discontinued selling this product in the second quarter of 2017. For the years ended December 31, 2017, 2016, and 2015, we recognized $17.8 million, $18.6 million, and $7.8 million in net revenues for the sale of this product, respectively. A 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 and firm purchase commitment to their net realizable value due to the anticipated discontinuation of the product.

In September 2017, the FDA granted approval of our ANDA for Sodium Bicarbonate injection.

For the years ended December 31, 2017, 2016, and 2015, we recorded net revenues of $35.4 million, $27.6 million, and $27.8 million, respectively, from the unapproved products currently on the market: atropine, calcium chloride, morphine, dextrose and epinephrine prefilled syringes. We have filed three ANDAs and are preparing additional applications with respect to the remaining unapproved products in order to 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.

In January, 2016, the Centers for Medicare and Medicaid Services, or CMS, issued a final rule that helped to clarify many of the changes made to the Medicaid Drug Rebate Program by the Affordable Care Act. The final rule attempts to provide drug manufacturers with the regulatory guidance necessary to ensure proper calculation and reporting of drug product and pricing information. Specifically, the final rule attempts to clarify the definition of what constitutes a manufacturer's "best price" and aligns it, where appropriate, to the definition of "Average Manufacturer Price", which is used to calculate drug rebates. Notwithstanding the final rule's guidance, a number of state and federal government agencies will continue to conduct investigations of manufacturers' reporting practices with respect to Average Wholesale Prices, or AWP, in which reports of inflated AWP may lead to excessive payments for prescription drugs.

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

Table of Contents

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.

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

57

Table of Contents

recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payer. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

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

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has 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

Table of Contents

authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws and regulations will involve substantial costs. Any state or federal regulatory review of us or the third parties with whom we contract, regardless of the outcome, would be costly and time-consuming.

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

Table of Contents

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. 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 patent litigation related to our sales of enoxaparin, and there is an ongoing related antitrust litigation. For further details, see the section titled Litigation in Note 17 in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report on Form 10-K. The protracted litigations 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 these litigations or in other litigations – 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.

We have filed patent applications covering compositions of, methods of making and/or methods of using, our proprietary

Table of Contents

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.

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

Table of Contents

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;
- changes in, or termination of our agreements with our business partners;
- developments concerning our sources of manufacturing supply;

Table of Contents

- 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;
- our overall effective tax rate, including impacts caused by any reorganization in our corporate structure, and any new legislation or regulatory developments, including the Tax Act;
- 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 18.5 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 will be sold, in the public market, the trading price of our common stock could decline.

63

Table of Contents

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 6, 2018, 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 28.2% of our outstanding common stock, including shares of common stock subject to options exercisable within 60 days of March 6, 2018. 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 31.9% 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 6, 2018. 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 or otherwise could cause our stock price to decline and negatively impact our business.

Since September 2015, UBS Bank USA has made extensions of credit in the aggregate amount of $7.8 million to Applied Physics & Chemistry Laboratories, Inc., or APCL, which is controlled by Jack Yongfeng Zhang and Mary Ziping Luo. The loan is secured by a pledge of 2,000,000 shares of our common stock currently held by APCL. Interest on the loan accrues at market rates. UBS Bank USA received customary fees and expense reimbursements in connection with these loans.

Since May 2017, UBS Bank Utah has made an extension of credit in the aggregate amount of $7.8 million to APCL. The loan is secured by a pledge of 1,907,898 shares of our common stock currently held by APCL. Interest on the loan accrues at market rates. UBS Bank Utah received customary fees and expense reimbursements in connection with these loans.

In October 2017, East West Bank entered into an agreement with Dr. Zhang and Dr. Luo whereby East West Bank would loan them up to $5,000,000. The loan is secured by a pledge of 650,000 shares of our common stock held by Dr. Zhang and 550,000 shares of our common stock held by Dr. Luo. Interest on the loan accrues at market rates.

We are not a party to these loans, which are full recourse against APCL and each of Dr. Zhang and Dr. Luo, respectively, and are secured by pledges of a portion of the shares 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 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. Furthermore, in the event of a default under the terms of such loans, the pledged shares may be acquired and sold by the lenders. 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

Table of Contents

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 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 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.

Table of Contents

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

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors may find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we 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

Table of Contents

proposing matters that can be acted upon at stockholder meetings; and

- establishing a classified Board of Directors, whereby only one-third of the members of our Board of Directors are elected at one time.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could delay or prevent a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our common stock.

Item 1B. Unresolved Staff Comments.

None.

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 75 buildings at six locations in the U.S., France and China, that comprise 1.8 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 continue to expand our facility in Nanjing, China and expect further significant 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, 2017:

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	353,600	Manufacturing, procurement, research and development, warehousing, and administration offices	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

Table of Contents

The properties leased by us have expiration dates ranging from 2018 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	184,120	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

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.

Table of Contents

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 closing sales price for our common stock during each of the quarterly periods indicated, as reported on the Nasdaq Global Select Market:

	Closing Sales Price	
	High	Low
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
2017		
First Quarter	$ 19.39	$ 12.20
Second Quarter	$ 17.86	$ 14.17
Third Quarter	$ 18.45	$ 14.73
Fourth Quarter	$ 19.75	$ 17.76

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 6, 2018, we had 46,350,595 shares of common stock outstanding held by approximately 184 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.

Table of Contents

Issuer Purchases of Equity Securities During the Quarter Ended December 31, 2017

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, 2017	70,000	$ 18.52	70,000	—
November 1 – November 30, 2017	127,900	18.27	127,900	—
December 1 – December 31, 2017	123,092	18.94	123,092	—

(1) During the fourth quarter of 2017, we repurchased shares of our common stock as part of the share buyback programs authorized by our Board of Directors on August 7, 2017. As of December 31, 2017, $9.1 million remained available under such programs.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during fiscal 2017 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

Table of Contents

information regarding securities authorized for issuance.

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 2017, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017 and 2016, 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 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015, 2014, and 2013, 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,				
	2017	2016	2015	2014	2013
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net revenues	$ 240,175	$ 255,165	$ 251,519	$ 210,461	$ 229,681
Cost of revenues	149,380	150,976	174,172	159,205	142,725
Gross profit	90,795	104,189	77,347	51,256	86,956
Operating (income) expenses:					
Selling, distribution and marketing	6,460	5,466	5,470	5,564	5,349
General and administrative	44,458	41,832	41,504	34,809	30,972
Research and development	43,415	41,199	37,271	28,866	33,145
Gain on sale of intangible assets	(2,643)	—	—	—	—
Total operating expenses	91,690	88,497	84,245	69,239	69,466
Income (loss) from operations	(895)	15,692	(6,898)	(17,983)	17,490
Non-operating income (expenses):					
Interest income	425	270	315	243	187
Interest expense	(826)	(1,024)	(987)	(609)	(958)
Other income (expenses), net	2,919	8	(2,794)	201	508
Total non-operating income (expenses)	2,518	(746)	(3,466)	(165)	(263)
Income (loss) before income taxes	1,623	14,946	(10,364)	(18,148)	17,227
Income tax expense (benefit)	(2,885)	4,414	(7,577)	(7,449)	5,365
Net income (loss)	$ 4,508	$ 10,532	$ (2,787)	$ (10,699)	$ 11,862
Net income (loss) per common share:					
Basic	$ 0.10	$ 0.23	$ (0.06)	$ (0.25)	$ 0.31
Diluted	$ 0.09	$ 0.22	$ (0.06)	$ (0.25)	$ 0.31
Weighted-average shares used to compute net income (loss) per common share:					
Basic	46,107	45,375	44,961	41,957	38,712
Diluted	48,367	47,504	44,961	41,957	38,883

71

Table of Contents

	December 31, 2017	2016	2015	2014	2013
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$ 72,384	$ 74,271	$ 67,359	$ 69,323	$ 54,912
Working capital	120,586	123,479	115,979	135,401	107,569
Total assets	454,665	427,738	390,136	389,370	338,748
Long-term debt and capital leases, including current portion	47,156	37,722	41,099	43,700	32,173
Retained earnings	76,235	70,855	60,323	63,110	73,809
Total stockholders' equity	337,329	329,255	295,510	281,860	251,545

Table of Contents

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. These risks, uncertainties and other factors, include among others, those identified under the "Special Note About Forward-Looking Statements," above and described in greater detail 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 as well as insulin API products. We currently manufacture and sell over 20 products. We are currently developing a portfolio of 15 generic abbreviated new drug applications, or ANDAs, three generic biosimilar product candidates and six proprietary product candidates, which are in various stages of development and target a variety of indications. With respect to these product candidates, we have three ANDAs, and two NDAs on file with the FDA.

Our largest products by net revenues currently include naloxone hydrochloride injection, lidocaine jelly and sterile solution, phytonadione injection, and enoxaparin sodium injection.

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

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 are in the process of transferring the manufacturing of these products to our facilities in California, which will require approvals from the UK Medicines and Healthcare products Regulatory Agency before we can relaunch the product candidates.

Business Segments

Our performance is assessed and resources are allocated based on the following two reportable segments: (1) finished pharmaceutical products and (2) API products. The finished pharmaceutical products segment currently manufactures, markets and distributes enoxaparin, naloxone, lidocaine, as well as various other critical and non-critical care drugs. The API segment currently manufactures and distributes 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.”

Table of Contents

Results of Operations

Year ended December 31, 2017 compared to year ended December 31, 2016

Net revenues

	Year Ended December 31, 2017	2016	Change Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 230,139	$ 240,221	$ (10,082)	(4) %
API	10,036	14,944	(4,908)	(33) %
Total net revenues	$ 240,175	$ 255,165	$ (14,990)	(6) %
Cost of revenues				
Finished pharmaceutical products	$ 133,336	$ 134,121	$ (785)	(1) %
API	16,044	16,855	(811)	(5) %
Total cost of revenues	$ 149,380	$ 150,976	$ (1,596)	(1) %
Gross profit	$ 90,795	$ 104,189	$ (13,394)	(13) %
as % of net revenues	38 %	41 %		

The decrease in net revenues of finished pharmaceutical products for 2017 was primarily due to the following changes:

	Year Ended December 31, 2017	2016	Change Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
Naloxone	$ 42,342	$ 47,532	$ (5,190)	(11) %
Phytonadione	37,946	33,315	4,631	14 %
Lidocaine	37,602	36,600	1,002	3 %
Enoxaparin	36,593	59,320	(22,727)	(38) %
Epinephrine	25,914	25,661	253	1 %
Other finished pharmaceutical products	49,742	37,793	11,949	32 %
Total finished pharmaceutical products net revenues	$ 230,139	$ 240,221	$ (10,082)	(4) %

The decrease in sales of enoxaparin was driven by lower unit volumes, which resulted in a decrease of approximately $13.1 million, as well as lower average selling prices, which resulted in a decrease of approximately $9.6 million. We expect that the average selling price and unit volumes of enoxaparin will continue to fluctuate in the near term as a result of competition.

Lower unit volumes of naloxone led to a decrease in sales of approximately $3.8 million, while lower average selling price caused a decrease in sales of approximately $1.4 million. We anticipate that sales of this product may fluctuate due to increased competition driven by future competitor launches.

Higher unit volumes of phytonadione led to an increase in sales of approximately $2.4 million, while higher average selling price caused an increase in sales of approximately $2.2 million. An increase in average selling prices of epinephrine caused an increase of approximately $10.4 million in net revenues, which was offset by the decrease in unit volumes which was primarily a result of the discontinuation of our epinephrine injection, USP vial product in the second quarter of 2017 in accordance with the FDA's request. Our epinephrine injection, USP vial product, was marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. During 2017, we recognized $17.8 million in net revenues for the sale of the discontinued vial product. The remainder of our epinephrine sales was from the pre-filled syringe, which remains on the market. Other finished pharmaceutical products increased in unit volumes due to a temporary competitor shortage.

Sales of RHI API decreased primarily because of lower shipments to MannKind in 2017.

Table of Contents

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 addition, most of our API sales are denominated in Euros, and the fluctuation in the value of the Euro versus the dollar has had, and will continue to have, an impact on API sales revenues in the near term. 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, 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 fees for 2018 of $0.9 million and for 2017 of $1.5 million in net revenues in our consolidated statement of operations for the year ended December 31, 2017 and 2016.

Cost of revenues

Cost of revenues decreased in dollar terms due to declines in units sold, primarily related to enoxaparin and RHI API declines. Gross margins declined due to lower selling prices for enoxaparin and naloxone. In addition, for 2017, a charge of $8.5 million was recorded to adjust certain inventory to their net realizable value, including $5.5 million for enoxaparin inventory due to a decrease in the forecasted average selling price. For 2016, a charge of $7.3 million was recorded to adjust certain inventory items to their net realizable value, including $3.1 for enoxaparin inventory items and $3.3 million for epinephrine injection, USP vial inventory items and related firm inventory purchase commitments.

Declining average selling prices and unit volume of enoxaparin and the discontinuance of our epinephrine injection, USP vial product will continue to put downward pressure on our gross margins. However, we believe that this trend will be offset by new product launches, including neostigmine methylsulfate, medroxyprogesterone acetate and sodium nitroprusside.

Selling, distribution, and marketing, and general and administrative

Change

	Year Ended December 31,			
	2017	2016	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 6,460	$ 5,466	$ 994	18 %
General and administrative	44,458	41,832	2,626	6 %

The increase in general and administrative expense was primarily due to an increase in legal expenses relating to our July 2017 patent trial (see Note 17 to the consolidated financial statements for more information).

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.

Table of Contents

Research and development

	Year Ended December 31, 2017	2016	Change Dollars	%	
	(in thousands)				
Salaries and personnel-related expenses	$ 15,973	$ 15,157	$ 816	5	%
Pre-launch inventory	2,002	1,096	906	83	%
Clinical trials	2,591	1,599	992	62	%
FDA fees	130	2,764	(2,634)	(95)	%
Testing, operating and lab supplies	13,571	12,310	1,261	10	%
Depreciation	4,956	4,736	220	5	%
Other expenses	4,192	3,537	655	19	%
Total research and development expenses	$ 43,415	$ 41,199	$ 2,216	5	%

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.

Testing, operating and lab supplies increased due to expenditures on materials for our pipeline products, particularly production of APIs for our pipeline at our ANP facility. FDA fees decreased in 2017 due to the NDA filing of our intranasal naloxone product candidate that was submitted in the second quarter of 2016. Pre-launch inventory increased due to pre-approval purchases of APIs for medroxyprogesterone acetate and sodium nitroprusside. Clinical trials expense increased due to spending on pilot trials for inhalation products.

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.

Gain on sale of intangible assets

	Year Ended December 31, 2017	2016	Change Dollars	%
	(in thousands)			

Gain on sale of intangible assets	$ (2,643)	$ —	$ (2,643)	N/A

In February 2017, we sold the ANDAs that we acquired in March 2016 and recognized a gain of $2.6 million (see Note 3 and Note 9 to the consolidated financial statements for more information).

Provision for income tax expense (benefit)

	Year Ended December 31, 2017	2016	Change Dollars	%
	(in thousands)			
Income tax expense (benefit)	$ (2,885)	$ 4,414	$ (7,299)	(165) %
Effective tax rate	(178) %	30 %		

The difference in income tax expense (benefit) in 2017 compared to 2016 was primarily due to changes in pre-tax income positions and excess share-based compensation benefits directly recorded as income tax benefit in 2017.

Table of Contents

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

Net revenues

	Year Ended December 31, 2016	2015	Change Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 240,221	$ 224,941	$ 15,280	7 %
API	14,944	26,578	(11,634)	(44) %
as % of 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	2015	Change Dollars	%
	(in thousands)			
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 a 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.

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.

Table of Contents

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.

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.

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.

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

	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.

Research and development

Year Ended December 31, 2016	Change