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, 2019

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 **(State or other jurisdiction of incorporation or organization)**	**33-0702205** **(I.R.S. Employer Identification No.)**
11570 6th Street **Rancho Cucamonga, CA** **(Address of principal executive offices)**	**91730** **(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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AMPH	The 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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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	☐	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 28, 2019 (the last business day of the registrant's most recently completed second fiscal quarter), based upon the closing price of Common Stock on such date as reported by Nasdaq Global Select Market, was approximately $638,120,912. 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 9, 2020, there were 46,238,303 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 2020 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

AMPHASTAR PHARMACEUTICALS, INC.
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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "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;
- 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;
- interruptions to our manufacturing and production as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks;
- the timing and likelihood of U.S. Food and Drug Administration, or 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;
- our expectations regarding the business expansion plans for our Chinese subsidiary, ANP;
- 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 active pharmaceutical ingredient, or 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;
- global, national and local economic and market conditions, specifically with respect to geopolitical uncertainty, and the outbreak of the coronavirus known as COVID-19;
- the impact of trade tariffs, export or import restrictions, or other trade barriers;
- the impact of Patient Protection and Affordable Care Act (as amended) and other legislative and regulatory healthcare reforms in the countries in which we operate including the potential for drug price controls;
- the impact of global and domestic tax reforms, including the Tax Cuts and Jobs Act of 2017, or the Tax Act;

- the timing for completion of the validation of the new construction at our ANP and Amphastar facilities; 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.

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. In November 2018, the FDA granted over-the-counter approval of our New Drug Application, or NDA, for our patented Primatene® Mist using a new hydrofluoroalkanes, or HFA, formulation.

We are currently developing a portfolio of 15 generic abbreviated new drug applications, or ANDAs, three biosimilar insulin product candidates and four proprietary product candidates, which are in various stages of development and target a variety of indications. We currently have seven ANDAs and one NDA on file with the FDA.

For the years ended December 31, 2019, 2018, and 2017, we recorded net revenues of $322.4 million, $294.7 million, and $240.2 million, respectively. We recorded net income of $48.9 million and $3.6 million for the years ended December 31, 2019 and 2017, respectively and recorded a net loss of $5.7 million for the year ended December 31, 2018.

Our largest products by net revenues currently include lidocaine jelly and sterile solution, phytonadione, enoxaparin sodium injection, naloxone hydrochloride injection, medroxyprogesterone acetate, and Primatene® Mist. We launched medroxyprogesterone acetate in the first quarter of 2018. In the fourth quarter of 2018, we launched our over-the-counter product Primatene® Mist. In July 2019, we began a national radio and television campaign for Primatene® Mist, which will continue throughout 2020.

Our multiple technological capabilities enable the development of technically challenging products with limited competition. These capabilities include characterizing complex molecules, analyzing and synthesizing 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.

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.

On May 20, 2019, we entered into a settlement agreement relating to the enoxaparin patent and antitrust litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc. Pursuant to the settlement agreement, the plaintiffs paid us $59.9 million on June 27, 2019. For more information regarding the enoxaparin patent and antitrust litigation, see Note 20 to the consolidated financial statements for more information regarding litigation matters.

Our Markets

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

- *Injectable market.* Based on an IQVIA National Sales Perspective Report, the U.S. generic injectable drug market in 2019 was over $11 billion. Our generic development portfolio is targeting opportunities in over $5 billion of this market. 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 an IQVIA National Sales Perspective Report, the U.S. inhalation drug market in 2019 was approximately $27.0 billion. Our generic development portfolio is targeting opportunities in over $9 billion of this market. 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 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.* 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.
- *Advanced technical capabilities and multiple delivery technologies.* We have developed multiple advanced technical capabilities that we incorporate into the development of our products and product candidates, including characterization of complex molecules, peptide and protein analysis and synthesis, immunogenicity studies, particle engineering and sustained-release technology. In addition, we apply these capabilities across our injectable, inhalation and intranasal 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 and development 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, acquisitions 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 including pharmaceutical formulation, process development, *in vivo* and *in vitro* studies, analytical chemistry, physical chemistry, drug delivery and clinical research. We believe that our scientific and technical expertise, coupled with our management team's business, legal, regulatory, and business development experience 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 product candidates, three biosimilar product candidates and four 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 four proprietary product candidates at various stages of development targeting a broad range of indications. We believe that proprietary products tend to face less competition than generic products due to market exclusivity, intellectual property protection and other barriers to entry. For these reasons, we believe that our proprietary products will provide us with the opportunity for higher margins and long-term revenue growth.

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

- *Target and integrate acquisitions of pharmaceutical companies, products and technologies.* We have a demonstrated ability to identify, acquire and integrate pharmaceutical companies, products and technologies to complement our internal product development capabilities. Companies we have acquired include (1) International Medication Systems, Limited or IMS, (2) Armstrong Pharmaceuticals, Inc. or Armstrong, (3) Nanjing Puyan Pharmaceutical Technology Co., Ltd. (which we renamed Amphastar Nanjing Pharmaceuticals Co., Ltd.), or ANP, (4) Nanjing Letop Medical Technology Co. Ltd. (which we renamed 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, as well as 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, in 2018, we received approval from the FDA for the manufacture of semi-purified heparin at our Chinese subsidiary, ANP. We plan to have ANP manufacture API for certain other products and product candidates.

Our Technical Capabilities

We develop, manufacture, market and sell generic and proprietary products that utilize injectable, inhalation and intranasal delivery systems. 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 and Intranasal.* We are focused on developing a range of generic and proprietary inhalation and intranasal 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. Additionally, we have extensive formulation and clinical experience in developing complex formulations that can be administered by intranasal delivery.

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, which allows for interchangeability with the reference drug product. Complex drugs typically have large molecules composed of a mixture of molecules that differ very slightly from one another. These slight

variances make such 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 that we have the technology to develop a variety of additional analytical tools that will enable us to characterize other complex molecules, including peptide and protein-based products.

- *Immunogenicity.* The ability of an antigen to elicit immune responses is called immunogenicity. Unwanted immunogenicity, which is strongly linked with peptide and 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 our characterization technology and immunogenicity studies, synthetic capabilities, 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 as well as demonstrate to the FDA sameness to the reference listed drugs.

- *Sustained-release.* We have developed technology aimed at improving drug delivery through sustained-release injectable products such as our medroxyprogesterone product, which is the generic version of Depo Provera®. The purpose of our sustained-release technology is to create products that require less dosing frequency, which we believe can lead to the diminishing of fluctuations of drug concentrations in a patient's blood stream that would otherwise require more frequent dosing. We plan to use our sustained-release technology to develop both generic and proprietary products.

Finished Pharmaceutical Products

Our Marketed Products

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

Enoxaparin

Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant, which is indicated for multiple indications, including the prevention and treatment of deep vein thrombosis. Enoxaparin is difficult to produce in part because the API is not easily obtained or manufactured. We manufacture the API for our enoxaparin product and perform all subsequent manufacturing of the finished product in-house.

Naloxone

We sell two versions of naloxone injections indicated for the emergency treatment of known or suspected opioid overdose.

Primatene® Mist

Primatene® Mist, an over-the-counter epinephrine inhalation product, is indicated 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.

In 2013, we filed an NDA for Primatene® Mist, which is delivered by a metered dose inhaler with a non-CFC propellant. In November 2018, the FDA granted over-the-counter approval of the NDA for Primatene® Mist. We began selling the new formulation of Primatene® Mist in the fourth quarter of 2018.

Other Marketed Products

Other finished pharmaceutical products that we currently market include the following:

- Cortrosyn® (cosyntropin for injection), a lyophilized powder that is indicated for use as a diagnostic agent in the screening of patients with adrenocortical insufficiency;
- Amphadase®, a bovine-sourced hyaluronidase injection that 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, a local anesthetic product used primarily for urological procedures;
- Lidocaine topical solution, a local anesthetic used for a variety of procedures;
- Phytonadione injection, an injection of Vitamin K1 that is used for newborn babies;
- Our portfolio of emergency syringe products, including critical care drugs such as atropine, calcium chloride, dextrose, epinephrine, lidocaine, and sodium bicarbonate, that are provided in pre-filled syringes and are designed for emergency use in hospital settings;
- Morphine injection in prefilled syringe, pain management product indicated for use with Patient Controlled Analgesia (PCA) pumps;
- Lorazepam injection, a sedative used prior to surgery and medical procedures;
- Procainamide, indicated for the treatment of documented ventricular arrhythmias;
- Neostigmine methylsulfate injection, 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
- Isoproterenol hydrochloride injection, indicated for multiple uses including mild or transient episodes of heart block that do not require electric shock or pacemaker therapy.

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, inhalable and intranasal 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 biosimilar product candidates and four 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 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 and synthesis.

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	✓	✓		✓	✓
Inhalation	✓		✓		

Our generic product candidates are at various stages of development, ranging from early formulation work to bioequivalence studies to having an ANDA on file with the FDA.

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, peptide and protein synthesis technology, complex formulation development, characterization analysis and immunogenicity studies, among others.

With respect to our proprietary pipeline strategy, we currently have four 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.

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 Complete Response Letter, or CRL, from the FDA, which identified 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 factor 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 and have sought an extension on our response to the CRL. However, there can be no guarantee that our response to the CRL will result in timely approval of intranasal naloxone or approval at all.

Other Proprietary Product Candidates

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

APIs

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.

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 $146.0 million, over five years from calendar years 2015 through 2019.

The MannKind agreement was amended several times between 2014 and 2019. In August 2019, we amended the Supply Agreement with MannKind whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional two years through 2026, which timeframe would have previously lapsed after calendar year 2024. As a result of this amendment, MannKind paid us an amendment fee of $2.75 million, which we recognized in net revenues in our consolidated statement of operations for the year ended December 31, 2019.

MannKind may request to purchase additional quantities of RHI API in excess of its annual minimum purchase commitments. 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 years ended December 31, 2019, 2018 and 2017, sales of RHI API to MannKind totaled $4.4 million, $8.1 million and $3.2 million, which fulfilled the 2019, 2018 and 2017 commitment of RHI API under the amended Supply Agreement, respectively.

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 addition to, and in consideration for the updated timeframe and other changes contained in the amendments to the Supply Agreement and Option Agreement, the amended Supply Agreement 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, 2019, we had over 446 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.

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. We had no significant backlog as of December 31, 2019. However, at the end of 2018, we experienced a backlog due to a slowdown in production linked to a new industry mandated serialization requirement, which we implemented in the fourth quarter. As a result, we ended 2018 with a backlog of approximately $5.0 million. We were able to resolve these production issues prior to year-end and believe we will be able to reduce the backlog in the near future. Historically, our backlog has not been 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 106 buildings at six locations in the United States, France and China, that comprise 2.0 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 this facility.

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 manufacture of inclusion bodies, which are our RHI API's starting material. As of December 31, 2019, we have spent $31.1 million and expect to complete this project by the end of 2020.

We believe that our current manufacturing capacity is adequate for the near term. We recently completed a project to increase production and modernize the facilities at our South El Monte, California plant. The project cost was $14.9 million. In February 2020, the FDA approved our supplemental ANDA to transfer production of Sodium Bicarbonate into this facility and we have begun manufacturing operations there.

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 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 that 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 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. In 2018, we received approval from the FDA for the manufacture of semi-purified heparin at ANP.

The U.S. Department of Agriculture, or USDA, the Animal and Plant Health Inspection Service, or APHIS, and the Veterinary Services regulates the importation of animals and animal-derived materials into the U.S. A USDA veterinary permit is required for importation of materials derived from animals or exposed to animal-source materials. Some of our raw materials sourced from foreign sources are subject to import regulations and permit requirements, including from the USDA. Recently, USDA enhanced its African swine fever, or ASF, surveillance efforts, including placing restrictions on the importation of pork products from affected countries, such as China, where the first cases of ASF were reported in August 2018. While ASF does not affect human health, it is a highly contagious and deadly disease to pig populations. Due to recent restrictions on importation of pig-derived products from ASF affected countries, in February 2020, we received a notice of non-renewal of our permit to import or transport heparin USP (or porcine heparin sodium powder) from China from one of our third-party heparin suppliers; accordingly, our import permit with respect to one of our third-party heparin suppliers has expired as of February 2020. We continue to work with APHIS on renewing our import permit for the importation of heparin USP from China with respect to one of our third-party heparin suppliers. We anticipate that our current supply of heparin USP in the United States is useable and sufficient for our manufacturing needs for the foreseeable future, and we are evaluating the use of heparin USP produced at our ANP facility. If we are unable to import raw materials, rely upon existing supplies of raw materials or manufacture raw materials in sufficient amounts for our manufacturing needs, we may be required to find alternative suppliers or sources of such materials, which would require prior FDA approval for such alternative suppliers or sources of such materials, which would disrupt or delay the manufacturing of our products.

We plan to have ANP manufacture APIs and starting materials for APIs for certain other products and product candidates, including isoproterenol and hyaluronidase, which ANP currently manufactures for Amphastar.

Sales and Marketing

Our products are primarily marketed and sold to institutions such as hospitals, long-term care facilities, alternate care sites, clinics, and doctors' offices. Additionally, we also sell to retail pharmacies. Most institutional customers 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,		
	2019	2018	2017
McKesson Corporation	25 %	27 %	27 %
AmerisourceBergen Corporation	24 %	27 %	28 %
Cardinal Health, Inc.	22 %	21 %	23 %

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 facilities. One or more of our proprietary product candidates may require deployment of a sales force either directly or through a strategic partner.

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, Nexus Pharmaceuticals, Apotex Corp, Amneal Biosciences, American Regent Inc., Hikma Pharmaceuticals USA, Inc., Par Pharmaceuticals, Cipla USA Inc., Meitheal Pharmaceuticals, Dr. Reddy's Laboratories, Inc., and Teva Pharmaceutical Industries Ltd. Competition in the generic pharmaceutical industry has increased as producers of branded products have entered the business by creating generic drug subsidiaries, purchasing generic drug companies, or licensing their products to generic manufacturers prior to patent expiration and/or as their patents expire. Therefore, our

competitors also include the innovator companies of our generic drug products. For example, enoxaparin is currently marketed by Sanofi S.A., or Sanofi, under the brand name Lovenox®. Sanofi also markets its authorized generic enoxaparin product through its subsidiary, Winthrop, Fresenius Kabi USA, Apotex Corp., Meithael Pharmaceuticals, Inc., 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.

Government Regulation

In the United States

General

Our operations and many of the products manufactured or sold by the company are subject to extensive regulation by a number of government agencies, both within and outside the United States. In the United States, the federal agencies that regulate the company's facilities, operations, employees, products (including their manufacture, sale, import and export) and services include: the U.S. Food and Drug Administration, the Drug Enforcement Agency, the Environmental Protection Agency, the Occupational Health & Safety Administration, the Department of Agriculture, the Department of Labor, the Department of Defense, Customs and Border Protection, the Department of Commerce, the Department of Treasury and others. International government agencies also regulate public health, product registration, manufacturing, environmental conditions, exports, imports, and other aspects of the company's global operations and products.

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.

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 to distribute these bioequivalent drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the API, drug product formulation, specifications, stability, analytical methods, manufacturing process validation data, quality control procedures and bioequivalence. Rather than demonstrating safety and effectiveness, an ANDA applicant must demonstrate that its product is bioequivalent to an approved reference drug. In certain situations, an applicant may submit an ANDA for a product with a strength or dosage form that differs from a reference drug based upon FDA approval of an ANDA Suitability Petition. The FDA will approve an ANDA Suitability Petition if it finds that the product does not raise questions of safety and efficacy requiring new clinical data. ANDAs generally cannot be submitted for products that are not bioequivalent to the referenced drug or that are labeled for a use that is not approved for the reference drug. Applicants seeking to market such products can submit an NDA under Section 505(b)(2) of the FFDCA with supportive data from clinical trials.

The Generic Drug User Fee Act, or GDUFA, was enacted by Congress in 2012 and was reauthorized as GDUFA II in 2017. GDUFA is designed to provide funding to the FDA to expedite timelines for the FDA's review of ANDA applications. GDUFA funding is intended to increase the ability of the FDA to perform critical program functions and to reduce costs. Under the GDUFA, the FDA has specific goals for reviewing ANDA applications. For example, as part of GDUFA II, the goal of the FDA is to complete the review of 90% of original ANDA applications within 10 months from filing of the ANDA. Under the previous GDUFA authorization, the average time for sponsors to obtain FDA approval of ANDAs was 32-34 months post-filing.

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 the 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 the 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, 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.

In 2017, the FDA Reauthorization Act of 2017, or FDARA, was passed, which created a new pathway to allow the FDA to expedite the development and review of an ANDA for a drug that is designated as a Competitive Generic Therapy, or CGT. To qualify for the designation, the FDA must confirm that the ANDA is for a generic drug in which there is inadequate generic competition. Inadequate generic competition is defined to mean, that there is not more than one approved drug in the active section of the Orange Book.

Once assigned CGT designation by the FDA, the FDA may take various actions to help expedite the development and review process. This includes priority granting and expediting review during Product Development and Pre-Submission Meetings, Mid-Review Cycle Meetings and provide for a more coordinated review of ANDA's with CGT.

As part of the FDARA, a new type of 180-day marketing exclusivity period for ANDA applicants with CGT designation has been created. Broadly, this exclusivity applies when the ANDA applicant is considered as the first approved applicant, and there is no other exclusivity period eligibility.

Three of our ANDAs on file and many of the products that we are developing qualify for CGT. Having a generic product designated as CGT provides for certain actions which the FDA may take in order to expedite the development and review of an ANDA.

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 Prescription Drug User Fee Act, or PDUFA, was enacted by Congress in 1992. It authorizes the FDA to collect fees from companies that produce certain new human drug and biological products. The fees collected are designed to play an important role in expediting the new drug approval process. Like GDUFA, PDUFA must be reauthorized every 5 years. It is currently authorized as PDUFA VI through September of 2022. As part of the PDUFA, the FDA has specific goals for reviewing NDA/BLA applications. For example, as part of PDUFA VI, the goal of the FDA is to complete the review of 90% of original NDAs that are not new molecular entities within 10 months of the date of filing the NDA.

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 that must satisfy the FDA and become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's cGMP regulations; and

- submission to and approval by the FDA of an NDA.

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

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

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

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

The Section 505(b)(2) NDA

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

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

The Biosimilar Application Approval Process

The BPCIA, passed by Congress in 2010, amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to biologics that have been approved in BLAs under the PHSA notwithstanding minor differences in clinically inactive components. A biosimilar application must contain information demonstrating (1) biosimilarity to the reference product, (2) sameness of strength, dosage form, route of administration and mechanism(s) of action with the reference product (where known), (3) approval of the reference product for the indication(s) proposed for the biosimilar product and (4) appropriate manufacturing facilities. FDA will approve the application based on a finding of biosimilarity or interchangeability with the reference product. A finding of biosimilarity must be based on (1) a demonstration that the products are "highly similar" notwithstanding minor differences in clinically inactive components, (2) animal studies, including an assessment of toxicity, and (3) a clinical study or studies (including an assessment of immunogenicity and pharmacokinetics or pharmacodynamics) sufficient to show the safety, purity and potency of the proposed product for one or more "appropriate" conditions of use for which licensure is sought and for which the reference product is

licensed, unless FDA waives a specific requirement. The definition of "biosimilar" requires that there be no clinically meaningful differences between the biosimilar and reference product with regard to safety, purity and potency.

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

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;

- 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 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.

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

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

From February 5, 2019 through February 12, 2019, 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 March 2017, 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 March 6, 2019. 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 February 25 through March 1, 2019, 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 2017 inspection as well as review of data to support our pending applications. The inspection resulted in multiple observations on Form 483. We responded to those observations on March 22, 2019. 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 July 23 through July 25, 2019, our Amphastar facility in Rancho Cucamonga, California was subject to a routine, post-marketing adverse drug experience reporting inspection, or PADE, by the FDA. The inspection included a review of our processes for collecting, reviewing, investigating and reporting post-marketing adverse drug experiences reported through various sources. The inspection resulted in no Form 483 findings. No further actions will be necessary.

From August 27 through September 04, 2019, one of our California clinical trial sites was subject to a pre-approval biomonitoring inspection by the FDA. The inspection included a review of the clinical trial data to support one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

From October 7 through October 11, 2019, our Chinese subsidiary ANP, was subject to a cGMP inspection by the FDA. The inspection included a review of compliance with FDA regulations relating to Good Manufacturing Practices. The inspection resulted in one observation on Form 483. We responded to that observation. We believe that our response to the observation will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From October 24 to November 5, 2019, our IMS facility in South El Monte, California was subject to a preapproval inspection by the FDA. The inspection included a review of data to support our pending applications. The inspection resulted in multiple observations on Form 483. We responded to the initial observations within the required timeframe, however, there was an additional request for information. We plan to submit our response in March 2020, and we believe it will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From November 18 to November 22, 2019, our Amphastar facility in Rancho Cucamonga, California was subject to a pre-approval biomonitoring inspection by the FDA. The inspection included review of the analytical laboratory used in support of one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

From November 18 to November 21, 2019, our IMS facility in South El Monte, California and our Amphastar facility in Rancho Cucamonga, California were subject to a pre-approval biomonitoring inspection by the FDA. The inspection included review of the analytical laboratory and an in vitro study used in support of one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

On December 18, 2019, our IMS facility in South El Monte, California was subject to an inspection by the FDA. The inspection was part of an overall investigation involving makers of opioid products. The inspection resulted in no Form 483 findings. No further actions will be necessary.

Foreign Regulatory Requirements

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

Prescription Drug Wrap-Up

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

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

The FDA has asserted that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally unless they fall within two "grandfather" exceptions to the new drug definition. The first is a provision in the new drug definition exempting drugs that were on the market prior to the passage of the FFDCA and that contain the same representations concerning the conditions of use as they did prior to passage of the FFDCA. The 1962 Amendments also exempt drugs that were not new drugs prior to the passage of the 1962 Amendments and that have the same composition and labeling as they had prior to the passage of the 1962 Amendments. The FDA and the courts have interpreted these two exceptions very narrowly. Therefore, the FDA could commence enforcement action at any time regarding any or all of our unapproved prescription products. The FDA 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 year ended December 31, 2017, we recognized $17.8 million in net revenues for the sale of this product. The FDA granted approval of our ANDAs for sodium bicarbonate injection and calcium chloride injection in September 2017 and May 2018, respectively.

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.

USDA Animal and Plant Health Inspection Service

USDA-APHIS regulates the importation of certain animals and animal-derived materials into the U.S. In particular, a USDA veterinary permit is required for importation of materials derived from animals or exposed to animal-source materials. Recently, USDA enhanced its ASF surveillance efforts, including restrictions on importation of pig-derived products from affected countries and testing for the ASF virus. While ASF does not affect human health, it is a highly contagious and deadly disease to local pig populations. ASF is currently widespread and endemic in various parts of Africa and Sardinia. In recent years, ASF has been reported in parts of the European Union and in China, where the first cases of ASF were reported in August 2018. Complying with additional requirements, such as additional analytical data and documentation of processing flow, may be required for obtaining an import permit for certain materials from affected countries. Changes made to suppliers or sources of raw materials for drug products will require prior FDA approval, which would disrupt or delay the manufacturing of our products.

Fraud and Abuse Laws

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

Federal False Claims Act

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

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $10,957 and $21,916 for each separate instance of a false claim, subject to adjustment for inflation. 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 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.

With respect to our existing generic products and generic product candidates, 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 2036. We also own several trademarks registered with the USPTO.

We own a U.S. patent covering the HFA version of Primatene® Mist: U.S. Patent Number 8,367,734, 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, our enoxaparin product 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. 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.

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, 2019, we had 2,027 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 that 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. Additionally, copies of materials filed by us with the SEC may be accessed at the SEC's website at www.sec.gov.

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

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes thereto. Our future operating results may vary substantially from anticipated results due to a number of risks and uncertainties, many of which are beyond our control. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. The following discussion highlights some of these risks and uncertainties and the possible impact of these risks on future results of operations. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the market value of our common stock could decline substantially and you could lose part or all of your investment.

Risks Relating to Our Business and Industry

Our 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, and whether our products are accepted by patients and physicians and are reimbursed by payers. Commercialization requires that we successfully and cost-effectively develop, test and manufacture or otherwise acquire both generic and proprietary products. All of our products must receive regulatory approval and meet (and continue to comply with) regulatory and safety standards. If health or safety concerns arise with respect to a product, we may be forced to withdraw it from the market. For example, as a result of environmental concerns over the use of chlorofluorocarbons, or CFCs, the FDA, issued a final rule on January 16, 2009, that required the phase-out of the CFC formulation of our Primatene® Mist product by December 31, 2011. As a result, in order to resume selling Primatene® Mist we had to develop a formulation of the product that uses hydrofluoroalkane, or HFA, as the propellant, and obtain FDA approval for the modified product, which took a significant amount of time and was not re-launched until December 2018. There can be no guarantee that our investment in research and development activities will result in FDA approval or produce commercially viable new products.

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 the FDA's requirement that we perform immunogenicity studies and the receipt of an FDA warning letter and FDA Import Alert by the supplier of the starting material for our enoxaparin product. Following FDA approval, we became involved in litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc., which further delayed the commercial launch of our enoxaparin product until January 2012. Delays in any part of the process, or our inability to obtain regulatory approval of our products, could adversely affect our operating results by restricting or delaying our introduction of new products, which could cause the market value of our products to decline. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially and adversely affected, and the market value of our common stock could decline.

Our ability to introduce new generic products also depends upon our success in challenging patent rights held by third

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

Our lidocaine, phytonadione, and enoxaparin products collectively represent a significant portion of our net revenues. If the sales volume or pricing of our lidocaine, phytonadione, and enoxaparin products continues to decline, 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 lidocaine products represented 14%, 15%, and 16% of our total net revenues for the years ended December 31, 2019, 2018, and 2017, respectively. Sales from our phytonadione product represented 14%, 14%, and 16% of our total net revenues for the years ended December 31, 2019, 2018, and 2017, respectively, and sales of our enoxaparin product represented 13%, 18%, and 15% of our total net revenues for the years ended December 31, 2019, 2018, and 2017, 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, or if the sales volume or pricing of lidocaine and phytonadione 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, our enoxaparin product experienced a decline in sales from $53.4 million in 2018 to $42.7 million in 2019 as a result of declining per unit prices as well as lower market share 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 lidocaine, phytonadione, and enoxaparin 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.

We incurred losses for fiscal 2018 and we may operate at a loss in future years while continuing to invest in developing new products.

We recorded a net loss of $5.7 million for the year ended December 31, 2018. Although we achieved net income in the years ended December 31, 2019 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 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 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, in 2009, we purchased 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. Subsequently, we received FDA approval to make heparin USP from crude heparin using processes at our ANP and IMS facilities. In 2013, our single source supplier of epinephrine API for our Primatene® Mist product 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 and 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.

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 manufacturing of insulin API for MannKind, and a significant portion of our manufacturing capacity in Rancho Cucamonga is utilized for the manufacture of enoxaparin. In November 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. Additionally, in December 2018, we again amended our supply agreement with MannKind to modify and extend the annual minimum purchase commitments under the Supply Agreement and the Option Agreement to cover calendar years 2019 through 2024. In August 2019, we amended the Supply Agreement with

MannKind to modify and extend the annual minimum purchase commitment under the Supply Agreement for an additional two years through 2026. 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.

Additionally, we are in the process of building significant capacity to make finished products at our ANP facility. This capacity is intended to be used to supply finished pharmaceutical products to China and other markets outside of the US. However, there is no guarantee that we will sell enough finished pharmaceutical products to take advantage of this new manufacturing capacity.

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, Nexus Pharmaceuticals, Apotex Corp., Amneal Biosciences, American Regent, Inc., Hikma Pharmaceuticals USA, Par Pharmaceuticals, Cipla USA Inc., Meitheal Pharmaceuticals, Dr, Reddy's Laboratories, Inc. and Teva Pharmaceutical Industries Ltd. Competition in the generic pharmaceutical industry has increased as producers of branded products have entered the business by creating generic drug subsidiaries, purchasing generic drug companies, or licensing their products to generic manufacturers prior to patent expiration and/or as their patents expire.

We face similar competition with respect to our over-the-counter product. Our product competes with other products that are owned and marketed by companies with much greater financial resources to reach consumers and market their products to influence end-customer buying decisions. There can be no assurance that we will be able to profitably market our over-the-counter product and money spent on such marketing efforts may reduce our ability to focus on and develop our pharmaceutical products.

Our business operates in the pharmaceutical industry, which is an industry characterized by intense competition. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products and/or processes competitive with, or superior to, our own. For example, a competitor has received FDA approval for their intranasal naloxone product in the markets for which we are currently seeking approval. We are concentrating the majority of our efforts and resources on developing product candidates utilizing our proprietary technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, labeling claims approved by the FDA for our products compared to claims approved for competitive products and the relative timing and sequence for commercial launch of new products by other companies that compete with our new products. If alternative technologies or other therapeutic approaches are adopted prior to our new product approvals, then the market for our new products may be substantially decreased, thus reducing our ability to generate future profits.

This intensely competitive environment requires an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of our products to healthcare professionals in private practice, group practices and managed care organizations. Our competitors vary depending upon product categories and, within each product category, upon dosage strengths and upon drug-delivery systems. Based on total assets, annual revenues and market capitalization, we are smaller than many of our national and international competitors with respect to both our generic and proprietary pharmaceutical products and product candidates. Many of our competitors have been in business for a longer period of time than us, have a greater number of products on the market and have greater financial and other resources than we do. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large

entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with large entities for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. Smaller companies may also prove to be significant 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, Apotex Corp. and Teva Pharmaceuticals Industries Ltd. also either market or plan to market a generic version of enoxaparin. Other companies may have received FDA approval of enoxaparin but have not launched the product, while other companies have filed ANDAs for enoxaparin with the FDA. 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 pricing pressure on many of our other products, including medroxyprogesterone, 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.

In addition, the goals established under the Generic Drug User Fee Act, and increased funding of the FDA's Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for some of our products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. While these FDA improvements are expected to benefit our generic product pipeline, they will also benefit competitors that seek to launch products in established generic markets where we currently offer products.

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

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

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

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

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

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

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

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

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

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

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

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

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

A significant proportion of our sales are made to relatively few U.S. wholesalers and group purchasing organizations.

These customers are continuing to undergo significant consolidation. Sales to three of these customers for the years ended December 31, 2019, 2018, and 2017, respectively, accounted for approximately 71%, 76%, and 78% 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.

At the same time, the traditional model for distribution of pharmaceutical products is also undergoing disruption as a result of the entry or potential entry of new competitors and significant mergers among key industry participants. For example, Amazon.com has made initial moves to develop a pharmaceutical distribution business. Also, the consolidation resulting from the merger between CVS Health and Aetna, if completed, is expected to create a vertically integrated organization with increased control over the physician and pharmacy networks and, ultimately, over which medicines are sold to patients. In addition, several major hospital systems in the United States announced a plan to form a nonprofit company that will provide U.S. hospitals with a number of generic drugs. In January 2018, Amazon Inc., Berkshire Hathaway Inc. and JPMorgan Chase & Co., announced that they plan to join forces by forming an independent health care company for their combined one million U.S. employees. This initiative is expected to further increase competition and enhance price erosion. These changes to the traditional supply chain could lead to our customers having increased negotiation leverage and to additional pricing pressure and price erosion.

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, and our Chief Operating Officer and Chief Scientist, Mary Z. Luo. 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, and 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, impact of outbreaks of health epidemics, such as the COVID-19 coronavirus outbreak, or changes in social, political, trade, health, economic, environmental, or climate-related 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 enoxaparin as well as the APIs for isoproterenol and nitroprusside at our manufacturing facility in China, and we plan to use this facility to manufacture several of the APIs for products in our pipeline. Additionally, we intend to continue to invest in the expansion of this manufacturing facility. Our manufacturing facility and operations in China involve significant risks, including:

- disruptions in the construction of the manufacturing facility;
- interruptions to our operations in China or the inability of our manufacturing facility to produce adequate quantities of raw materials or APIs to meet our needs as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, including the recent outbreaks that impact animal-derived products, such as the importation of pig-derived crude heparin from countries impacted by the African swine flu, and outbreak of the coronavirus known as COVID-19, which has resulted in and may in the future result in, business closures, transportation restrictions, import and export complications, and otherwise cause shortages in the supply of raw materials or cause disruptions in our manufacturing capability;
- product supply disruptions and increased costs as a result of heightened exposure to changes in the policies of the Chinese government, political unrest or unstable economic conditions in China;
- the imposition of tariffs or other trade barriers as a result of changes in social, political, and economic conditions or in laws, regulations, and policies governing foreign trade, including the tariffs previously implemented and additional tariffs that have been proposed by the U.S. government on various imports from China and by the Chinese government on certain U.S. goods, the scope and duration of which, if implemented, remain uncertain;
- the nationalization or other expropriation of private enterprises or intellectual property by the Chinese government, which could result in the total loss of our investment in China; and
- interruptions to our manufacturing or business operations resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics such as coronavirus, or outbreaks in livestock or animals that impact or restrict importation, use, or distribution of animal-derived products.

Any of these matters could materially and adversely affect our business and results of operations. These interruptions or failures could impair our ability to operate our business, impede the commercialization of our product candidates or delay the introduction of new products, impact our product quality, or impair our competitive position.

We are actively monitoring and assessing the potential impact of the recent COVID-19 coronavirus outbreak that began in China in December 2019. This includes evaluating the impact on our employees, suppliers, and logistics providers as well as evaluating governmental actions being taken to curtail the spread of the virus. The Chinese government has also implemented work restrictions that prohibited many employees from going to work. At this time, it is unclear if the Chinese government will further extend any of the current restrictions or if further restrictions will be put into place by the government. In addition, many countries have placed significant bans on travel to and from China, with many countries and airlines suspending flights to and from mainland China. Any material adverse effect on our employees, suppliers, and logistics providers could have a material adverse effect on our manufacturing operations in China or the supply of raw materials or APIs originating from China.

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 is 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;
- difficulty hiring and retaining appropriate personnel due to intense competition for such resources and resulting wage inflation in the cities where our operations are located;
- different labor regulations, especially in the European Union, where labor laws are generally more advantageous to employees as compared to the United States, including deemed hourly wage and overtime regulations in these locations;
- the uncertainty of protection for intellectual property rights in some countries and resulting exposure to misappropriation of intellectual property or information that is proprietary to us, our customers and other third parties;
- 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;
- exposure to liabilities under both U.S. and foreign laws, including export and antitrust regulations, anti-corruption and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, and similar applicable laws and regulations in other jurisdictions, and any trade regulations ensuring fair trade practices;
- uneven electricity supply that can negatively impact manufacturing;
- heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;
- fluctuations in currency exchange rates and regulatory compliance;
- delays, inefficiencies, and other challenges inherent to efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits, and compliance programs;
- potentially adverse tax consequences, including multiple and possibly overlapping tax structures; and

- interruptions to our manufacturing or business operations resulting from trade restrictions, political and economic instability, political unrest, war, terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics such as the coronavirus and African swine flu outbreaks.

Furthermore, weak domestic or global economic conditions or fear or anticipation of such conditions could adversely affect our business, financial condition, results of operations and prospects in a number of ways, including lower prices for our products, reduced sales and lower or no growth. For example, the global macroeconomic environment could be negatively affected by, among other things, instability in global economic markets resulting from increased U.S. trade tariffs and trade disputes between the U.S. and other countries, instability in the global credit markets, the impact and uncertainty regarding global central bank monetary policy, rising interest rates and increased inflation, the instability in the geopolitical environment as a result of the United Kingdom's "Brexit" decision to withdraw from the European Union, economic challenges in China and ongoing U.S. and foreign governmental debt concerns. Such challenges have caused, and are likely to continue to cause, uncertainty and instability in local economies and in global financial markets, particularly if any future sovereign debt defaults or significant bank failures or defaults occur. Market uncertainty and instability in Europe or Asia could intensify or spread further, particularly if ongoing stabilization efforts prove insufficient. Continuing or worsening economic instability could adversely affect sales of our products. Continued turmoil in the geopolitical environment in many parts of the world may also affect the overall demand for our products. Although we do not believe that our business, financial condition, results of operations and prospects have been significantly adversely affected by economic and political uncertainty in Europe, Asia or other countries to date, deterioration of such conditions may harm our business, financial condition, results of operations and prospects in the future. A prolonged period of economic uncertainty or a downturn may also significantly affect financing markets, the availability of capital and the terms and conditions of financing arrangements, including the overall cost of financing. Circumstances may arise in which we need, or desire, to raise additional capital, and such capital may not be available on commercially reasonable terms, or at all.

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, results of operations and financial condition.

Adverse changes to import restrictions relating to certain animal-derived products or raw materials we use from affected countries could disrupt our supply chain and result in delays in the manufacturing of our products.

Some of our raw materials, such as certain animal-derived materials, sourced from foreign sources are subject to import regulations and permit requirements, including from the USDA. The APHIS within the USDA has regulatory oversight over certain animals and animal-derived products that could pose a risk to domestic agriculture. Recently, USDA has increased its African swine flu surveillance efforts, including additional testing and enhanced restrictions on importation of certain porcine products from affected countries, like China. In February 2020, we received a notice of non-renewal of our permit to import or transport crude heparin USP from one of our third-party heparin supplies in China due to the recent outbreak of the African swine flu in China, requiring additional information on the processing flow providing all treatment parameters and times for the porcine heparin material. Accordingly, our import permit has expired as of February 2020, but we continue to work with APHIS on renewing our import permit for the importation of heparin USP from China. We anticipate that our current supply of heparin USP in the United States is useable and sufficient for our manufacturing needs for the foreseeable future, and we are investigating the use of heparin USP produced at ANP. If we are unable to import raw materials, rely upon existing supplies of raw materials or manufacture raw materials in sufficient amounts for our manufacturing needs, we may be required to find alternative suppliers or sources of such materials, which could disrupt or delay the manufacturing of our products. The success of our business operations and sales with respect to our heparin products will also depend on our continued efforts to maintain the proper product quality and safety profile of the crude heparin obtained either from China or an alternative source.

Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers may materially harm our business.

We are continuing to expand our international operations as part of our growth strategy. There is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, government regulations and tariffs. The current U.S. presidential administration has called for substantial changes to U.S. foreign trade policy with respect to China and other countries, including the

possibility of imposing greater restrictions on international trade and significant increases in tariffs on goods imported into the United States. In September 2018, the U.S. Trade Representative (the "USTR") enacted a tariff on the import of other Chinese products, with a combined import value of approximately $200 billion. The tariff became effective on September 24, 2018, with an initial rate of 10%, which was increased to 25% on May 10, 2019. Additionally, the Trump Administration continues to signal that it may alter trade agreements and terms between China and the United States, including limiting trade with China. Tariffs on imports of APIs and starting materials used in our products, or retaliatory trade measures taken by China or other countries, including restricted access to APIs or starting materials used in our products, causing us to raise prices or make changes to our products, could materially harm our business, financial condition and results of operations. Further, the continued threats of tariffs, trade restrictions, and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales. Although the United States and China signed a phase one trade deal on January 15, 2020, given the relatively fluid regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, a trade war, further governmental action related to tariffs or international trade policies, or additional tax or other regulatory changes in the future could occur and could directly and adversely impact our financial results and results of operations.

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 of 1977, as amended and similar applicable laws and regulations in other jurisdictions 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 operations 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 acts committed by our affiliates, employees or agents which may violate these laws and regulations. Violations of 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 economic reforms and to return to a more centrally planned economy or regional or local variations in the implementation of economic policies, could have a significant effect on economic conditions in China or particular

regions thereof and could require us to divest ourselves of any interest we then hold in Chinese properties or entities, including our Chinese operating subsidiary, 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 investments 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.

Our financial performance is impacted by the financial performance of our Chinese operating subsidiary, ANP.

Because we consolidate ANP's financial results in our results of operations, our financial performance is impacted by the financial performance of ANP. ANP's financial performance may be affected by a number of factors, including, but not limited to:

- ANP's ability to execute on its expansion plans;
- the commercial success of ANP's APIs, starting materials and finished pharmaceutical products;
- results of clinical trials of our product candidates or those of ANP's customers;
- pricing actions by competitors;
- the timing of orders or any cancellation of orders from ANP's customers;
- manufacturing or supply interruptions;
- actions taken by current and potential business partners;
- actions by regulatory bodies, such as the FDA or the CFDA;
- changes or developments in laws or regulations;
- disputes or other developments relating to patents or other proprietary rights;
- litigation or investigations involving ANP, our industry, or both; and
- ANP's ability to control costs, including its operating expenses.

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

On January 31, 2020, the United Kingdom, or UK, left the European Union, or EU, (commonly referred to as the "Brexit"). Brexit creates an uncertain political and economic environment in the UK and potentially across other EU member states for the foreseeable future, including during the transitional period while the UK government continues to negotiate the terms of the UK's future relationship with the EU, and such uncertainties could impair or limit our ability to transact business in the member EU states. In the long term, the UK may develop its own legislation that diverges

from that in the EU. Since the regulatory framework for pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit will materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK.

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 British pound sterling currency or other currencies, including the euros. 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 operational implications and disruptions to our commercial and business operations in the UK, including our relationships with potential customers, distribution partners, suppliers and employees.

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 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, IMS, Armstrong, and AFP, products, but our insurance coverage is subject to deductibles and 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, some acquisitions may require regulatory approvals before products may be sold by us, which may not be obtained on a timely basis, or at all. For example, in August 2016, our UK subsidiary acquired IMS UK. We are in the process of transferring the manufacturing of the purchased products to our facility in California. The transfer will require approval of the UK Medicines and Healthcare products Regulatory Agency and other related agencies before the products can be sold by us. It is possible that the integration of some acquired technologies, information systems and data could increase our risk of experiencing a data security or privacy incident. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, customer or employee base, including diversion of management's attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies that we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. If we are unable to successfully integrate technologies, products, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences.

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

We intend to conduct an extensive due diligence investigation for any business we consider acquiring. Intensive due diligence is often time consuming and expensive due to the operations, finance and legal professionals who may be involved in the due diligence process. Even if we conduct extensive due diligence on a target business which we acquire, we may not identify all material issues that are present inside a particular target business. If our due diligence fails to discover or identify material issues relating to a target business, industry or the environment in which the target business operates, we may be forced to later write-down or write-off assets, restructure the target business' 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 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 Act was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case to the District Court to determine whether the remaining provisions of the ACA are invalid. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. In addition, the Trump administration has also proposed the establishment of an “international pricing index”, which may

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

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

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of prescription drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Additionally, on January 31, 2019, HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufactures to Medicare Part D plan sponsors, Medicaid managed care organizations, and those entities' pharmacy benefit managers, the purpose of which is to further reduce the cost of drug

products to consumers. On October 9, 2019, HHS, OIG and CMS issued two proposed rules that set forth modifications to the Federal Anti-Kickback Statute, Civil Monetary Penalties Law and Physician Self-Referral Law (or the Stark Law) regulations to promote value-based and coordinated care arrangements. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

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), or ASC 606, as subsequently amended, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. ASC 606 became effective for us beginning the first quarter of fiscal 2018, and we have adopted it using the modified retrospective transition method. 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.

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, 2019, the value of our goodwill and intangible assets net of accumulated amortization was $41.2 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 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 affects 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 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.

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. We have in the past, identified a material weakness in our internal control over financial reporting, which was remediated; however, our remediation efforts may not enable us to avoid a material weakness in the future. Ensuring that we have adequate internal financial and accounting controls and procedures in place to help produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. We ceased to be an emerging growth company on December 31, 2019, and no longer take advantage of the exemptions in the Jumpstart Our Business Startups Act, or JOBS Act. Accordingly, our independent registered public accounting firm is required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. 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. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation by our independent registered public accounting firm.

In the event that our Chief Executive Officer, Chief Financial Officer, or independent registered public accounting firm determines 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, breaches of the covenants under our credit facilities, 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.

On December 22, 2017, the U.S. government 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 interest, and a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred. Our financial statements for the current year now reflect the effects of the Tax Act based on current guidance, including remeasurement of our deferred tax assets and liabilities, as well as the effects of the reduced rate of the U.S. corporate income tax and certain other provisions of the Tax Act on our effective tax rate and operating results. The U.S. Treasury Department, the IRS, and state tax authorities will continue to interpret or issue guidance on

how provisions of the Tax Act will be applied or otherwise administered. As future guidance is issued, we may make adjustments to amounts that we have previously recorded that may materially impact our financial statements in the period in which the adjustments are made.

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. 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 expenses, 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 breach or failure.

We, our collaborators, third-party providers, distributors, customers and other contractors utilize information technology systems and networks to transmit, store and otherwise process electronic data in connection with our business activities. This includes our clinical data and business proprietary information, Electronic Data Interchange, or EDI, on purchase orders, invoices, chargebacks, etc. We, and others on our behalf, also collect and process certain personal data, including about our personnel, business partners, website visitors and others, which may be subject to applicable data protection laws and regulations. We, and others on our behalf, rely on complex information technology systems, including Internet-based systems, to transmit, store and otherwise process such data in support of our supply chain processes, operations, and communications. Despite our implementation of security measures to protect the confidentiality, integrity, and availability of the systems and data within our control from various threats (e.g., cyber-attack, insider threat, accidental disclosure, intellectual property theft and economic espionage, natural disaster, war, terrorism, telecommunications and electrical outage), risks remain.

Potential legal (regulatory or contractual), financial, operational, and reputational harm may arise from the accidental or unlawful destruction, damage, loss, unavailability, alteration, impairment, misuse, unauthorized disclosure of, or unauthorized access to (i) our data, which is transmitted, stored or otherwise processed by us or by collaborators, third-party providers, distributors and other contractors on our behalf (a “data security incident”); and (ii) the systems upon which we rely for our operations (an “other event”). For example:

- The accidental or unlawful loss, unavailability or alteration 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 as well as significantly increase our costs to recover or reproduce the data.

- The size and complexity of our systems make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes, which may result in the loss of key information or the impairment of production and other supply chain processes, adversely affecting our business.

- Any data security incident or other event, either on its own or as a pattern, may require costly response and remediation efforts, trigger litigation or adverse regulatory action arising from or related to such an incident or event, and result in significant additional expense to implement further data protection measures. Integrating the systems and data of any acquired entity may in some cases further increase these risks due to unforeseen threats and vulnerabilities.

- Similarly, a data security incident or other event experienced by our collaborators, third-party providers, distributors and other contractors may hinder our product development, supply chain, other business operations, or our regulatory and contractual obligations to others and could also give rise to litigation or adverse regulatory action.

There can be no assurance that we will be successful in preventing data security incidents or other events nor that we will be successful in mitigating their effects, despite the implementation of security measures for systems and data within our control. Similarly, there can be no assurance that our collaborators, third-party providers, distributors and other contractors will be successful in protecting our data on their systems or in protecting other systems upon which we may rely. Any such data security incident or other event could have a material adverse effect on our business and prospects.

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 require regulatory approval 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 require the submission of drug applications to the FDA. All of our products are subject to compliance with the FFDCA and/or the Public Health Service Act, or PHSA, and with the FDA's implementing regulations. Failure to adhere to applicable statutory or regulatory requirements by us or our business partners would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive as well.

We may encounter delays or agency rejections during any stage of the regulatory review and approval process based

upon a variety of factors, including without limitation the failure to provide clinical data demonstrating compliance with the FDA's requirements for safety, efficacy and quality. Those requirements may become more stringent prior to submission of our applications for approval or during the review of our applications due to changes in the law or changes in FDA policy or the adoption of new regulations. After submission of an application, the FDA may refuse to file the application, deny approval of the application or require additional testing or data. The FDA can convene an Advisory Committee to assist the FDA in examining specific issues related to the application. For example, we initially filed an NDA, for our Primatene® Mist product in July 2013, but FDA approval was not granted until November 2018 due to delays caused by the FDA's requirement that we provide additional non-clinical information, label revision and follow-up studies (including label comprehension and behavioral/human factor studies), and that we make packaging and label revisions. Additionally, we received Complete Response Letters, or CRLs, from the FDA asking for more information before they could approve the ANDA for our epinephrine vial product. These CRLs have delayed the approval of this product.

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

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

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

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

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

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

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

Some of our new drug candidates must be approved in NDAs based on clinical studies demonstrating safety and/or

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

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

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

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

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

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

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 rights to third parties 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 particle engineering or synthetic APIs for any of our product candidates, 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 and there is no guarantee that we will obtain regulatory approval or, upon commercialization, market acceptance of these products.

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

In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, 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 product candidates 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. Further, to the extent patients or their physicians are slow to adopt our generic products or do not consider our generic products as therapeutically equivalent, physicians may prescribe the branded products or otherwise instruct pharmacists to not substitute for our generic products, which would substantially harm our business.

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

We plan to build on our existing platforms to produce biosimilar products in the future. In 2010, Congress amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to previously approved biologics notwithstanding minor 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 is in the process of publishing regulations governing this process and only 16 biosimilar applications have been approved as of December 31, 2018. 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 16 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.

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.

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 utilized 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;
- 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.

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. For example, our facilities in Rancho Cucamonga, CA, South El Monte, CA and Nanjing, China were all subject to FDA cGMP inspections during 2019. 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 discontinue 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.

Data collection under European and state laws in the U.S. is governed by restrictive regulations addressing the collection, use, processing and, in the case of Europe, cross-border transfer, of personal information.

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.

We may collect, process, use or transfer personal information from individuals located in the European Union in connection with our business. The collection and use of personal health data in the European Union are governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or the GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Union may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, U.S. states are adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements related to personal information. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

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. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our products, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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.

Some of our prescription products are marketed without FDA approval. These products, like many other prescription drugs on the market that the FDA have not been formally evaluated as being effective, contain active ingredients that were first marketed prior to the enactment of the Federal Food, Drug, and Cosmetic Act, or 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 us to 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 an injunction, product seizure and/or 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 the 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 help address a national drug shortage, while we prepared and filed applications for approval of the products. Between August and October, 2010, we reintroduced atropine, morphine, dextrose, and epinephrine prefilled syringes.

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, 2019, 2018, and 2017, we recorded net revenues of $39.3 million, $26.4 million, and $22.0 million, respectively, from our unapproved products. Our unapproved products currently on the market include: atropine, morphine, dextrose and epinephrine prefilled syringes. We have filed three ANDAs and one NDA with respect to our remaining unapproved products in order to mitigate all risk associated with the marketing of unapproved drug products. Prior to the approval of our ANDA and NDA submissions, we continue to operate in compliance with 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. These investigations could have a material adverse effect on our business, financial position and results of operations.

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.

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 Anti-kickback statue, 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 new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information;

- the FFDCA and similar laws regulating advertisement and labeling;

- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, require applicable manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to certain payments or other transfers of value made to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

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

- 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;

- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources;

- state and local laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration,

and items of value provided to healthcare professionals and entities;

- state and local laws that require the registration of pharmaceutical sales representatives; and
- state and foreign laws also govern the privacy and security of personal information (including health information) in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

If the activities of any of our business partners are found to be in violation of these laws or any other federal and state fraud and abuse laws, they may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its activities with regard to the commercialization of our products, which could harm the commercial success of our products and materially affect our business, financial condition and results of operations. While we have implemented numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state

regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the corporate integrity agreement. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and adverse effect on our product sales, business and results of operations.

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

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to:

- comply with the laws of the FDA, EMA, and other comparable foreign regulatory authorities;
- provide true, complete, and accurate information to the FDA, EMA, and other comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or
- report financial information or data accurately or to disclose unauthorized activities to us.

Our business operations, including research, sales, marketing, education, and other business arrangements, in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. While we have a code of conduct and ethics, it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Relating to our Intellectual Property

Our success depends on our ability to detect, protect, and enforce 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 be granted 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. Further, we may not be able to detect an unauthorized use of our intellectual property rights if a competitor uses our intellectual property confidentially, in-house, with no public disclosure.

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, particularly in other countries where intellectual property rights are not highly developed or protected. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Patent claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

Enforcement of our intellectual property rights may not be pursued in some situations in which an alleged infringer may have a more dominant intellectual property position or for other business reasons.

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 granted. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks or we may not have adequate resources to enforce our trademarks.

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

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights; in such case, we will need to defend against such proceedings. For example, the field of generic pharmaceuticals is characterized by frequent litigation that occurs in connection with generic pharmaceutical companies filing ANDAs, Paragraph IV certifications and attempting to invalidate the patents of the proprietary reference drug. Any non-generic products that we successfully develop may be subject to such challenge by third parties. As a generic pharmaceutical company, we also expect to file ANDAs and 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 received a complaint on December 20, 2018, related to our ANDA submitted seeking approval to engage in the commercial manufacture, use and sale of a proposed generic vasopressin injection USP. Additionally, we have also been involved in patent litigation and antitrust litigation related to our sales of enoxaparin. For further details, see the section titled Litigation in Note 20 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 in 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 and technologies. Our ability to commercialize any proprietary product successfully will largely depend upon our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our proprietary products business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

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

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

We rely on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, know-how, confidential or proprietary information and technologies, 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, know-how, or other confidential or proprietary information and technologies 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, know-how, and our other confidential and proprietary information and technologies, 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. In addition, we may not be able to detect any unauthorized disclosure of our trade secrets, know-how and our other confidential and proprietary information and technologies if such disclosure was conducted confidentially without public disclosure.

There is a risk that our trade secrets, know-how, and other confidential and proprietary information and technologies 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 know-how, and other confidential and proprietary information and technologies, our competitive position may be adversely affected. Enforcement of claims that a third party has illegally obtained and is using trade secrets, know-how, and other confidential and proprietary information and technologies, is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods, know-how and trade secrets, we may not be able to prevail in an intellectual property litigation against them, which could have a material adverse effect on our business.

There can be no assurance of timely patent and trademark 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 and trademark applications in a timely manner. Consequently, our patent and trademark applications may be delayed for many years (if they issue 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 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;
- 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 18.4 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.

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 9, 2020, Jack Y. Zhang and Mary Z. Luo, or Drs. Zhang and Luo, each of whom serves as one of our directors and executive officers, and their affiliates beneficially own approximately 27.5% of our outstanding common stock, including shares of common stock subject to options exercisable within 60 days of March 9, 2020. 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 31.4% 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 9, 2020. 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, depriving our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company and might ultimately affect the market price of our common stock.

Jack Y. Zhang and Mary Z. 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, or UBS 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 Y. Zhang and Mary Z. Luo. The loan is secured by a pledge of 1,675,000 shares of our common stock currently held by APCL. Interest on the loan accrues at market rates. UBS received customary fees and expense reimbursements in connection with these loans.

Since May 2017, UBS Bank Utah, or UBS 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 Utah received customary fees and expense reimbursements in connection with these loans.

In October 2017, East West Bank, or East West, entered into an agreement with Drs. Zhang and Luo whereby East West would loan them up to $5.0 million. 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.

In May 2018, Drs. Zhang and Luo entered into a business loan agreement with Cathay Bank, or Cathay, for the extension of credit in the aggregate amount of $25.0 million. The loan is secured by pledged shares of our common stock currently held by APCL. Interest on the loan accrues at market rates. Cathay received customary fees and expense reimbursements in connection with this loan.

We are not a party to these loans, which are full recourse against APCL and each of Drs. Zhang and Luo, respectively, and are secured by pledges of a portion of the shares of our common stock currently beneficially owned by Drs. Zhang and Luo.

If the price of our common stock declines, Drs. Zhang and Luo may be forced by these financial institutions 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 and Drs. Zhang and Luo prohibit the non-pledged shares currently owned by Drs. Zhang and 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 our common stock following a margin call that is not satisfied may cause the price of our common stock to decline further.

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

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. In addition, 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.

While we have engaged in repurchases of our common stock, any future decisions to reduce or discontinue repurchasing our common stock pursuant to our previously announced repurchase program could cause the market price for our common stock to decline.

Although our Board has authorized a share repurchase program, and we repurchased approximately 1.1 million of our shares during 2019 for $22.3 million, any determination to continue to execute our stock repurchase program as planned will be subject to, among other things, our financial position and results of operations, available cash and cash flow, capital requirements, and other factors, as well as our Board's continuing determination that the repurchase program is in the best interests of our shareholders and is in compliance with all laws and agreements applicable to the repurchase

program. Our stock repurchase program does not obligate us to acquire any specific number of shares. If we fail to meet any expectations related to stock repurchases, the market price of our stock could decline significantly, and could have a material adverse impact on investor confidence. Additionally, price volatility of our stock over a given period may cause the average price at which we repurchase our own stock to exceed the stock market price at a given point in time.

We may further increase or decrease the amount of repurchases of our common stock in the future. Any reduction or discontinuance by us of repurchases of our common stock pursuant to our current share repurchase authorization program could cause the market price of our common stock to decline. Moreover, in the event repurchases of our common stock are reduced or discontinued, our failure or inability to resume repurchasing common stock at historical levels could result in a lower market valuation of our common stock.

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 since we ceased to be an "emerging growth company", as defined in the JOBS Act on December 31, 2019. 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.

As of December 31, 2019, we are no longer an "emerging growth company" as defined in JOBS Act, and are now required to comply with additional disclosure and reporting requirements. We have previously taken advantage of the JOBS Act's reduced disclosure requirements applicable to "emerging growth companies" regarding executive compensation and exemptions from the requirements of holding advisory say-on-pay votes on executive compensation. We are no longer eligible for such reduced disclosure requirements and exemptions and are now also required to comply with any new or revised financial accounting standards applicable to public companies without an extended transition period. These additional reporting requirements may increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to these public company requirements. Failure to comply with these requirements could also subject us to enforcement actions by the SEC, further increase costs and divert management's attention, damage our reputation and adversely affect our business, operating results or financial condition.

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 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.

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

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

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

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with 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 106 buildings at six locations in the U.S., France and China, that comprise 2.0 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, 2019:

Location	Aggregate Facility Size (in square feet)	Primary Use	Segment
Rancho Cucamonga, CA	267,674	Headquarters, research and development, laboratories, manufacturing, packaging, warehousing and administrative offices	Finished pharmaceutical products
Éragny-sur-Epte, France	251,983	Manufacturing, laboratories, warehousing and administrative offices	API
Canton, MA	251,750	Manufacturing, packaging, warehousing, distribution and administrative offices	Finished pharmaceutical products
Nanjing, China	393,125	Manufacturing, procurement, research and development, warehousing, and administrative offices	Finished pharmaceutical products
Chino, CA	57,968	Research and development, and laboratories	Finished pharmaceutical products
South El Monte, CA	21,200	Manufacturing	Finished pharmaceutical products

The properties leased by us have expiration dates ranging from 2020 to 2029 (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	232,863	Manufacturing, laboratories and administrative offices	Finished pharmaceutical products
Rancho Cucamonga, CA	180,019	Warehousing, distribution and administrative offices	Finished pharmaceutical products
South El Monte, CA	312,158	Manufacturing, packaging, warehousing, distribution and administrative 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 nationwide 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 20 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.

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.

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.

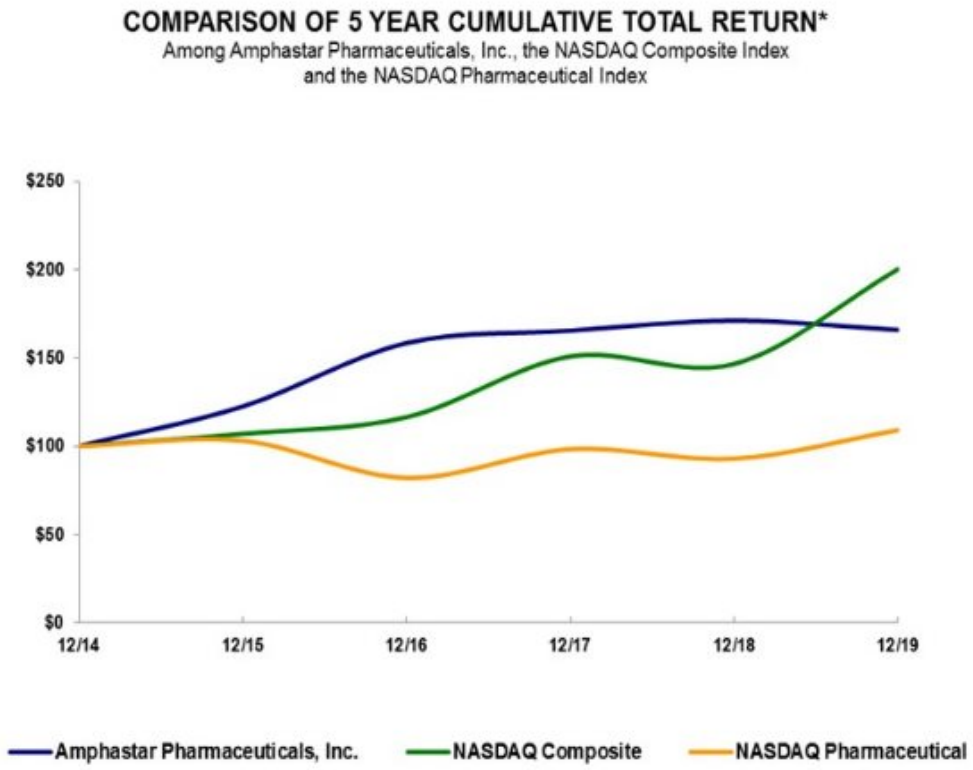
Holders of Record

At March 9, 2020, we had 46,238,303 shares of common stock outstanding held by approximately 150 stockholders of record of our common stock. We believe the actual number of stockholders is greater than this number of record holders, including 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 December 31, 2014, with the cumulative stockholder return since December 31, 2014, on two indices: the Nasdaq Composite Index and the Nasdaq Pharmaceutical Index. The graph assumes an initial investment of $100 on December 31, 2014, both in our common stock and 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.



Issuer Purchases of Equity Securities During the Quarter Ended December 31, 2019

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, 2019	250,437	$ 19.89	250,437	—
November 1 – November 30, 2019	270,776	18.31	270,776	—
December 1 – December 31, 2019	198,423	19.23	198,423	—

(1) During the fourth quarter of 2019, we repurchased shares of our common stock as part of the share buyback programs authorized by our Board of Directors on May 6, 2019. As of December 31, 2019, $21.8 million remained available for repurchase under such programs.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during fiscal 2019 other than transactions previously reported in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Securities Authorized for Issuance Under Equity Compensation Plans

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

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 2019, 2018 and 2017 and the consolidated balance sheet data as of December 31, 2019 and 2018, 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 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016, and 2015, 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,				
	2019	2018	2017	2016	2015
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net revenues	$ 322,357	$ 294,666	$ 240,175	$ 255,165	$ 251,519
Cost of revenues	190,434	187,681	149,666	150,969	174,157
Gross profit	131,923	106,985	90,509	104,196	77,362
Operating (income) expenses:					
Selling, distribution and marketing	12,830	8,156	6,460	5,466	5,470
General and administrative	50,279	49,888	44,458	41,832	41,504
Research and development	68,853	57,564	43,503	41,522	37,838
Gain on sale of intangible assets	—	—	(2,643)	—	—
Total operating expenses	131,962	115,608	91,778	88,820	84,812
Income (loss) from operations	(39)	(8,623)	(1,269)	15,376	(7,450)
Non-operating income (expenses):					
Interest income	997	456	425	270	315
Interest expense	(119)	(243)	(826)	(1,024)	(987)
Other income (expenses), net	59,389	(1,516)	2,919	8	(2,794)
Total non-operating income (expenses)	60,267	(1,303)	2,518	(746)	(3,466)
Income (loss) before income taxes	60,228	(9,926)	1,249	14,630	(10,916)
Income tax provision (benefit)	13,723	(3,266)	(2,398)	4,810	(8,302)
Net income (loss)	$ 46,505	$ (6,660)	$ 3,647	$ 9,820	$ (2,614)
Net income (loss) attributable to non-controlling interest	$ (2,434)	$ (922)	$ —	$ —	$ —
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 48,939	$ (5,738)	$ 3,647	$ 9,820	$ (2,614)
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:					
Basic	$ 1.04	$ (0.12)	$ 0.08	$ 0.22	$ (0.06)
Diluted	$ 0.98	$ (0.12)	$ 0.08	$ 0.21	$ (0.06)
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:					
Basic	46,982	46,395	46,107	45,375	44,961
Diluted	49,907	46,395	48,367	47,504	44,961

	December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$ 89,515	$ 93,323	$ 72,384	$ 74,271	$ 67,359
Working capital	165,232	113,508	120,586	123,479	116,181
Total assets	586,971	513,563	451,072	425,006	388,116
Long-term debt and finance leases, including current portion	47,135	50,213	47,156	37,722	41,099
Retained earnings	116,370	67,485	72,642	68,123	58,303
Total stockholders' equity	381,366	332,435	333,736	326,523	293,490

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 Item 1A, "Risk Factors."

In this section, we generally discuss the results of our operations for the year ended December 31, 2019 compared to the year ended December 31, 2018. For a discussion of the year ended December 31, 2018 to the year ended December 31, 2017, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 15, 2019, which discussion is hereby incorporated herein by reference.

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 biosimilar insulin product candidates and four proprietary product candidates, which are in various stages of development and target a variety of indications. Seven of the ANDAs and one NDA are currently on file with the FDA.

Our largest products by net revenues currently include lidocaine jelly sterile solution, phytonadione, enoxaparin sodium injection, naloxone hydrochloride injection, medroxyprogesterone acetate, and Primatene® Mist. We launched medroxyprogesterone acetate in the first quarter of 2018. In the fourth quarter of 2018, we launched our over-the-counter product Primatene® Mist. In July 2019, we began a national radio and television campaign for Primatene® Mist, which will continue throughout 2020.

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, API, 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 products.

In July 2018, our Chinese subsidiary, ANP, completed a private placement of its common equity interest and received approximately $56.3 million of cash proceeds. We have retained approximately 58% of the equity interest in ANP following the private placement. ANP's net income or loss after July 2, 2018, is attributed to us in accordance with our equity interest of approximately 58% in ANP.

On May 20, 2019, we entered into a settlement agreement relating to the enoxaparin patent and antitrust litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc. Pursuant to the settlement agreement, the plaintiffs paid us $59.9 million on June 27, 2019. For more information regarding the enoxaparin patent and antitrust litigation, see Note 20 to the consolidated financial statements for more information regarding litigation matters.

Business Segments

As of December 31, 2019, 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 manufactures markets and distributes enoxaparin, naloxone, phytonadione, lidocaine, medroxyprogesterone acetate, Primatene® Mist, as well as various other critical and non-critical care drugs. The API segment manufactures and distributes RHI API and porcine insulin API for external customers and internal product development. Information reported herein is consistent with how it is reviewed and evaluated by our chief operating decision maker. Factors used to identify our segments include markets, customers and products.

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

Results of Operations

Year ended December 31, 2019 compared to year ended December 31, 2018

Net revenues

	Year Ended December 31,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 302,000	$ 271,059	$ 30,941	11 %
API	20,357	23,607	(3,250)	(14)%
Total net revenues	$ 322,357	$ 294,666	$ 27,691	9 %
Cost of revenues				
Finished pharmaceutical products	$ 165,424	$ 157,839	$ 7,585	5 %
API	25,010	29,842	(4,832)	(16)%
Total cost of revenues	$ 190,434	$ 187,681	$ 2,753	1 %
Gross profit	$ 131,923	$ 106,985	$ 24,938	23 %
as % of net revenues	*41 %*	*36 %*		

The increase in net revenues of finished pharmaceutical products for 2019 was primarily due to the following changes:

	Year Ended December 31,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
Lidocaine	$ 46,013	$ 43,328	$ 2,685	6 %
Phytonadione	45,786	41,897	3,889	9 %
Enoxaparin	42,695	53,371	(10,676)	(20)%
Naloxone	34,761	37,195	(2,434)	(7)%
Medroxyprogesterone	27,850	24,071	3,779	16 %
Primatene® Mist	18,065	3,574	14,491	405 %
Epinephrine	13,885	10,055	3,830	38 %
Other finished pharmaceutical products	72,945	57,568	15,377	27 %
Total finished pharmaceutical products net revenues	$ 302,000	$ 271,059	$ 30,941	11 %

Primatene® Mist reflects sales for a full year as the product was launched in December 2018. Sales of Primatene® Mist increased in the fourth quarter of 2019 as a result of our nationwide television and radio advertising campaign and the launch of the product into Walmart. $2.2 million of the increase in sales of lidocaine was driven by higher average selling prices while the remainder was largely due to higher unit volumes. A higher average selling price led to $6.7 million of the sales increase in phytonadione, which was partially offset by a decrease in unit volumes. The increase in sales of epinephrine was driven primarily by higher unit volumes. Enoxaparin sales decreased due to lower unit volumes by $21.7 million as a result of increased competition, which was partially offset by $11.0 million, due to an increase in average selling prices because of a change in customer mix. $1.6 million of the decrease in naloxone sales were due to

lower average selling prices, while the remainder of the decline was primarily due to lower unit volumes. Medroxyprogesterone sales increased due to an increase in unit volumes, as the product was launched in 2018, so that year did not reflect a full year of sales.

Other finished pharmaceutical products sales increased primarily due to higher unit sales volumes of atropine, calcium chloride and dextrose, which were in high demand due to market shortages.

We anticipate that sales of naloxone, enoxaparin, and medroxyprogesterone will continue to fluctuate in the future as a result of competition.

Sales of API primarily depend on the timing of customer purchases. In August 2019, we amended the Supply Agreement with MannKind Corporation, or MannKind, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional two years through 2026, which timeframe would have previously lapsed after calendar year 2024. MannKind paid us an amendment fee of $2.75 million, which we recognized in net revenues during the year ended December 31, 2019.

We anticipate that sales of API will continue to fluctuate and may decrease due to the inherent uncertainties related to sales to MannKind. In addition, most of our API sales are denominated in euros, and the fluctuation in the value of the euro versus the U.S. dollar has had, and will continue to have, an impact on API sales revenues in the near term.

A significant portion of our customer shipments in any period relate to orders received and shipped in the same period, generally resulting in low product backlog relative to total shipments at any time. We had no significant backlog as of December 31, 2019. Historically, our backlog has not been a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

Cost of revenues

The launch of Primatene® Mist, which is a higher margin product, as well as the higher average selling price of phytonadione, helped increase our gross margins for the year ended December 31, 2019. Gross margins for Primatene® Mist were magnified by the use of API and components which were expensed to pre-launch inventory in prior years.

The cost of heparin, which is the starting material for enoxaparin, has increased and is expected to increase further, putting downward pressure on our gross margins. However, we believe that this trend will be offset by sales of our higher-margin products, such as medroxyprogesterone, isoproterenol and Primatene® Mist, which were launched over the past two years.

Selling, distribution, and marketing, and general and administrative

	Year Ended December 31,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 12,830	$ 8,156	$ 4,674	57 %
General and administrative	50,279	49,888	391	1 %

The increase in selling, distribution, and marketing expenses was primarily due to marketing expenses related to Primatene® Mist, including the cost of a national television and radio marketing campaign which began in July 2019. The increase in general and administrative expense was primarily due to an increase in personnel cost and an increase in accounting audit fees and consultant fees associated with our compliance with public company reporting obligations. This was partially offset by a decrease in legal expenses as a result of the enoxaparin patent and antitrust litigation settlement (see Note 20 to the consolidated financial statements for more information regarding litigation matters).

We expect that selling, distribution and marketing expenses will increase due to the increase in marketing expenditures for Primatene® Mist. 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. Legal fees may fluctuate due to the timing of patent challenges and other litigation matters.

Research and development

	Year Ended December 31,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 27,503	$ 18,125	$ 9,378	52 %
Pre-launch inventory	54	2,375	(2,321)	(98)%
Clinical trials	8,707	3,939	4,768	121 %
FDA fees	860	2,118	(1,258)	(59)%
Testing, operating and lab supplies	15,640	21,089	(5,449)	(26)%
Depreciation	8,591	5,131	3,460	67 %
Other expenses	7,498	4,787	2,711	57 %
Total research and development expenses	$ 68,853	$ 57,564	$ 11,289	20 %

Research and development costs consist primarily of costs associated with the research and development of our product candidates including the cost of developing APIs. We expense research and development costs as incurred.

Salaries and personnel-related expenses as well as depreciation expense increased in 2019 primarily due to API and key component development at our ANP facility. Clinical trial expense increased due to external studies related to our generic product pipeline, primarily for our inhalation ANDAs and our insulin biosimilar programs.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. We expect that research and development expenses will increase on an annual basis due to increased clinical trial costs related to our biosimilar and inhalation product candidates. These expenditures will include costs of APIs developed internally as well as APIs purchased externally, the cost of purchasing reference listed drugs and the costs of performing the clinical trials. As we undertake new and challenging research and development projects, we anticipate that the associated costs will increase significantly over the next several quarters and years.

Other income (expense), net

	Year Ended December 31,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Other income (expenses), net	$ 59,389	$ (1,516)	$ 60,905	NM

In June 2019, we recognized a gain of $59.9 million relating to our settlement of the enoxaparin patent and antitrust litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc. For more information regarding the enoxaparin patent and antitrust litigation, see Note 20 to the consolidated financial statements for more information regarding litigation matters.

Income tax provision (benefit)

	Year Ended December 31,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Income tax provision (benefit)	$ 13,723	$ (3,266)	$ 16,989	NM
Effective tax rate	*23 %*	*33 %*		

The difference in income tax provision (benefit) was primarily due to differences in pre-tax income (loss) positions.

Liquidity and Capital Resources

Cash Requirements and Sources

We need capital resources to maintain and expand our business. We expect our cash requirements to increase significantly in the foreseeable future as we sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our current development-stage product candidates and pursue strategic acquisitions of

businesses or assets. Our future capital expenditures include projects to upgrade, expand and improve our manufacturing facilities in the United States, China, and France. Our cash obligations include the principal and interest payments due on our existing loans and lease payments, as described below and throughout this Annual Report on Form 10-K. As of December 31, 2019, our foreign subsidiaries collectively held $31.3 million in cash and cash equivalents. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least the next 12 months. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the receipt of regulatory approval for any product candidates that we are developing or the timing of any product introductions, which could be lengthy or ultimately unsuccessful.

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

Working capital increased $51.7 million to $165.2 million at December 31, 2019, compared to $113.5 million at December 31, 2018.

Cash Flows from Operations

The following table summarizes our cash flows from operating, investing, and financing activities for the years ended December 31, 2019 and 2018.

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 41,762	$ 38,191
Investing activities	(50,527)	(42,182)
Financing activities	(3,783)	25,008
Effect of exchange rate changes on cash	(104)	(274)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ (12,652)	$ 20,743

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $41.8 million for the year ended December 31, 2019, which included net income of $46.5 million, primarily as a result of the receipt of the $59.9 million relating to the litigation settlement with Momenta Pharmaceuticals, Inc. and Sandoz Inc. Non-cash items were primarily comprised of $18.1 million of depreciation and amortization, and $17.3 million of share-based compensation expense.

Additionally, there was a net cash outflow from changes in operating assets and liabilities of $51.7 million which resulted from the decrease in accounts receivable, offset by an increase in inventory, as well as a decrease in accounts payable and accrued liabilities. The decrease in accounts receivable was due to the timing of sales. The increase in inventory was primarily due to increased purchases of raw materials and the production of finished goods for enoxaparin and Primatene® Mist with an impact of $29.2 million and $9.3 million, respectively. We plan to utilize deferred tax credits to offset a significant portion of the tax liability related to our 2019 U.S. federal and California state taxable income, resulting in only $4.6 million tax payments. Accounts payable and accrued liabilities decreased primarily due to the timing of payments.

Net cash provided by operating activities was $38.2 million for the year ended December 31, 2018, which included net loss of $6.7 million. Non-cash items were primarily comprised of $16.5 million of depreciation and amortization, and $16.7 million of share-based compensation expense.

Additionally, there was a net cash inflow from changes in operating assets and liabilities of $12.1 million which resulted from the increase in accounts payable and accrued liabilities offset by an increase in accounts receivable and inventory. The increase in accounts receivable was due to an increase in sales. An increase in inventory, due to increased purchases of raw materials for Primatene® Mist, enoxaparin and other products in the U.S., was partially offset by a decrease in finished RHI API at AFP. Accounts payable and accrued liabilities increased, primarily due to the timing of payments.

Investing Activities

Net cash used in investing activities was $50.5 million for the year ended December 31, 2019, primarily as a result of $41.6 million in purchases of property, plant, and equipment, which included $11.3 million incurred in the United States, $6.8 million in France, and $23.5 million in China. Additionally, we purchased $8.8 million in short-term investments in 2019.

Net cash used in investing activities was $42.2 million for the year ended December 31, 2018, primarily as a result of $46.8 million in purchases of property, plant, and equipment, which included $15.7 million incurred in the United States, $9.3 million in France, and $21.8 million in China. The cash used was partially offset by the $4.4 million receipt of the remaining consideration of the sale of various ANDAs in February 2017 (see Note 10 to the consolidated financial statements for more information).

Financing Activities

Net cash used in financing activities was $3.8 million for the year ended December 31, 2019, primarily as a result of $22.3 million used to purchase treasury stock, which was partially offset by the receipt of $18.3 million for the ANP private placement, and $3.4 million in net proceeds received from our equity plans. Additionally, we received $3.6 million from borrowings on an equipment line of credit, and made $6.8 million in principal payments on our long-term debt and lines of credit.

Net cash provided by financing activities was $25.0 million for the year ended December 31, 2018, primarily as a result of $38.0 million received from the ANP private placement and $8.9 million of proceeds received from our equity plans, which was partially offset by $25.0 million used to purchase treasury stock. Additionally, we received proceeds of $8.4 million primarily from borrowings on an equipment line of credit, and made $5.7 million in principal payments on our long-term debt.

Debt and Borrowing Capacity

Our outstanding debt obligations are summarized as follows:

	December 31, 2019	2018	Change
	(in thousands)		
Short-term debt and current portion of long-term debt	$ 7,741	$ 18,229	$ (10,488)
Long-term debt	39,394	31,984	7,410
Total debt	$ 47,135	$ 50,213	$ (3,078)

As of December 31, 2019, we had $41.4 million in unused borrowing capacity under revolving lines of credit and equipment lines of credit with Cathay Bank and East West Bank.

Lines of credit bear variable interest rates and are secured by inventory, accounts receivable, intangible assets, and equipment. The weighted average interest rates on lines of credit as of December 31, 2019 and 2018 were 4.0% and 5.6%, respectively. We have also entered into or refinanced certain mortgage and equipment loans with Cathay Bank and East West Bank, which bear variable or fixed interest rates and are secured by buildings and equipment. On certain loans with East West Bank, we have entered into fixed interest rate swap contracts to exchange the variable interests for fixed interest rates without the exchange of underlying notional debt amounts.

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

Critical Accounting Policies

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

Revenue Recognition

In 2018, we adopted ASC 606, *Revenue from Contracts with Customers*, or ASC 606, using the modified retrospective transition method. The adoption of ASC 606 did not have a material impact on our revenues recognition or on the consolidated financial statements and related disclosures. According to ASC 606, revenue is recognized at the time that our customers obtain control of the promised goods. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, after customers have accepted test samples of the products to be shipped. The results for the reporting period beginning after January 1, 2018, are presented in accordance with the new standard, although comparative information continues to be reported under the accounting standards and policies in effect for those periods.

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

The consideration we receive in exchange for our goods or services is only recognized when it is probable that a significant reversal will not occur. The consideration to which we expect to be entitled includes a stated list price, less various forms of variable consideration. We make significant estimates for related variable consideration at the point of sale, including chargebacks, rebates, product returns, other discounts and allowances.

Provision for estimated chargebacks, rebates, discounts, product returns and doubtful accounts is made at the time of sale and is analyzed and adjusted, if necessary, at each balance sheet date.

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

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

- contract pricing and return terms of our agreements with customers;

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

Provision for Chargebacks and Rebates

The provision for chargebacks and rebates is a significant estimate used in the recognition of revenue. Wholesaler chargebacks relate to sales terms under which we agree to reimburse wholesalers for differences between the gross sales prices at which we sell our products to wholesalers and the actual prices of such products that wholesalers resell them under our various contractual arrangements with third parties such as hospitals and group purchasing organizations in the United States. Rebates include primarily amounts paid to retailers, payers, and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements. We estimate chargebacks and rebates using the expected value method at the time of sale to wholesalers based on wholesaler inventory stocking levels, historic chargeback and rebate rates, and current contract pricing.

The provision for chargebacks and rebates is reflected as a component of net revenues. The following table is an analysis of the chargeback and rebate provision:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Beginning balance	$ 22,423	$ 18,470
Provision for chargebacks and rebates	131,524	125,112
Credits and payments issued to third parties	(132,303)	(121,159)
Ending balance	$ 21,644	$ 22,423

Changes in the chargeback provision from period to period are primarily dependent on our sales to wholesalers, the level of inventory held by wholesalers, and the wholesalers' customer mix. Changes in the rebate provision from period to period are primarily dependent on retailer's and other indirect customers' purchases. The approach that we use to estimate chargebacks and rebates has been consistently applied for all periods presented. Variations in estimates have been historically small. We continually monitor the provision for chargebacks and rebates and make adjustments when we believe that the actual chargebacks and rebates may differ from the estimates. The settlement of chargebacks and rebates generally occurs within 30 days to 60 days after the sale to wholesalers. Accounts receivable and/or accounts payable and accrued liabilities are reduced and/or increased by the chargebacks and rebate amounts depending on whether we have the right to offset with the customer. Of the provision for chargebacks and rebates as of December 31, 2019 and 2018, $15.4 million and $12.0 million were included in accounts receivable, net, on the consolidated balance sheets, respectively. The remaining provision as of December 31, 2019 and 2018, was $6.2 million and $10.4 million, which were included in accounts payable and accrued liabilities, respectively.

Accrual for Product Returns

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

realize that such factors could ultimately lead to increased returns. We analyze these situations on a case-by-case basis and make adjustments to the product return reserve as appropriate.

The provision for product returns is reflected as a component of net revenues. The following table is an analysis of the product return liability:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Beginning balance	$ 8,030	$ 6,522
Provision for product returns	7,305	4,149
Credits issued to third parties	(4,996)	(2,641)
Ending balance	$ 10,339	$ 8,030

Of the provision for product returns as of December 31, 2019 and 2018, $7.1 million and $5.3 million were included in accounts payable and accrued liabilities on the consolidated balance sheets, respectively. The remaining provision of $3.2 million and $2.7 million were included in other long-term liabilities, respectively. For the years ended December 31, 2019 and 2018, our aggregate product return rate was 1.1% and 1.3% of qualified sales, respectively.

Inventory

Inventories consist of currently marketed products and products manufactured under contract. Inventories are stated using the first-in, first-out method, on a consistent basis. Inventory is stated at the lower of cost and net realizable value. We adjust inventories to their net realizable value: (i) if a launch of a new product is delayed and inventory may not be fully utilized and could be subject to impairment, (ii) when a product is close to expiration and not expected to be sold, (iii) when a product has reached its expiration date, (iv) when a product is not expected to be sellable, and (v) when the net realizable value is below cost. In determining the net realizable value of an inventory item, we consider factors such as the amount of inventory on hand, its remaining shelf life, its regulatory approval status, and current and expected market conditions, including management forecasts and levels of competition.

Impairment of Intangible and Long-Lived Assets

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

The indefinite-lived intangible asset, the Primatene® trademark acquired in June 2008, and goodwill are tested for impairment annually, in the fourth quarter, or more frequently if indicators of impairment are present. An impairment loss is recorded if the asset's fair value is less than its carrying value. We also periodically review the Primatene® trademark to determine if events and circumstances continue to support an indefinite useful life. When we choose to perform a qualitative assessment, we evaluate economic, industry and company-specific factors as an initial step. If we determine it is more likely than not that the Primatene® trademark is impaired or the fair value of a reporting unit is less than its carrying amount, further quantitative impairment process is then performed; otherwise, no further testing is required. If the life is no longer indefinite, the asset is tested for impairment, and the carrying value, after recognition of

any impairment loss, is amortized over its remaining useful life. No impairment of indefinite-lived intangible asset and goodwill was recorded during the years ended December 31, 2019, 2018, or 2017, respectively.

Deferred Income Taxes

We utilize the liability method of accounting for income taxes under which deferred taxes are determined based on the temporary differences between the financial statements and the tax basis of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized.

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

Share-Based Compensation

Options issued under our 2015 Equity Incentive Award Plan, or the 2015 Plan, and our Amended and Restated 2005 Equity Incentive Award Plan, or 2005 Plan, are granted at exercise prices equal to or greater than the fair value of the underlying common shares on the date of grant and vest based on continuous service. There have been no awards with performance conditions and no awards with market conditions. The options have a contractual term of five to ten years and generally vest over a three- to five-year period.

For awards issued prior to the listing of our common stock on The Nasdaq Global Select Market, or Nasdaq, the fair value of the common stock utilized in the fair value estimation of award arrangements has been determined by our board of directors, utilizing contemporaneous third-party valuations. Following the listing of our common stock on Nasdaq, we use the closing stock price as reported on Nasdaq on the grant date for the fair value of its stock.

We use the Black-Scholes option pricing model to determine the fair value of options awards. The Black-Scholes option pricing model has various inputs such as the common share price on the date of grant, exercise price, the risk-free interest rate, volatility, expected life and dividend yield, all of which are estimates. We used the risk free rate on U.S. Treasury securities at the time of grant for instruments with maturities commensurate with the expected term of the stock option. Our volatility estimate was based on the weighted average historical volatility of our stock price since IPO and the stock price from a set of peer companies, since our shares do not have sufficient trading history. We consider factors such as stage of life cycle, competitors, size, market capitalization and financial leverage in the selection of similar entities. Our dividend yield was assumed to be 0%, because we have no plans to pay dividends. We estimate the expected term of options with consideration of vesting date, contractual term, and historical experience for employee exercise and post-vesting employment termination behavior after our common stock has been publicly traded. The expected term of “plain vanilla” options is estimated based on the midpoint between the vesting date and the end of the contractual term under the simplified method.

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

Effective January 1, 2017, we prospectively adopted certain requirements of Auditing Standards Update, or ASU, No. 2016-09. As a result, cash flows related to excess tax benefits are classified in operating activities and all excess tax benefits and tax deficiencies are directly included in income tax expense or benefit in the consolidated statement of operations without adjusting prior periods. Additionally, ASU No. 2016-09 eliminated the requirement that excess tax benefits from share-based compensation reduce taxes payable prior to being recognized in the financial statements. Upon adoption of ASU No. 2016-09, the cumulative excess benefits of stock compensation of $0.9 million that was not previously recognized was established on the balance sheet resulting in an increase in deferred tax assets and retained earnings.

Business Combinations

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

Acquisition-related costs that we incur to effect a business combination are expensed in the periods in which the costs are incurred. When the operations of the acquired businesses were not material to our consolidated financial statements, no pro forma presentations were disclosed.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02 *Leases*, which is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU and the related clarifications subsequently issued by the FASB became effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. In July 2018, the FASB further amended the standard to allow for a new transition method that offers the option of using the effective date as the date of initial application. We elected the alternative transition method and therefore have not adjusted comparative-period financial information. On January 1, 2019, we adopted ASC 842, which resulted in the recognition of right-of-use assets of approximately $13.9 million and lease liabilities of approximately $14.1 million related to our operating lease commitments. We elected the available practical expedients at transition including the package of expedients pursuant to which (i) we have not reassessed our prior conclusion related to whether a contract contains a lease, the underlying lease classification or accounting for initial direct cost in a lease, and (ii) we have elected the hindsight practical expedient of determining the lease term and the short-term lease exception such that it did not recognize a right-of-use asset or lease liability for leases with a term of 12 months or less. The new standard also provided practical expedients for our ongoing accounting and we have elected the practical expedient of not separating lease and non-lease components for our asset classes. Footnote 18 provides details on our current operating lease arrangements. The adoption of ASC 842 did not have a material impact on our results of operations or cash flows.

In June 2016, the FASB issued ASU No. 2016-13 *Financial Instruments – Credit Losses*, which is aimed at providing financial statement users with more useful information about the expected credit losses on financial instruments and other commitments to extend credit. The standard update changes the impairment model for financial assets measured at amortized cost, requiring presentation at the net amount expected to be collected. The measurement of expected credit losses requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Available-for-sale debt securities with unrealized losses will be recorded through an allowance for credit losses. The ASU and the related clarifications subsequently issued by FASB will become effective for our interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted for interim or annual periods after December 31, 2019. We will be required to apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. This new guidance will apply to our held-to-maturity investments and trade receivables. We do not believe the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04 *Simplifying the Test for Goodwill Impairment*, which eliminates the requirement to calculate the implied fair value of goodwill. An entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The update also eliminated the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative

assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020, and applied on a prospective basis. Early adoption is permitted for interim and annual goodwill impairment testing dates after January 1, 2017. We currently do not believe that the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13 *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which removes, modifies, and adds certain disclosure requirements to ASC 820, Fair Value Measurement. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted. We do not believe that the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-14 *Disclosure Framework – Changes to the Disclosure Requirements for Defined Benefit Plans*, which removes, modifies, and adds certain disclosure requirements to ASC 715-20, Defined Benefit Plans. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2021. Early adoption is permitted. We do not believe that the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-15 *Customer's Accounting for Implementation Cost Incurred in a Cloud Computing Arrangement that is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalized implementation cost incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The guidance also requires the entity to expense the capitalized implementation cost of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonable certain renewals. This guidance is effective for our interim and annual reporting periods after December 31, 2019. The adoptions of the guidance will not have a material impact on our consolidated financial statements and related disclosures.

In October 2018, the FASB issued ASU No. 2018-17 *Targeted Improvements to Related Party Guidance for Variable Interest Entities*, which requires indirect interests held through related parties in common control arrangements be considered on a proportional basis for determining whether fees paid to decision makers and service providers are variable interests. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted. We currently do not believe that the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU No. 2018-18 *Clarifying the Interaction between Topic 808 and Topic 606*, which requires transactions in collaborative arrangements to be accounted for under ASC 606, Revenue from Contracts with Customers, or ASC 606, if the counterparty is a customer for a good or service that is a distinct unit of account. The amendments also preclude entities from presenting consideration from transactions with a collaborator that is not a customer together with revenue recognized from contracts with customers. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted, including in any interim period. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12 *Simplifying the Accounting for Income Taxes (Topic 740)*, which simplifies various aspects related to accounting for income taxes. The amendment also improves consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The guidance is effective for our interim and annual reporting periods after the year ended December 15, 2020, with early adoption permitted. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

Non-GAAP Financial Measures

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

Contractual Obligations

Set forth below are our contractual payment obligations (including interest obligations but excluding intercompany obligations) as of December 31, 2019:

Contractual Obligations[1]	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(in thousands)		
Long-term debt[2]	$ 55,130	$ 9,453	$ 18,393	$ 7,900	$ 19,384
Operating leases	24,975	4,239	8,093	4,086	8,557
Finance leases	877	311	507	51	8
Facility construction in Nanjing, China[3]	1,500	1,500	—	—	—
Purchase obligations[4]	37,987	37,639	129	219	—
	$ 120,469	$ 53,142	$ 27,122	$ 12,256	$ 27,949

(1) The table above excludes our liability for uncertain tax positions of $8.3 million because the timing of any related payments cannot be reasonably estimated.
(2) Long-term debt includes accrued and unpaid interest. As of December 31, 2019, the principal amount of long-term debt with variable interest exposure was $14.5 million. As of December 31, 2019, the weighted average variable interest rate on our long-term debt was 4.7%.
(3) Obligation to develop a facility in Nanjing, China. Please see "— Investment in China" below for further discussion.
(4) The purchase obligations principally relate to inventory and pharmaceutical manufacturing and laboratory equipment. We anticipate meeting these purchase obligations through a combination of cash on hand, future cash flows from operations and debt and lease facilities.

Off-Balance Sheet Arrangements

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

Investment in China

In accordance with certain agreements between ANP and the Chinese government, in January 2010 and November 2012, we acquired certain land-use rights for $1.2 million and $1.3 million, respectively. As required by these agreements, we have committed to spending approximately $15.0 million in the related land development, which primarily includes the construction of fixed assets according to a specified timetable. As of December 31, 2019, we have spent $13.5 million on such construction. We anticipate that this spending commitment will be met by the end of 2020.

Government Regulation

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

From February 5, 2019 through February 12, 2019, 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 March 2017, 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 March 6, 2019. 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 February 25 through March 1, 2019, 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 2017 inspection as well as review of data to support our pending applications. The inspection resulted in multiple observations on Form 483. We responded to those observations on March 22, 2019. 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 July 23 through July 25, 2019, our Amphastar facility in Rancho Cucamonga, California was subject to a routine, post-marketing adverse drug experience reporting inspection, or PADE, by the FDA. The inspection included a review of our processes for collecting, reviewing, investigating and reporting post-marketing adverse drug experiences reported through various sources. The inspection resulted in no Form 483 findings. No further actions will be necessary.

From August 27 through September 04, 2019, one of our California clinical trial sites was subject to a pre-approval biomonitoring inspection by the FDA. The inspection included a review of the clinical trial data to support one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

From October 7 through October 11, 2019, our Chinese subsidiary ANP, was subject to a cGMP inspection by the FDA. The inspection included a review of compliance with FDA regulations relating to Good Manufacturing Practices. The inspection resulted in one observation on Form 483. We responded to that observation. We believe that our response to the observation will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From October 24 to November 5, 2019, our IMS facility in South El Monte, California was subject to a preapproval inspection by the FDA. The inspection included a review of data to support our pending applications. The inspection resulted in multiple observations on Form 483. We responded to the initial observations within the required timeframe, however, there was an additional request for information. We plan to submit our response in March 2020, and we believe that it will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From November 18 to November 22, 2019, our Amphastar facility in Rancho Cucamonga, California was subject to a pre-approval biomonitoring inspection by the FDA. The inspection included review of the analytical laboratory used in support of one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

From November 18 to November 21, 2019, our IMS facility in South El Monte, California and our Amphastar facility in Rancho Cucamonga, California were subject to a pre-approval biomonitoring inspection by the FDA. The inspection included review of the analytical laboratory and an in vitro study used in support of one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

On December 18, 2019, our IMS facility in South El Monte, California was subject to an inspection by the FDA. The inspection was part of an overall investigation involving makers of opioid products. The inspection resulted in no Form 483 findings. No further actions will be necessary.

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

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

Investment Risk

We regularly review the carrying value of our investments and identify and recognize losses, for income statement purposes, when events and circumstances indicate that any declines in the fair values of such investments below our accounting basis are other than temporary. As of December 31, 2019, none of our investments experienced any declines in fair value that are other than temporary. We do not enter into investments for trading or speculative purposes.

As of December 31, 2019, we had $27.6 million deposited in seven banks located in China, $3.0 million deposited in one bank located in France, and $0.8 million deposited in one bank located in the United Kingdom. We also maintained $44.2 million in cash equivalents that include money market accounts as of December 31, 2019. Additionally, we maintain approximately $2.8 million in corporate bonds as of December 31, 2019. The remaining amounts of our cash equivalent as of December 31, 2019, are in non-interest bearing accounts.

As of December 31, 2018, we had $31.4 million deposited in seven banks located in China, $5.5 million deposited in one bank located in France, and $1.0 million deposited in one bank located in the United Kingdom. We also maintained $40.9 million in cash equivalents that include money market accounts, as of December 31, 2018. The remaining amounts of our cash equivalent as of December 31, 2018, are in non-interest bearing accounts.

Interest Rate Risk

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

As of December 31, 2019, we had $47.1 million in long-term debt and finance leases outstanding. Of this amount, $14.5 million had variable interest rates which were not locked-in through fixed interest rate swap contracts. The debt with variable interest rate exposure had a weighted-average interest rate of 4.7% at December 31, 2019. An increase in the index underlying these rates of 1% (100 basis points) would increase our annual interest expense on the debt with variable interest rate exposure by approximately $0.1 million per year.

As of December 31, 2018, we had $50.2 million in long-term debt and capital leases outstanding. Of this amount, $13.4 million had variable interest rates that were not locked in through fixed interest rate swap contracts. The debt with variable interest rate exposure had a weighted-average interest rate of 5.2% at December 31, 2018.

Foreign Currency Exchange Risk

Our finished pharmaceutical products are primarily sold in the U.S. domestic market, and have little exposure to foreign currency price fluctuations. However, as a result of our acquisition of the API manufacturing business in France, we are exposed to market risk related to changes in foreign currency exchange rates. Specifically, our insulin sales contracts are frequently denominated in euros, which are subject to fluctuations relative to the USD.

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

Our French subsidiary, AFP, maintains its books of record in euros. Our U.K. subsidiary, IMS UK, maintains its books of record in British pounds. The results of operations are translated to USD at the average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing exchange rate at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other comprehensive income (loss).

We are also exposed to the potential earnings effects from intercompany foreign currency assets and liabilities that arise from normal trade receivables and payables and other intercompany loans.

As of December 31, 2019, a 10% unfavorable change in the exchange rate of the U.S. dollar strengthening against the foreign currencies to which we have exposure would result in approximately $2.5 million reduction of foreign currency gains, and approximately $3.5 million reduction in other comprehensive income.

As of December 31, 2019 and 2018, our foreign subsidiaries had cash balances denominated in foreign currencies in the amount of $5.2 million and $17.6 million, respectively.

Item 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Amphastar Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amphastar Pharmaceuticals, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework and our report dated March 16, 2020 expressed an unqualified opinion thereon.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method for accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1998.

Irvine, California

March 16, 2020

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 73,685	$ 86,337
Restricted cash	1,865	1,865
Short-term investments	11,675	2,831
Restricted short-term investments	2,290	2,290
Accounts receivable, net	45,376	52,163
Inventories	110,501	69,322
Income tax refunds and deposits	311	49
Prepaid expenses and other assets	9,538	5,485
Total current assets	255,241	220,342
Property, plant, and equipment, net	233,856	210,418
Finance lease right-of-use assets	887	—
Operating lease right-of-use assets	18,805	—
Goodwill and intangible assets, net	41,153	42,267
Other assets	11,156	9,918
Deferred tax assets	25,873	30,618
Total assets	$ 586,971	$ 513,563
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 77,051	$ 87,418
Income taxes payable	2,042	1,187
Current portion of long-term debt	7,741	18,229
Current portion of operating lease liabilities	3,175	—
Total current liabilities	90,009	106,834
Long-term reserve for income tax liabilities	3,425	415
Long-term debt, net of current portion	39,394	31,984
Long-term operating lease liabilities, net of current portion	16,315	—
Deferred tax liabilities	867	1,031
Other long-term liabilities	9,433	8,940
Total liabilities	159,443	149,204
Commitments and contingencies		
Stockholders' equity:		
Preferred stock: par value $0.0001; 20,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock: par value $0.0001; 300,000,000 shares authorized; 52,495,483 and 46,576,968 shares issued and outstanding as of December 31, 2019 and 51,438,675 and 46,631,118 shares issued and outstanding as of December 31, 2018, respectively	5	5
Additional paid-in capital	367,305	344,434
Retained earnings	116,370	67,485
Accumulated other comprehensive loss	(4,687)	(4,013)
Treasury stock	(97,627)	(75,476)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	381,366	332,435
Non-controlling interests	46,162	31,924
Total equity	427,528	364,359
Total liabilities and stockholders' equity	$ 586,971	$ 513,563

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2019	2018	2017
Net revenues	$ 322,357	$ 294,666	$ 240,175
Cost of revenues	190,434	187,681	149,666
Gross profit	131,923	106,985	90,509
Operating expenses:			
Selling, distribution, and marketing	12,830	8,156	6,460
General and administrative	50,279	49,888	44,458
Research and development	68,853	57,564	43,503
Gain on sale of intangible assets	—	—	(2,643)
Total operating expenses	131,962	115,608	91,778
Income (loss) from operations	(39)	(8,623)	(1,269)
Non-operating (expenses) income:			
Interest income	997	456	425
Interest expense	(119)	(243)	(826)
Other income (expenses), net	59,389	(1,516)	2,919
Total non-operating (expenses) income, net	60,267	(1,303)	2,518
Income (loss) before income taxes	60,228	(9,926)	1,249
Income tax provision (benefit)	13,723	(3,266)	(2,398)
Net income (loss)	$ 46,505	$ (6,660)	$ 3,647
Net loss attributable to non-controlling interests	$ (2,434)	$ (922)	$ —
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 48,939	$ (5,738)	$ 3,647
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:			
Basic	$ 1.04	$ (0.12)	$ 0.08
Diluted	$ 0.98	$ (0.12)	$ 0.08
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:			
Basic	46,982	46,395	46,107
Diluted	49,907	46,395	48,367

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Year Ended December 31,		
	2019	2018	2017
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 48,939	$ (5,738)	$ 3,647
Other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc., net of income taxes			
Foreign currency translation adjustment	(576)	(1,957)	2,713
Change in pension obligations	(98)	44	(117)
Total other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	(674)	(1,913)	2,596
Total comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 48,265	$ (7,651)	$ 6,243

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock				Accumulated	Treasury Stock		Total		
	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Other Comprehensive Income (loss)	Shares	Amount	Amphastar Stockholders' Equity	Non-controlling Interest	Total
Balance as of December 31, 2016	47,765,149	5	283,123	68,123	(4,696)	(1,516,527)	(20,032)	326,523	—	326,523
Beginning balance adjustment to retained earnings as a result of the adoption of ASU No. 2016-09	—	—	—	872	—	—	—	872	—	872
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	3,647	—	—	—	3,647	—	3,647
Other comprehensive income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	2,596	—	—	2,596	—	2,596
Purchase of treasury stock	—	—	—	—	—	(1,905,653)	(30,747)	(30,747)	—	(30,747)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(77)	—	—	6,549	77	—	—	—
Issuance of common stock in connection with the Company's equity plans	2,274,063	—	13,758	—	—	—	—	13,758	—	13,758
Share-based compensation expense	—	—	17,087	—	—	—	—	17,087	—	17,087
Balance as of December 31, 2017	50,039,212	5	313,891	72,642	(2,100)	(3,415,631)	(50,702)	333,736	—	333,736
Beginning balance adjustment as a result of the adoption of new accounting standards	—	—	—	582	—	—	—	582	—	582
Net loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	(5,738)	—	—	—	(5,738)	—	(5,738)
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(1,913)	—	—	(1,913)	—	(1,913)
Proceeds from the private placement of ANP	—	—	5,190	—	—	—	—	5,190	32,846	38,036
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(922)	(922)
Purchase of treasury stock	—	—	—	—	—	(1,414,924)	(25,047)	(25,047)	—	(25,047)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(273)	—	—	22,998	273	—	—	—
Issuance of common stock in connection with the Company's equity plans	1,399,463	—	8,946	—	—	—	—	8,946	—	8,946
Share-based compensation expense	—	—	16,680	—	—	—	—	16,680	—	16,680
Balance as of December 31, 2018	51,438,675	5	344,434	67,485	(4,013)	(4,807,557)	(75,476)	332,435	31,924	364,359
Beginning balance adjustment as a result of the adoption of new accounting standards	—	—	—	(54)	—	—	—	(54)	—	(54)
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	48,939	—	—	—	48,939	—	48,939
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(674)	—	—	(674)	—	(674)
Proceeds from the private placement of ANP	—	—	2,588	—	—	—	—	2,588	16,378	18,966
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(2,434)	(2,434)
Purchase of treasury stock	—	—	—	—	—	(1,122,781)	(22,291)	(22,291)	—	(22,291)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(140)	—	—	11,823	140	—	—	—
Issuance of common stock in connection with the Company's equity plans	1,056,808	—	3,422	—	—	—	—	3,422	—	3,422
Share-based compensation expense	—	—	17,001	—	—	—	—	17,001	294	17,295
Balance as of December 31, 2019	52,495,483	$ 5	$ 367,305	$ 116,370	$ (4,687)	(5,918,515)	$ (97,627)	$ 381,366	$ 46,162	$ 427,528

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2019	2018	2017
Cash Flows From Operating Activities:			
Net income (loss)	$ 46,505	$ (6,660)	$ 3,647
Reconciliation to net cash provided by operating activities:			
Loss (gain) on impairment and disposal of assets	1,036	1,429	(2,337)
Depreciation of property, plant, and equipment	17,073	14,529	12,954
Amortization of product rights, trademarks, and patents	1,037	1,987	2,856
Operating lease right-of-use asset amortization	3,011	—	—
Share-based compensation expense	17,295	16,680	17,087
Changes in reserve for uncertain tax positions	3,010	(464)	34
Changes in deferred taxes, net	4,542	(1,414)	4,386
Changes in operating assets and liabilities:			
Accounts receivable, net	6,702	(16,295)	(8,102)
Inventories	(41,103)	(5,984)	18,650
Prepaid expenses and other assets	(3,604)	1,375	(4,817)
Income tax refund, deposits, and payable	591	3,849	(11,836)
Operating lease liabilities	(2,613)	—	—
Accounts payable and accrued liabilities	(11,720)	29,159	6,687
Net cash provided by operating activities	41,762	38,191	39,209
Cash Flows From Investing Activities:			
Purchases and construction of property, plant, and equipment	(41,555)	(46,808)	(35,099)
Proceeds from the sale of property, plant and equipment	—	245	—
Sale of intangible assets	—	4,400	2,000
Purchase of short-term investments	(8,815)	(308)	(5,645)
Maturity of short-term investments	—	91	3,650
Changes in restricted short-term investments	—	—	(900)
Payment of deposits and other assets	(157)	198	(896)
Net cash used in investing activities	(50,527)	(42,182)	(36,890)
Cash Flows From Financing Activities:			
Proceeds from the private placement of ANP	18,298	38,036	—
Proceeds from equity plans, net of withholding tax payments	3,421	8,946	13,758
Purchase of treasury stock	(22,291)	(25,047)	(30,747)
Proceeds from borrowing under lines of credit	—	347	—
Repayments under lines of credit	(347)	—	—
Proceeds from issuance of long-term debt	3,570	8,431	18,983
Principal payments on long-term debt	(6,434)	(5,705)	(9,712)
Net cash (used in) provided by financing activities	(3,783)	25,008	(7,718)
Effect of exchange rate changes on cash	(104)	(274)	504
Net increase (decrease) in cash, cash equivalents, and restricted cash	(12,652)	20,743	(4,895)
Cash, cash equivalents, and restricted cash at beginning of period	88,202	67,459	72,354
Cash, cash equivalents, and restricted cash at end of period	$ 75,550	$ 88,202	$ 67,459
Noncash Investing and Financing Activities:			
Capital expenditure included in accounts payable	$ 10,622	$ 8,386	$ 6,710
Operating lease right-of-use assets	$ 7,978	$ —	$ —
Equipment acquired under finance leases	$ 143	$ 14	$ —
Supplemental Disclosures of Cash Flow Information:			
Interest paid, net of capitalized interest	$ 2,435	$ 2,376	$ 1,877
Income taxes paid	$ 5,717	$ 339	$ 4,876

See accompanying notes to consolidated financial statements

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business

Amphastar Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, hereinafter referred to as "the Company") is a specialty pharmaceutical company that develops, manufactures, markets, and sells generic and proprietary injectable, inhalation, and intranasal products, including products with high technical barriers to market entry. Additionally, the Company sells insulin active pharmaceutical ingredient, or API, products. Most of the Company's products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. The Company's insulin API products are sold to other pharmaceutical companies for use in their own products and are being used by the Company in the development of injectable finished pharmaceutical products. The Company's inhalation product, Primatene® Mist is primarily distributed through drug retailers.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, and are prepared in accordance with United States generally accepted accounting principles, or GAAP. All intercompany activity has been eliminated in the preparation of the consolidated financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

The Company's subsidiaries include: (1) International Medication Systems, Limited, or IMS, (2) Armstrong Pharmaceuticals, Inc., or Armstrong, (3) Amphastar Nanjing Pharmaceuticals Inc., or ANP, (4) Nanjing Letop Fine Chemistry Co., Ltd., or Letop, (5) Nanjing Hanxin Pharmaceutical Technology Co., Ltd., or Hanxin, (6) Nanjing Baixin Trading Co., Ltd., or Baixin, (7) Amphastar France Pharmaceuticals, S.A.S., or AFP, (8) Amphastar UK Ltd., or AUK, and (9) International Medication Systems (UK) Limited, or IMS UK.

In July 2018, the Company's Chinese subsidiary, ANP, completed a private placement of its common equity interest to accredited investors for aggregate gross proceeds of approximately $57 million. While investors were initially required to complete their contributions in cash by December 31, 2018, ANP granted an extension to certain investors. Certain investors contributed their payments in Chinese yuan, which resulted in a difference in U.S. dollars, or USD, due to currency fluctuations subsequent to the execution of the placement agreement. A total of $56.3 million was received by ANP and the difference was expensed in the quarter ended March 31, 2019. The Company has retained approximately 58% of the equity interest in ANP following the private placement and continues to consolidate the financial results of ANP with the Company's results of operations. ANP's net income after July 2, 2018, was attributed to the Company in accordance with the Company's equity interest of approximately 58% in ANP.

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The principal accounting estimates include: determination of allowances for doubtful accounts and discounts, provision for chargebacks and rebates, provision for product returns, adjustment of inventory to their net realizable values, impairment of long-lived and intangible assets and goodwill, self-insured claims, workers' compensation liabilities, litigation reserves, stock price volatilities for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

The functional currency of the Company, its domestic subsidiaries, its Chinese subsidiary ANP, and its U.K. subsidiary, AUK, is the USD. ANP maintains its books of record in Chinese yuan. These books are remeasured into the functional

currency of USD using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign currency exchange gains and losses are reflected in the Company's consolidated statements of operations.

The Company's French subsidiary, AFP, maintains its book of record in euros. ANP's other Chinese subsidiaries, maintain their books of record in Chinese yuan. AUK's subsidiary, IMS UK, maintains its book of record in British pounds. These local currencies have been determined to be the subsidiaries' respective functional currencies. These books of record are translated into USD using average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other accumulated comprehensive income (loss). The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other accumulated comprehensive income (loss). The unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature for the years ended December 31, 2019, 2018, and 2017 were a $0.7 million gain, a $1.5 million gain, and a $4.3 million gain, respectively.

Comprehensive Income (Loss)

For the years ended December 31, 2019, 2018 and 2017, the Company included its foreign currency translation gain or loss and change in pension obligation of its defined benefit pension plan as part of its comprehensive income (loss). There was no material income tax provision (benefit) allocated to other comprehensive loss for the years ended December 31, 2019 and 2018. Income tax expense of $1.5 million was allocated to other comprehensive income for the year ended December 31, 2017.

Shipping and Handling Costs

For the years ended December 31, 2019, 2018, and 2017, the Company included shipping and handling costs of approximately $4.3 million, $3.7 million, and $3.0 million, respectively, in selling, distribution and marketing expenses in the accompanying consolidated statements of operations.

Advertising Costs

In connection with the launch of Primatene® Mist, in July 2019, the Company began to incur advertising costs. Advertising costs are expensed as incurred, except for costs related to the development of a major commercial or media campaign, which are expensed in the period in which commercial or campaign is first presented, and is reflected as a component of selling, distribution and marketing in the Company's consolidated statement of operations. For the year ended December 31, 2019, advertising cost was $4.3 million.

Research and Development Costs

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

The Company may produce or purchase inventories prior to or with the expectation of receiving marketing authorization in the near term, based on operational decisions about the most effective use of existing resources. This inventory is referred to as pre-launch inventory. It is the Company's accounting policy that the pre-launch inventory is capitalized if it has a probable future economic benefit. If marketing authorization is received and previously expensed pre-launch inventory is sold, such sales may contribute up to a 100% margin to the Company's operating results. Pre-launch

inventory costs include cost of work in process, materials, and finished drug products. As of December 31, 2019, 2018, and 2017, the Company did not have material capitalized pre-launch inventory.

Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, restricted cash and short-term investments, accounts receivable, accounts payable, accrued expenses, and short-term borrowings approximate fair value due to the short maturity of these items. The majority of the Company's long-term obligations consist of variable rate debt, and their carrying value approximates fair value as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities. The Company at times enters into fixed interest rate swap contracts to exchange the variable interest rates for fixed interest rates without the exchange of the underlying notional debt amounts. Such interest rate swap contracts are recorded at their fair values.

Cash and Cash Equivalents

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

Short-Term Investments

Short-term investments as of December 31, 2019 consisted of certificates of deposit and investment grade corporate bonds with original expiration dates within 12 months.

Restricted Cash

Restricted cash is collateral required for the Company to guarantee certain vendor payments in France. As of December 31, 2019 and 2018, the restricted cash balance was $1.9 million.

Restricted Short-Term Investments

Restricted short-term investments consist of certificates of deposit that are collateral for standby letters of credit to qualify for workers' compensation self-insurance. The certificates of deposit have original maturities greater than three months. As of December 31, 2019 and 2018, the balance of restricted short-term investments was $2.3 million.

Allowance for Doubtful Accounts Receivable

The Company evaluates the collectability of accounts receivable based on a combination of factors. When the Company is aware of circumstances that may impair a customer's ability to pay subsequent to the original sale, the Company records a specific allowance to reduce the amounts receivable to the amount that the Company reasonably believes to be collectable. For all other customers, the Company recognizes an allowance for doubtful accounts based on factors that include the length of time the receivables are past due, industry and geographic concentrations, the current business environment and historical collection experience. As of December 31, 2019 and 2018, the Company's allowance for doubtful accounts was $1.1 million and $0.5 million, respectively.

Inventories

Inventories consist of currently marketed products and products manufactured under contract. Inventories are stated using the first-in, first-out method, on a consistent basis. The Company states inventory at the lower of cost and net realizable value. Provisions are made for slow-moving, unsellable, or obsolete items. Net realizable value is determined using the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Property, Plant and Equipment

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

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

Intangible Assets

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

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

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

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

Deferred Income Taxes

The Company utilizes the liability method of accounting for income taxes, under which deferred taxes are determined based on the temporary differences between the financial statements and the tax basis of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized.

Impairment of Indefinite-Lived Intangible Asset and Goodwill

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

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Self-Insured Claims

The Company is primarily self-insured, up to certain limits, for workers' compensation claims. The Company has purchased stop-loss insurance, which will reimburse the Company for individual claims in excess of $350,000 annually or aggregate claims exceeding $3.5 million annually. Operations are charged with the cost of claims reported and an estimate of claims incurred but not reported. A liability for unpaid claims and the associated claim expenses, including incurred but not reported losses, is actuarially determined and reflected in accrued liabilities in the accompanying consolidated balance sheets. Total expense under the program was approximately $0.4 million, $2.6 million, and $1.5 million, for the years ended December 31, 2019, 2018 and 2017, respectively. The self-insured claims liability was $4.9 million and $5.6 million at December 31, 2019 and 2018, respectively. The determination of such claims and expenses and the appropriateness of the related liability is reviewed periodically and updated, as necessary. Changes in estimates are recorded in the period identified.

Business Combinations

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

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

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02 *Leases*, which is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU and the related clarifications subsequently issued by the FASB became effective for the Company's interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. In July 2018, the FASB further amended the standard to allow for a new transition method that offers the option of using the effective date as the date of initial application. The Company elected the alternative transition method and therefore has not adjusted comparative-period financial information. On January 1, 2019, the Company adopted ASC 842, which resulted in the recognition of right-of-use assets of approximately $13.9 million and lease liabilities of approximately $14.1 million related to its operating lease commitments. The Company elected the available practical expedients at transition including the package of expedients pursuant to which (i) the Company has not reassessed its prior conclusion related to whether a contract contains a lease, the underlying lease classification or accounting for initial direct cost in a lease, and (ii) the Company has elected the hindsight practical expedient of determining the lease term and the short-term lease exception such that it did not recognize a right-of-use asset or lease liability for leases with a term of 12 months or less. The new standard also provided practical expedients for the Company's ongoing accounting and the Company has elected the practical expedient of not separating lease and non-lease components for its asset classes. Footnote 18 provides details on the Company's current operating lease arrangements. The adoption of ASC 842 did not have a material impact on the Company's results of operations or cash flows.

In June 2016, the FASB issued ASU No. 2016-13 *Financial Instruments – Credit Losses*, which is aimed at providing financial statement users with more useful information about the expected credit losses on financial instruments and

other commitments to extend credit. The standard update changes the impairment model for financial assets measured at amortized cost, requiring presentation at the net amount expected to be collected. The measurement of expected credit losses requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Available-for-sale debt securities with unrealized losses will be recorded through an allowance for credit losses. The ASU and the related clarifications subsequently issued by FASB will become effective for the Company's interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted for interim or annual periods after December 31, 2019. The Company will be required to apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. This new guidance will apply to the Company's held-to-maturity investments and trade receivables. The Company does not believe the adoption of this accounting guidance will have a material impact on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04 *Simplifying the Test for Goodwill Impairment*, which eliminates the requirement to calculate the implied fair value of goodwill. An entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The update also eliminated the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and applied on a prospective basis. Early adoption is permitted for interim and annual goodwill impairment testing dates after January 1, 2017. The Company currently does not believe that the adoption of this accounting guidance will have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13 *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which removes, modifies, and adds certain disclosure requirements to ASC 820, Fair Value Measurement. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted. The Company does not believe that the adoption of this accounting guidance will have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-14 *Disclosure Framework – Changes to the Disclosure Requirements for Defined Benefit Plans*, which removes, modifies, and adds certain disclosure requirements to ASC 715-20, Defined Benefit Plans. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2021. Early adoption is permitted. The Company does not believe that the adoption of this accounting guidance will have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-15 *Customer's Accounting for Implementation Cost Incurred in a Cloud Computing Arrangement that is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalized implementation cost incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The guidance also requires the entity to expense the capitalized implementation cost of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonable certain renewals. This guidance is effective for the Company's interim and annual reporting periods after December 31, 2019. The adoptions of the guidance will not have a material impact on its consolidated financial statements and related disclosures.

In October 2018, the FASB issued ASU No. 2018-17 *Targeted Improvements to Related Party Guidance for Variable Interest Entities*, which requires indirect interests held through related parties in common control arrangements be considered on a proportional basis for determining whether fees paid to decision makers and service providers are variable interests. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted. The Company currently does not believe that the adoption of this accounting guidance will have a material impact on its consolidated financial statements and related disclosures.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In November 2018, the FASB issued ASU No. 2018-18 *Clarifying the Interaction between Topic 808 and Topic 606*, which requires transactions in collaborative arrangements to be accounted for under ASC 606, Revenue from Contracts with Customers, or ASC 606, if the counterparty is a customer for a good or service that is a distinct unit of account. The amendments also preclude entities from presenting consideration from transactions with a collaborator that is not a customer together with revenue recognized from contracts with customers. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted, including in any interim period. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12 *Simplifying the Accounting for Income Taxes (Topic 740)*, which simplifies various aspects related to accounting for income taxes. The amendment also improves consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The guidance is effective for the Company's interim and annual reporting periods after the year ended December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

Note 3. Business Acquisitions

Acquisition of fourteen injectable products from Hikma Pharmaceuticals PLC

In March 2016, the Company acquired 14 abbreviated new drug applications, or ANDAs, representing 11 different injectable chemical entities from Hikma Pharmaceuticals PLC, or Hikma, for $4.0 million. This transaction was accounted for as a business combination in accordance with ASC 805. The ANDAs were estimated to have a fair value of $4.0 million, and were subject to a straight-line amortization over a useful life of approximately 15 years.

In February 2017, the Company sold these products to an unrelated party. (See note 10)

Note 4. Revenue Recognition

In accordance with ASC 606, revenue is recognized at the time that the Company's customers obtain control of the promised goods.

Generally, revenue is recognized at the time of product delivery to the Company's customers. In some cases, revenue is recognized at the time of shipment when stipulated by the terms of the sale agreements.

The consideration the Company receives in exchange for its goods or services is only recognized when it is probable that a significant reversal will not occur. The consideration to which the Company expects to be entitled includes a stated list price, less various forms of variable consideration. The Company makes significant estimates for related variable consideration at the point of sale, including chargebacks, rebates, product returns, other discounts and allowances.

Provision for estimated chargebacks, rebates, discounts, product returns and doubtful accounts is made at the time of sale and is analyzed and adjusted, if necessary, at each balance sheet date.

Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, and after the customer has accepted test samples of the products to be shipped.

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

AMPHASTAR PHARMACEUTICALS, INC.
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Provision for Chargebacks and Rebates

The provision for chargebacks and rebates is a significant estimate used in the recognition of revenue. Wholesaler chargebacks relate to sales terms under which the Company agrees to reimburse wholesalers for differences between the gross sales prices at which the Company sells its products to wholesalers and the actual prices of such products that wholesalers resell under the Company's various contractual arrangements with third parties such as hospitals and group purchasing organizations in the United States. Rebates include primarily amounts paid to retailers, payers, and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements. The Company estimates chargebacks and rebates using the expected value method at the time of sale to wholesalers based on wholesaler inventory stocking levels, historic chargeback and rebate rates, and current contract pricing.

The provision for chargebacks and rebates is reflected as a component of net revenues. The following table is an analysis of the chargeback and rebate provision:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Beginning balance	$ 22,423	$ 18,470
Provision for chargebacks and rebates	131,524	125,112
Credits and payments issued to third parties	(132,303)	(121,159)
Ending balance	$ 21,644	$ 22,423

Changes in the chargeback provision from period to period are primarily dependent on the Company's sales to its wholesalers, the level of inventory held by wholesalers, and the wholesalers' customer mix. Changes in the rebate provision from period to period are primarily dependent on retailer's and other indirect customers' purchases. The approach that the Company uses to estimate chargebacks has been consistently applied for all periods presented. Variations in estimates have been historically small. The Company continually monitors the provision for chargebacks and rebates and makes adjustments when it believes that the actual chargebacks and rebates may differ from the estimates. The settlement of chargebacks and rebates generally occurs within 30 days to 60 days after the sale to wholesalers. Accounts receivable and/or accounts payable and accrued liabilities are reduced and/or increased by the chargebacks and rebate amounts depending on whether the Company has the right to offset with the customer. Of the provision for chargebacks and rebates as of December 31, 2019 and 2018, $15.4 million and $12.0 million were included in accounts receivable, net, on the consolidated balance sheets, respectively. The remaining provision as of December 31, 2019 and 2018 was $6.2 million and $10.4 million, respectively, which were included in accounts payable and accrued liabilities, respectively.

Accrual for Product Returns

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

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The provision for product returns is reflected as a component of net revenues. The following table is an analysis of the product return liability:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Beginning balance	$ 8,030	$ 6,522
Provision for product returns	7,305	4,149
Credits issued to third parties	(4,996)	(2,641)
Ending balance	$ 10,339	$ 8,030

Of the provision of product returns as of December 31, 2019 and 2018, $7.1 million and $5.3 million were included in accounts payable and accrued liabilities on the consolidated balance sheets, respectively. The remaining provision of $3.2 million and $2.7 million were included in other long-term liabilities, respectively. For the years ended December 31, 2019 and 2018, the Company's aggregate product return rate was 1.1% and 1.3% of qualified sales, respectively.

Note 5. Income (Loss) per Share Attributable to Amphastar Pharmaceuticals, Inc. Shareholders

Basic net income (loss) per share attributable to Amphastar Pharmaceuticals Inc. shareholders is calculated based upon the weighted-average number of shares outstanding during the period. Diluted net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders gives effect to all potential dilutive shares outstanding during the period, such as stock options, non-vested restricted stock units, and shares issuable under the Company's Employee Stock Purchase Plan, or ESPP and to the reallocation of net income attributable to non-controlling interest from the assumed dilutive effect of stock options issued under the 2018 ANP Equity Incentive Plan, or the 2018 Plan.

For the year ended December 31, 2019, options to purchase 803,257 shares of stock with a weighted-average exercise price of $21.99 per share, and the reallocation of net income attributable to non-controlling interests were excluded in the computation of diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. shareholders because the effect would be anti-dilutive.

As the Company reported a net loss for the year ended December 31, 2018, the diluted net loss per share attributable to Amphastar Pharmaceuticals, Inc. shareholders, as reported, equals the basic net loss per share attributable to Amphastar Pharmaceuticals, Inc. shareholders since the effect of the assumed exercise of stock options, vesting of non-vested RSUs, and issuance of common shares under the Company's ESPP are anti-dilutive. Total stock options, non-vested RSUs, and shares issuable under the Company's ESPP excluded from the year ended December 31, 2018, net loss per share were 10,105,565 stock options, 1,206,661 non-vested RSUs, and 51,792 shares issuable under the ESPP.

For the year ended December 31, 2017, options to purchase 839,651 shares of stock with a weighted-average exercise price of $26.43 per share, were excluded in the computation of diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. shareholders because the effect from the assumed exercise of these options would be anti-dilutive.

AMPHASTAR PHARMACEUTICALS, INC.
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The following table provides the calculation of basic and diluted net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders for each of the periods presented:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands, except per share data)		
Basic and dilutive numerator:			
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 48,939	$ (5,738)	$ 3,647
Denominator:			
Weighted-average shares outstanding — basic	46,982	46,395	46,107
Net effect of dilutive securities:			
Incremental shares from equity awards	2,925	—	2,260
Weighted-average shares outstanding — diluted	49,907	46,395	48,367
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders — basic	$ 1.04	$ (0.12)	$ 0.08
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders — diluted	$ 0.98	$ (0.12)	$ 0.08

Note 6. Segment Reporting

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

- Finished pharmaceutical products
- API

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

AMPHASTAR PHARMACEUTICALS, INC.
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Selected financial information by reporting segment is presented below:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Net revenues:			
Finished pharmaceutical products	$ 302,000	$ 271,059	$ 230,139
API	20,357	23,607	10,036
Total net revenues	322,357	294,666	240,175
Gross profit:			
Finished pharmaceutical products	136,576	113,220	96,517
API	(4,653)	(6,235)	(6,008)
Total gross profit	131,923	106,985	90,509
Operating expenses	131,962	115,608	91,778
Loss from operations	(39)	(8,623)	(1,269)
Non-operating income (expense)	60,267	(1,303)	2,518
Income (loss) before income taxes	$ 60,228	$ (9,926)	$ 1,249

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

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

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Finished pharmaceutical products net revenues:			
Lidocaine	$ 46,013	$ 43,328	$ 37,602
Phytonadione	45,786	41,897	37,946
Enoxaparin	42,695	53,371	36,593
Naloxone	34,761	37,195	42,342
Medroxyprogesterone	27,850	24,071	—
Primatene® Mist	18,065	3,574	—
Epinephrine	13,885	10,055	25,914
Other finished pharmaceutical products	72,945	57,568	49,742
Total finished pharmaceutical products net revenues	$ 302,000	$ 271,059	$ 230,139

The amount of depreciation and amortization expense included in cost of revenues, by reporting segments is presented below:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Depreciation and amortization expense			
Finished pharmaceutical products	$ 5,581	$ 4,872	$ 5,338
API	1,477	1,181	1,081
Total depreciation and amortization expense	$ 7,058	$ 6,053	$ 6,419

AMPHASTAR PHARMACEUTICALS, INC.
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Discontinuation of Epinephrine Injection, USP Vial Product

In February 2017, the U.S. Food and Drug Administration, or FDA, requested the Company to discontinue the manufacturing and distribution of its epinephrine injection, USP vial product, which had been marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. The Company discontinued selling this product in the second quarter of 2017. For the year ended December 31, 2017, the Company recognized $17.8 million in net revenues for the sale of this product.

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

	Net Revenue Year Ended December 31,			Long-Lived Assets December 31,	
	2019	2018	2017	2019	2018
	(in thousands)				
United States	$ 304,896	$ 279,122	$ 234,321	$ 108,399	$ 109,331
China	1,481	—	—	79,846	58,059
France	15,980	15,544	5,854	45,611	43,028
United Kingdom	—	—	—	—	—
Total	$ 322,357	$ 294,666	$ 240,175	$ 233,856	$ 210,418

Note 7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc., or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. The Company considers these three customers to be its major customers, as each individually and these customers collectively, represented a significant percentage of the Company's net revenue for the years ended December 31, 2019, 2018, and 2017, and accounts receivable as of December 31, 2019 and 2018, respectively. The following table provides accounts receivable and net revenue information for these major customers:

	% of Total Accounts Receivable		% of Net Revenue Year Ended December 31,		
	December 31, 2019	December 31, 2018	2019	2018	2017
McKesson	34 %	28 %	25 %	27 %	27 %
AmerisourceBergen	13 %	19 %	24 %	27 %	28 %
Cardinal Health	17 %	21 %	22 %	21 %	23 %

Supplier Concentrations

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

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Note 8. Fair Value Measurements

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

- *Level 1* – Inputs to measure fair value are based on quoted prices (unadjusted) in active markets on identical assets or liabilities;
- *Level 2* – Inputs to measure fair value are based on the following: a) quoted prices in active markets on similar assets or liabilities, b) quoted prices for identical or similar instruments in inactive markets, or c) observable (other than quoted prices) or collaborated observable market data used in a pricing model from which the fair value is derived; and
- *Level 3* – Inputs to measure fair value are unobservable and the assets or liabilities have little, if any, market activity; these inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on best information available in the circumstances.

As of December 31, 2019, cash equivalents include money market accounts. Short-term investments consist of certificates of deposit as well as investment-grade corporate bonds with original expiration dates within 12 months. The certificates of deposit are carried at amortized cost in the Company's consolidated balance sheet, which approximates their fair value determined based on Level 2 inputs. The corporate bonds are classified as held-to-maturity and are carried at amortized cost, which approximates their fair value determined based on Level 2 inputs. The restrictions on restricted cash and short-term investments have a negligible effect on the fair value of these financial assets.

The fair value of the Company's financial assets and liabilities measured on a recurring basis as of December 31, 2019 and 2018, are as follows:

	Total	(Level 1)	(Level 2)	(Level 3)
	(in thousands)			
Cash equivalents - money market	$ 29,521	$ 29,521	$ —	$ —
Restricted cash - money market	1,865	1,865	—	—
Short-term investments - certificates of deposit	8,867	—	8,867	—
Restricted short-term investments - certificates of deposit	2,290	—	2,290	—
Corporate bonds	2,789	—	2,789	—
Fair value measurement as of December 31, 2019	$ 45,332	$ 31,386	$ 13,946	$ —
Cash equivalents - money market	$ 40,907	$ 40,907	$ —	$ —
Restricted cash - money market	1,865	1,865	—	—
Short-term investments - certificates of deposit	2,831	—	2,831	—
Restricted short-term investments - certificates of deposit	2,290	—	2,290	—
Fair value measurement as of December 31, 2018	$ 47,893	$ 42,772	$ 5,121	$ —

The Company does not hold any Level 3 instruments that are measured for fair value on a recurring basis.

Nonfinancial assets and liabilities are not measured at fair value on a recurring basis but are subject to fair value adjustments in certain circumstances. These items primarily include long-lived assets, goodwill, and intangible assets for which the fair value of assets is determined as part of the related impairment test. As of December 31, 2019 and 2018, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

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Note 9. Investments

A summary of the Company's investments that are classified as held-to-maturity are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Corporate bonds	$ 2,790	$ —	$ (1)	$ 2,789
Total investments as of December 31, 2019	$ 2,790	$ —	$ (1)	$ 2,789

The Company believes that the unrealized losses disclosed above were primarily driven by interest rate changes rather than by unfavorable changes in the credit ratings associated with these securities and as a result, the Company continues to expect to collect the principal and interest due on its debt securities that have an amortized cost in excess of fair value. At each reporting period, the Company evaluates securities for impairment when the fair value of the investment is less than its amortized cost. The Company evaluated the underlying credit quality and credit ratings of the issuers, noting neither a significant deterioration since purchase nor any other factors that would lead us to believe that any impairment is not temporary.

Note 10. Goodwill and Intangible Assets

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

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	9,226	3,152	6,074
Patents	12	486	255	231
Land-use rights	39	2,540	551	1,989
Other intangible assets	4	69	69	—
Subtotal	12	12,321	4,027	8,294
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,634	—	3,634
Subtotal	*	32,859	—	32,859
As of December 31, 2019	*	$45,180	$ 4,027	$41,153

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	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
Cortrosyn® product rights	12	$ 27,134	$ 27,134	$ —
IMS (UK) international product rights	10	8,911	2,153	6,758
Patents	12	486	213	273
Land-use rights	39	2,540	486	2,054
Other intangible assets	4	69	63	6
Subtotal	12	39,140	30,049	9,091
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,951	—	3,951
Subtotal	*	33,176	—	33,176
As of December 31, 2018	*	$ 72,316	$ 30,049	$ 42,267

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

Sale of Fourteen Injectable ANDAs

In February 2017, the Company sold the 14 ANDAs it acquired in March 2016 from Hikma to an unrelated party. The consideration included a purchase price of $6.4 million of which $1.0 million was received upon closing, $1.0 million was received in the second quarter of 2017 and the remaining $4.4 million was received in January 2018. In addition to the purchase price, the purchaser agreed to pay the Company a royalty fee equal to 2% of net sales derived from purchaser's sales of the products for the period from February 2017 through February 2027. The Company has not recognized any royalty fee revenue. The Company recognized a gain of $2.6 million within operating (income) expenses on its consolidated statement of operations for the year ended December 31, 2017.

Goodwill

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

	December 31, 2019	December 31, 2018
	(in thousands)	
Beginning balance	$ 3,951	$ 4,461
Currency translation	(317)	(510)
Ending balance	$ 3,634	$ 3,951

Primatene® Trademark

In January 2009, the Company acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene® Mist, an over-the-counter bronchodilator product, recorded at the allocated fair value of $29.2 million, which is its carrying value as of December 31, 2019.

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

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As a result of environmental concerns about chlorofluorocarbons, or CFCs, the FDA required the CFC formulation of Primatene® Mist to be phased out on December 31, 2011.

In 2013, the Company filed a new drug application, or NDA, for Primatene® Mist, which utilizes a non-CFC propellant. In November 2018, the FDA granted over-the-counter approval of the NDA for Primatene® Mist, and the Company re-launched this product in December 2018.

Amortization

Included in cost of revenues for the years ended December 31, 2019, 2018 and 2017 is product rights amortization expense of $1.0 million, $1.8 million, and $2.7 million, respectively.

As of December 31, 2019, the expected amortization expense for all amortizable intangible assets during the next five fiscal years ended December 31 and thereafter is as follows:

	(in thousands)
2020	$ 1,031
2021	1,031
2022	1,011
2023	1,002
2024	1,002
Thereafter	3,217
Total amortizable intangible assets	8,294
Indefinite-lived intangibles	32,859
Total intangibles (net of accumulated amortization)	$ 41,153

Note 11. Inventories

Inventories consist of the following:

	December 31,	
	2019	2018
	(in thousands)	
Raw materials and supplies	$ 59,233	$ 30,153
Work in process	35,548	30,272
Finished goods	15,720	8,897
Total inventories	$ 110,501	$ 69,322

Charges of $9.4 million, $12.9 million, and $8.5 million were included in the cost of revenues in the Company's consolidated statements of operations for the years ended December 31, 2019, 2018, and 2017, respectively, to adjust the Company's inventory and related purchase commitments to their net realizable value. For the year ended December 31, 2019, the charge included $5.8 million as a result of an increase in purchases of higher price heparin. For the year ended December 31, 2018, the charge included $9.1 million related to enoxaparin inventory due to a decrease in the forecasted average selling price. For the year ended December 31, 2017, the charge included $5.5 million related to enoxaparin inventory due to a decrease in the forecasted average selling price.

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Note 12. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	December 31,	
	2019	2018
	(in thousands)	
Buildings	$ 117,928	$ 96,287
Leasehold improvements	29,531	26,755
Land	7,603	7,628
Machinery and equipment	164,802	143,299
Furniture, fixtures, and automobiles	22,043	19,151
Construction in progress	56,354	66,390
Total property, plant, and equipment	398,261	359,510
Less accumulated depreciation	(164,405)	(149,092)
Total property, plant, and equipment, net	$ 233,856	$ 210,418

The Company incurred depreciation expense of $17.1 million, $14.5 million, and $13.0 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Interest expense capitalized was approximately $2.3 million, $2.2 million, and $1.1 million, for the years ended December 31, 2019, 2018, and 2017, respectively.

Note 13. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	December 31,	
	2019	2018
	(in thousands)	
Accrued customer fees and rebates	$ 9,633	$ 15,215
Accrued payroll and related benefits	21,872	19,430
Accrued product returns, current portion	7,126	5,349
Accrued loss on firm purchase commitments	3,352	5,355
Other accrued liabilities	10,007	10,746
Total accrued liabilities	51,990	56,095
Accounts payable	25,061	31,323
Total accounts payable and accrued liabilities	$ 77,051	$ 87,418

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Note 14. Debt

Debt consists of the following:

	December 31,	
	2019	2018
	(in thousands)	
Loans with East West Bank		
Equipment loan paid off January 2019	$ —	$ 128
Line of credit facility due December 2020	—	—
Mortgage payable due February 2021	3,401	3,491
Equipment loan due June 2021	1,837	3,061
Equipment loan due December 2022	6,000	8,000
Line of credit facility due February 2024	3,570	—
Mortgage payable due October 2026	3,400	3,463
Mortgage payable due June 2027	8,659	8,801
Loans with Cathay Bank		
Line of credit facility due May 2020	—	—
Mortgage payable due August 2027	7,452	7,627
Acquisition loan due June 2024	10,928	13,025
Loans with Bank of Nanjing		
Working capital loan paid off June 2019	—	347
Loans with Seine-Normandie Water Agency		
French government loan due June 2020	28	55
French government loan due July 2021	114	172
French government loans due December 2026	374	436
Payment Obligation to Merck	561	552
Equipment under Finance Leases	811	—
Equipment under Capital Leases	—	1,055
Total debt	47,135	50,213
Less current portion of long-term debt	7,741	18,229
Long-term debt, net of current portion	$ 39,394	$ 31,984

Loans with East West Bank

Equipment Loan—Paid off January 2019

In July 2013, the Company entered into an $8.0 million line of credit facility. In January 2015, the Company drew down $6.2 million from the line of credit facility. Subsequently, the facility was converted into a term equipment loan with an outstanding principal balance of $6.2 million and a maturity date of January 2019. Borrowings under the facility were secured by equipment. In January 2019, the Company repaid all outstanding amounts due under this loan.

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Line of Credit Facility—Due December 2020

In March 2012, the Company entered into a $10.0 million line of credit facility, which bears a variable interest rate at the prime rate as published by *The Wall Street Journal*. Borrowings under the facility are secured by inventory and accounts receivable. In March 2016, the facility was amended to increase the line of credit to $15.0 million. This facility matured in December 2018.

In January 2019, the Company amended the facility to extend the maturity date to December 2020. As of December 31, 2019, the Company did not have any amounts outstanding under this facility.

Mortgage Payable—Due February 2021

The Company refinanced the mortgage term loan in January 2016, which had an outstanding principal balance of $3.7 million at December 31, 2015, and a maturity date of February 2021. The refinanced loan is payable in monthly installments with a final balloon payment of $3.3 million. The refinanced loan is secured by one of the buildings at the Company's Rancho Cucamonga, California, headquarters complex. The refinanced loan has a variable interest rate at the prime rate as published by *The Wall Street Journal*. As of December 31, 2019, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. The Company has entered into a fixed interest rate swap contract on this loan to exchange the variable interest rate for a fixed interest rate of 4.39% over the life of the loan without the exchange of the underlying notional debt amount. The interest rate swap contract does not qualify for hedge accounting, and is recorded at fair value for an immaterial amount based on Level 2 inputs.

Equipment Loan–Due June 2021

In March 2016, the Company entered into a $5.0 million equipment credit facility. In May 2017, the Company converted the outstanding balance of $5.0 million into a term equipment loan that matures in June 2021. Borrowings under the loan are secured by equipment. The loan bears a variable interest rate at the prime rate as published by *The Wall Street Journal*. As of December 31, 2019, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. The Company has entered into a fixed interest rate swap contract on this facility to exchange the variable interest rate for a fixed interest rate of 4.86% over the life of the facility without the exchange of the underlying notional debt amount. The interest rate swap contract does not qualify for hedge accounting and is recorded at fair value for an immaterial amount based on Level 2 inputs.

Equipment Loan—Due December 2022

In June 2017, the Company entered into an $8.0 million equipment credit line with an 18-month draw down period. Interest payments are due monthly through December 2018 at the prime rate as published by *The Wall Street Journal*. After the draw down period, the outstanding principal balance converts into a 48-month term loan which bears a variable interest rate at the prime rate as published by *The Wall Street Journal*. The loan matures in December 2022, and the principal and interest payments are due monthly. Borrowings under the facility are secured by equipment.

In June 2018, the Company drew down $8.0 million on the equipment credit line and in December 2018, the credit line converted into an equipment loan. As of December 31, 2019, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. The Company entered into a fixed interest rate swap contract on this facility to exchange the variable interest rate for a fixed interest rate of 5.87% over the life of the facility without the exchange of the underlying notional debt amount. The interest rate swap contract does not qualify for hedge accounting and is recorded at fair value of approximately $0.1 million based on Level 2 inputs.

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Equipment credit line—Due February 2024

In January 2019, the Company entered into a $10.0 million equipment credit line with East West Bank which has a 12-month draw down period. Interest payments are due monthly through February 2020 at the prime rate as published by *The Wall Street Journal* minus 1%. After the draw down period, the outstanding principal balance converts into a 48-month term loan which bears a variable interest rate at the prime rate as published by *The Wall Street Journal* minus 1%. The loan matures in February 2024, and the principal and interest payments are due monthly. Borrowings under the facility are secured by equipment. As of December 31, 2019, the Company has drawn $3.6 million from the equipment line of credit.

Subsequently, in January 2020, the Company drew an additional $3.0 million on the equipment credit line and in February 2020, the credit line converted into a $6.6 million equipment loan. The Company entered into a fixed interest rate swap contract on this facility to exchange the variable interest rate for a fixed interest rate of 3.85% over the life of the facility without the exchange of the underlying notional debt amount. The interest rate swap contract does not qualify for hedge accounting and will be recorded at fair value based on Level 2 inputs.

Mortgage Payable—Due October 2026

In September 2006, the Company entered into a mortgage term loan in the principal amount of $2.8 million, which matured in September 2016. The Company refinanced the mortgage term loan in September 2016, which increased the principal amount to $3.6 million and extended the maturity date to October 2026. The refinanced loan is payable in monthly installments with a final balloon payment of $2.9 million. The refinanced loan was secured by one of the buildings at the Company's Rancho Cucamonga, California, headquarters complex. The refinanced loan bears a variable interest rate at the one-month LIBOR rate plus 2.75%. As of December 31, 2019, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. Subsequently, the Company entered into a fixed interest rate swap contract on this loan to exchange the variable interest rate for a fixed interest rate of 4.15% until October 2021 without the exchange of the underlying notional debt amount. The interest rate swap contract does not qualify for hedge accounting, and is recorded at fair value for an immaterial amount based on Level 2 inputs.

Mortgage Payable—Due June 2027

In May 2017, the Company entered into a mortgage term loan in the principal amount of $9.0 million, which matures in June 2027. The loan is payable in monthly installments with a final balloon payment of $7.4 million plus interest. The loan is secured by one of the buildings at the Company's Rancho Cucamonga, California, headquarters complex and two buildings at the Company's Chino, California, facility. The loan bears a variable interest rate at the one-month LIBOR rate plus 2.5%. As of December 31, 2019, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. The Company entered into a fixed interest rate swap contract on this loan to exchange the variable interest rate for a fixed interest rate of 4.79% until June 2024 without the exchange of the underlying notional debt amount. The interest rate swap contract does not qualify for hedge accounting, and is recorded at fair value of approximately $0.3 million based on Level 2 inputs.

Loans with Cathay Bank

Line of Credit Facility—Due May 2020

In April 2012, the Company entered into a $20.0 million revolving line of credit facility. Borrowings under the facility are secured by inventory, accounts receivable, and intangibles held by the Company. The facility bears a variable interest rate at the prime rate as published by *The Wall Street Journal* with a minimum interest rate of 4.00%. In July 2018, the Company amended the facility to extend the maturity date from May 2018 to May 2020. As of December 31, 2019, the Company did not have any amounts outstanding under this facility.

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Mortgage Payable—Due August 2027

In August 2017, the Company refinanced the mortgage term loan that had been entered into on April 2014, with a principal balance outstanding of $7.9 million. The loan is payable in monthly installments and is secured by the building at the Company's Canton, Massachusetts location. The loan bears interest at a fixed rate of 4.70% for the first five years of the loan; thereafter, the loan bears a variable interest rate at the prime rate as published by *The Wall Street Journal* and matures in June 2027. As of December 31, 2019, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

Acquisition Loan with Cathay Bank—Due June 2024

On April 22, 2014, in conjunction with the Merck API Transaction, the Company entered into a secured term loan with Cathay Bank as lender. The principal amount of the loan was $21.9 million and had a variable interest rate at the prime rate as published by *The Wall Street Journal*, with a minimum interest rate of 4.00%. The loan was secured by 65% of the issued and outstanding shares of stock in AFP and certain assets of the Company, including accounts receivable, inventory, certain investment property, goods, deposit accounts, and general intangibles but not including the Company's equipment and real property.

In July 2019, the Company amended the acquisition loan relating to the AFP acquisition. The amendment was effective in June 2019. Under the amended loan agreement, the maturity date was extended to June 2024. The acquisition loan bears a variable interest rate at the prime rate as published by *The Wall Street Journal*, with a minimum interest rate of 5.00%. Beginning in August 2019, and through the maturity date, the Company must make monthly payments of principal and interest based on the then outstanding amount of the loan amortized over a 60-month period. As of December 31, 2019, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

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

Loan with Bank of Nanjing

Working Capital Loan —Paid off June 2019

In June 2018, the Company entered into a working capital loan of $1.5 million. The loan had a variable interest rate at the benchmark interest rate of the People's Bank of China. Interest payments were due monthly. In June 2019, the Company repaid all outstanding amounts due under this loan.

Loans with Seine-Normandie Water Agency

In January 2015, the Company entered into three French government loans with the Seine-Normandie water agency in the aggregate amount of $0.7 million. The loans have maturities that range between three to six years, include annual equal payments and bears no interest.

In December 2018, the Company entered into two additional French government loans with the Seine-Normandie water agency in the aggregate amount $0.5 million. The loans have 8 year lives, and include annual equal payments and bear no interest.

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As of December 31, 2019, the payment obligation had an aggregate book value of $0.5 million, which approximates fair value. The fair value of the payment obligation was determined by using the interest rate associated with the Company's acquisition loan with Cathay Bank that bears a variable interest rate at the prime rate as published by *The Wall Street Journal*, with a minimum interest rate of 4.00%. Such interest rate is deemed to be a Level 2 input for measuring fair value.

Payment Obligation to Merck

On April 30, 2014, in conjunction with the Company's acquisition of Merck Sharpe & Dohme's, API manufacturing business in Éragny-sur-Epte, France, or the Merck API Transaction, the Company entered into a commitment obligation with Merck, in the principal amount of $16.0 million. The terms of the purchase price include annual payments over four years and bear a fixed interest rate of 3.00%.

As of December 31, 2019, the payment obligation had a balance of $0.6 million, which approximates fair value. The fair value of the payment obligation was determined by using the interest rate associated with the Company's acquisition loan with Cathay Bank that bears a variable interest rate at the prime rate as published by *The Wall Street Journal*, with a minimum interest rate of 4.00%. Such interest rate is deemed to be a Level 2 input for measuring fair value.

Covenants

At December 31, 2019 and 2018, the Company was in compliance with its debt covenants, which include profitability, a minimum current ratio, minimum debt service coverage, minimum tangible net worth, maximum debt-to-effective-tangible-net-worth ratio, and minimum deposit requirement computed on a consolidated basis.

Long-Term Debt Maturities

As of December 31, 2019, the principal amounts of long-term debt maturities during each of the next five fiscal years ending December 31 are as follows:

	Long-term Debt
	(in thousands)
2020	$ 7,376
2021	9,674
2022	5,839
2023	3,985
2024	2,025
Thereafter	17,425
	$ 46,324

Note 15. Income Taxes

The Tax Cuts and Jobs Act, or the Tax Act, was enacted on December 22, 2017. The Tax Act, among other things, reduced the statutory U.S. federal corporate income tax rate from 35% to 21% and required companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred. As of December 31, 2017, the Company recorded a provisional expense amount of $0.6 million related to the remeasurement of certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. During the year ended December 31, 2018, the Company completed its determination of the accounting implications of the Tax Act resulting in no material changes to the provisional amounts recorded as of December 31, 2017.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Income (loss) before income taxes:			
United States	$ 77,092	$ 3,580	$ 6,892
Foreign	(16,864)	(13,506)	(5,643)
Total income (loss) before taxes	$ 60,228	$ (9,926)	$ 1,249

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

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Current provision (benefit):			
Federal	$ 4,283	$ 32	$ (6,380)
State	430	343	133
Foreign	1,514	773	643
Total current provision (benefit)	6,227	1,148	(5,604)
Deferred provision (benefit):			
Federal	9,825	(687)	6,340
State	499	(3,900)	(2,169)
Foreign	(2,828)	173	(965)
Total deferred provision (benefit)	7,496	(4,414)	3,206
Total provision (benefit) for income taxes	$ 13,723	$ (3,266)	$ (2,398)

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

	Year Ended December 31,		
	2019	2018	2017
Statutory federal income tax (benefit)	21.0 %	21.0 %	35.0 %
State tax expense, net of federal tax benefit	1.2	28.3	(106.0)
Foreign tax rate differences	1.2	4.0	3.9
Foreign valuation allowance	2.5	(42.0)	129.1
Qualified production activities deduction	—	—	89.6
Research and development credits	(4.8)	28.0	(250.1)
Share-based compensation	(1.5)	5.1	(166.2)
Executive compensation	2.9	(12.4)	17.1
Deferred tax remeasurement	—	1.0	49.5
Employee-related expenses	0.2	(0.4)	6.3
Other	0.1	0.3	(0.2)
Effective tax rate (benefit)	22.8 %	32.9 %	(192.0)%

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards, and the tax effects of net operating loss carryforwards.

AMPHASTAR PHARMACEUTICALS, INC.
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The significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2019	2018
	(in thousands)	
Deferred tax assets:		
Research and development credits	$ 18,603	$ 22,690
Net operating loss carryforward	10,782	9,951
Inventory capitalization and reserve	8,518	6,212
Share-based compensation	6,390	6,162
Operating leases	4,741	—
Accrued expenses	4,153	4,149
Accrued chargebacks	3,729	3,103
Product return allowance	2,835	2,314
Intangibles	2,124	2,124
Other	85	1,741
Total deferred tax assets	61,960	58,446
Deferred tax liabilities:		
Depreciation/amortization	11,528	9,684
Intangibles	6,743	6,303
Operating leases	4,571	—
Federal impact of state deferred taxes	3,674	3,769
Total deferred tax liabilities	26,516	19,756
Valuation allowance	(10,438)	(9,103)
Net deferred tax assets	$ 25,006	$ 29,587

Effective January 1, 2017, the Company adopted ASU No. 2016-09, under which differences between the tax deduction for share-based awards and the related compensation expenses recognized under ASC 718 are prospectively accounted for as a component of the provision for income taxes. In addition, ASU No. 2016-09 eliminated the requirement that excess tax benefits from share-based compensation reduce taxes payable prior to being recognized in the financial statements. As a result of the adoption of ASU No. 2016-09, the cumulative excess benefits of stock compensation of $0.9 million that was not previously recognized was established on the balance sheet resulting in an increase in deferred tax assets and retained earnings.

Effective January 1, 2018, the Company adopted ASU No. 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, pursuant to which the income tax consequences of intra-entity transfer of an asset other than inventory is required to be recognized in the period in which the transfer occurs. The Company adopted the standard on a modified retrospective basis resulting in an increase of deferred tax assets and the beginning balance of retained earnings by $0.5 million, respectively.

Net Operating Loss Carryforwards and Tax Credits

At December 31, 2019, the Company had approximately $1.6 million California net operating loss carryforwards, or NOL carryforwards, and no material U.S. federal or other state NOL carryforwards. The California NOL carryforwards begin to expire in 2031. The Company had foreign NOL carryforwards of approximately $42.9 million which can be used annually with certain limitations and have an indefinite carryforward period.

At December 31, 2019, the Company had federal and California research and development tax credit carryforwards of approximately $3.8 million and $20.0 million, respectively. The federal research and development tax credit begins to expire in 2040. The California research and development tax credit has an indefinite carryforward period.

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

Valuation Allowance

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

As of December 31, 2015, the Company assessed the realizability of the deferred tax assets of AFP and determined that it was not more likely than not that the net deferred tax assets of AFP would be realized. Therefore, the Company established a full valuation allowance as of December 31, 2015. The Company has discontinued recognizing AFP income tax benefits until it is determined that it is more likely than not that AFP will generate sufficient taxable income to realize its deferred income tax assets. As of December 31, 2019 and 2018, the Company had a full valuation allowance against the net deferred tax assets of AFP, which totaled $10.4 million and $9.1 million, respectively.

Undistributed Earnings from Foreign Operations

As of December 31, 2019 and 2018, deferred income taxes have not been provided on foreign operations. The foreign subsidiaries have accumulated losses of approximately $44.9 million and $30.7 million, respectively, and as such there are no earnings in which to provide taxes. It is the Company's plan not to repatriate future foreign earnings to the U.S.

Uncertain Income Tax Positions

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

	December 31,		
	2019	2018	2017
	(in thousands)		
Balance at the beginning of the year	$ 6,994	$ 7,438	$ 6,686
Deductions based on tax positions related to prior years	—	(1,566)	—
Additions based on tax positions related to the current year	1,382	1,304	1,300
Deductions based on tax audit settlement	(45)	(126)	—
Deductions based on statute of limitations	—	(56)	(548)
Balance at the end of the year	$ 8,331	$ 6,994	$ 7,438

Included in the balance of unrecognized tax benefits as of December 31, 2019, was $8.1 million that represents the portion that would impact the effective income tax rate if recognized. During the year ended December 31, 2018, the Company reduced unrecognized tax benefits for tax positions related to prior years by $1.6 million and for tax audit settlement by $0.1 million as the result of a state tax audit resolution.

The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax provision. For the years ended December 31, 2019 and 2018, the Company recognized accrued interest of approximately $0.3 million and $0.1 million, respectively, related to its uncertain tax positions.

The Company and/or one or more of its subsidiaries filed income tax returns in the U.S. federal jurisdiction and various U.S. states and foreign jurisdictions. In June 2017, the Internal Revenue Service, or IRS, commenced an audit of the Company's 2015 income tax return. In February 2018, the IRS completed the examination resulting in no changes to reported tax. In August 2011, the California Franchise Tax Board commenced an audit of the Company's 2007, 2008,

and 2009 tax returns. In June 2018, the Franchise Tax Board completed the examination resulting in no material tax liability. The Company is subject to income tax audit by tax authorities for tax years 2016 to 2018 for federal, 2015 to 2018 for states and 2009 to 2018 for foreign.

Note 16. Stockholders' Equity

Common and Preferred Stock

The Company's Certificate of Incorporation, as amended and restated in June 2014 in connection with the closing of its initial public offering, authorizes the Company to issue 300,000,000 shares of common stock, $0.0001 par value per share, and 20,000,000 shares of preferred stock, $0.0001 par value per share. As of December 31, 2019 and 2018, there were no shares of preferred stock issued or outstanding.

Equity Plans

As of December 31, 2019, the Company has two equity plans: the 2015 Equity Incentive Plan, or 2015 Plan, and the 2014 Employee Stock Purchase Plan or ESPP. Prior to the adoption of these plans, the Company granted options pursuant to the Amended and Restated 2005 Equity Incentive Award Plan and the 2002 Amended and Restated Stock Option/Stock Issuance Plan. Upon termination of the predecessor plans, the shares available for grant at the time of termination, and shares subsequently returned to the plans upon forfeiture or option termination, were transferred to the successor plan in effect at the time of share return. The Company issues new shares of common stock upon exercise of stock options, vesting of restricted stock units, or RSU, and settlement of ESPP, with the exception of the awards granted to employees at AFP, which are settled through re-issuance of the Company's treasury shares.

The 2015 Equity Incentive Plan

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

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

As of December 31, 2019, the Company reserved an aggregate of 6,213,797 shares of common stock for future issuance under the 2015 Plan. In January 2020, an additional 1,164,425 shares were reserved under the 2015 Plan pursuant to the evergreen provision.

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Amended and Restated 2005 Equity Incentive Award Plan

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

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

2014 Employee Stock Purchase Plan

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

As of December 31, 2019, the Company has issued 659,535 shares of common stock under the ESPP and 1,340,465 shares of its common stock remains available for issuance under the ESPP.

For the year ended December 31, 2019, 2018, and 2017, the Company recorded ESPP expense of $0.7 million, $0.7 million, and $0.6 million, respectively.

Share Buyback Program

In November 2014, the Company's Board of Directors authorized a $10.0 million share buyback program, which was completed in December 2015. In November 2015, the Company's Board of Directors authorized an additional $10.0 million to the Company's share buyback program, which was completed in December 2016. In November 2016, the Company's Board of Directors authorized an increase of $20.0 million to the Company's share buyback program, which was completed in August 2017. In August 2017, the Company's Board of Directors authorized an additional $20.0 million to the Company's share buyback program, which was completed in April 2018. In May 2018, the Company's Board of Directors authorized an increase of $20.0 million to the Company's share buyback program, which was completed in April 2019. In May 2019, the Company's Board of Directors authorized an increase of $20.0 million to the Company's share buyback program, which was completed in January 2020. In November 2019, the Company's Board of Directors authorized an increase of $20.0 million to the Company's share buyback program, which is expected to continue for an indefinite period of time. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

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

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Pursuant to the Company's share buyback program, the Company purchased 1,122,781 shares, 1,414,924 shares, and 1,905,653, shares of its common stock during the years ended December 31, 2019, 2018 and 2017, totaling $22.3 million, $25.0 million, and $30.7 million, respectively.

Share-Based Award Activity and Balances (excluding the ANP Equity Plan)

The Company accounts for share-based compensation payments in accordance with ASC 718, which requires measurement and recognition of compensation expense at fair value for all share-based payment awards made to employees and directors. Under these standards, the fair value of option awards and the option components of the ESPP awards are estimated at the grant date using the Black-Scholes option-pricing model. The fair value of RSUs is estimated at the grant date using the Company's common share price. Prior to the adoption of ASU No. 2018-07, *Improvements to Non-employees Share-Based Payment Accounting*, non-vested stock options held by non-employees are revalued at each balance sheet date. As a result of the Company's early adoption of the guidance on July 1, 2018, stock options held by non-employees are no longer revalued after grant. The portion that is expected to vest is amortized and recognized in compensation expense on a straight-line basis over the requisite service period, generally from the grant date to the vesting date.

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

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

- *Determination of Fair Value of the Underlying Common Stock.* For options and ESPP awards granted after the completion of the Company's initial public offering, the fair value for its underlying common stock is determined using the closing price on the date of grant as reported on the Nasdaq Global Select Market, or Nasdaq. For awards issued prior to the listing of our common stock on Nasdaq, the fair value of the common stock utilized in the fair value estimation of award arrangements has been determined by our board of directors, utilizing contemporaneous third-party valuations. Following the listing of our common stock on Nasdaq, we use the closing stock price as reported on Nasdaq on the grant date for the fair value of its stock.

- *Expected Volatility.* The Company has limited data regarding company-specific historical or implied volatility of its share price. Consequently, the Company estimates its volatility based on the weighted average historical volatility of our stock price since IPO and the stock price from a set of peer companies, since our shares do not have sufficient trading history. Management considers factors such as stage of life cycle, competitors, size, market capitalization and financial leverage in the selection of similar entities.

- *Expected Term.* The expected term represents the period of time in which the options granted are expected to be outstanding. The Company estimates the expected term of options with consideration of vesting date, contractual term, and historical experience for exercise and post-vesting employment or contractual termination behavior after its common stock has been publicly traded. The expected term of "plain vanilla" options is estimated based on the midpoint between the vesting date and the end of the contractual term under the simplified method permitted by the SEC implementation guidance. The weighted-average expected term of the Company's options is approximately five years.

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

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

The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual experience differs from those estimates. For the years ended December 31, 2019, 2018 and 2017, the Company estimated an average overall forfeiture rate of 5%, 5%, and 7%, respectively, based on historical experience. Forfeiture rates are separately estimated for its (1) directors and officers, (2) management personnel and (3) other employees. Share-based compensation is recorded net of expected forfeitures. The Company periodically assesses the forfeiture rate and the amount of expense recognized based on estimated historical forfeitures as compared to actual forfeitures. Changes in estimates are recorded in the period they are identified.

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

The weighted-averages for key assumptions used in determining the fair value of options granted during the years ended December 31, 2019, 2018, and 2017 are as follows:

	Year Ended December 31,		
	2019	2018	2017
Average volatility	42.5 %	39.9 %	37.0 %
Risk-free interest rate	2.4 %	2.7 %	2.1 %
Weighted-average expected life in years	5.7	5.7	5.5
Dividend yield rate	— %	— %	— %

Stock Options

A summary of option activity under all plans for the year ended December 31, 2019, is presented below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value[1] (in thousands)
Outstanding as of December 31, 2018	10,105,565	$ 14.69		
Options granted	1,059,964	20.98		
Options exercised	(1,297,533)	15.10		
Options cancelled	(11,630)	17.84		
Options expired	(92,881)	20.12		
Outstanding as of December 31, 2019	9,763,485	$ 15.26	4.74	$ 42,388
Exercisable as of December 31, 2019	7,016,352	$ 14.15	3.69	$ 36,438

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the Company's common stock for those awards that have an exercise price below the estimated fair value at December 31, 2019.

During the years ended December 31, 2019, 2018, and 2017, the Company recorded expense of $8.1 million, $8.2 million, and $8.6 million, respectively, related to stock options granted under all plans.

AMPHASTAR PHARMACEUTICALS, INC.
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Information relating to option grants and exercises is as follows:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands, except per share data)		
Weighted-average grant date fair value per option share	$ 8.48	$ 7.80	$ 4.98
Intrinsic value of options exercised	7,718	7,372	17,247
Cash received from options exercised	7,761	11,753	19,098
Total fair value of the options vested during the year	7,613	7,972	7,263

A summary of the status of the Company's non-vested options as of December 31, 2019, and changes during the year ended December 31, 2019, are presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2018	3,279,026	$ 5.47
Options granted	1,059,964	8.48
Options vested	(1,580,227)	4.82
Options forfeited	(11,630)	7.58
Non-vested as of December 31, 2019	2,747,133	6.99

As of December 31, 2019, there was $11.9 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.2 years and will be adjusted for future changes in estimated forfeitures.

Restricted Stock Units

The Company grants restricted stock units, or RSUs, to certain employees and members of the Board of Directors with a vesting period of up to five years. The grantee receives one share of common stock at a specified future date for each RSU awarded. The RSUs may not be sold or otherwise transferred until certificates of common stock have been issued, recorded, and delivered to the participant. The RSUs do not have any voting or dividend rights prior to the issuance of certificates of the underlying common stock. The share-based expense associated with these grants was based on the Company's common stock fair value at the time of grant and is amortized over the requisite service period, which generally is the vesting period, using the straight-line method. During the years ended December 31, 2019, 2018, and 2017, the Company recorded expenses of $8.2 million, $7.7 million, and $7.9 million, respectively, related to RSU awards granted under all plans.

As of December 31, 2019, there was $12.9 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.2 years and will be adjusted for future changes in estimated forfeitures.

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Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued as Compensation[1]
		(in thousands)
RSUs outstanding at December 31, 2018	1,206,661	
RSUs granted	443,082	$ 8,983
RSUs forfeited	(6,747)	
RSUs vested[2]	(543,500)	
RSUs outstanding at December 31, 2019	1,099,496	

(1) The total FMV is derived from the number of RSUs granted times the current stock price on the date of grant.
(2) Of the vested RSUs, 238,690 shares of common stock were surrendered to fulfil tax withholding obligations

The 2018 ANP Equity Incentive Plan

In December 2018, ANP's board of directors approved the 2018 Plan, which is set to expire in December 2023. The 2018 Plan permits the grant of stock options and other equity awards in ANP shares to ANP employees. In June 2019, ANP issued 3,648,932 stock options to its employees under the 2018 Plan all of which were still outstanding at December 31, 2019. The options vest over a period of approximately four years and have up to a 10 year contractual term. The total fair value of the options awarded was $2.1 million. For the year ended December 31, 2019, the Company recorded expense of $0.3 million related to stock options issued by ANP under the 2018 Plan, respectively.

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

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Cost of revenues	$ 3,819	$ 3,923	$ 3,756
Operating expenses:			
Selling, distribution, and marketing	387	383	302
General and administrative	11,538	10,853	11,643
Research and development	1,551	1,521	1,386
Total share-based compensation	$ 17,295	$ 16,680	$ 17,087

Note 17. Employee Benefits

401(k) Plan

The Company has a defined contribution 401(k) plan, or the Plan, whereby eligible employees voluntarily contribute up to a defined percentage of their annual compensation. The Company matches contributions at a rate of 50% on the first 6% of employee contributions, and pays the administrative costs of the Plan. Total employer contributions for the years ended December 31, 2019, 2018, and 2017 were approximately $1.5 million, $1.3 million, and $1.1 million, respectively.

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Defined Benefit Pension Plan

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

The liability under the plan is based on a discount rate of 0.90% and 1.70% as of December 31, 2019 and 2018, respectively. The liability is included in accrued liabilities in the accompanying consolidated balance sheets. The plan is currently unfunded, and the benefit obligation under the plan was $2.4 million and $2.2 million at December 31, 2019 and 2018, respectively. Expense under the plan was $0.2 million, $0.3 million, and $0.2 million for the years ended December 31, 2019, 2018, and 2017, respectively. Gain or loss due to change in actuarial valuation of the Company's defined benefit pension plan is recorded in other comprehensive income (loss).

Deferred Compensation Plan

In December 2019, the Company established a non-qualified deferred compensation plan. The deferred compensation plan allows certain eligible participants to defer a portion of their cash compensation and provides a matching contribution at the discretion of the Company. The plan obligations are payable upon retirement, termination of employment and/or certain other times in a lump-sum distribution or in installments, as elected by the participant in accordance with the plan. Participants can allocate their deferred compensation amongst various investment options with earnings accruing to the participant. The Company has established a Rabbi Trust to fund the plan obligations and to hold the plan assets. Eligible participants can begin making contributions to the plan in January 2020.

Note 18. Commitments and Contingencies

Lease Liabilities

On January 1, 2019, the Company adopted ASC 842, which resulted in the recognition of right-of-use, or ROU, assets of approximately $13.9 million and related lease liabilities of approximately $14.1 million in the consolidated balance sheet as of December 31, 2019, related to its operating lease commitments. ROU assets represent the Company's right to control an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As most of its leases do not provide an implicit rate, the Company used its incremental borrowing rate based on the information available at the commencement date in determining the discount rate used to present value the lease payments. The Company leases real and personal property, in the normal course of business, under various non-cancelable operating leases. The Company, at its option, can renew a substantial portion of its leases, at the market rate, for various renewal periods ranging from one to six years.

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The components of lease costs for the year ended December 31, 2019 were as follows:

	Year Ended December 31, 2019
Operating lease costs	$ 3,981
Short-term lease costs	613
Finance lease costs	
Amortization of right-of-use assets	351
Interest on lease liabilities	46
Total finance lease costs	$ 397
Total lease costs	$ 4,991

Other information pertaining to leases is as follows:

	Year Ended December 31, 2019 (in thousands, except lease term and discount rate)
Supplemental cash flow information	
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows from operating leases	$ 3,531
Operating cash flows from finance leases	46
Financing cash flows from finance leases	354
Right-of use assets obtained in exchange for lease liabilities	
Operating leases	7,978
Finance leases	143
Weighted-average remaining lease term (years)	
Operating leases	8.1
Finance leases	2.8
Weighted-average discount rate	
Operating leases	5.9 %
Finance leases	4.6 %

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Future minimum rental payments under leases that have initial or remaining non-cancelable lease terms in excess of 12 months as of December 31, 2019, are as follows:

	Operating Leases	Finance Leases	Total
	(in thousands)		
2020	$ 4,239	$ 311	$ 4,550
2021	4,405	315	4,720
2022	3,688	192	3,880
2023	2,475	31	2,506
2024	1,611	20	1,631
Thereafter	8,555	6	8,561
Total lease payments	$ 24,973	$ 875	$ 25,848
Less: interest	5,483	64	5,547
Total	$ 19,490	$ 811	$ 20,301

Purchase Commitments

As of December 31, 2019, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $38.0 million. The Company anticipates that most of these commitments with a remaining term in excess of one year will be fulfilled by 2021.

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

In accordance with certain agreements between ANP and the Chinese government, in January 2010 and November 2012, the Company acquired certain land-use rights for $1.2 million and $1.3 million, respectively. As required by these agreements, the Company committed to spend approximately $15.0 million in the related land development, which primarily includes the construction of fixed assets according to a specific timetable. As of December 31, 2019, the Company has spent $13.5 million on such construction. The Company anticipates that this spending commitment will be met by the end of 2020.

Note 19. Related-Party Transactions

ANP Private Placement

As discussed in footnote 2, in July 2018, ANP completed a private placement of its common equity interest and received approximately $56.3 million of cash proceeds. In connection with the private placement, all of the executive officers of the Company, Stephen Shohet, Howard Lee, and Richard Koo, directors of the Company, and certain employees of ANP entered into subscription agreements (each, a "Subscription Agreement") for the indirect investment in ANP. These Subscription Agreements were transacted either through an investment in Amphastar Cayman, a Cayman Islands limited liability company, or Qianqia or Zhongpan, Chinese partnerships. The aggregate gross proceeds received from management and directors were approximately $29.7 million.

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Note 20. Litigation

Momenta/Sandoz Enoxaparin Patent and Antitrust Litigation

In September 2011, Momenta Pharmaceuticals, Inc., or Momenta, a Boston based pharmaceutical company, and Sandoz Inc., or Sandoz, the generic division of Novartis, initiated litigation against the Company for alleged patent infringement of two patents related to testing methods for batch release of enoxaparin, which the Company refers to as the "'886 patent" and the "'466 patent." The lawsuit was filed in the United States District Court for the District of Massachusetts, or the Massachusetts District Court.

On September 17, 2015, the Company initiated an antitrust lawsuit by filing a complaint in the California District Court against Momenta and Sandoz, or the Defendants. The Company's complaint generally asserted that Defendants had engaged in certain types of illegal, monopolistic, and anticompetitive conduct giving rise to various causes of action against them. This lawsuit was subsequently transferred to the Massachusetts District Court.

On May 20, 2019, the Company and the Plaintiffs entered into a Settlement Agreement to fully settle the patent litigation and antitrust litigation. The Settlement Agreement was contingent upon the District Court's granting a Joint Motion to Vacate the Patent Judgment and thereafter, the Plaintiffs' payment of $59.9 million to the Company. On June 18, 2019, the parties filed a Joint Motion to Vacate the Patent Judgment with the District Court, and on the same day, the District Court granted such motion. Accordingly, on June 19, 2019, the parties filed Joint Stipulations with the District Court to dismiss the patent litigation and the antitrust litigation, each of which is self-executing and effective upon filing pursuant to the Federal Rules of Civil Procedure 41(a)(1)(A)(ii). Furthermore, on June 26, 2019, the Federal Circuit issued an Order and a Mandate dismissing the appeal of the patent litigation. On June 27, 2019, pursuant to the Settlement Agreement, the Plaintiffs paid the Company $59.9 million. The Company is not entitled to future rights or royalties related to this settlement. Accordingly, the Company recorded the settlement amount as other income (expenses), in its consolidated statements of operations.

False Claims Act Litigation

In January 2009, the Company filed a qui tam complaint in the U.S. District Court for the Central District of California, or the California District Court, alleging that Aventis Pharma S.A., or Aventis, through its acquisition of a patent through false and misleading statements to the U.S. Patent and Trademark Office, as well as through false and misleading statements to the FDA, overcharged the federal and state governments for its Lovenox® product.

On May 11, 2017, the Company's lawsuit against Aventis was dismissed for lack of jurisdiction. On July 14, 2017, Aventis filed an application with the District Court for entitlement to attorneys' fees and expenses. On November 20, 2017, the District Court issued its order granting Aventis' application for fees, stating that it would refer the matter to a magistrate judge for a report and recommendation regarding the amount of the award to be made.

On February 12, 2019, the District Court approved of the parties' consent for the Magistrate Judge to conduct all further proceedings in this matter at the district court level, including determining the amount of attorneys' fees to be awarded and entering a final judgment. The Magistrate Judge held a hearing on the Application on May 8, 2019. At the May 8, 2019 hearing, the Magistrate Judge did not rule on the Application, but indicated that a written opinion on this Application for Fees and Expenses would be forthcoming. The Company intends to continue to vigorously defend against any imposition of attorneys' fees and expenses in this case.

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Epinephrine (0.1 mg/mL) Patent Litigation

On June 28, 2018, Belcher Pharmaceuticals, LLC, or Belcher initiated a lawsuit in the United States District Court for the District of Delaware by filing a complaint against IMS for infringement of U.S. Patent No. 9,283,197 (the "197 Patent") with regard to IMS's New Drug Application No. 211363, filed under 21 U.S.C. § 355(b)(2) of the Hatch-Waxman Act, for FDA approval to manufacture and sell 0.1 mg/mL epinephrine injections. On July 3, 2019, Parties filed a Joint Stipulation to stay the litigation pending the Court's ruling on the outcome of Belcher's trial with Hospira. On August 19, 2019, the judge signed the order staying the litigation pending the Court's ruling on the outcome of Belcher's trial with Hospira. The Company intends to vigorously defend this lawsuit.

Vasopressin (20 units/mL) Patent Litigation

On December 20, 2018, Par Pharmaceutical, Inc., Par Sterile Products, LLC and Endo Par Innovation Company (collectively, "Par") initiated a patent lawsuit by filing a Complaint against the Company in the United States District Court for the District of Delaware for infringement of U.S. Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent"), 9,744,209 ("the '209 Patent"), 9,744,239 ("the '239 Patent"), 9,750,785 ("the '785 Patent") and 9,937,223 ("the '223 Patent") (collectively, "Par Patents") with regard to the Company's Abbreviated New Drug Application No. 211,857 for FDA approval to manufacture and sell Vasopressin (20 units/ mL). The Company filed its Answer to this Complaint on February 19, 2019. On April 18, 2019, the Court held a scheduling conference and entered a Scheduling Order.

On September 27, 2019, the Court entered a Revised Scheduling Order that consolidates the Company's vasopressin patent lawsuit with two other vasopressin patent lawsuits filed by Par in the same Court, Par v. Amneal Pharmaceuticals GMBH et al., and Par v. American Regent, Inc. (collectively, the "Consolidated Vasopressin Patent Lawsuits"). In the Revised Scheduling Order, trial is still scheduled for January 2021 and the Company's 30-month FDA stay is maintained at May 21, 2021. On the same day, the Court entered a Protective Order on the Consolidated Vasopressin Patent Lawsuits. On December 9, 2019, the Court entered a Second Revised Scheduling Order to include Fresenius Kabi USA, LCC as part of the Consolidated Vasopressin Patent Lawsuit, with trial still scheduled for January 2021 and the Company's 30-month FDA stay still maintained at May 21, 2021. The Company intends to vigorously defend this patent lawsuit.

Regadenoson (0.4 mg/5 mL, 0.08 mg/mL) Patent Litigation

On February 25, 2020, Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. (collectively, "Astellas-Gilead") initiated a patent lawsuit by filing a Complaint in the United States District Court for the District of Delaware against IMS for infringement of U.S. Patent Nos. 8,106,183 (the "'183 patent"), RE47,301 (the "'301 patent"), and 8,524,883 (the "'883 patent") (collectively, "Astellas-Gilead Patents") with regard to IMS's Abbreviated New Drug Application No. 214,252 for FDA approval to manufacture and sell 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of Regadenoson. On March 4, 2020, IMS filed its Answer to the Complaint and its Counterclaims. The Company intends to vigorously defend this patent lawsuit.

Employment Litigation

On September 11, 2019, a former employee ("Plaintiff") initiated an employment litigation against IMS et al. by filing a Complaint having individual and class action claims for alleged violations of various California labor laws pertaining to wage and hour, and other state laws (collectively, "First Employment Litigation"). This Complaint was filed in the Superior Court of California. On September 18, 2019, Plaintiff filed a First Amended Complaint. Status Conference is set for April 17, 2020, because the Parties have scheduled mediation on April 3, 2020.

On January 21, 2020, Plaintiff filed a Second Amended Complaint that alleges only Private Attorney General Act, Or PAGA, claims. On February 24, 2020, IMS filed an Answer to the Second Amended Complaint.

AMPHASTAR PHARMACEUTICALS, INC.
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Additionally, on February 14, 2020, the Plaintiff filed another Complaint against IMS in the Superior Court of California alleging various individual claims relating to disability discrimination and retaliation. The Company intends to vigorously defend these Employment Litigations.

Other Litigation

The Company is also subject to various other claims and lawsuits from time to time arising in the ordinary course of business.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. In the opinion of management, the ultimate resolution of any such matters is not expected to have a material adverse effect on its financial position, results of operations, or cash flows; however, the results of litigation and claims are inherently unpredictable and the Company's view of these matters may change in the future. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

Note 21. Quarterly Financial Data (Unaudited)

	2019 Quarters			
	First	Second[1]	Third	Fourth
	(in thousands, except per share data)			
Net revenues				
Finished pharmaceutical products	$ 74,539	$ 73,735	$ 75,729	$ 77,997
API	5,251	5,312	4,408	5,386
Total net revenues	$ 79,790	$ 79,047	$ 80,137	$ 83,383
Gross profit				
Finished pharmaceutical products	$ 32,312	$ 34,540	$ 34,992	$ 34,732
API	(1,409)	(2,153)	260	(1,351)
Total gross profit	$ 30,903	$ 32,387	$ 35,252	$ 33,381
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 868	$ 47,787	$ 1,310	$ (1,026)
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:				
Basic	46,744	47,107	47,239	46,840
Diluted	50,416	49,894	50,075	46,840
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:				
Basic	$ 0.02	$ 1.01	$ 0.03	$ (0.02)
Diluted	$ 0.02	$ 0.96	$ 0.03	$ (0.02)

(1) Includes the patent and antitrust litigation settlement (see note 20)

AMPHASTAR PHARMACEUTICALS, INC.
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	2018 Quarters			
	First	Second	Third	Fourth
	(in thousands, except per share data)			
Net revenues				
Finished pharmaceutical products	$ 53,117	$ 63,241	$ 71,767	$ 82,934
API	5,276	7,799	3,776	6,756
Total net revenues	$ 58,393	$ 71,040	$ 75,543	$ 89,690
Gross profit				
Finished pharmaceutical products	$ 19,636	$ 27,649	$ 30,571	$ 35,364
API	(2,664)	(1,585)	(1,311)	(675)
Total gross profit	$ 16,972	$ 26,064	$ 29,260	$ 34,689
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ (7,141)	$ (2,853)	$ 2,389	$ 1,867
Weighted-average shares used to compute net income per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:				
Basic	46,514	46,557	46,241	46,268
Diluted	46,514	46,557	48,281	49,181
Net income per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:				
Basic	$ (0.15)	$ (0.06)	$ 0.05	$ 0.04
Diluted	$ (0.15)	$ (0.06)	$ 0.05	$ 0.04

Net income (loss) per share amounts for the fiscal quarters have been calculated independently and may not in the aggregate equal the amount for the full year.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of senior management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on the evaluation under that framework and applicable SEC rules, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Our internal control over financial reporting as of December 31, 2019 has been audited by Ernst & Young, LLP, an independent registered public accounting firm, as stated in their report appearing below.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management overriding of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Amphastar Pharmaceuticals, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Amphastar Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework (the COSO criteria). In our opinion, Amphastar Pharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Amphastar Pharmaceuticals, Inc. as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated March 16, 2020 expressed an unmodified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Irvine, California
March 16, 2020

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be included in our Proxy Statement for our 2020 Annual Meeting of Stockholders to be filed within 120 days after our fiscal year end of December 31, 2019, or 2020 Proxy Statement, and is incorporated by reference into this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information required by this item will be included in our 2020 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be included in our 2020 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be included in our 2020 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services.

Information required by this item will be included in our 2020 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements filed as part of this report are listed in Part II, Item 8 of this report.

(2) No other financial schedules have been included because they are not applicable, not required or because required information is included in the consolidated financial statements or notes thereto.

(b)The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on July 1, 2014)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
4.2	Description of Securities Registered Under Section 12 of the Exchange Act
10.1+	Amended and Restated 2005 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.2+	Form of Stock Option Grant Notice and Stock Option Agreement under the Amended and Restated 2005 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.3+	Form of Deferred Stock Unit Notice of Grant and Deferred Stock Unit Agreement under the Amended and Restated 2005 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.4	Business Loan Agreement, dated December 31, 2010, between International Medication Systems, Limited and East West Bank, as amended (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.5	Revolving Loan and Security Agreement, dated April 10, 2012, between Amphastar Pharmaceuticals, Inc. and Cathay Bank (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.6	Business Loan Agreement, dated July 5, 2013, between International Medication Systems, Limited, Amphastar Pharmaceuticals, Inc. and East West Bank (incorporated by reference to Exhibit 10.10 the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.7◊	Transfer Contract for the Right to the Use of State-owned Land, dated December 29, 2009, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and Nanjing Xingang Hi-Tech Company Limited (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.8◊	Investment Agreement, dated July 5, 2010, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and the Management Committee of the Nanjing Economic and Technological Development Zone (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.9◊	Transfer Contract for the Right to the Use of State-owned Land, dated December 31, 2010, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and Nanjing Xingang Hi-Tech Company Limited. (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.10†	Long-Term Supply Agreement, dated November 30, 2008, between Qingdao Jiulong Biopharmaceutical Co., Ltd. and International Medication Systems, Limited (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)

10.11+	2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.12	Asset Purchase Agreement, dated April 30, 2014, among Diosynth France, Amphastar France Pharmaceuticals SAS and Schering-Plough (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.13	Loan Agreement, dated April 22, 2014, between Amphastar Pharmaceuticals, Inc. and Cathay Bank (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.14	Promissory Note, dated April 22, 2014, by Amphastar Pharmaceuticals, Inc. payable to Cathay Bank in the original principal sum of $21,900,000 (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.15+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Jack Zhang (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.16+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Mary Luo (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.17+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Jason Shandell (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.18+	Employment Agreement, dated March 11, 2014, between Amphastar Pharmaceuticals, Inc. and William Peters (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.19†	Supply Agreement, dated July 31, 2014, between MannKind Corporation and Amphastar France Pharmaceuticals, S.A.S. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014)
10.20	First Amendment to Supply Agreement, dated October 31, 2014, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014)
10.21+	2015 Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 1, 2015)
10.22	Business Loan Agreement, dated January 28, 2016, between Amphastar Pharmaceuticals, Inc. and East West Bank in the original principal sum of $3,724,841. (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2016)
10.23	Equipment Line of Credit Agreement, dated March 7, 2016, between International Medication Systems, Limited and East West Bank in the principal sum of $5,000,000. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2016)
10.24	Fifth Modification to the Revolving Line of Credit Agreement, dated March 7, 2016, between International Medication Systems, Limited and East West Bank in the principal sum of $15,000,000. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2016)
10.25	Fourth Modification to the Revolving Line of Credit Agreement, dated June 23, 2016, between Amphastar Pharmaceuticals, Inc. and Armstrong Pharmaceuticals, Inc. and Cathay Bank in the principal sum of $20,000,000. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2016)
10.26	Business Loan Agreement, dated September 8, 2016, between Amphastar Pharmaceuticals, Inc. and East West Bank in the original principal sum of $3,591,250. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2016)

10.27†	Second Amendment to Supply Agreement, dated November 9, 2016, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2017)
10.28	Business Loan Agreement, dated May 11, 2017, between International Medication Systems, Limited and East West Bank in the original principal sum of $5,000,000. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017)
10.29	Business Loan Agreement, dated May 18, 2017, between Amphastar Pharmaceuticals, Inc. and East West Bank in the original principal sum of $9,000,000. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017)
10.30	Sixth Modification to the Revolving Line of Credit Agreement, dated May 3, 2017, between International Medication Systems, Limited and East West Bank in the principal sum of $15,000,000. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017)
10.31	Equipment Line of Credit, dated June 28, 2017, between International Medication Systems, Limited and East West Bank in the original principal sum of $8,000,000. (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017)
10.32	Business Loan Agreement, dated August 14, 2017, between Armstrong Pharmaceuticals, Inc. and Cathay Bank in the original principal sum of $7,865,000. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2017)
10.33	Partnership Agreement by and between Zhang Chongqing, Bill Zhang and Applied Physics & Chemistry Laboratories, Inc. dated July 27, 2018. (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018)
10.34	Fourth Amendment to Supply Agreement, dated December 24, 2018, by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2018)
10.35	Equipment Line of Credit, dated January 8, 2019, between International Medication Systems, Limited and East West Bank in the original principal sum of $10,000,000. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2019)
10.36	First Modification to the Loan Agreement, dated April 22, 2019, between Amphastar Pharmaceuticals, Inc. and Cathay Bank. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2019)
10.37	Ninth Amendment to the Acquisition Loan, dated July 19, 2019 between Amphastar Pharmaceuticals, Inc. and Cathay Bank. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2019)
10.38*	Fifth Amendment to the Supply Agreement by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc., dated August 2, 2019. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2019)
10.39	Amphastar Pharmaceuticals, Inc. Employee Deferred Compensation Plan, effective December 1, 2019
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101.INS	XBRL Instance Document – The instance document does not appear in the interactive data file because its XBRL tags are embedded within the XBRL document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definitions Linkbase Document

The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act (including this Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

* Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10).

+ Indicates a management contract or compensatory plan or arrangement.

◊ English translation of original Chinese document.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and file separately with the SEC.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: **/s/ JACK Y. ZHANG**
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

Date: March 16, 2020

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: **/s/ WILLIAM J. PETERS**
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 16, 2020

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Jack Y. Zhang and William J. Peters, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated:

Signature	Title	Date
/s/ JACK Y. ZHANG Jack Yongfeng Zhang	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2020
/s/ MARY Z. LUO Mary Z. Luo	Chairman, Chief Operating Officer and Director	March 16, 2020
/s/ WILLIAM J. PETERS William J. Peters	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2020
/s/ JASON B. SHANDELL Jason B. Shandell	President and Director	March 16, 2020
/s/ RICHARD KOO Richard Koo	Director	March 16, 2020
/s/ HOWARD LEE Howard Lee	Director	March 16, 2020
/s/ FLOYD PETERSEN Floyd Petersen	Director	March 16, 2020
/s/ RICHARD PRINS Richard Prins	Director	March 16, 2020
/s/ DIANE G. GERST Diane G. Gerst	Director	March 16, 2020
/s/ MICHAEL A. ZASLOFF Michael A. Zasloff	Director	March 16, 2020

Exhibit 4.2

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following information describes our common stock and preferred stock, as well as certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws. This description is only a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which have been filed with the SEC as exhibits to this Annual Report on Form 10-K, as well as to applicable provisions of the Delaware General Corporation Law.

General

Our authorized capital stock consists of 320,000,000 shares of capital stock with a $0.0001 par value per share, of which 300,000,000 shares may be common stock and 20,000,000 shares may be preferred stock.

Common Stock

Each holder of our common stock is entitled to one vote for each share on all matters to be voted upon by the stockholders. Subject to any preferential rights of any outstanding preferred stock, holders of our common stock are entitled to receive ratably the dividends, if any, as may be declared from time to time by the board of directors out of funds legally available therefor. We do not currently pay a dividend on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in our assets remaining after the payment of liabilities and any preferential rights of any outstanding preferred stock.

Holders of our common stock have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Our common stock is listed on the Nasdaq Global Select Market under the symbol "AMPH." The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. There are no restrictions presently on the repurchase or redemption of any shares of our preferred stock.

Effect of Certain Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and the Delaware Anti-Takeover Statute

Some provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could make the following transactions more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or

- removal of our incumbent officers and directors.

Those provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids and to promote stability in our management. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our amended and restated certificate of incorporation and our amended and restated bylaws, as applicable, among other things:

- provide that our board is classified into three classes of directors, which may discourage a third party from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors;

- provide that special meetings of the stockholders may be called only by our chairman of the board, Chief Executive Officer, President, Chief Operating Officer, or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors of our board of directors;

- establish procedures with respect to stockholder proposals and stockholder nominations, including requiring that advance written notice of a stockholder proposal or director nomination generally must be received at our principal executive offices not less than 90 nor more than 120 days prior to the first anniversary of the previous year's annual meeting of stockholders;

- do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in the board of directors and, as a result, may have the effect of deterring a hostile takeover or delaying or preventing changes in control or management of our company;

- provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum, and not by the stockholders;

- require that the vote of holders of 66 2/3% of the voting power of the outstanding shares entitled to vote generally in the election of directors is required to amend various provisions of our amended and restated certificate of incorporation and amended and restated bylaws, including provisions relating to:

    - the number of directors on our board of directors;

    - the election, qualification and term of office of our directors;

    - filling vacancies on our board of directors;

    - the indemnification of our officers and directors;

    - removal of members of our board of directors; and

    - certain other provisions of our amended and restated certificate of incorporation and amended and restated bylaws;

- provide that no action may be effected by our stockholders by written consent, but must be effected at a duly-called annual or special meeting; and

- allow us to issue without stockholder approval up to 20,000,000 shares of undesignated preferred stock with rights senior to those of the common stock and that otherwise could adversely affect the rights and powers, including voting rights, of the holders of common stock. In some circumstances, this issuance could have the effect of decreasing the market price of the common stock as well as having the anti-takeover effect discussed above two-thirds of our outstanding capital stock entitled to vote generally in the election of directors.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not for determining the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers, and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock.

Exhibit 10.39

AMPHASTAR PHARMACEUTICALS, INC.
DEFERRED COMPENSATION PLAN

Effective Date
December 1, 2019

Amphastar Pharmaceuticals, Inc. Deferred Compensation Plan

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ARTICLE I
Establishment and Purpose

Amphastar Pharmaceuticals, Inc. (the "Company") has adopted this Amphastar Pharmaceuticals, Inc. Deferred Compensation Plan, applicable to Compensation deferred under Compensation Deferral Agreements submitted on and after the Effective Date and Company Contributions credited on or after the Effective Date.

The purpose of the Plan is to attract and retain key employees by providing them with an opportunity to defer receipt of a portion of their salary, bonus, and other specified compensation. The Plan is not intended to meet the qualification requirements of Code Section 401(a), but is intended to meet the requirements of Code Section 409A, and shall be operated and interpreted consistent with that intent.

The Plan constitutes an unsecured promise by a Participating Employer to pay benefits in the future. Participants in the Plan shall have the status of general unsecured creditors of the Company or the Participating Employer, as applicable. Each Participating Employer shall be solely responsible for payment of the benefits attributable to services performed for it. The Plan is unfunded for Federal tax purposes and is intended to be an unfunded arrangement for eligible employees who are part of a select group of management or highly compensated employees of the Employer within the meaning of Sections 201(2), 301(a)(3) and 401(a)(1) of ERISA and independent contractors. Any amounts set aside to defray the liabilities assumed by the Company or an Participating Employer will remain the general assets of the Company or the Participating Employer and shall remain subject to the claims of the Company's or the Participating Employer's creditors until such amounts are distributed to the Participants.

ARTICLE II
Definitions

2.1 Account. Account means a bookkeeping account maintained by the Committee to record the payment obligation of a Participating Employer to a Participant as determined under the terms of the Plan. The Committee may maintain an Account to record the total obligation to a Participant and component Accounts to reflect amounts payable at different times and in different forms. Reference to an Account means any such Account established by the Committee, as the context requires. Accounts are intended to constitute unfunded obligations within the meaning of Sections 201(2), 301(a)(3) and 401(a)(1) of ERISA.

2.2 Account Balance. Account Balance means, with respect to any Account, the total payment obligation owed to a Participant from such Account as of the most recent Valuation Date.

2.3 Affiliate. Affiliate means a corporation, trade or business that, together with the Company, is treated as a single employer under Code Section 414(b) or (c).

2.4 Beneficiary. Beneficiary means a natural person, estate, or trust designated by a Participant in accordance with Section 6.5 hereof to receive payments to which a Beneficiary is entitled in accordance with provisions of the Plan.

2.5 Board of Directors. Board of Directors means, for a Participating Employer organized as a corporation, its board of directors and for a Participating Employer organized as a limited liability company, its board of managers.

2.6 Business Day. Business Day means each day on which the New York Stock Exchange is open for business.

2.7 Change in Control. Change in Control means, with respect to a Participating Employer that is organized as a corporation, any of the following events: (i) a change in the ownership of the Participating Employer, (ii) a change in the effective control of the Participating Employer, or (iii) a change in the ownership of a substantial portion of the assets of the Participating Employer.

Change in Ownership. For purposes of this Section, a change in the ownership of the Participating Employer occurs on the date on which any one person, or more than one person acting as a group, acquires ownership of stock of the Participating Employer that, together with stock held by such person or group constitutes more than 50% of the total fair market value or total voting power of the stock of the Participating Employer. The acquisition by a person or group owning more than 50% of the total fair market value or total voting power of the stock of such Participating Employer of additional shares of such Participating Employer shall not constitute a "change of the ownership" of such Participating Employer.

Change in Effective Control. A change in the effective control of the Participating Employer occurs on the date on which either: (i) a person, or more than one person acting as a group, acquires ownership of stock of the Participating Employer possessing 30% or more of the total voting power of the stock of the Participating Employer, taking into account all such stock acquired during the 12-month period ending on the date of the most recent acquisition, provided that the acquisition by a person or group owning more than 30% of the total fair market value or total voting power of the stock of such Participating Employer of additional shares of such Participating Employer shall not constitute a "change of effective control" of such Participating Employer, or (ii) a majority of the members of the Participating Employer's Board of Directors is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of such Board of Directors prior to the date of the appointment or election, but only if no other corporation is a majority shareholder of the Participating Employer.

Change in Ownership of Substantial Portion of Assets. A change in the ownership of a substantial portion of assets occurs on the date on which any one person, or more than one person acting as a group, other than a person or group of persons that is related to the Participating Employer, acquires assets from the Participating Employer that have a total

gross fair market value equal to or more than 40% of the total gross fair market value of all of the assets of the Participating Employer immediately prior to such acquisition or acquisitions, taking into account all such assets acquired during the 12-month period ending on the date of the most recent acquisition. A transfer of assets shall not be treated as a "change in the ownership of a substantial portion of the assets" when such transfer is made to an entity that is controlled by the shareholders of the transferor corporation as determined under Treas. Reg. section 1.409A-3(i)(5)(vii)(B).

An event constitutes a Change in Control with respect to a Participant only if the Participant performs services for the Participating Employer that has experienced the Change in Control, or the Participant's relationship to the affected Participating Employer otherwise satisfies the requirements of Treasury Regulation Section 1.409A-3(i)(5)(ii).

Notwithstanding anything to the contrary herein, with respect to a Participating Employer that is a partnership or limited liability company, Change in Control means only a change in the ownership of such entity or a change in the ownership of a substantial portion of the assets of such entity, and the provisions set forth above respecting such changes relative to a corporation shall be applied by analogy. Any reference to a "majority shareholder" shall be treated as referring to a partner or member that (a) owns more than 50% of the capital and profits interest of such entity, and (b) alone or together with others is vested with the continuing exclusive authority to make management decisions necessary to conduct the business for which the partnership or limited liability company was formed.

2.8 Claimant. Claimant means a Participant or Beneficiary filing a claim under Article XI of this Plan.

2.9 Code. Code means the Internal Revenue Code of 1986, as amended from time to time.

2.10 Code Section 409A. Code Section 409A means section 409A of the Code, and regulations and other guidance issued by the Treasury Department and Internal Revenue Service thereunder.

2.11 Committee. Committee means the Company or a committee appointed by the Company to administer the Plan.

2.12 Company. Company means Amphastar Pharmaceuticals, Inc.

2.13 Company Contribution. Company Contribution means a credit by a Participating Employer to a Participant's Account(s) in accordance with the provisions of Article V of the Plan. Unless the context clearly indicates otherwise, a reference to Company Contribution shall include Earnings attributable to such contribution.

2.14 Compensation. Compensation means a Participant's salary, bonus, commission, and such other cash or equity-based compensation approved by the Committee as Compensation that may be deferred under Section 4.2 of this Plan, excluding any compensation that has

been previously deferred under this Plan or any other arrangement subject to Code Section 409A and excluding any compensation that is not U.S. source income.

2.15 Compensation Deferral Agreement. Compensation Deferral Agreement means an agreement between a Participant and a Participating Employer that specifies: (i) the amount of each component of Compensation that the Participant has elected to defer to the Plan in accordance with the provisions of Article IV, and (ii) the Payment Schedule applicable to one or more Accounts.

2.16 Deferral. Deferral means a credit to a Participant's Account(s) that records that portion of the Participant's Compensation that the Participant has elected to defer to the Plan in accordance with the provisions of Article IV. Unless the context of the Plan clearly indicates otherwise, a reference to Deferrals includes Earnings attributable to such Deferrals.

2.17 Earnings. Earnings means an adjustment to the value of an Account in accordance with Article VII.

2.18 Effective Date. Effective Date means December 1, 2019.

2.19 Eligible Employee. Eligible Employee means an Employee who is a member of a select group of management or highly compensated employees or an independent contractor who has been notified during an applicable enrollment of his or her status as an Eligible Employee. The Committee has the discretion to determine which Employees and independent contractors are Eligible Employees for each enrollment.

2.20 Employee. Employee means a common-law employee of an Employer.

2.21 Employer. Employer means the Company and each Affiliate.

2.22 ERISA. ERISA means the Employee Retirement Income Security Act of 1974, as amended from time to time.

2.23 Flex Account. Flex Account means a Separation Account or Specified Date Account established under the terms of a Participant's Compensation Deferral Agreement. Unless the Committee specifies otherwise, a Participant may maintain no more than five (5) Flex Accounts at any one time.

2.24 Participant. Participant means an individual described in Article III.

2.25 Participating Employer. Participating Employer means the Company and each Affiliate who has adopted the Plan with the consent of the Company. Each Participating Employer shall be identified on Schedule A attached hereto.

2.26 Payment Schedule. Payment Schedule. Payment Schedule means the date as of which payment of an Account will commence and the form in which payment of such Account

will be made under the terms of a payment election in effect for such Account under the terms of this Plan.

2.27 Performance-Based Compensation. Performance-Based Compensation means Compensation where the amount of, or entitlement to, the Compensation is contingent on the satisfaction of pre-established organizational or individual performance criteria relating to a performance period of at least 12 consecutive months. Organizational or individual performance criteria are considered pre-established if established in writing by not later than 90 days after the commencement of the period of service to which the criteria relate, provided that the outcome is substantially uncertain at the time the criteria are established. Performance-Based Compensation shall not include any Compensation payable upon the Participant's death or disability (as defined in Treas. Section 1.409A-1(e)) without regard to the satisfaction of the performance criteria.

2.28 Plan. Plan means "Amphastar Pharmaceuticals, Inc. Deferred Compensation Plan" as documented herein and as may be amended from time to time hereafter. However, to the extent permitted or required under Code Section 409A, the term Plan may in the appropriate context also means a portion of the Plan that is treated as a single plan under Treas. Reg. Section 1.409A-1(c), or the Plan or portion of the Plan and any other nonqualified deferred compensation plan or portion thereof that is treated as a single plan under such section.

2.29 Plan Year. Plan Year means January 1 through December 31.

2.30 Retirement Account. Retirement Account means an Account established by the Committee to record Company Contributions and Deferrals allocated to the Retirement Account pursuant to a Participant's Compensation Deferral Agreement, payable to a Participant upon Separation from Service in accordance with Section 6.3.

2.31 Separation Account. Separation Account means an Account established by the Committee in accordance with a Participant's Compensation Deferral Agreement to record Deferrals allocated to such Account by the Participant and which are payable upon the Participant's Separation from Service as set forth in Section 6.3. The Committee may limit the number of Separation Accounts that may be maintained at any one time by a Participant, as set forth in the Plan's enrollment materials.

2.32 Separation from Service. Separation from Service means an Employee's termination of employment with the Employer and all Affiliates.

Except in the case of an Employee on a bona fide leave of absence as provided below, an Employee is deemed to have incurred a Separation from Service if the Employer and the Employee reasonably anticipated that the level of services to be performed by the Employee after a date certain would be reduced to 20% or less of the average services rendered by the Employee during the immediately preceding 36-month period (or the total period of employment, if less than 36 months), disregarding periods during which the Employee was on a bona fide leave of absence.

An Employee who is absent from work due to military leave, sick leave, or other bona fide leave of absence shall incur a Separation from Service on the first date immediately following the later of: (i) the six month anniversary of the commencement of the leave, or (ii) the expiration of the Employee's right, if any, to reemployment under statute or contract.

If a Participant ceases to provide services as an Employee and begins providing services as an independent contractor for the Employer, a Separation from Service shall occur only if the parties anticipate that the level of services to be provided as an independent contractor are such that a Separation from Service would have occurred if the Employee had continued to provide services at that level as an Employee. If, in accordance with the preceding sentence, no Separation from Service occurs as of the date the individual's employment status changes, a Separation from Service shall occur thereafter only upon the 12-month anniversary of the date all contracts with the Employer have expired, provided the Participant does not perform services for the Employer during that time.

For purposes of determining whether a Separation from Service has occurred, the Employer means the Employer as defined in Section 2.21 of the Plan, except that in applying Code sections 1563(a)(1), (2) and (3) for purposes of determining whether another organization is an Affiliate of the Company under Code Section 414(b), and in applying Treasury Regulation Section 1.414(c)-2 for purposes of determining whether another organization is an Affiliate of the Company under Code Section 414(c), "at least 50 percent" shall be used instead of "at least 80 percent" each place it appears in those sections.

The Committee specifically reserves the right to determine whether a sale or other disposition of substantial assets to an unrelated party constitutes a Separation from Service with respect to a Participant providing services to the seller immediately prior to the transaction and providing services to the buyer after the transaction.

2.33 Specified Date Account. Specified Date Account means an Account established by the Committee to record the amounts payable in a future year as specified in the Participant's Compensation Deferral Agreement. The Committee may limit the number of Specified Date Accounts that may be maintained at any one time by a Participant, as set forth in the Plan's enrollment materials.

2.34 Substantial Risk of Forfeiture. Substantial Risk of Forfeiture has the meaning specified in Treas. Reg. Section 1.409A-1(d).

2.35 Unforeseeable Emergency. Unforeseeable Emergency means a severe financial hardship to the Participant resulting from an illness or accident of the Participant, the Participant's spouse, the Participant's dependent (as defined in Code section 152, without regard to section 152(b)(1), (b)(2), and (d)(1)(B)), or a Beneficiary; loss of the Participant's property due to casualty (including the need to rebuild a home following damage to a home not otherwise covered by insurance, for example, as a result of a natural disaster);

or other similar extraordinary and unforeseeable circumstances arising as a result of events beyond the control of the Participant. The types of events which may qualify as an Unforeseeable Emergency may be limited by the Committee.

2.36 Valuation Date. Valuation Date means each Business Day.

2.37. Years of Service. A Year of Service with respect to an Employee is each 12 month period of service with an Employer and all Affiliates, commencing on the Employee's hire date and each anniversary thereof.

ARTICLE III
Eligibility and Participation

3.1 Eligibility and Participation. All Eligible Employees may enroll in the Plan. Eligible Employees become Participants on the first to occur of (i) the date on which the first Compensation Deferral Agreement becomes irrevocable under Article IV, or (ii) the date Company Contributions are credited to an Account on behalf of such Eligible Employee.

3.2 Duration. Only Eligible Employees may submit Compensation Deferral Agreements during an enrollment and receive Company Contributions during the Plan Year. A Participant who is no longer an Eligible Employee but has not incurred a Separation from Service will not be allowed to submit Compensation Deferral Agreements but may otherwise exercise all of the rights of a Participant under the Plan with respect to his or her Account(s). On and after a Separation from Service, a Participant shall remain a Participant as long as his or her Account Balance is greater than zero (0). All Participants, regardless of employment status, will continue to be credited with Earnings and during such time may continue to make allocation elections as provided in Section 7.4. An individual shall cease being a Participant in the Plan when his Account has been reduced to zero (0).

3.3 Rehires. An Eligible Employee who Separates from Service and who subsequently resumes performing services for an Employer in the same calendar year (regardless of eligibility) will have his or her Compensation Deferral Agreement for such year, if any, reinstated, but his or her eligibility to participate in the Plan in years subsequent to the year of rehire shall be governed by the provisions of Section 3.1.

ARTICLE IV
Deferrals

4.1 Deferral Elections, Generally.

(a) An Eligible Employee may make an initial election to defer Compensation by submitting a Compensation Deferral Agreement during the enrollment periods established by the Committee and in the manner specified by the Committee, but in any event, in accordance with Section 4.2. Unless an earlier date is specified in the Compensation Deferral Agreement, deferral elections with respect to a

Compensation source (such as salary, bonus or other Compensation) become irrevocable on the latest date applicable to such Compensation source under Section 4.2.

(b) A Compensation Deferral Agreement that is not timely filed with respect to a service period or component of Compensation, or that is submitted by a Participant who Separates from Service prior to the latest date such agreement would become irrevocable under Section 409A, shall be considered null and void and shall not take effect with respect to such item of Compensation. The Committee may modify or revoke any Compensation Deferral Agreement prior to the date the election becomes irrevocable under the rules of Section 4.2.

(c) The Committee may permit different deferral amounts for each component of Compensation and may establish a minimum or maximum deferral amount for each such component. Unless otherwise specified by the Committee in the Compensation Deferral Agreement, Participants may defer up to (75%) of their base compensation and up to (100%) of bonus, commissions, or other Compensation earned during a Plan Year.

(d) Deferrals of cash Compensation shall be calculated with respect to the gross cash Compensation payable to the Participant prior to any deductions or withholdings, but shall be reduced by the Committee as necessary so as not to exceed 100% of the cash Compensation of the Participant remaining after deduction of all required income and employment taxes, required employee benefit deductions, deferrals to 401(k) plans and other deductions required by law. Changes to payroll withholdings that affect the amount of Compensation being deferred to the Plan shall be allowed only to the extent permissible under Code Section 409A.

(e) The Eligible Employee shall specify on his or her Compensation Deferral Agreement the amount of Deferrals and whether to allocate Deferrals to the Retirement Account or to one or more Flex Accounts. If no designation is made, Deferrals shall be allocated to the Retirement Account.

4.2 Timing Requirements for Compensation Deferral Agreements.

(a) *Initial Eligibility.* The Committee may permit an Eligible Employee to defer Compensation earned in the first year of eligibility. The Compensation Deferral Agreement must be filed within 30 days after attaining Eligible Employee status and becomes irrevocable not later than the 30th day.

A Compensation Deferral Agreement filed under this paragraph applies to Compensation earned after the date that the Compensation Deferral Agreement becomes irrevocable.

(b) *Prior Year Election.* Except as otherwise provided in this Section 4.2, the Committee may permit an Eligible Employee to defer Compensation by filing a

Compensation Deferral Agreement no later than December 31 of the year prior to the year in which the Compensation to be deferred is earned. A Compensation Deferral Agreement filed under this paragraph shall become irrevocable with respect to such Compensation not later than the December 31 filing deadline.

(c) *Performance-Based Compensation.* The Committee may permit an Eligible Employee to defer Compensation which qualifies as Performance-Based Compensation by filing a Compensation Deferral Agreement no later than the date that is six months before the end of the applicable performance period, provided that:

(i) the Participant performs services continuously from the later of the beginning of the performance period or the date the performance criteria are established through the date the Compensation Deferral Agreement is submitted; and

(ii) the Compensation is not readily ascertainable as of the date the Compensation Deferral Agreement is filed.

Any election to defer Performance-Based Compensation that is made in accordance with this paragraph and that becomes payable as a result of the Participant's death or disability (as defined in Treas. Reg. Section 1.409A-1(e)) or upon a change in control (as defined in Treas. Reg. Section 1.409A-3(i)(5)) prior to the satisfaction of the performance criteria, will be void unless it would be considered timely under another rule described in this Section.

(d) *Short-Term Deferrals.* The Committee may permit Compensation that meets the definition of a "short-term deferral" described in Treas. Reg. Section 1.409A-1(b)(4) to be deferred in accordance with the rules of Section 6.9, applied as if the date the Substantial Risk of Forfeiture lapses is the date payments were originally scheduled to commence, provided, however, that the provisions of Section 6.9(b) shall not apply to payments attributable to a change in control (as defined in Treas. Reg. Section 1.409A-3(i)(5)). A Compensation Deferral Agreement submitted in accordance with this paragraph becomes irrevocable on the latest date it could be submitted under Section 6.9.

(e) *Certain Forfeitable Rights.* With respect to a legally binding right to a payment in a subsequent year that is subject to a forfeiture condition requiring the Participant's continued services for a period of at least 12 months from the date the Participant obtains the legally binding right, the Committee may permit an Eligible Employee to defer such Compensation by filing a Compensation Deferral Agreement on or before the 30th day after the legally binding right to the Compensation accrues, provided that the Compensation Deferral Agreement is submitted at least 12 months in advance of the earliest date on which the forfeiture condition could lapse. The Compensation Deferral Agreement described in this paragraph becomes irrevocable not later than such 30th day. If

the forfeiture condition applicable to the payment lapses before the end of such 12-month period as a result of the Participant's death or disability (as defined in Treas. Reg. Section 1.409A-3(i)(4)) or upon a change in control (as defined in Treas. Reg. Section 1.409A-3(i)(5)), the Compensation Deferral Agreement will be void unless it would be considered timely under another rule described in this Section.

(f) *"Evergreen" Deferral Elections.* The Committee, in its discretion, may provide that Compensation Deferral Agreements will continue in effect for subsequent years or performance periods by communicating that intention to Participants in writing prior to the date Compensation Deferral Agreements become irrevocable under this Section 4.2. An evergreen Compensation Deferral Agreement may be revoked or modified in writing prospectively by the Participant or the Committee with respect to Compensation for which such election remains revocable under this Section 4.2.

A Compensation Deferral Agreement is deemed to be revoked for subsequent years if the Participant is not an Eligible Employee as of the last permissible date for making elections under this Section 4.2 or if the Compensation Deferral Agreement is cancelled in accordance with Section 4.6.

4.3 Allocation of Deferrals. A Compensation Deferral Agreement may allocate Deferrals to the Retirement Account or to one or more Flex Accounts. The Committee may, in its discretion, establish in a written communication during enrollment a minimum deferral period for the establishment of a Specified Date Account (for example, the second Plan Year following the year Compensation is first allocated to such Accounts). In the event a Participant's Compensation Deferral Agreement allocates a component of Compensation to a Specified Date Account that commences payment in the year such Compensation is earned, the Compensation Deferral Agreement shall be deemed to allocate the Deferral to the Participant's Specified Date Account having the next earliest payment year. If the Participant has no other Specified Date Accounts, the Committee will allocate the Deferral to the Retirement Account.

4.4 Deductions from Pay. The Committee has the authority to determine the payroll practices under which any component of Compensation subject to a Compensation Deferral Agreement will be deducted from a Participant's Compensation.

4.5 Vesting. Participant Deferrals of cash Compensation shall be 100% vested at all times. Deferrals of vesting awards of Compensation shall become vested in accordance with the provisions of the underlying award.

4.6 Cancellation of Deferrals. The Committee may cancel a Participant's Deferrals: (i) for the balance of the Plan Year in which an Unforeseeable Emergency occurs, (ii) if deferrals must be suspended under this Plan as a result of a hardship distribution under the Employer's 401(k) plan, through the end of the Plan Year containing the last day on which deferrals must be suspended in accordance with the Plan and regulations issued

under Code Section 401(k), and (iii) during periods in which the Participant is unable to perform the duties of his or her position or any substantially similar position due to a mental or physical impairment that can be expected to result in death or last for a continuous period of at least six months, provided cancellation occurs by the later of the end of the taxable year of the Participant or the 15th day of the third month following the date the Participant incurs the disability (as defined in this paragraph (iii)).

ARTICLE V
Company Contributions

5.1 Discretionary Company Contributions. A Participating Employer may, from time to time in its sole and absolute discretion, credit discretionary Company Contributions in the form of matching, profit sharing or other contributions to any Participant in any amount determined by the Participating Employer. Company Contributions are credited to the Participant's Retirement Account.

Make-Up Matching Contribution. Company Contributions may take the form of "make-up" matching contributions, at the same matching contribution rate provided under the Company 401(k) plan with respect to Deferrals that reduce 401(k) plan compensation below the limitation set forth in Code Section 401(a)(17).

Supplemental Matching Contribution. Company Contributions may take the form of "supplemental" matching contributions, at the same contribution rate provided under the Company 401(k) plan with respect to compensation deferred above the compensation limit set forth in Code Section 401(a)(17).

Discretionary Company Contribution. Discretionary Company Contributions are credited at the sole discretion of the Participating Employer and the fact that a discretionary Company Contribution is credited in one year shall not obligate the Participating Employer to continue to make such Company Contributions in subsequent years.

5.2 Vesting. Company Contributions vest according the schedule specified by the Committee on or before the time the contributions are made. Make-up and supplemental matching contributions vest at the same rate as matching contributions under the Company 401(k) plan.

Deferrals of equity-based Compensation will vest as provided under the terms of the applicable award.

All Company Contributions become 100% vested, if while employed by an Employer, a Participant dies, becomes disabled, his or her Employer experiences a change in control as determined by the Company or the Participant attains age 65. The Committee reserves the right to accelerate vesting to any Participant in any amount in its sole discretion.

ARTICLE VI
Payments from Accounts

6.1 General Rules. A Participant's Accounts become payable upon the first to occur of the payment events applicable to such Account under (i) Sections 6.2 or 6.3 (subject to retirement eligibility) and (ii) Sections 6.4 through 6.6.

Payment events and Payment Schedules elected by the Participant shall be set forth in a valid Compensation Deferral Agreement that establishes the Account to which such elections apply in accordance with Article IV or in a valid modification election applicable to such Account as described in Section 6.9.

Payment amounts are based on Account Balances as of the last Valuation Date of the month next preceding the month actual payment is made.

6.2 Specified Date Accounts.

Commencement. Payment is made or begins in the year designated by the Participant. The earliest payment year for a Specified Date Account is the second Plan Year after the Plan Year to which the Compensation Deferral Agreement that establishes the Account applies. If an earlier year is designated, the election will be deemed to have designated the second year.

Form of Payment. Payment will be made in a lump sum, unless the Participant elected to receive a designated number of annual installments up to 5 years.

The time and form of payment of Specified Date Accounts is unaffected by an earlier Separation from Service if Separation from Service occurs on or after the date the Participant attains age 55 and 10 Years of Service. If Separation from Service occurs prior to age 55 and 10 Years of Service, all unpaid Specified Date Accounts will be paid as provided in Section 6.3

6.3 Separation from Service. Upon a Participant's Separation from Service other than death, the Participant is entitled to receive his or her vested Retirement Account and Separation Accounts. If Separation from Service occurs before the Participant attains age 55 and 10 Years of Service, all unpaid Specified Date Accounts also will be paid as provided under this Section 6.3.

Commencement. The Retirement Account, all Separation Accounts and all Specified Date Accounts payable under this Section 6.3 commence payment in the calendar year next following the calendar year in which Separation from Service occurs.

A Participant may elect to commence payment from the Retirement Account or any Separation Account in a later calendar year (for example, the third calendar year after

Separation from Service). The election will apply only if the Participant's Separation from Service occurs on or after he date the Participant attains age 55 and 10 Years of Service.

Notwithstanding any other provision of this Plan, payment to a Participant who is a "specified employee" as defined in Code Section 409A(a)(2)(B) will commence no earlier than six months following his or her Separation from Service.

Form of Payment. The Retirement Account and Separation Accounts will be paid in a single lump sum unless the Participant elected with respect to an Account to receive a designated number of annual installments up to 15 years. A Participant's election to receive installment payments will apply only if the Participant's Separation from Service occurs on or after the date the Participant has attained age 55 and 10 Years of Service.

6.4 Death. Notwithstanding anything to the contrary in this Article VI, upon the death of the Participant (regardless of whether such Participant is an Employee at the time of death), all remaining vested Account Balances shall be paid to his or her Beneficiary in a single lump sum no later than December 31 of the calendar year following the year of the Participant's death.

(a) *Designation of Beneficiary in General*. The Participant shall designate a Beneficiary in the manner and on such terms and conditions as the Committee may prescribe. No such designation shall become effective unless filed with the Committee during the Participant's lifetime. Any designation shall remain in effect until a new designation is filed with the Committee; provided, however, that in the event a Participant designates his or her spouse as a Beneficiary, such designation shall be automatically revoked upon the dissolution of the marriage unless, following such dissolution, the Participant submits a new designation naming the former spouse as a Beneficiary. A Participant may from time to time change his or her designated Beneficiary without the consent of a previously-designated Beneficiary by filing a new designation with the Committee.

(b) *No Beneficiary*. If a designated Beneficiary does not survive the Participant, or if there is no valid Beneficiary designation, amounts payable under the Plan upon the death of the Participant shall be paid to the Participant's spouse, or if there is no surviving spouse, then to the duly appointed and currently acting personal representative of the Participant's estate.

6.5 Unforeseeable Emergency. A Participant who experiences an Unforeseeable Emergency may submit a written request to the Committee to receive payment of all or any portion of his or her vested Accounts. If the emergency need cannot be relieved by cessation of Deferrals to the Plan, the Committee may approve an emergency payment therefrom not to exceed the amount reasonably necessary to satisfy the need, taking into account the additional compensation that is available to the Participant as the result of cancellation of deferrals to the Plan, including amounts necessary to pay any taxes or penalties that the Participant reasonably anticipates will result from the payment. The amount of the

emergency payment shall be subtracted from the Separation Accounts and then from the Specified Date Accounts, starting with the Account having the latest commencement date until fully distributed, then continuing in this manner with the next latest Account until the full amount of the distribution is made. Emergency payments shall be paid in a single lump sum within the 90-day period following the date the payment is approved by the Committee. The Committee may specify that Deferrals will be distributed before any Company Contributions.

6.6 Administrative Cash-Out of Small Balances. Notwithstanding anything to the contrary in this Article VI, the Committee may at any time and without regard to whether a payment event has occurred, direct in writing an immediate lump sum payment of the Participant's Accounts if the balance of such Accounts, combined with any other amounts required to be treated as deferred under a single plan pursuant to Code Section 409A, does not exceed the applicable dollar amount under Code Section 402(g)(1)(B), provided any other such aggregated amounts are also distributed in a lump sum at the same time.

6.7 Acceleration of or Delay in Payments. Notwithstanding anything to the contrary in this Article VI, the Committee, in its sole and absolute discretion, may elect to accelerate the time or form of payment of an Account, provided such acceleration is permitted under Treas. Reg. Section 1.409A-3(j)(4). The Committee may also, in its sole and absolute discretion, delay the time for payment of an Account, to the extent permitted under Treas. Reg. Section 1.409A-2(b)(7).

6.8 Rules Applicable to Installment Payments. If a Payment Schedule specifies installment payments, payments will be made beginning as of the payment commencement date for such installments and shall continue to be made in each subsequent payment period until the number of installment payments specified in the Payment Schedule has been paid. The amount of each installment payment shall be determined by dividing (a) by (b), where (a) equals the Account Balance as of the last Valuation Date in the month preceding the month of payment and (b) equals the remaining number of installment payments. For purposes of Section 6.9, installment payments will be treated as a single payment. If an Account is payable in installments, the Account will continue to be credited with Earnings in accordance with Article VII hereof until the Account is completely distributed.

6.9 Modifications to Payment Schedules. A Participant may modify the Payment Schedule elected by him or her with respect to an Account, consistent with the permissible Payment Schedules available under the Plan for the applicable payment event, provided such modification complies with the requirements of this Section 6.9.

(a) *Time of Election*. The modification election must be submitted to the Committee not less than 12 months prior to the date payments would have commenced under the Payment Schedule in effect prior to modification (the "Prior Election").

(b) *Date of Payment under Modified Payment Schedule*. The date payments are to commence under the modified Payment Schedule must be no earlier than five

years after the date payment would have commenced under the Prior Election. Under no circumstances may a modification election result in an acceleration of payments in violation of Code Section 409A. If the Participant modifies only the form, and not the commencement date for payment, payments shall commence on the fifth anniversary of the date payment would have commenced under the Prior Election.

(c) *Irrevocability; Effective Date*. A modification election is irrevocable when filed and becomes effective 12 months after the filing date.

(d) *Effect on Accounts*. An election to modify a Payment Schedule is specific to the Account or payment event to which it applies, and shall not be construed to affect the Payment Schedules or payment events of any other Accounts.

ARTICLE VII
Valuation of Account Balances; Investments

7.1 Valuation. Deferrals shall be credited to appropriate Accounts on the date such Compensation would have been paid to the Participant absent the Compensation Deferral Agreement. Valuation of Accounts shall be performed under procedures approved by the Committee.

7.2 Earnings Credit. Each Account will be credited with Earnings on each Business Day, based upon the Participant's investment allocation among a menu of investment options selected in advance by the Committee, in accordance with the provisions of this Article VII ("investment allocation").

7.3 Investment Options. Investment options will be determined by the Committee. The Committee, in its sole discretion, shall be permitted to add or remove investment options from the Plan menu from time to time, provided that any such additions or removals of investment options shall not be effective with respect to any period prior to the effective date of such change.

7.4 Investment Allocations. A Participant's investment allocation constitutes a deemed, not actual, investment among the investment options comprising the investment menu. At no time shall a Participant have any real or beneficial ownership in any investment option included in the investment menu, nor shall the Participating Employer or any trustee acting on its behalf have any obligation to purchase actual securities as a result of a Participant's investment allocation. A Participant's investment allocation shall be used solely for purposes of adjusting the value of a Participant's Account Balances.

A Participant shall specify an investment allocation for each of his Accounts in accordance with procedures established by the Committee. Allocation among the investment options must be designated in increments of 1%. The Participant's investment allocation will become effective on the same Business Day or, in the case of investment allocations received after a time specified by the Committee, the next Business Day.

A Participant may change an investment allocation on any Business Day, both with respect to future credits to the Plan and with respect to existing Account Balances, in accordance with procedures adopted by the Committee. Changes shall become effective on the same Business Day or, in the case of investment allocations received after a time specified by the Committee, the next Business Day, and shall be applied prospectively.

7.5 Unallocated Deferrals and Accounts. If the Participant fails to make an investment allocation with respect to an Account, such Account shall be invested in an investment option, the primary objective of which is the preservation of capital, as determined by the Committee.

7.6 Company Stock. Equity-based Compensation Deferrals will be credited in the form of units with each unit equal in value to one share of Company stock, based on the units awarded to the Participant under the terms of the Company's equity compensation plan. Each unit will be paid in the form of one share of Company stock. A Participant may not allocate units to another investment option under the Plan. A Participant may not allocate cash Deferrals into units of Company Stock. Dividend equivalents will be credited as provided in the equity compensation plan and treated as Earnings for purposes of determining the time and form of payment from the Plan.

7.7 Valuations Final After 180 Days. The Participant shall have 180 days following the Valuation Date on which the Participant failed to receive the full amount of Earnings and to file a claim under Article XI for the correction of such error.

ARTICLE VIII
Administration

8.1 Plan Administration. This Plan shall be administered by the Committee which shall have discretionary authority to make, amend, interpret and enforce all appropriate rules and regulations for the administration of this Plan and to utilize its discretion to decide or resolve any and all questions, including but not limited to eligibility for benefits and interpretations of this Plan and its terms, as may arise in connection with the Plan. Claims for benefits shall be filed with the Committee and resolved in accordance with the claims procedures in Article XI.

8.2 Administration Upon Change in Control. Upon a change in control affecting the Company, the Committee, as constituted immediately prior to such change in control, shall continue to act as the Committee. The Committee, by a vote of a majority of its members, shall have the authority (but shall not be obligated) to appoint an independent third party to act as the Committee. For purposes of this Section 8.2, a "change in control" means a change in control within the meaning of the rabbi trust agreement associated with the Plan or if no such definition is provided, the term shall have the meaning under Code Section 409A.

Upon such change in control, the Company may not remove the Committee or its members, unless a majority of Participants and Beneficiaries with Account Balances consent to the removal and replacement of the Committee. Notwithstanding the foregoing, the Committee shall not have authority to direct investment of trust assets under any rabbi trust described in Section 10.2.

The Participating Employers shall, with respect to the Committee identified under this Section: (i) pay all reasonable expenses and fees of the Committee, (ii) indemnify the Committee (including individuals serving as Committee members) against any costs, expenses and liabilities including, without limitation, attorneys' fees and expenses arising in connection with the performance of the Committee's duties hereunder, except with respect to matters resulting from the Committee's gross negligence or willful misconduct, and (iii) supply full and timely information to the Committee on all matters related to the Plan, any rabbi trust, Participants, Beneficiaries and Accounts as the Committee may reasonably require.

8.3 Withholding. The Participating Employer shall have the right to withhold from any payment due under the Plan (or with respect to any amounts credited to the Plan) any taxes required by law to be withheld in respect of such payment (or credit). Withholdings with respect to amounts credited to the Plan shall be deducted from Compensation that has not been deferred to the Plan.

8.4 Indemnification. The Participating Employers shall indemnify and hold harmless each employee, officer, director, agent or organization, to whom or to which are delegated duties, responsibilities, and authority under the Plan or otherwise with respect to administration of the Plan, including, without limitation, the Committee, its delegees and its agents, against all claims, liabilities, fines and penalties, and all expenses reasonably incurred by or imposed upon him or it (including but not limited to reasonable attorney fees) which arise as a result of his or its actions or failure to act in connection with the operation and administration of the Plan to the extent lawfully allowable and to the extent that such claim, liability, fine, penalty, or expense is not paid for by liability insurance purchased or paid for by the Participating Employer. Notwithstanding the foregoing, the Participating Employer shall not indemnify any person or organization if his or its actions or failure to act are due to gross negligence or willful misconduct or for any such amount incurred through any settlement or compromise of any action unless the Participating Employer consents in writing to such settlement or compromise.

8.5 Delegation of Authority. In the administration of this Plan, the Committee may, from time to time, employ agents and delegate to them such administrative duties as it sees fit, and may from time to time consult with legal counsel who shall be legal counsel to the Company.

8.6 Binding Decisions or Actions. The decision or action of the Committee in respect of any question arising out of or in connection with the administration, interpretation and application of the Plan and the rules and regulations thereunder shall be final and conclusive and binding upon all persons having any interest in the Plan.

ARTICLE IX
Amendment and Termination

9.1 Amendment and Termination. The Company may at any time and from time to time amend the Plan or may terminate the Plan as provided in this Article IX. Each Participating Employer may also terminate its participation in the Plan.

9.2 Amendments. The Company, by action taken by its Board of Directors, may amend the Plan at any time and for any reason, provided that any such amendment shall not reduce the vested Account Balances of any Participant accrued as of the date of any such amendment or restatement (as if the Participant had incurred a voluntary Separation from Service on such date). The Board of Directors of the Company may delegate to the Committee the authority to amend the Plan without the consent of the Board of Directors for the purpose of: (i) conforming the Plan to the requirements of law; (ii) facilitating the administration of the Plan; (iii) clarifying provisions based on the Committee's interpretation of the Plan documents; and (iv) making such other amendments as the Board of Directors may authorize. No amendment is needed to revise the list of Participating Employers set forth on Schedule A attached hereto.

9.3 Termination. The Company, by action taken by its Board of Directors, may terminate the Plan and pay Participants and Beneficiaries their Account Balances in a single lump sum at any time, to the extent and in accordance with Treas. Reg. Section 1.409A-3(j)(4)(ix).

9.4 Accounts Taxable Under Code Section 409A. The Plan is intended to constitute a plan of deferred compensation that meets the requirements for deferral of income taxation under Code Section 409A. The Committee, pursuant to its authority to interpret the Plan, may sever from the Plan or any Compensation Deferral Agreement any provision or exercise of a right that otherwise would result in a violation of Code Section 409A.

ARTICLE X
Informal Funding

10.1 General Assets. Obligations established under the terms of the Plan may be satisfied from the general funds of the Participating Employers, or a trust described in this Article X. No Participant, spouse or Beneficiary shall have any right, title or interest whatever in assets of the Participating Employers. Nothing contained in this Plan, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind, or a fiduciary relationship, between the Participating Employers and any Employee, spouse, or Beneficiary. To the extent that any person acquires a right to receive payments hereunder, such rights are no greater than the right of an unsecured general creditor of the Participating Employer.

10.2 Rabbi Trust. A Participating Employer may, in its sole discretion, establish a grantor trust, commonly known as a rabbi trust, as a vehicle for accumulating assets to pay benefits under the Plan. Payments under the Plan may be paid from the general assets of the Participating Employer or from the assets of any such rabbi trust. Payment from any

such source shall reduce the obligation owed to the Participant or Beneficiary under the Plan.

If a rabbi trust is in existence upon the occurrence of a "change in control", as defined in such trust, the Participating Employer shall, upon such change in control, and on each anniversary of the change in control, contribute in cash or liquid securities such amounts as are necessary so that the value of assets after making the contributions exceed 125% of the total value of all Account Balances.

ARTICLE XI
Claims

11.1 Filing a Claim. Any controversy or claim arising out of or relating to the Plan shall be filed in writing with the Committee which shall make all determinations concerning such claim. Any claim filed with the Committee and any decision by the Committee denying such claim shall be in writing and shall be delivered to the Participant or Beneficiary filing the claim (the "Claimant"). Notice of a claim for payments shall be delivered to the Committee within 90 days of the latest date upon which the payment could have been timely made in accordance with the terms of the Plan and Code Section 409A, and if not paid, the Participant or Beneficiary must file a claim under this Article XI not later than 180 days after such latest date. If the Participant or Beneficiary fails to file a timely claim, the Participant forfeits any amounts to which he or she may have been entitled to receive under the claim.

(a) *In General.* Notice of a denial of benefits (other than claims based on disability) will be provided within 90 days of the Committee's receipt of the Claimant's claim for benefits. If the Committee determines that it needs additional time to review the claim, the Committee will provide the Claimant with a notice of the extension before the end of the initial 90-day period. The extension will not be more than 90 days from the end of the initial 90-day period and the notice of extension will explain the special circumstances that require the extension and the date by which the Committee expects to make a decision.

(b) *Disability Benefits.* Notice of denial of claims based on disability will be provided within forty-five (45) days of the Committee's receipt of the Claimant's claim for disability benefits. If the Committee determines that it needs additional time to review the disability claim, the Committee will provide the Claimant with a notice of the extension before the end of the initial 45-day period. If the Committee determines that a decision cannot be made within the first extension period due to matters beyond the control of the Committee, the time period for making a determination may be further extended for an additional 30 days. If such an additional extension is necessary, the Committee shall notify the Claimant prior to the expiration of the initial 30-day extension. Any notice of extension shall indicate the circumstances necessitating the extension of time, the date by which the Committee expects to furnish a notice of decision, the specific standards on

which such entitlement to a benefit is based, the unresolved issues that prevent a decision on the claim and any additional information needed to resolve those issues. A Claimant will be provided a minimum of 45 days to submit any necessary additional information to the Committee. In the event that a 30-day extension is necessary due to a Claimant's failure to submit information necessary to decide a claim, the period for furnishing a notice of decision shall be tolled from the date on which the notice of the extension is sent to the Claimant until the earlier of the date the Claimant responds to the request for additional information or the response deadline.

(c) *Contents of Notice.* If a claim for benefits is completely or partially denied, notice of such denial shall be in writing. Any electronic notification shall comply with the standards imposed by Department of Labor Regulation 29 CFR 2520.104b-1(c)(1)(i), (iii), and (iv). The notice of denial shall set forth the specific reasons for denial in plain language. The notice shall: (i) cite the pertinent provisions of the Plan document, and (ii) explain, where appropriate, how the Claimant can perfect the claim, including a description of any additional material or information necessary to complete the claim and why such material or information is necessary. The claim denial also shall include an explanation of the claims review procedures and the time limits applicable to such procedures, including the right to appeal the decision, the deadline by which such appeal must be filed and a statement of the Claimant's right to bring a civil action under Section 502(a) of ERISA following an adverse decision on appeal and the specific date by which such a civil action must commence under Section 11.4.

In the case of a complete or partial denial of a disability benefit claim, the notice shall provide such information and shall be communicated in the manner required under applicable Department of Labor regulations.

11.2 Appeal of Denied Claims. A Claimant whose claim has been completely or partially denied shall be entitled to appeal the claim denial by filing a written appeal with a committee designated to hear such appeals (the "Appeals Committee"). A Claimant who timely requests a review of the denied claim (or his or her authorized representative) may review, upon request and free of charge, copies of all documents, records and other information relevant to the denial and may submit written comments, documents, records and other information relating to the claim to the Appeals Committee. All written comments, documents, records, and other information shall be considered "relevant" if the information: (i) was relied upon in making a benefits determination, (ii) was submitted, considered or generated in the course of making a benefits decision regardless of whether it was relied upon to make the decision, or (iii) demonstrates compliance with administrative processes and safeguards established for making benefit decisions. The review shall take into account all comments, documents, records, and other information submitted by the Claimant relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination. The Appeals Committee may, in its sole discretion and if it deems appropriate or necessary, decide to hold a hearing with respect to the claim appeal.

(a) *In General.* Appeal of a denied benefits claim (other than a disability benefits claim) must be filed in writing with the Appeals Committee no later than 60 days after receipt of the written notification of such claim denial. The Appeals Committee shall make its decision regarding the merits of the denied claim within 60 days following receipt of the appeal (or within 120 days after such receipt, in a case where there are special circumstances requiring extension of time for reviewing the appealed claim). If an extension of time for reviewing the appeal is required because of special circumstances, written notice of the extension shall be furnished to the Claimant prior to the commencement of the extension. The notice will indicate the special circumstances requiring the extension of time and the date by which the Appeals Committee expects to render the determination on review. The review will take into account comments, documents, records and other information submitted by the Claimant relating to the claim without regard to whether such information was submitted or considered in the initial benefit determination.

(b) *Disability Benefits.* Appeal of a denied disability benefits claim must be filed in writing with the Appeals Committee no later than 180 days after receipt of the written notification of such claim denial. The review shall be conducted in accordance with applicable Department of Labor regulations.

The Appeals Committee shall make its decision regarding the merits of the denied claim within 45 days following receipt of the appeal (or within 90 days after such receipt, in a case where there are special circumstances requiring extension of time for reviewing the appealed claim). If an extension of time for reviewing the appeal is required because of special circumstances, written notice of the extension shall be furnished to the Claimant prior to the commencement of the extension. The notice will indicate the special circumstances requiring the extension of time and the date by which the Appeals Committee expects to render the determination on review. Following its review of any additional information submitted by the Claimant, the Appeals Committee shall render a decision on its review of the denied claim.

(c) *Contents of Notice.* If a benefits claim is completely or partially denied on review, notice of such denial shall be in writing. Any electronic notification shall comply with the standards imposed by Department of Labor Regulation 29 CFR 2520.104b-1(c)(1)(i), (iii), and (iv). Such notice shall set forth the reasons for denial in plain language.

The decision on review shall set forth: (i) the specific reason or reasons for the denial, (ii) specific references to the pertinent Plan provisions on which the denial is based, (iii) a statement that the Claimant is entitled to receive, upon request and free of charge, reasonable access to and copies of all documents, records, or other information relevant (as defined above) to the Claimant's claim, and (iv) a statement of the Claimant's right to bring an action under Section 502(a) of

ERISA, following an adverse decision on review and the specific date by which such a civil action must commence under Section 11.4.

For the denial of a disability benefit, the notice will also include such additional information and be communicated in the manner required under applicable Department of Labor regulations.

11.3 Claims Appeals Upon Change in Control. Upon a change in control, the Appeals Committee, as constituted immediately prior to such change in control, shall continue to act as the Appeals Committee. The Company may not remove any member of the Appeals Committee, but may replace resigning members if 2/3rds of the members of the Board of Directors of the Company and a majority of Participants and Beneficiaries with Account Balances consent to the replacement. For purposes of this Section 11.3, a "change in control" means a change in control within the meaning of the rabbi trust agreement associated with the Plan or if no such definition is provided, the term shall have the meaning under Code Section 409A.

The Appeals Committee shall have the exclusive authority at the appeals stage to interpret the terms of the Plan and resolve appeals under the Claims Procedure.

Each Participating Employer shall, with respect to the Committee identified under this Section: (i) pay its proportionate share of all reasonable expenses and fees of the Appeals Committee, (ii) indemnify the Appeals Committee (including individual committee members) against any costs, expenses and liabilities including, without limitation, attorneys' fees and expenses arising in connection with the performance of the Appeals Committee hereunder, except with respect to matters resulting from the Appeals Committee's gross negligence or willful misconduct, and (iii) supply full and timely information to the Appeals Committee on all matters related to the Plan, any rabbi trust, Participants, Beneficiaries and Accounts as the Appeals Committee may reasonably require.

11.4 Legal Action. A Claimant may not bring any legal action, including commencement of any arbitration, relating to a claim for benefits under the Plan unless and until the Claimant has followed the claims procedures under the Plan and exhausted his or administrative remedies under Sections 11.1 and 11.2. No such legal action may be brought more than twelve (12) months following the notice of denial of benefits under Section 11.2, or if no appeal is filed by the applicable appeals deadline, twelve (12) months following the appeals deadline.

If a Participant or Beneficiary prevails in a legal proceeding brought under the Plan to enforce the rights of such Participant or any other similarly situated Participant or Beneficiary, in whole or in part, the Participating Employer shall reimburse such Participant or Beneficiary for all legal costs, expenses, attorneys' fees and such other liabilities incurred as a result of such proceedings. If the legal proceeding is brought in connection with a change in control as defined in Section 11.3, the Participant or Beneficiary may file a claim directly with the trustee for reimbursement of such costs,

expenses and fees. For purposes of the preceding sentence, the amount of the claim shall be treated as if it were an addition to the Participant's or Beneficiary's Account Balance and will be included in determining the Participating Employer's trust funding obligation under Section 10.2.

11.5 Discretion of Appeals Committee. All interpretations, determinations and decisions of the Appeals Committee with respect to any claim shall be made in its sole discretion, and shall be final and conclusive.

11.6 Arbitration.

(a) *Prior to Change in Control.* If, prior to a change in control as defined in Section 11.3, any claim or controversy between a Participating Employer and a Participant or Beneficiary is not resolved through the claims procedure set forth in Article XI, such claim shall be submitted to and resolved exclusively by expedited binding arbitration by a single arbitrator. Arbitration shall be conducted in accordance with the following procedures:

The complaining party shall promptly send written notice to the other party identifying the matter in dispute and the proposed remedy. Following the giving of such notice, the parties shall meet and attempt in good faith to resolve the matter. In the event the parties are unable to resolve the matter within 21 days, the parties shall meet and attempt in good faith to select a single arbitrator acceptable to both parties. If a single arbitrator is not selected by mutual consent within ten Business Days following the giving of the written notice of dispute, an arbitrator shall be selected from a list of nine persons each of whom shall be an attorney who is either engaged in the active practice of law or recognized arbitrator and who, in either event, is experienced in serving as an arbitrator in disputes between employers and employees, which list shall be provided by the main office of either JAMS, the American Arbitration Association ("AAA") or the Federal Mediation and Conciliation Service. If, within three Business Days of the parties' receipt of such list, the parties are unable to agree on an arbitrator from the list, then the parties shall each strike names alternatively from the list, with the first to strike being determined by the flip of a coin. After each party has had four strikes, the remaining name on the list shall be the arbitrator. If such person is unable to serve for any reason, the parties shall repeat this process until an arbitrator is selected.

Unless the parties agree otherwise, within 60 days of the selection of the arbitrator, a hearing shall be conducted before such arbitrator at a time and a place agreed upon by the parties. In the event the parties are unable to agree upon the time or place of the arbitration, the time and place shall be designated by the arbitrator after consultation with the parties. Within 30 days of the conclusion of the arbitration hearing, the arbitrator shall issue an award, accompanied by a written decision explaining the basis for the arbitrator's award.

In any arbitration hereunder, the Participating Employer shall pay all administrative fees of the arbitration and all fees of the arbitrator, except that the Participant or Beneficiary may, if he/she/it wishes, pay up to one-half of those amounts. Each party shall pay its own attorneys' fees, costs, and expenses, unless the arbitrator orders otherwise. The prevailing party in such arbitration, as determined by the arbitrator, and in any enforcement or other court proceedings, shall be entitled, to the extent permitted by law, to reimbursement from the other party for all of the prevailing party's costs (including but not limited to the arbitrator's compensation), expenses, and attorneys' fees. The arbitrator shall have no authority to add to or to modify this Plan, shall apply all applicable law, and shall have no lesser and no greater remedial authority than would a court of law resolving the same claim or controversy. The arbitrator shall have no authority to add to or to modify this Plan, shall apply all applicable law, and shall have no lesser and no greater remedial authority than would a court of law resolving the same claim or controversy. The arbitrator shall, upon an appropriate motion, dismiss any claim without an evidentiary hearing if the party bringing the motion establishes that it would be entitled to summary judgment if the matter had been pursued in court litigation.

The parties shall be entitled to discovery as follows: Each party may take no more than three depositions. The Participating Employer may depose the Participant or Beneficiary plus two other witnesses, and the Participant or Beneficiary may depose the Participating Employer, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, plus two other witnesses. Each party may make such reasonable document discovery requests as are allowed in the discretion of the arbitrator.

The decision of the arbitrator shall be final, binding, and non-appealable, and may be enforced as a final judgment in any court of competent jurisdiction.

This arbitration provision of the Plan shall extend to claims against any parent, subsidiary, or affiliate of each party, and, when acting within such capacity, any officer, director, shareholder, Participant, Beneficiary, or agent of any party, or of any of the above, and shall apply as well to claims arising out of state and federal statutes and local ordinances as well as to claims arising under the common law or under this Plan.

Notwithstanding the foregoing, and unless otherwise agreed between the parties, either party may apply to a court for provisional relief, including a temporary restraining order or preliminary injunction, on the ground that the arbitration award to which the applicant may be entitled may be rendered ineffectual without provisional relief.

Any arbitration hereunder shall be conducted in accordance with the Federal Arbitration Act: provided, however, that, in the event of any inconsistency

between the rules and procedures of the Act and the terms of this Plan, the terms of this Plan shall prevail.

If any of the provisions of this Section 11.6(a) are determined to be unlawful or otherwise unenforceable, in the whole part, such determination shall not affect the validity of the remainder of this section and this section shall be reformed to the extent necessary to carry out its provisions to the greatest extent possible and to insure that the resolution of all conflicts between the parties, including those arising out of statutory claims, shall be resolved by neutral, binding arbitration. If a court should find that the provisions of this Section 11.6(a) are not absolutely binding, then the parties intend any arbitration decision and award to be fully admissible in evidence in any subsequent action, given great weight by any finder of fact and treated as determinative to the maximum extent permitted by law.

The parties do not agree to arbitrate any putative class action or any other representative action. The parties agree to arbitrate only the claims(s) of a single Participant or Beneficiary.

(b) *Upon Change in Control.* Upon a change in control as defined in Section 11.3, Section 11.6(a) shall not apply and any legal action initiated by a Participant or Beneficiary to enforce his or her rights under the Plan may be brought in any court of competent jurisdiction. Notwithstanding the Appeals Committee's discretion under Sections 11.3 and 11.5, the court shall apply a de novo standard of review to any prior claims decision under Sections 11.1 through 11.3 or any other determination made by the Company, its Board of Directors, a Participating Employer, the Committee, or the Appeals Committee.

ARTICLE XII
General Provisions

12.1 Assignment. No interest of any Participant, spouse or Beneficiary under this Plan and no benefit payable hereunder shall be assigned as security for a loan, and any such purported assignment shall be null, void and of no effect, nor shall any such interest or any such benefit be subject in any manner, either voluntarily or involuntarily, to anticipation, sale, transfer, assignment or encumbrance by or through any Participant, spouse or Beneficiary. Notwithstanding anything to the contrary herein, however, the Committee has the discretion to make payments to an alternate payee in accordance with the terms of a domestic relations order (as defined in Code Section 414(p)(1)(B)).

The Company may assign any or all of its liabilities under this Plan in connection with any restructuring, recapitalization, sale of assets or other similar transactions affecting a Participating Employer without the consent of the Participant.

12.2 No Legal or Equitable Rights or Interest. No Participant or other person shall have any legal or equitable rights or interest in this Plan that are not expressly granted in this Plan.

Participation in this Plan does not give any person any right to be retained in the service of the Participating Employer. The right and power of a Participating Employer to dismiss or discharge an Employee is expressly reserved. The Participating Employers make no representations or warranties as to the tax consequences to a Participant or a Participant's beneficiaries resulting from a deferral of income pursuant to the Plan.

12.3 No Employment Contract. Nothing contained herein shall be construed to constitute a contract of employment between an Employee and a Participating Employer.

12.4 Notice. Any notice or filing required or permitted to be delivered to the Committee under this Plan shall be delivered in writing, in person, or through such electronic means as is established by the Committee. Notice shall be deemed given as of the date of delivery or, if delivery is made by mail, as of the date shown on the postmark on the receipt for registration or certification. Written transmission shall be sent by certified mail to:

AMPHASTAR PHARMACEUTICALS, INC.
11570 6TH STREET
RANCHO CUCAMONGA, CALIFORNIA 91730
ATTN: HUMAN RESOURCES

Any notice or filing required or permitted to be given to a Participant under this Plan shall be sufficient if in writing or hand-delivered, or sent by mail to the last known address of the Participant.

12.5 Headings. The headings of Sections are included solely for convenience of reference, and if there is any conflict between such headings and the text of this Plan, the text shall control.

12.6 Invalid or Unenforceable Provisions. If any provision of this Plan shall be held invalid or unenforceable, such invalidity or unenforceability shall not affect any other provisions hereof and the Committee may elect in its sole discretion to construe such invalid or unenforceable provisions in a manner that conforms to applicable law or as if such provisions, to the extent invalid or unenforceable, had not been included.

12.7 Lost Participants or Beneficiaries. Any Participant or Beneficiary who is entitled to a benefit from the Plan has the duty to keep the Committee advised of his or her current mailing address. If benefit payments are returned to the Plan or are not presented for payment after a reasonable amount of time, the Committee shall presume that the payee is missing. The Committee, after making such efforts as in its discretion it deems reasonable and appropriate to locate the payee, shall stop payment on any uncashed checks and may discontinue making future payments until contact with the payee is restored. If the Committee is unable to locate the Participant or Beneficiary after five years of the date payment is scheduled to be made, provided that a Participant's Account shall not be credited with Earnings following the first anniversary of such date on which payment is to be made and further provided, however, that such benefit shall be

reinstated, without further adjustment for interest, if a valid claim is made by or on behalf of the Participant or Beneficiary for all or part of the forfeited benefit.

12.8 Facility of Payment to a Minor. If a distribution is to be made to a minor, or to a person who is otherwise incompetent, then the Committee may, in its discretion, make such distribution: (i) to the legal guardian, or if none, to a parent of a minor payee with whom the payee maintains his or her residence, or (ii) to the conservator or committee or, if none, to the person having custody of an incompetent payee. Any such distribution shall fully discharge the Committee, the Company, and the Plan from further liability on account thereof.

12.9 Governing Law. To the extent not preempted by ERISA, the laws of the State of California shall govern the construction and administration of the Plan.

12.10 Compliance With Code Section 409A; No Guarantee. This Plan is intended to be administered in compliance with Code Section 409A and each provision of the Plan shall be interpreted consistent with Code Section 409A. Although intended to comply with Code Section 409A, this Plan shall not constitute a guarantee to any Participant or Beneficiary that the Plan in form or in operation will result in the deferral of federal or state income tax liabilities or that the Participant or Beneficiary will not be subject to the additional taxes imposed under Section 409A. No Employer shall have any legal obligation to a Participant with respect to taxes imposed under Code Section 409A.

IN WITNESS WHEREOF, the undersigned executed this Plan as of the 22nd day of October, 2019, to be effective as of the Effective Date.

AMPHASTAR PHARMACEUTICALS, INC.

By: William Peters (Print Name)
Its: CFO (Title)
/s/ William Peters (Signature)

Amphastar Pharmaceuticals, Inc. Deferred Compensation Plan

Schedule A

Participating Employers

Amphastar Pharmaceuticals, Inc.

Exhibit 21.1

SUBSIDIARIES OF THE COMPANY

Company Name	State of Incorporation/ Organization	Country of Incorporation/ Organization
International Medication Systems, Limited	California	United States of America
Armstrong Pharmaceuticals, Inc.	Massachusetts	United States of America
Amphastar Nanjing Pharmaceuticals, Inc.		China
Nanjing Letop Fine Chemistry Co., Ltd.		China
Nanjing Hanxin Medical Technology Co., Ltd.		China
Nanjing Baixin Trading Co., Ltd.		China
Amphastar France Pharmaceuticals, S.A.S.		France
Amphastar UK Limited		United Kingdom
International Medication Systems (UK) Limited		United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-197054) pertaining to the 1999-2002 Stock Option/Stock Issuance Plans, the Amended and Restated 2005 Equity Incentive Award Plan and the 2014 Employee Stock Purchase Plan of Amphastar Pharmaceuticals, Inc.,
(2) Registration Statement (Form S-8 No. 333-203017) pertaining to the Amended and Restated 2005 Equity Incentive Award Plan of Amphastar Pharmaceuticals, Inc.,
(3) Registration Statement (Form S-8 No. 333-205470) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(4) Registration Statement (Form S-8 No. 333-210213) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(5) Registration Statement (Form S-8 No. 333-216700) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(6) Registration Statement (Form S-8 No. 333-223651) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(7) Registration Statement (Form S-3 No. 333-228318) of Amphastar Pharmaceuticals, Inc., and
(8) Registration Statement (Form S-8 No. 333-230330) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.

of our reports dated March 16, 2020, with respect to the consolidated financial statements of Amphastar Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Amphastar Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Amphastar Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Irvine, California
March 16, 2020

EXHIBIT 31.1

Certification

I, Jack Y. Zhang, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Amphastar Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2020

By: **/s/ JACK Y. ZHANG**
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification

I, William J. Peters, certify that:

1. I have reviewed this Annual Report on Form 10-K of Amphastar Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2020

By: **/s/ WILLIAM J. PETERS**
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

The undersigned officer of Amphastar Pharmaceuticals, Inc. (the "Company"), hereby certifies, to the best of such officer's knowledge, that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: March 16, 2020

By: **/s/ JACK Y. ZHANG**
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

The undersigned officer of Amphastar Pharmaceuticals, Inc. (the "Company"), hereby certifies, to the best of such officer's knowledge, that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: March 16, 2020

By: **/s/ WILLIAM J. PETERS**
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.