Amphastar Pharmaceuticals, Inc.
Form 10-K
March 15, 2019

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, 2018

OR

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

For the transition period from ____ to _____

Commission File Number 001-36509

Amphastar Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

11570 6th Street,

Rancho Cucamonga, CA 91730

(Address of principal executive offices, including zip code)

(909) 980-9484

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2018, based upon the closing price of Common Stock on such date as reported by Nasdaq Global Select Market, was approximately $454,913,022. Shares of common stock known to be held by directors, executive officers and holders of 5% or more of the outstanding common stock of the registrant are not included in the computation. No determination has been made that such persons are "affiliates" of the registrant for any other purpose.

At March 8, 2019, there were 46,788,811 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 2019 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements relate to future events or future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by the forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the sales and marketing of our products;
- our expectations regarding our manufacturing and production and the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- the timing and likelihood of FDA approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- our ability to compete in the development and marketing of our products and product candidates;
- our expectations regarding the business expansion plans of 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;
- the impact of trade tariffs or other trade barriers;
- the impact of the 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 IMS 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

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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 Food and Drug Administration, or FDA, granted over-the-counter approval of our New Drug Application, or NDA, for Primatene® Mist in a new CFC-free formulation. We began selling Primatene® Mist in the fourth quarter of 2018.

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

For the years ended December 31, 2018, 2017, and 2016, we recorded net revenues of $294.7 million, $240.2 million, and $255.2 million, respectively. We recorded a net loss of $5.7 million for the year ended December 31, 2018 and recorded net income of $3.6 million and $9.8 million for the years ended December 31, 2017 and 2016, respectively.

Our largest products by net revenues currently include enoxaparin sodium injection, naloxone hydrochloride injection, lidocaine jelly and sterile solution, phytonadione, and medroxyprogesterone acetate. We launched neostigmine methysulfate in the fourth quarter of 2017, medroxyprogesterone acetate in the first quarter of 2018, isoproterenol hydrochloride injection in the third quarter of 2018, and Primatene® Mist in the fourth quarter of 2018.

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

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- 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.

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 to accredited investors for aggregate gross proceeds of approximately $57 million, of which $38.0 million had been received by ANP as of December 31, 2018. While investors were initially required to complete their contributions in cash by December 31, 2018, ANP granted an extension to certain investors. Subsequently, including the funds from the extension, the proceeds ANP received from the private placement totaled $56.3 million. In connection with the private placement, all of our executive officers, Stephen Shohet, Howard Lee, and Richard Koo, our directors, and certain employees of ANP entered into subscription agreements for the indirect investment in ANP. The aggregate gross proceeds received from management and directors was approximately $29.7 million. We have retained approximately 58% of the equity interest in ANP immediately after the private placement. ANP intends to use the net proceeds from the private placement for its business expansion plans. 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.

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 2018 was approximately $10.6 billion. Our generic development portfolio is targeting opportunities in over $5.0 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 2018 was approximately $27.1 billion. Our generic development portfolio is targeting opportunities in over $10.0 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 hydrofluoroalkanes, or HFAs, to release its dose when the patient activates the device. The DPI, which does not rely on a propellant, is also widely used. As in the case of injectables, there are significant technical barriers to manufacturing inhalation products. The evolution of inhalation delivery technologies from nebulizers and CFCs to HFAs and DPIs has required manufacturers of inhalation products to re-formulate their products, which in many cases may require technical engineering

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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 such as pharmaceutical formulation, process development, in vivo studies, analytical chemistry, physical chemistry, drug delivery and clinical research. We believe that our scientific and technical expertise, coupled with our management team’s 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 ANDAs, three biosimilar product candidates and five 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

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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 five proprietary product candidates at various stages of development targeting a broad range of indications. We believe that proprietary products tend to face less competition than generic products due to market exclusivity, intellectual property protection and other barriers to entry. For these reasons, we believe that our proprietary products will provide us with the opportunity for higher margins and long-term revenue growth.
- Leverage our vertically integrated infrastructure to drive operational efficiencies. We believe our vertically integrated infrastructure provides significant benefits including better operating efficiencies, accelerated product development and internal control over product quality. Our ability to manufacture our own API allows us to develop products that other companies may not focus on due to the uncertainty of API supply. In addition, our vertically integrated infrastructure, including our research and development capabilities, allows us to conduct technically challenging studies in-house. We believe this vertically integrated infrastructure has led, and will continue to lead, to a competitive portfolio of products and product candidates.
- Target and integrate acquisitions of pharmaceutical companies, products and technologies. We have a demonstrated ability to identify, acquire and integrate pharmaceutical companies, products and technologies to complement our internal product development capabilities. We have acquired (1) International Medication Systems, Limited or IMS, (2) Armstrong Pharmaceuticals, Inc. or Armstrong, (3) Nanjing Puyan Pharmaceutical Technology Co., Ltd. (which we renamed as Amphastar Nanjing Pharmaceuticals Co., Ltd.), or ANP, (4) Nanjing Letop Medical Technology Co. Ltd. (which we renamed as Nanjing Letop Fine Chemistry Co. Ltd., or Letop, (5) Merck's API Manufacturing Business in Éragny-sur-Epte, France, in connection with which, we established our French subsidiary, Amphastar France Pharmaceuticals, S.A.S., or AFP, and (6) International Medication Systems (UK) Limited, or IMS UK. Products we have acquired include Cortrosyn® and Epinephrine Mist, and trade names such as Primatene®. We believe that our scientific and managerial expertise and our integration experience have improved the quality of the product lines and companies that we have acquired, which has had, and we believe will continue to have, a positive effect on our results of operations. For example, 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.

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- 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. In January 2012, we commenced sales of our enoxaparin product.

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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. We acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene®, and the associated CFC inventory, from Wyeth Consumer Healthcare Division in 2008 for $33.1 million. At the time of the transaction, the Environmental Protection Agency was reviewing a possible ban on all CFC formulated products. In our first full year of sales of the CFC formulation of Primatene® Mist, we generated cash flows from sales of the product in excess of the purchase price. We filed an investigational new drug application, or IND, for Primatene® Mist for mild symptoms of intermittent asthma in October 2009.

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 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 morphine, 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;
- 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.

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Our Product Candidates

We seek to develop product candidates with high technical barriers to competitive market entry that leverage our technical capabilities and other competitive advantages. We are focused on both generic and proprietary product candidates in the injectable and inhalable markets. The product candidates in our pipeline are in various stages of development, with a number of these candidates still in early stages of development. We currently have over 20 product candidates in our pipeline, including 15 generic ANDAs, three biosimilar product candidates and five 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	ü	ü	ü	ü	ü
Inhalation					

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

Proprietary Product Candidates

Our integrated technical skills and expertise provide a strong basis for the development of proprietary drug candidates. These skills include new chemical entity assessment, 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 five 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.

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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 identifies four primary issues that need to be addressed prior to approval of our NDA. The four issues are comprised of (1) improving on our human factors validation study, (2) modifying the delivery accuracy verification method, (3) improving our standards of device reliability, and (4) adjusting the volume per actuation to account for pediatric use down to birth. We intend to continue to work with the FDA to address their concerns in the CRL 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 four 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 €120.1 million, or approximately $146.0 million, over five years from calendar years 2015 through 2019. Specifically, the minimum annual purchase commitment was approximately €27.1 million in 2015, and approximately €23.3 million each year from 2016 through 2019.

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

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