

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
(State or other jurisdiction of
incorporation or organization)

33-072025

(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.

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;
- 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

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

- 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

Explore Litigation Insights

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E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.