Amphastar Pharmaceuticals, Inc.
Form 10-K
March 26, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2014

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 x

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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

Aggregate market value of registrant's common stock held by non-affiliates of the registrant on June 30, 2014, based upon the closing price of Common Stock on such date as reported by NASDAQ Global Select Market, was approximately $430,686,276. Shares of common stock known to be owned by directors and executive officers of the Registrant subject to Section 16 of the Securities Exchange Act of 1934 are not included in the computation. No determination has been made that such persons are "affiliates" within the meaning of Rule 12b-2 under the Exchange Act.

At March 18, 2015, there were 44,564,667, shares of the registrant's Common Stock outstanding.

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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 2015 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," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "c or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the sales and marketing of our products, including our enoxaparin product;
- our expectations regarding the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- our beliefs about and objectives for future operations;
- the timing and likelihood of FDA approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- our ability to compete in the development and marketing of our products and product candidates;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies;
- 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 on our products and our ability to successfully defend these in cases of alleged infringement;
- the implementations of our business strategies, product candidates and technology;
- the potential for exposure to product liability claims;
- future acquisitions 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; and

- our financial performance expectations, including our expectations regarding our revenue, cost of revenue, gross profit or gross margin, operating expenses, including changes in research and development, sales and marketing and general and administrative expenses, and our ability to achieve and maintain future profitability.

You should read this Annual Report and the documents that we reference elsewhere in this Annual Report completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied 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 Part I. 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. 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.

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Item 1. Business.

Overview

Amphastar Pharmaceuticals, together with its subsidiaries (collectively "Amphastar," "the Company," "we," "our," and "us"), is a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically-challenging generic and proprietary injectable and inhalation products. Additionally, in 2014, we commenced sales of insulin active pharmaceutical ingredient, or insulin API, products. We currently manufacture and sell 17 products and are developing a portfolio of 13 generic and eight proprietary injectable and inhalation product candidates. For the years ended December 31, 2014, 2013, and 2012, we recorded net revenues of $210.5 million, $229.7 million, and $204.3 million, respectively. We recorded a net loss of $10.7 million for the year ended December 31, 2014 and recorded net income of $11.9 million and $18.1 million for the years ended December 31, 2013 and 2012, respectively.

Our largest product by net revenues is currently enoxaparin sodium injection, the generic equivalent of Sanofi S.A.'s Lovenox®. Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant and is indicated for multiple indications including the prevention and treatment of deep vein thrombosis. We commenced sales of our enoxaparin product in January 2012, and for the years ended December 31, 2014, 2013, and 2012, we recognized net revenues from the sale of our enoxaparin product of $107.5 million, $145.9 million, and $127.7 million, respectively. We believe that our enoxaparin product demonstrates our capabilities in characterizing complex molecules (which is a process that involves a determination of physiochemical properties, biological activity, immunochemical properties and purity), developing therapeutically equivalent generic versions of drugs with large, complex molecules and meeting regulatory requirements.

In addition to our currently marketed products, we have a pipeline of 21 generic and proprietary product candidates in various stages of development which target a variety of indications. With respect to these product candidates, we have filed three abbreviated new drug applications, or ANDAs, one new drug application, or NDA, and one NDA supplement with the U.S. Food and Drug Administration, or FDA.

Our product candidate, Primatene® Mist HFA, an over-the-counter epinephrine inhalation product, is intended to be used for the temporary relief of mild asthma symptoms. In 2013, we filed an NDA for Primatene® Mist HFA. In May 2014, we received a complete response letter, or CRL, from the FDA, which required additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, the CRL noted current Good Manufacturing Practices, or cGMP, deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved and accordingly, we believe this condition for approval has been satisfied. We met with the FDA in October 2014 to discuss preliminary data results and to clarify the FDA requirements for further studies. We are in the process of generating the remaining data required by the CRL and plan to submit an NDA amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product candidate or approval at all.

Our Amphadase® product candidate is a bovine-sourced hyaluronidase injection. We received approval of our NDA for Amphadase® from the FDA in 2004, but we discontinued the product in 2009 due to a lack of API supply. We filed an NDA supplement in December 2013 to qualify our own manufactured API. There can be no assurance that we will receive approval for this or any of our other product candidates.

Our multiple technological capabilities enable the development of technically-challenging products. These capabilities include characterizing complex molecules, analyzing peptides and proteins, conducting immunogenicity studies, engineering particles and improving drug delivery through sustained-release technology. These technological capabilities have enabled us to produce bioequivalent versions of complex drugs and support the development and manufacture of a broad range of dosage formulations, including solutions, emulsions, suspensions and lyophilized products, as well as products administered via 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 research and development capabilities;

require raw materials or an API 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.

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Not all of our products will include all of these characteristics. Moreover, we will 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. We believe that 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.

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 target the manufacture and sale of certain APIs.

Injectable market. Based on an IMS Health National Sales Perspective Report, the U.S. generic injectable drug market in 2014 was approximately $8.0 billion, of which our generic development portfolio is targeting over $5.0 billion. The injectable market requires highly technical manufacturing capabilities and compliance with strict 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 IMS Health National Sales Perspective Report, the U.S. inhalation drug market in 2014 was approximately $21.9 billion, of which our generic development portfolio is targeting over $9.0 billion. Inhalation drug therapy is used extensively to treat respiratory conditions such as asthma and chronic obstructive pulmonary disease. The MDI is the most widely used device to deliver inhalation therapies. It uses pressurized gas, historically chlorofluorocarbons, or CFCs, and more recently hydrofluoroalkanes, or HFAs, to release its dose when the device is activated by the patient. The DPI, which does not rely on a propellant, is also widely used. As in the case of injectables, there are significant technical barriers to manufacturing inhalation products. The evolution of inhalation delivery technologies from nebulizers and CFCs to HFAs and DPIs has required manufacturers of inhalation products to re-formulate their products, which in many cases may require technical engineering capabilities, additional regulatory approvals and modified delivery devices. Additionally, the development of generic HFA and DPI products will require bioequivalence studies for FDA approval.

Our Strengths

We have built our company by integrating the following capabilities and strengths that we believe enable us to compete effectively in the pharmaceutical industry:

Robust portfolio of products and product candidates. Including our enoxaparin product, we have 17 commercial products and 21 product candidates at different stages of development. We also continue to develop our product candidates, which represent our longer-term growth opportunities.

Advanced technical capabilities and multiple delivery technologies. We have developed several advanced technical capabilities that we incorporate into the development of our products and product candidates, including characterization of complex molecules, peptide and protein analysis, immunogenicity studies, particle engineering and sustained-release technology. In addition, we apply these capabilities across our injectable and inhalation

delivery technologies. Our injectable delivery technologies enable us to develop and manufacture generic and proprietary injectables in normal solution, lyophilized, suspension, jelly and emulsion forms, as well as in pre-filled syringes. Our inhalation technologies cover a variety of delivery methods, including DPIs and HFA formulations of MDIs. These technical capabilities form the foundation for our strategy to develop products with high barriers to market entry targeting a wide range of indications.

Vertically integrated infrastructure. We are a vertically integrated company with the demonstrated ability to advance a product candidate from the research stage through commercialization. Our capabilities include strong research and development expertise, sophisticated pharmaceutical engineering capabilities, comprehensive manufacturing capabilities, including the ability to synthesize and manufacture our own API, a strict quality assurance system, extensive regulatory and clinical experience and established marketing and distribution relationships. We believe our vertical integration allows us to achieve better operating efficiencies, accelerated product development and internal control over product quality.

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Experienced management team with deep scientific expertise. Our management team has a successful track record in product development, project management, quality assurance and sales and marketing, as well as established relationships with our key customers, partners and suppliers. Our research and development leadership has deep expertise in areas such as pharmaceutical formulation, process development, in vivo studies, analytical chemistry, physical chemistry, drug delivery and clinical research. We believe that our scientific and technical expertise, coupled with our management team's experience and industry relationships, will enable us to successfully expand our position with respect to our current products and establish a meaningful market position for our product candidates.

Our Strategy

Our goal is to be an industry leader in the development, manufacturing and marketing of technically-challenging injectable and inhalation pharmaceutical products. To achieve this goal, we are pursuing the following key strategies:

Diversify our revenues by commercializing our product candidates. Assuming we are successful in developing and obtaining regulatory approvals, we plan to commercialize our product candidates and thereby diversify our sources of revenues. We have 21 product candidates in various stages of development, including 13 generic product candidates and eight 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 eight 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 International Medication Systems, Limited, or IMS, Armstrong Pharmaceuticals, Inc., or Armstrong, Nanjing Puyan Pharmaceutical Technology Co., Ltd. (which we renamed Amphastar Nanjing Pharmaceuticals Co., Ltd.), or ANP, and 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. Products we have acquired include Cortrosyn® and Epinephrine Mist, and trade names such as Primatene® Mist. We believe that our scientific and managerial expertise and our integration

experience have improved the quality of the product lines and companies that we have acquired, which has had, and we believe will continue to have, a positive effect on our results of operations. For example, if approval is received from the FDA, we plan to have our acquired subsidiary ANP provide us with access to certain raw materials for the manufacture of the API for our enoxaparin product and eventually to manufacture API for our other products and product candidates.

Our Technical Capabilities

We develop, manufacture, market and sell generic and proprietary products targeting injectable and inhalation markets. We also manufacture and sell insulin API.

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Injectable. Our injectable product technologies enable us to develop and manufacture generic and proprietary injectables in liquid, lyophilized, suspension and emulsion forms, as well as pre-filled syringes. We have multiple injectable facilities that include aseptic filling lines dedicated to the sterile manufacture and fill of injectable products. Additionally, we maintain compliance with cGMP regulations which has enabled us to obtain regulatory approvals and support commercial supply.

Inhalation. We are focused on developing a range of generic and proprietary inhalation products utilizing a variety of delivery technologies. We have expertise in formulating HFA-based MDIs as well as packaging our inhalation drugs in DPIs, blister packs and other forms for loading in a variety of inhalation devices. As with our injectable products, we maintain compliance with cGMP regulations, which we believe will enable us to obtain regulatory approvals and support commercial supply.

We have advanced capabilities that enable us to focus on developing technically-challenging products.

Characterization of complex molecules. Characterization of complex molecules includes a determination of physiochemical properties, biological activity, immunochemical properties and purity. Such characterization is important in the development of a generic product that is the same as a reference drug product, which in turn allows the generic drug developer to demonstrate such “sameness” to the FDA. Complex molecule drugs typically have large molecules composed of a mixture of molecules that differ very slightly from one another. These slight variances make complex molecules difficult to characterize. We have developed analytical tools that have enabled us to characterize complex molecules in our products and product candidates. We believe we have the technology to develop a variety of additional analytical tools that will enable us to characterize other complex molecules, including peptide and protein-based products.

Immunogenicity. The ability of an antigen to elicit immune responses is called immunogenicity. Unwanted immunogenicity, which is strongly linked with protein drug products, occurs when a patient mounts an undesired immune response against a drug therapy. As a result, the FDA has signaled that they may require immunogenicity studies as part of the new pathway for biosimilars and biogenerics, and in the past the FDA has required these studies in connection with the approval of products with complex molecules. We gained expertise in immunogenicity by performing immunogenicity studies in connection with the FDA approval process for our enoxaparin product. We believe that our experience in conducting these difficult immunogenicity studies will be of primary importance in our future efforts to develop complex molecules, biosimilar and biogeneric product candidates.

Peptide and protein product development and production. The development of peptide and protein drug products utilizes characterization technology and immunogenicity studies as well as recombinant DNA, or rDNA, API manufacturing technology. We have experience in the use of rDNA manufacturing technology which includes the genetic engineering of host cells, fermentation to promote cell culture growth and isolation and purification of the desired protein from the cell culture. Through each step, testing is required to ensure that only the desired protein is included in the finished product. We believe that this technology will allow us to develop protein and peptide drug products.

Particle engineering. Particle engineering is important in the field of pulmonary drug delivery as there is a direct relationship between the properties of a particle and its absorption by the lungs. We believe our expertise and technology applicable to particle engineering and physical chemistry allows us to engineer the size, shape, surface smoothness and distribution of particles to develop inhalation products that are more easily dispersed through targeted areas. We believe this expertise will allow us to formulate difficult to disperse inhalation products.

Sustained-release. We have developed technology aimed at improving drug delivery through sustained-release injectable products. The purpose of our sustained-release technology is to create products that require less dosing

frequency and that we believe can diminish the fluctuations of drug concentrations in a patient's blood stream that otherwise require more frequent dosing. We plan to use our sustained-release technology to develop both generic and proprietary products.

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