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Amphastar Pharmaceuticals, Inc.
Form 8-K
July 07, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)

June 30, 2016

Amphastar Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

| | | |
|---------------------------------|--------------|---------------------|
| Delaware | 001-36509 | 33-0702205 |
| (State or other jurisdiction of | (Commission | (IRS Employer |
| incorporation) | File Number) | Identification No.) |

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11570 6th Street
Rancho Cucamonga, California 91730

(Address of principal executive offices, including zip code)

(909) 980-9484

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 1.01. Entry into a Material Definitive Agreement.

On June 30, 2016, Amphastar Pharmaceuticals, Inc. (the “Company”) and Actavis Laboratories FL, Inc., formerly known as Watson Laboratories, Inc. – Florida and Andrx Pharmaceuticals, Inc. (“Actavis”), entered into a Seventh Amendment and Termination Agreement (the “Amendment”) with respect to the Distribution Agreement by and between the Company and Actavis dated May 2, 2005, as amended by the First Amendment dated August 15, 2008, the Second Amendment dated February 19, 2013, the Third Amendment dated April 1, 2014, the Fourth Amendment dated January 7, 2015, the Fifth Amendment dated February 4, 2015, and the Sixth Amendment dated March 6, 2015 (as amended, the “Agreement”). The Agreement relates to, among other things, Actavis’ certain exclusive marketing rights for the Company’s enoxaparin product, which generally extend to the U.S. retail pharmacy market. The Agreement was filed as Exhibit 10.7 to the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 15, 2016 (incorporated by reference to Exhibit 10.7 to the Company’s Registration Statement on Form S-1 filed with the SEC on May 20, 2014).

The Amendment deletes Section 2.2.3 of the Agreement, which concerns certain non-competition provisions, effective as of the Amendment date. In addition, the Amendment terminates the Agreement upon the earlier of (i) January 1, 2017 and (ii) such earlier date that is thirty days (30) after Actavis notifies the Company in writing that Actavis has less than thirty (30) days inventory of the Product (as defined in the Agreement) remaining in Actavis’ possession or scheduled to be delivered pursuant to the pending purchase orders (collectively, the “Termination Date”). Actavis must use Commercially Reasonable Efforts (as defined in the Agreement) to sell its remaining inventory of the Product.

The Amendment also provides that the Company shall have the right to appoint a new distributor for the Company’s enoxaparin product as of the date of execution, provided that neither the Company nor such new distributor shall distribute, sell or otherwise commercialize the Product in the retail market subject to the Agreement prior to the Termination Date of the Agreement. In the event that the Company or any distributor distributes, sells or otherwise commercializes the Product to Purchaser Customers (as defined in the Agreement) in the markets subject to the Agreement prior to the Termination Date, Actavis may terminate the Agreement upon written notice to the Company and, in addition to any other remedy available in law or in equity, upon such termination, the Company agrees to promptly repurchase all of Actavis’ remaining inventory of the Product at a price equal to the amount paid by Actavis for such inventory. The Amendment also contains certain provisions related to the extension of the Termination Date, allocation of product labelling expenses, and the release of future claims.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Amendment, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated herein by reference.

ITEM 1.02. Termination of a Material Definitive Agreement.

The information contained in Item 1.01 above is incorporated by reference into this Item 1.02.

ITEM 7.01. Regulation FD Disclosure.

The information contained in Item 1.01 above is incorporated by reference into this Item 7.01.

Upon termination of the Agreement, the Company will continue to sell its enoxaparin product to the U.S. retail market for, which may include entry into agreements with new distributors or independent sales representatives and/or the initiation of direct sales efforts with new or existing customers. No assurance can be given that the Company's efforts to sell its enoxaparin product to the retail market, will be successful.

The information set forth in this Item 7.01 is intended to be furnished and 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 it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|-------------|--|
| 10.1 | Seventh Amendment and Termination Agreement by and between the Company and Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc. – Florida and as Andrx Pharmaceuticals, Inc.) dated June 30, 2016. |

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 hereunto duly authorized.

Date: July 7, 2016

AMPHASTAR
PHARMACEUTICALS, INC.

By: /S/WILLIAM J. PETERS
William J. Peters
Chief Financial Officer and
Senior Vice President
