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Amphastar Pharmaceuticals, Inc.
Form 8-K
November 10, 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)

November 9, 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 November 9, 2016, Amphastar Pharmaceuticals, Inc. (the “Company”) and MannKind Corporation (“MannKind”) entered into a Second Amendment (the “Supply Agreement Amendment”) to the Supply Agreement dated July 31, 2014, as amended by the First Amendment to the Supply Agreement dated October 31, 2014 (as amended, the “Supply Agreement”), pursuant to which the Company agreed to manufacture for and supply to MannKind certain quantities of recombinant human insulin (“RHI”) for use in MannKind’s product, Afrezza, in accordance with MannKind’s specifications and agreed-upon quality standards. The Supply Agreement and the First Amendment to the Supply Agreement were filed as Exhibits 10.1 and 10.2 to the Company’s Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 13, 2014.

Under the terms of the Supply Agreement Amendment, MannKind’s aggregate total purchase commitment of RHI under the Supply Agreement has not been reduced; however, the annual minimum purchase commitments of RHI under the Supply Agreement have been modified and extended to cover calendar years 2014 through 2023, which timeframe had previously lapsed after calendar year 2019. Specifically, the minimum annual purchase commitment in calendar year 2016 has been cancelled, and the minimum annual purchase commitments in calendar years 2017 through 2023 have been modified to be €2.7 million of insulin in the fourth quarter of 2017, €8.9 million in 2018, €11.6 million in 2019, €15.5 million in 2020 and in 2021, and €19.4 million in 2022 and in 2023. MannKind may request to purchase additional quantities of RHI in excess of its annual minimum purchase commitments. The Supply Agreement Amendment also (i) modifies, and shortens, the expiry dates for RHI delivered to MannKind pursuant to the Supply Agreement, (ii) modifies the timing of MannKind’s payment for the minimum annual purchase commitment in calendar year 2017, and (iii) adds a pre-payment requirement for purchases of RHI by MannKind in calendar years 2017 and 2018.

In addition to, and in consideration of the amended timeframe and other amendments contained in the Supply Agreement Amendment and in the Option Agreement Amendment (as defined below), the Supply Agreement Amendment provides for the grant by MannKind to the Company of a right of first refusal to participate in the development and commercialization of Afrezza in China through a collaborative arrangement..

The Supply Agreement Amendment also extends the term of the Supply Agreement to December 31, 2023, and it can be renewed for additional, successive two-year terms upon 12 months written notice, given prior to the end of the initial term or any additional two year term. The termination provisions set forth in the Supply Agreement have not otherwise been modified by the Supply Agreement Amendment.

The foregoing description of the Supply Agreement Amendment does not purport to be complete and is qualified in its entirety by reference to the terms of the Supply Agreement Amendment, which the Company intends to file as an exhibit to the Company’s Annual Report on Form 10-K for the year ended December 31, 2016.

ITEM 8.01. Other Events.

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

On November 9, 2016, the Company and MannKind entered into a First Amendment (the “Option Agreement Amendment”) to the Insulin Option Purchase Agreement dated January 1, 2015 (the “Option Agreement”), pursuant to which MannKind has the option to purchase RHI in excess of the minimum purchase commitments specified in the Supply Agreement for the period specified in the Supply Agreement, which, as amended, extends through calendar year 2023. 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 the Company a specified capacity cancellation fee. The Option Agreement Amendment extends the timing for payment of the capacity cancellation fee for 2017 and decreases the amounts payable as capacity cancellation fees for 2018 and 2019 in the event MannKind fails to exercise their minimum annual purchase option for any given year

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: November 10, 2016

AMPHASTAR
PHARMACEUTICALS, INC.

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