

Edgar Filing: Emergent BioSolutions Inc. - Form 8-K

Emergent BioSolutions Inc.
Form 8-K
October 25, 2018

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): October 25, 2018

EMERGENT BIOSOLUTIONS INC.
(Exact name of registrant as specified in its charter)

| | | |
|---|--------------------------|--------------------------------------|
| DELAWARE | 001-33137 | 14-1902018 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

400 Professional Drive, Suite 400,
Gaithersburg, Maryland 20879
(Address of principal executive offices, including zip code)

(240) 631-3200
(Registrant's telephone number, including area code)

N/A
(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 (see General Instruction A.2. below):

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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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.

Item 8.01 Other Events.

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd. (collectively, "Adapt") and Opiant Pharmaceuticals, Inc. ("Opiant") received notice from Perrigo UK FINCO Limited Partnership ("Perrigo"), that Perrigo had filed an Abbreviated New Drug Application ("ANDA"), with the United States Food and Drug Administration (the "FDA"), seeking regulatory approval to market a generic version of NARCAN[®] (naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253 (the "'253 Patent"), 9,468,747 (the "'747 Patent"), 9,561,177 (the "'177 Patent"), 9,629,965 (the "'965 Patent") and 9,775,838 (the "'838 Patent") (collectively, the "Patents-In-Suit"). Perrigo's notice letter asserts that its generic product will not infringe any valid and enforceable claim of the Patents-In-Suit.

On October 25, 2018, Emergent BioSolutions' Adapt subsidiaries and Opiant (collectively, the "Plaintiffs") filed a complaint for patent infringement against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. As a result of timely filing the lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the Court. The Plaintiffs seek, among other relief, an order that the effective date of FDA approval of the ANDA be a date no earlier than the expiration of each of the Patents-In-Suit, as well as equitable relief enjoining Perrigo from infringing these patents, and monetary relief as a result of any such infringement. Emergent continues to vigorously enforce the intellectual property portfolio related to NARCAN[®] Nasal Spray.

SIGNATURE

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.

EMERGENT BIOSOLUTIONS INC.

Dated: October 25, 2018 By: /s/ RICHARD S. LINDAHL

Name: Richard S. Lindahl

Title: Executive Vice President, Chief Financial Officer and Treasurer