

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

April 10, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or Section 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 10, 2019

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-31361
(Commission
File Number)

35-2089858
(IRS Employer
Identification No.)

4131 ParkLake Ave., Suite #225

Raleigh, NC

27612

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: 919-582-9050

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 to 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))

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

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 1.01 Entry into a Material Definitive Agreement

License Agreement with Shionogi Inc.

On April 4, 2019 (the **Effective Date**), BioDelivery Sciences International, Inc. (the **Company**) and Shionogi Inc., a Delaware corporation (**Shionogi**), entered into an exclusive license agreement (the **License Agreement**) for the commercialization of Symproic® (naldemedine tosylate) (the **Product**) in the United States including Puerto Rico (the **Territory**) for opioid-induced constipation in adult patients with chronic non-cancer pain (the **Field**).

Pursuant to the terms of the License Agreement, and subject to the conditions set forth therein, the Company will pay Shionogi a \$30 million up-front payment, payable in two installments (i.e., \$20 million on the Effective Date and \$10 million on the six-month anniversary of the Effective Date (or earlier if the License Agreement is assigned or transferred), and quarterly, tiered royalty payments on potential sales of the Product in the Territory that range from 8.5% to 17.5% (plus an additional 1% of net sales on a pass-through basis to a third party licensor of Shionogi) of net sales based on volume of net sales and whether the Product is being sold as an authorized generic.

The Company and Shionogi have made customary representations and warranties and have agreed to certain other customary covenants, including confidentiality, limitation of liability and indemnity provisions.

Either party may terminate the License Agreement for cause if the other party materially breaches or defaults in the performance of its obligations, and, if curable, such material breach remains uncured for 120 days (30 days for non-payment). Unless earlier terminated, the License Agreement will continue in effect until the expiration of the Company's royalty obligations which expire on the latest of: (a) the expiration of all regulatory exclusivity for the Product in the Field in the Territory, (b) expiration of the last to expire orange book patent in the Territory, (c) the date of a final court decision holding all the unexpired claims of the orange book patents to be invalid or unenforceable, or (d) the tenth (10th) anniversary of the Effective Date for Product (or, for Symproic commercialized by the Company as an authorized generic in accordance with the License Agreement (the **AG Product**), the seventh (7th) anniversary of the first commercial sale of AG Product in the Territory). Upon expiration of the License Agreement, all licenses granted to Company for the Product in the Field and in the Territory survive and become fully-paid, royalty-free, perpetual and irrevocable.

The Company and Shionogi have also entered into a customary supply agreement under which Shionogi will supply the Product to the Company at cost plus an agreed upon markup for an initial term of up to two years. In the event the Company elects to source the Product from a third party supplier, Shionogi would continue to supply the Company with naldemedine tosylate for use in such Product at cost plus such agreed upon markup for the duration of the License Agreement. The Company and Shionogi also entered into a customary transition services and distribution agreement under which Shionogi will continue to perform certain sales, distribution and related activities and commercialization and administrative services on the Company's behalf until June 30, 2019, or such later date as may be agreed by the parties pursuant to the transition services and distribution agreement (the **Transition Date**) (during which time, in lieu of paying royalties and cost-plus supply, distribution and transitional services during this period, Shionogi will retain 35% of the net sales of Product in the Territory and remit the remaining 65% of net sales to the Company) and certain other customary transitional services (if so requested by the Company), initially at no cost and thereafter, at a specified hourly rate for a term not to exceed three months from the Transition Date or the term of the Agreement.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the text of the License Agreement, a copy of which is filed as Exhibit 10.1 hereto.

CRG Term Loan Amendment

On April 4, 2019, the Company entered into a third amendment (the Third Amendment) to the term loan agreement, dated as of February 21, 2017 and as amended on December 15, 2017 and on May 16, 2018 (the Loan Agreement), among the Company, the subsidiary guarantors, CRG Servicing LLC, as administrative agent and collateral agent (in such capacity, the Administrative Agent), and the lenders listed therein (the Lenders). The general terms, conditions and covenants of the Loan Agreement and the security granted by the Company and its subsidiaries thereunder are described in the Company's Current Report on Form 8-K, filed with the SEC on February 27, 2017, as subsequently amended, which description is incorporated herein by reference.

Pursuant to the Third Amendment, the Administrative Agent and the Lenders consent to the Borrower's entry into the License Agreement. The foregoing description of the Third Amendment does not purport to be complete and is qualified in its entirety by reference to the text of the Amendment, a copy of which is filed as Exhibit 10.2 hereto.

Item 7.01 Regulation FD Disclosure.

On April 10, 2019, the Company and Shionogi issued a press release announcing the execution of the License Agreement. A copy of the press release is attached as Exhibit 99.1 hereto.

The information set forth under Item 7.01 and in Exhibit 99.1 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 shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Information.

With respect to the Company's ongoing litigation related to BUNAVAI®, as disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2018, on February 7, 2019, the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office (USPTO) issued its decision on the remanded claims, denying three of the Company's *inter partes* review claims. On March 11, 2019, the Company filed a notice of appeal with the USPTO. Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC) has filed a motion to dismiss the appeal, which is pending.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

- 10.1* License Agreement, by and between the Company and Shionogi, dated as of April 4, 2019.
- 10.2 Third Amendment to the Loan Agreement, among the Company, the subsidiary guarantors, the Administrative Agent and the Lenders, dated as of April 4, 2019.
- 99.1 Press release, dated April 10, 2019, announcing the License Agreement between the Company and Shionogi.

* Confidential portions of this exhibit have been omitted.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

April 10, 2019

**BIODELIVERY SCIENCES INTERNATIONAL,
INC.**

By: /s/ Mary Theresa Coelho

Name: Mary Theresa Coelho

Title: Chief Financial Officer and Treasurer