

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

February 06, 2018

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): February 6, 2018 (February 2, 2018)

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

On February 5, 2018, BioDelivery Sciences International, Inc. (the Company) entered into indemnification agreements (the Indemnification Agreements) with each member of its board of directors (each, an Indemnitee). The form of Indemnification Agreement (the Form of Indemnification Agreement) was approved by the board of directors of the Company.

The Indemnification Agreements are intended to clarify and supplement the indemnification rights and obligations of the Indemnitees and the Company already included in the Company's Certificate of Incorporation, as amended, and Second Amended and Restated Bylaws, and generally provide that, subject to certain exceptions specified in the Indemnification Agreements, the Company will indemnify the Indemnitee to the fullest extent permitted by Delaware law in the event the Indemnitee becomes subject to or a participant in certain claims or proceedings as a result of the Indemnitee's service as a director or officer. The Company will also, subject to certain exceptions and repayment conditions, be obligated to advance to the Indemnitee specified indemnifiable expenses incurred in connection with such claims or proceedings.

The description of the Indemnification Agreements set forth in this Item 1.01 is not complete and is qualified in its entirety by reference to the full text of the Form of Indemnification Agreement which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On February 2, 2018, the Company engaged Mark A. Sirgo, the Company's Vice Chairman and former President and Chief Executive Officer (Sirgo), to provide certain transitional consulting services to the Company under the direction of the Chairman of the Board of the Company. The engagement by Sirgo as a consultant was made pursuant to a consulting agreement between the Company and Sirgo (the Consulting Agreement) and shall continue until terminated by either party at any time after March 31, 2018. After March 31, 2018, the Consulting Agreement shall become at-will, meaning that either Sirgo or the Company may terminate the Consulting Agreement at any time, for any reason, upon written notice to the other party.

Pursuant to the Consulting Agreement Sirgo will be paid a cash fee as follows: (i) \$30,000 per month for services provided in the months of January, February, and March 2018; and (ii) after March 31, 2018, at the rate of \$250 per hour.

The description of the Consulting Agreement set forth in this Item 5.02 is not complete and is qualified in its entirety by reference to the full text of the Consulting Agreement which is filed as Exhibit 10.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 8.01. Other Information.

On February 2, 2018, the Company entered into a Settlement Agreement (the Settlement Agreement) with Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. (collectively, Teva) to resolve the Company's previously reported BELBUCA® patent litigation against Teva pending in the United States District Court for the District of Delaware.

As part of the Settlement Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, the Company has granted Teva a non-exclusive license (for which the Company will receive no current or future payments) that permits Teva to first begin

selling its generic version of the Company's BELBUCA® product in the U.S. on January 23, 2027 or earlier under certain circumstances (including, for example, upon (i) the delisting of the patents-in-suit from the U.S. Food and Drug Administration Orange Book, (ii) the granting of a license by the Company to a third party to launch another generic form of BELBUCA® at a date prior to January 23, 2027, or (iii) the occurrence of certain conditions regarding BELBUCA® market share).

On February 6, 2018, the Company issued a press release announcing that it had entered into the Settlement Agreement. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	<u>Form of Indemnification Agreement</u>
10.2	<u>Consulting Agreement, dated February 2, 2018, between the Company and Sirgo.</u>
99.1	<u>Press release, dated February 6, 2018, announcing the Company's entry into a settlement agreement with Teva.</u>

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, the press release included herein, and any statements of representatives and partners of the Company related thereto contain, or may contain, among other things, certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as projects, may, will, could, would, should, believes, expects, anticipates, plans, potential or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the results of the operations of the Company and any anticipated benefits of the Company's settlement with Teva as described in the attached press release) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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.

February 6, 2018

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Ernest R. De Paolantonio

Name: Ernest R. De Paolantonio

Chief Financial Officer, Treasurer and

Title: Secretary