

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

December 31, 2009

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): December 31, 2009 (December 30, 2009)

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.)

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801 Corporate Center Drive, Suite #210

Raleigh, NC
(Address of principal executive offices)

27607
(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))

Item 1.01 Entry into a Material Definitive Agreement.

Agreement Relating to the Settlement of a Dispute with Accentia Biopharmaceuticals, Inc.

On December 30, 2009, BioDelivery Sciences International, Inc. (the Company) and Accentia Biopharmaceuticals, Inc. (ABPI), a related party of the Company through common ownership and management, entered into an Emezine Settlement Agreement (the Agreement) between the Company, Accentia, the Company's wholly-owned subsidiary Arius Pharmaceuticals, Inc. (Arius) and Accentia Pharmaceuticals, Inc. (f/k/a TEAMM Pharmaceuticals Inc. and referred to herein as TEAMM), and together with ABPI (Accentia), a wholly owned subsidiary of ABPI. The Agreement is filed as Exhibit 10.1 to this Current Report on Form 8-K.

The purpose of the Agreement is to memorialize the terms and conditions of a settlement between the Company and Accentia (the Settlement) of claims by TEAMM relating to a Distribution Agreement, dated March 12, 2004 (the Distribution Agreement), between Arius and TEAMM. At the time the Distribution Agreement was entered into, Arius was not affiliated with the Company. Arius was acquired by the Company in August 2004.

On November 10, 2008, Accentia filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code (the Reorganization).

The Distribution Agreement related to the marketing and distribution of Emezine, a product licensed by Arius from Reckitt Benckiser Healthcare (UK) Limited (Reckitt) that the Company was developing from 2004 to 2006. Following the issuance in February 2006 by the U.S. Food and Drug Administration (FDA) of a non-approvable letter with respect to the New Drug Application (NDA) for Emezine, the Company began an evaluation of the prospects for Emezine. In 2007, the Company ceased its Emezine related efforts and on December 17, 2008, the Distribution Agreement was terminated in conjunction with the exercise by Reckitt of its rights to cancel the Emezine license with Arius and cause the reversion of the rights to Emezine back to Reckitt.

The purpose of the Settlement is to settle TEAMM's claims against the Company as it relates to all aspects of the development of Emezine under the terminated Distribution Agreement. As disclosed in the Company's Form 10-Q for the period ended September 30, 2009, the Company does not believe that Accentia's claims have merit, but the Company also believes that the alternative of a protracted dispute would be distracting, time consuming and costly at a time when the Company is focusing its efforts on the commercial launch of ONSOLIS, its first approved product, and on the development of its product pipeline including BEMA Buprenorphine. As such, the Company has elected to enter into the Agreement.

The Agreement is subject to a final, non-appealable order of the bankruptcy court overseeing the Reorganization (the Bankruptcy Court).

Summary of the Agreement

Release of Claims, Payment and Grant of Product Rights

The Agreement provides that the Company and Accentia mutually release all claims that either may have against each other and, in connection therewith, the Company will:

(a) pay \$2.5 million to Accentia (the \$2.5 Million Payment); and

(b) grant the following royalty rights (the Product Rights) to Accentia with respect to the Company's BEMA Granisetron product candidate (BEMA Granisetron) (or in the event it is not BEMA Granisetron, the third Company product candidate (excluding BEMA Buprenorphine) as to which the Company files an NDA, which, together with BEMA Granisetron, shall be referred to hereinafter as the Product);

(i) 70/30 split (Company/Accentia) of royalty received if a third party sells the Product and 85/15 split on net sales if the Company sells the Product; and

(ii) The Company will, from the sale of the Product, fully recover amounts equal to (1) all internal and external worldwide development costs of the Product (Costs) plus interest (measured on weighted average prime interest rate from first dollar spent until Product launch) and (2) the \$2.5 Million Payment plus interest (measured on weighted average prime interest rate from the time of payment until Product launch) before Accentia begins to receive its split as described in (b) (i) above.

However, should the Company receive any sublicensing or milestone payments associated with the Product up to and including the NDA approval, the Company will apply 30% of such payments toward payback of the Costs of the Product plus interest and the \$2.5 Million Payment plus the interest.

The \$2.5 Million Payment shall be made upon approval of the Agreement by the Bankruptcy Court and subsequent to a 10 day appeal period, and only if no appeals are received. However, the transfer of Products Rights shall become effective only upon Accentia's exit from Reorganization as evidenced by an effective reorganization plan for Accentia that is confirmed by the Bankruptcy Court, and any conditions to the plan have been satisfied or waived by Accentia. If Accentia does not exit Reorganization by December 31, 2010, the transfer of Product Rights shall be deemed terminated and of no force or effect.

In the event of a proposed sale of the Company or its assets, the Company shall have the right to terminate its Product Right payment obligations and all other obligations to Accentia under the Agreement upon the payment to Accentia of an amount equal to the greater of: (i) Four Million Five Hundred Thousand Dollars (\$4,500,000), or (ii) the fair market value of the Product Rights as determined by an independent third party appraiser. Further, if the Product Right is terminated, the Warrant described below will be terminated if not already exercised, and, if exercised, an amount equal to the strike price will, in addition to the amount in (i) or (ii) above, be paid to Accentia. The Company and Accentia have also agreed to negotiate in good faith to determine a payment amount at any time the Company wishes to repurchase the Product Rights.

Grant of Biovest Warrant to the Company

In addition, pursuant to the Agreement, the Company will receive a warrant (Warrant) to purchase two (2) million shares of Accentia s majority-owned subsidiary, Biovest International, Inc. (Biovest) from Accentia, with a strike price equal to 120% of the closing bid price of Biovest s common stock as of the date the Bankruptcy Court enters a final order authorizing Accentia to carry out the Agreement, with the issuance of the Warrant to occur upon the \$2.5 Million Payment by the Company. The Warrant will be exercisable immediately and for a period of seven (7) years from the date of issuance. During the initial two (2) year exercise period, any exercise of the Warrant by the Company will be subject to approval by Biovest.

Company Special Independent Committee

The Agreement was negotiated on behalf of the Company by a special independent committee of the Company s board of directors (the Committee) composed of William B. Stone, Mark A. Sirgo and John J. Shea, each of whom are not conflicted as a result of any association with Accentia. The Committee was constituted and empowered with all rights and privileges of the full board of directors to negotiate, settle and undertake all other actions in connection with the dispute with Accentia. Two of the Company s directors, Dr. Frank E. O Donnell (who serves as Chairman of the Company s board of directors) and William S. Poole, are, respectively, the Chairman and Chief Executive Officer and a director of Accentia. In addition, James A. McNulty, the Company s Chief Financial Officer, acts as Accentia s corporate secretary and treasurer. These individuals did not and will not participate as part of the Committee in its negotiations, deliberations or approvals in connection with this matter.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

- 10.1 Emezine Settlement Agreement, dated December 30, 2009, between the Company, Accentia, Arius and TEAMM.
- 10.2 Warrant, dated January , 2010, for the Company to purchase 2,000,000 shares of Biovest International, Inc. from Accentia.
- 10.3 Escrow Agreement, dated December 30, 2009, the Company, Accentia, Arius, TEAMM and American Stock Transfer & Trust Company, LLC, as escrow agent with respect to the \$2.5 Million Payment.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K and the exhibits hereto and the 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", "could", "would", "should", "believes", "expects", "anticipates", "estimates", "intends", "plans" 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 impact of the Company's agreement with Accentia described herein, 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).

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.

December 31, 2009

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: */s/* MARK A. SIRGO
Name: **Mark A. Sirgo**
Title: **President and Chief Executive Officer**