BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
September 10, 2007

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) September 10, 2007 (September 4, 2007)

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**0-28931**	**35-2089858**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2501 Aerial Center Parkway, Suite 205

Morrisville, North Carolina	**07103**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (919) 653-5160

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.

A. Meda License

On September 5, 2007, BioDelivery Sciences International, Inc. (the Company) entered into a definitive License and Development Agreement (the License Agreement) with Meda AB, a Swedish company (Meda), and Arius Pharmaceuticals, Inc., a wholly-owned subsidiary of the Company (Arius), pursuant to which the Company and Arius agreed to grant to Meda an exclusive commercial license to manufacture, market, sell, and, following regulatory approval, continue development of the Company s BEMA Fentanyl product in the United States, Mexico and Canada.

Pursuant to the License Agreement, the Company will receive:

$30 million milestone payment upon closing, which is contingent upon antitrust approval by the Federal Trade Commission, which typically occurs within 30 days of filing the applicable request.

An additional $30 million milestone payment concurrently with receipt of approval of BEMA Fentanyl by the U.S. Food and Drug Administration (FDA), unless the Company has not, at such time, manufactured stocks of BEMA Fentanyl, in bulk or finished form, sufficient for commercial launch of BEMA Fentanyl in the U.S., in which case $15 million will be paid upon FDA approval and $15 million will be paid upon the earlier of: (A) the date that such sufficient launch stocks are manufactured or (B) the first commercial sale of BEMA Fentanyl. The Company anticipates that it will have sufficient launch stocks of BEMA Fentanyl product concurrently with FDA approval of BEMA Fentanyl.

A significant double digit royalty on net sales of BEMA Fentanyl in the covered territories, subject to certain third party royalty adjustments and other adjustments in the event of certain specific supply disruptions. The License Agreement provides for certain guaranteed minimum annual royalties to the Company during the second through seventh years following the product s first commercial sale.

Sales milestones: A total of $30 million payable at:

$10 million when annual sales exceeds $75 million;

$10 million when annual sales exceeds $125 million; and

$10 million when annual sales exceeds $175 million

Also, pursuant to the License Agreement, BDSI has been granted certain rights to co-promote BEMA Fentanyl using its own sales force, with financial support by Meda of such efforts for a period of 3 years. In addition, Meda is subject to certain minimum sales call and advertising and promotional expenditure requirements under the License Agreement, and has agreed to support costs of clinical development undertaken following FDA approval to pursue approval of additional indications for BEMA Fentanyl.

In connection with the License Agreement, on September 5, 2007, the Company, Arius and Meda entered into a BEMA Fentanyl Supply Agreement pursuant to which the Company and Arius agreed to supply to Meda, and Meda agreed to acquire from BDSI, all of Meda s needs of BEMA Fentanyl products and related placebos and demonstration samples in connection with Meda s BEMA Fentanyl development, marketing, sales efforts.

B. U.S. BEMA Asset Acquisition

On September 5, 2007, Arius Two, Inc., a wholly owned subsidiary of the Company (Arius Two), exercised a previously granted option and purchased from QLT USA, Inc. (QLT) the BEMA drug delivery technology and intellectual property assets specifically related to the development and commercialization of BEMA in the United States (the BEMA U.S. Rights) from QLT pursuant to an Intellectual Property Assignment Agreement entered into by the parties (the IP Agreement). Arius had previously licensed the BEMA U.S. Rights from QLT.

In consideration for the BEMA U.S. Rights, Arius Two paid QLT $7 million, consisting of $3 million in cash and a promissory note, secured by the purchased assets, in the principal amount of $4 million. Payments under such note are due as follows: (i) $2 million within ten (10) business days of FDA approval of a product based on the BEMA technology and (ii) $2 million within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA -based products reach $30 million. The Company used the proceeds of a $3 million secured loan from Southwest Bank of St. Louis (Southwest Bank) described below to fund the initial payment to QLT.

In connection with the IP Agreement, QLT and Arius entered into a Termination Agreement, dated September 5, 2007 (the Termination Agreement), whereby the license previously held by Arius for the use, development, and commercialization of BEMA technology in the United States (the U.S. License) was terminated upon Arius Two s acquisition of the U.S. BEMA Rights. CDC IV, LLC (CDC), as third party beneficiary of the U.S. License, consented to the termination effected by the Termination Agreement.

In connection with the transactions described above in Items 1.01 (A) and 1.01(B), certain consents and agreements were required of CDC. The Company is a party to several existing agreements with CDC pursuant to which CDC has funded the development of BEMA Fentanyl. CDC entered into agreements with the Company as of September 5, 2007 wherein CDC granted the consents and waivers necessary to enable Arius Two to purchase the BEMA U.S. Rights from QLT as contemplated by the IP Agreement and its related agreements. In addition, CDC granted the required consents and waivers necessary, under the terms of CDC s agreements with the Company, to enable the Company to enter into and perform its obligations under the License Agreement with Meda.

C. CDLA Amendment/CDC Dispute Resolution/CDC Royalty Acquisition

CDLA Amendment

In order to facilitate the transaction with Meda, on September 5, 2007, the Company and CDC entered into an amendment (the CDLA Amendment) to that certain Clinical Development and License Agreement, dated July 14, 2005, between the Company and CDC (as amended, the CDLA) clarifying certain royalty adjustment provisions thereof.

Dispute Resolution Agreement

On September 5, 2007, in connection with CDC s consent to the Meda transaction, the Company and CDC entered into a Dispute Resolution Agreement (the DRA) pursuant to which the Company and CDC agreed to waive and dismiss with prejudice all current disputes between the Company and CDC concerning each of: (i) the CDLA and (ii) that certain Securities Purchase Agreement, dated May 16, 2006 (as amended, the SPA), by and among the Company and CDC.

Royalty Acquisition and Amendment

As a condition to CDC s entrance into the Dispute Resolution Agreement and its consent to the Meda transaction, the Company and CDC have entered into a Royalty Purchase and Amendment Agreement, dated September 5, 2007 (the RPAA) pursuant to which: (i) the right of first negotiation on Company financings described in Section E(4) of the SPA (as modified by that certain Stipulation, Index no. 06/603626, ordered by the Supreme Court of the State of New York, County of New York in October 2006 (as previously disclosed)), was amended to covert such right into a right of first refusal on Company financings (the ROFR) and (ii) the Company granted CDC a 1% royalty on sales of the next BEMA product including an active pharmaceutical ingredient other than fentanyl to receive FDA approval (the Next BEMA Product).

Pursuant to the ROFR, if the Company desires to enter into a transaction with any third party to offer and sell its debt and/or equity securities for cash other than in connection with: (i) a bona fide commercial partnering transaction relating to BEMA™ Fentanyl product or (ii) any debt financing from a federal or state accredited bank, provided the annualized interest rate thereunder will not exceed 18% (a Financing Transaction), the Company shall first provide CDC a written notice containing all of the terms and conditions pursuant to which BDSI would enter the Financing Transaction (the Definitive Terms). For a period of ten (10) days following CDC s receipt of the Definitive Terms (the Acceptance Period), CDC shall have the right, but not the obligation, (the Acceptance Right) to elect in writing to engage in the Financing Transaction on the Definitive Terms. If, during the Acceptance Period, CDC elects to exercise its Acceptance Right, the Company and CDC agree to then exclusively negotiate, definitive documentation relating to the Financing Transaction for a period not to exceed thirty (30) days from the date of CDC s exercise of its Acceptance Right. The definitive documentation shall be based upon, and shall be consistent in all material respects with, the Definitive Terms, without modification. If, during the Acceptance Period, CDC does not elect to exercise its Acceptance Right, or, in the event the Acceptance Right is exercised but a closing of the Financing Transaction does not occur within the thirty (30) day period referred to) above, then the Company shall have sixty (60) days in which to consummate a Financing Transaction with any third party with no further action or approval required by the CDC; provided, however, that the terms and conditions of such transaction shall be not less favorable to the Company than the terms and conditions set forth in the Definitive Terms.

The ROFR will cease at any time the Company maintain a volume weighted average stock price of $9.00 per share (as adjusted for stock splits, reverse stock splits, stock dividends and such similar transactions) for ten (10) trading days during any twenty (20) consecutive trading day period.

In connection with the 1% royalty grant: (i) CDC shall have the option to exchange its royalty rights to the Next BEMA Product in favor of royalty rights to a substitute BEMA product, (ii) the Company shall have the right, no earlier than six (6) months prior to the initial commercial

launch of the Next BEMA Product, to propose in writing and negotiate the key terms pursuant to which it would repurchase the royalty from CDC, (iii) CDC s right to the royalty shall immediately terminate at any time if annual net sales of the Next BEMA Product equal less than seven $7.5 million in any calendar year following the third (3rd) anniversary of initial launch of the product and CDC receives $18,750 in three (3) consecutive quarters as payment for CDC s one percent (1%) royalty during such calendar year and (iv) CDC shall have certain information rights with respect to the Next BEMA Product.

Allonge

In connection with the RPAA, the Company and CDC entered into an Allonge, dated September 5, 2007 (the Allonge), amending a promissory note dated March 12, 2007 (the March Note) in the amount of $1,900,000, executed by the Company in favor of CDC. Pursuant to the Allonge, the March Note is amended so that any breach or default under the RPAA shall also be considered an event of default under the March Note.

D. Southwest Bank of St. Louis Note and Security Agreement

In order to fund the initial payment to QLT for the BEMA U.S. Rights, the Company borrowed $3 million from Southwest Bank. To evidence the loan, the Company entered into a Promissory Note, dated September 4, 2007, in favor of Southwest Bank (the Promissory Note). The Promissory Note provides for the principal amount to be paid in full no later than October 31, 2007. The Promissory Note bears interest at prime rate plus 1%. The Company expects to repay the amounts due under the Promissory Note from the initial milestone payment expected from Meda.

The principal reason for incurring the debt from Southwest Bank and making the initial payment for the BEMA U.S. Rights in advance of the execution of the Meda License Agreement was for the Company to be able to avoid having to pay to QLT a milestone payment which would have been due to QLT under the existing (now terminated) license agreement for the BEMA technology.

In connection with the Promissory Note, the Company entered into a Security Agreement with Southwest Bank, dated September 4, 2007 (the Security Agreement), granting Southwest Bank a security interest in all of its assets, other than any asset for which an encumbrance would require the consent of a third party, including intellectual property licensed from third parties.

Under the Security Agreement, Southwest Bank may call an event of default under limited circumstances, which include: (i) default in the due and punctual payment of any installment of principal or interest on the Promissory Note when and as the same become due and payable, whether at maturity or by acceleration or otherwise which is not cured within any applicable cure period; (ii) default in the performance or observance of or under any covenant, agreement or provision contained in the Security Agreement or in any instrument or document delivered to Southwest Bank in connection with or pursuant to the Security Agreement which continues for a period of 30 days after notice thereof to the Company from Southwest Bank, or if any such instrument or document terminates or becomes void or unenforceable without the written consent of Southwest Bank; or (iii) Southwest Bank shall receive at any time a notice or report from the Secretary of State of Delaware indicting that Southwest Bank s security interest is not prior to all other security interests reflected in such report. Upon an event of default, Southwest Bank may declare all amounts due under the Promissory Note due and payable.

Pursuant to a Continuing Contract of Guarantee, dated September 4, 2007, Frank E. O Donnell, Jr., the Company s Chairman of the Board (O Donnell) and a trust for the benefit of O Donnell have agreed to guarantee the Company s obligations under the Promissory Note and Security Agreement. In addition, pursuant to Hypothecation Agreement, dated September 4, 2007, Hopkins Capital Group II, LLC (HCG II), a significant stockholder of the Company controlled by O Donnell, has agreed to pledge certain assets of HCG II to secure the Company s obligations under the Promissory Note and Security Agreement.

E. HCG II Agreements

As a condition to the execution of the agreements with CDC, HCG II and the Company have agreed to terminate an option previously granted to HCG II in March 2007 to purchase a revenue participation on future BEMA Fentanyl product sales for $5 million dollars. In consideration of this agreement, HCG II was granted a warrant to purchase 475,000 shares of the Company s common stock at an exercise price of $5.55 per share.

In connection therewith, HCG II was granted certain registration rights with respect to shares of common stock underlying these warrants and other unregistered shares of Company common stock held by HCG II, representing approximately 3.98 million shares in the aggregate. The Company is required to file a registration statement with the SEC registering such shares for resale, which registration statement is required to be filed by December 4, 2007.

Item 1.02 Termination of a Material Definitive Agreement

As more fully described in Item 1.01, which information is incorporated in this Item 1.02 by reference, in connection with Arius Two s acquisition of the BEMA U.S. Rights, Arius has terminated its rights to the U.S. License.

As more fully described in Item 1.01, which information is incorporated in this Item 1.02 by reference, the Company and HCG II have terminated that certain option to purchase a revenue participation on future BEMA Fentanyl product sales.

Item 2.01 Completion of Acquisition or Disposition of Assets

As more fully described in Item 1.01, which information is incorporated in this Item 1.02 by reference, Arius Two has acquired the BEMA U.S. Rights from QLT.

As more fully described in Item 1.01, which information is incorporated in this Item 1.02 by reference, Arius has disposed of its U.S. License.

Item 2.03 Creation of a Direct Financial Obligation

As more fully described in Item 1.01, which information is incorporated in this Item 2.03 by reference, Arius Two has entered into a Secured Promissory Note in favor of QLT in principal amount of $4 million dollars. The Company has provided a guaranty of such obligation to QLT through its execution of that certain Guaranty dated September 5, 2007.

As more fully described in Item 1.01, which information is incorporated in this Item 2.03 by reference, the Company has entered into a Promissory Note in favor of Southwest Bank in principal amount of $3 million dollars.

Item 3.02 Unregistered Sales of Equity Securities

As more fully described in Item 1.01, which information is incorporated in this Item 2.03 by reference, on September 5, 2007, the Company has issued to a HCG II warrant to purchase 475,000 shares of its common stock at an exercise price of $5.55 per share. The warrant expires on the second (2nd) anniversary following the approval by the relevant governmental authority(ies) required for the initial launch, marketing and sale of a BEMA formulated product of the Company for human therapeutic use in a particular jurisdiction (including but not limited,

in jurisdictions other than the United States, to all pricing and reimbursement approvals). The warrants were issued pursuant to exemption from registration under Section 4(2) of the Securities Act of 1933, as amended.

Item 7.01 Regulation FD Disclosure

In connection with the Meda License described in Item 1.01, the Company issued a press release on September 5, 2007. This press release is attached to this Current Report as Exhibit 99.1.

In connection with the acquisition of the BEMA U.S. Rights, the Company issued a press release on September 10, 2007. This press release is attached to this Current Report as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

Set forth below is a list of Exhibits included as part of this Current Report.

4.1	Warrant for 475,000 shares issued to HCG II.
4.2	Registration Rights Agreement dated September 5, 2007, by and among the Company and Hopkins Capital.
*10.1	License and Development Agreement dated September 5, 2007, by and among the Company, Arius, and Meda.
*10.2	BEMA Fentanyl Supply Agreement dated September 5, 2007, by and among the Company, Arius, and Meda.
*10.3	Sublicensing Consent dated September 5, 2007, by and among Arius and Arius Two.
*10.4	License Agreement dated September 5, 2007, by and among Arius and Arius Two.
*10.5	Intellectual Property Assignment Agreement dated September 5, 2007, by and among QLT and Arius Two.
10.6	Amended and Restated Patent and Trademark Security Agreement dated September 5, 2007, by and among Arius Two and QLT.
10.7	Amended and Restated Security Agreement dated September 5, 2007, by and among Arius Two and QLT.
10.8	Amended and Restated Patent and Trademark Security Agreement dated September 5, 2007, by and among Arius Two and QLT.
10.9	Amended and Restated Security Agreement dated September 5, 2007, by and among Arius Two and QLT.
10.10	Assignment of Patents and Trademarks dated September 5, 2007, by and among Arius Two and QLT.
10.11	Termination Agreement dated September 5, 2007, by and among Arius, QLT and CDC (solely as third party beneficiary).
10.12	Patent and Trademark Security Agreement dated September 5, 2007, by and among Arius Two and QLT.
10.13	Security Agreement dated September 5, 2007, by and among Arius Two and QLT.
10.14	Second Amendment Agreement dated September 5, 2007, by and among Arius Two and Arius.

*10.15	Secured Promissory Note dated September 5, 2007, by Arius Two in favor of QLT.
10.16	Guaranty dated September 5, 2007, by the Company in favor of QLT.
10.17	BEMA Acquisition Consent, Amendment and Waiver dated September 5, 2007, by and among the Company, Arius, Arius Two, and CDC.
*10.18	Sublicensing Consent and Amendment dated September 5, 2007, by and among the Company, Arius, CDC and Meda.
*10.19	Royalty Purchase and Amendment Agreement dated September 5, 2007, by and among the Company and CDC.
*10.20	Amendment to Clinical Development and License Agreement, dated September 5, 2007, by and among CDC, the Company, Arius, and Arius Two.
10.21	Dispute Resolution Agreement dated September 5, 2007, by and among the Company and CDC.
10.22	Promissory Note dated September 4, 2007, by the Company in favor of Southwest Bank.
10.23	Security Agreement dated September 4, 2007, by and among the Company and Southwest Bank.
10.24	Continuing Contract of Guarantee dated September 4, 2007, by and among Francis O Donnell, Jr. and Kathleen M. O Donnell, as trustee of the Francis E. O Donnell, Jr. Irrevocable Trust, and Southwest Bank.
10.25	Hypothecation Agreement dated September 4, 2007, by HCG II in favor of Southwest Bank.
10.26	Acknowledgement by CDC to Meda, dated September 5, 2007.
10.27	Side Letter Agreement by and among QLT and CDC, dated September 5, 2007.
10.28	Side Letter Agreement by and among the Company, Arius, Arius Two and CDC, dated September 5, 2007.
10.29	Side Letter Agreement by and among QLT and Meda, dated September 5, 2007.
10.30	Confirmation to Meda of the Company, Arius and Arius 2, dated September 5, 2007.

10.31	Allonge by and among the Company and CDC, dated September 5, 2007.
99.1	Press Release, dated September 5, 2007 regarding Meda transaction.
99.2	Press Release, dated September 10, 2007, regarding BEMA U.S. Rights acquisition.

*** Confidential treatment is requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.**

This Current Report on Form 8-K may contain, among other things, certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements with respect to the Company s plans, objectives, expectations and intentions and other statements identified by words such as may , could , would , should , believes , expects , anticipates , estimates , 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. Actual results may differ 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.

September 10, 2007

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty
Name: James A. McNulty
Title: Secretary, Treasurer and CFO