BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
August 26, 2004

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) August 26, 2004 (August 23, 2004)

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.)**

UMDNJ Medical School

185 South Orange Avenue, Bldg #4

Newark, New Jersey	**07103**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code (973) 972-0015

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.

On August 23, 2004, BioDelivery Sciences International, Inc. (the **Company**) terminated its previously disclosed Facility Credit Agreement, dated August 2, 2004 (the **Facility**), with Hopkins Capital Group II, LLC (**HCG**), an affiliated entity of the Company which is controlled and partially-owned by Dr. Francis E. O Donnell, Jr., the Company s Chairman and CEO. Contemporaneously with such termination, the Company also entered into a binding, enforceable letter of intent for an Equity Line of Credit Agreement (the **Equity Line Agreement**) to replace the Facility. The letter of intent is fully binding on HCG, and the parties have agreed to enter into further appropriate documentation to memorialize their agreement by September 3, 2004. The Equity Line Agreement was approved by the Company s board of directors on August 23, 2004.

Pursuant to the Equity Line Agreement, HCG will agree, as requested by the Company, to invest up to $4,000,000 in the Company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock of BDSI (the **Series B Preferred**). The holders of the Series B Preferred will be entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred will be convertible at any time as of or after April 1, 2006 at a price equal to $4.25 per share. The Series B Preferred will rank senior to shares of the Company s common stock and the Company s Series A Non-Voting Convertible Preferred Stock, will have registration rights, dividend and liquidation preferences and certain other privileges. The Series B Preferred can not be redeemed at the election of HCG, but the Company has the right, in its discretion at any time, to redeem the shares of Series B Preferred stock for cash equal to the amount invested under the Equity Line Agreement plus accrued dividends thereon.

Item 1.02 Termination of a Material Definitive Agreement.

As described above, on August 23, 2004, the Company terminated the Facility with HCG and contemporaneously with such termination entered into a binding, enforceable letter of intent with respect to the Equity Line Agreement.

Item 2.01. Completion of Acquisition or Disposition of Assets.

On August 24, 2004, the Company closed its previously announced acquisition (the **Acquisition**) of Arius Pharmaceuticals, Inc., a Delaware corporation (**Arius**). As a result of the consummation of the Acquisition, Arius has been reorganized with and into a newly formed, wholly-owned subsidiary of the Company.

As part of the Acquisition, the Company has issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of a newly designated, non-voting and non-interest bearing, series of convertible preferred stock. The newly-created Series A Non-Voting Convertible Preferred Stock (the **Series A Preferred**) is convertible (upon the satisfaction of certain conditions) into shares of the Company s common stock (the **Common Stock**) on a one for one basis. Shares of Series A Preferred are eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first proposed product (ii) 30 days notice to the Company of a Conversion Event (hereinafter defined) or (iii) five (5) years from the closing date of the Acquisition. The term **Conversion Event** is defined in the Certificate of Designation of the Series A Preferred to mean the failure of the Company to provide at least $3,000,000 to Arius as required to: (i) pay Atrix Laboratories, Inc. (NASDAQ:ATRX) (**Atrix**) $1,000,000 by August 24, 2004 pursuant to the terms of a license agreement between Arius and Atrix (described below) and (ii) fund, in a total amount of no less than $2,000,000, the operations of Arius. The holders of the Series A Preferred enjoy certain other rights and privileges.

The terms of the Series A Preferred include a provision that if, at the time that any shares of Series A Preferred are converted, the Common Stock is listed for quotation on The Nasdaq SmallCap Market or The Nasdaq National Market (collectively, **Nasdaq**), then, without the prior approval of the Company s stockholders in accordance with the rules of Nasdaq, the Company shall be prohibited from issuing shares of Common Stock to the extent that the total aggregate number of shares of Common Stock issued or deemed to be issued would exceed 19.99% of the issued and outstanding shares of Common Stock immediately prior to the effective time of the Acquisition.

As part of the closing, Dr. Mark A. Sirgo, a founder and the President and CEO of Arius, has entered into an employment agreement with the Company and has been named Senior Vice President of Commercialization and Corporate Development of the Company. Dr. Andrew Finn, also a founder and the Chief Operating Officer of Arius, has also entered into an employment agreement with BDSI and has been named Senior Vice President of Product Development at BDSI.

Arius is a specialty drug delivery company whose portfolio of potential products will be focused on acute treatment opportunities for surgical and oncology patients. In 2004, Arius acquired an exclusive worldwide license to the BEMA (buccal or mouth) delivery technology developed by Atrix. In connection with the closing, the Company made available to Arius $1 million under the Equity Line Agreement for payment by Arius of a license fee to Atrix as required under the Arius/Atrix agreement.

Arius is a party to the following material agreements:

1. License Agreement, dated May 27, 2004, and Clinical Supply Agreement, dated July 15, 2004, with Atrix Laboratories, Inc.

On May 27, 2004, Arius entered into a worldwide, exclusive royalty-bearing license agreement (the **Atrix License Agreement**) with Atrix Laboratories, Inc. (**Atrix**) to develop, market, and sell products incorporating Atrix s BEMA technology (as further described below), including its BEMA fentanyl product, and to use the BEMA trademark in conjunction therewith. All research and development related to the BEMA technology, including three existing Investigational New Drug Applications (INDs) are in the process of being transferred to Arius in accordance with the Atrix License Agreement. Under the terms of the Atrix License Agreement, Arius is required to pay Atrix: (i) an upfront licensing fee of $1 million, which was made available to Arius for payment to Atrix in conjunction with the Acquisition, (ii) additional cash payments upon achievement of certain developmental and regulatory milestones, (iii) for reimbursement for research and development support, and (iv) royalties on commercial sales of all BEMA products. A joint development management committee comprised of representatives of Arius and Atrix will oversee product development. Arius will be responsible for the research and development of the products, including costs and expenses, and for their sale, marketing, manufacture, and distribution, provided that, under the terms of a clinical supply agreement between Atrix and Arius entered into pursuant to the license agreement, Atrix shall provide Arius with certain supplies of BEMA-fentanyl product for clinical trials for a limited period of time, at Arius expense. Atrix retains certain co-promotion rights to the BEMA fentanyl product. The BEMA technology consists of a pre-formed biodegradable polymer disc for either systemic (transmucosal) or local drug delivery.

2. Agreement for the Licence and Supply of Buccal Prochlorperazine Maleate with Reckitt Benckiser Healthcare (UK) Limited dated January 6, 2004.

Effective January 6, 2004, Arius entered into an exclusive royalty-bearing license with Reckitt Benckiser Healthcare (UK) Limited (**RB**) to develop, market, and sell RB s Emezine (buccal prochlorperazine maleate) product for the treatment of nausea and vomiting in the United States, and to use the

Emezine trademark in conjunction therewith. Under the terms of the license agreement, Arius is required to pay RB: (i) an upfront licensing fee, which has been previously paid in accordance with the Reckitt agreement, (ii) an additional cash payment upon achievement of a certain developmental and regulatory milestone, and (iii) royalties on commercial sales of the licensed product. Arius will be responsible for the development of the product, including costs and expenses, and for its sale, marketing, and distribution in the United States. In addition, Arius shall be required to obtain from RB, and RB shall be required to supply to Arius, at Arius expense, all product to be sold under the license.

3. Distribution Agreement with TEAMM Pharmaceuticals, Inc. dated March 17, 2004.

On March 17, 2004, Arius granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc. (**TEAMM**) with respect to Arius Emezine(buccal prochlorperazine maleate) product for the treatment of nausea and vomiting, to which Arius obtained United States rights under Arius exclusive license with RB. In exchange for the grant of such rights, TEAMM: (i) has previously paid to Arius an upfront fee, (ii) has previously paid to Arius an initial milestone payment and shall in the future pay to Arius certain additional milestone payments upon achievement of certain developmental and regulatory milestones, (iii) shall support Arius clinical development costs with respect to such product, and (iv) shall pay royalties to Arius based on the sales of such product. In addition, Arius shall be obligated to supply TEAMM, at TEAMM s expense, with such products for sale and promotional use. TEAMM is a specialty pharmaceutical company and wholly owned subsidiary of Accentia Biopharmaceuticals, Inc., which in turn is a portfolio company of The Hopkins Capital Group, LLC. The Hopkins Capital Group, LLC is controlled by Dr. Francis E. O Donnell, Jr., the President and Chief Executive Officer of the Company, and HCG (referenced above), an affiliate of The Hopkins Capital Group, LLC, owns a significant percentage of the Company s common stock as of the date of this Report.

Item 3.02 Unregistered Sales of Equity Securities.

On August 24, 2004, the Company announced that $1,250,000 was drawn down under the Equity Line Agreement as of August 24, 2004, the proceeds of which have been used by the Company in connection with the closing of the Acquisition. Pursuant to the Equity Line Agreement, in consideration of its funding, HCG shall receive shares of Series B Preferred.

Item 8.01. Other Events.

On August 24, 2004, the Company announced that as of the quarter ended March 31, 2004, it was out of compliance with the cash to total liabilities ratio covenant contained in its $1 million Loan Agreement (the **GB Loan Agreement**) with Gold Bank (**Gold Bank**). The GB Loan Agreement was entered into by the Company in April 2003 and has been used to finance equipment at the Company s formulation facility in Newark, New Jersey. There is presently approximately $800,000 due under this facility, which is secured by the Company s equipment in Newark.

On August 24, 2004, the Company also announced that since May 14, 2004 it has been operating under a Limited Waiver and Forbearance Agreement with Gold Bank pursuant to which Gold Bank agreed, in consideration of a $10,000 fee payment, to waive compliance with the cash to liabilities covenant through June 30, 2004, which forbearance period has been extended to September 30, 2004 by the payment of subsequent $5,000 monthly payments. As previously announced in its Form 10-QSB for the quarter ended June 30, 2004, the Company is actively seeking ways to refinance and repay the Gold Bank debt.

On August 24, 2004, the Company further announced that Gold Bank indicated to the Company its belief that the Acquisition and associated transactions requires their consent. The Company believes that it has structured the Acquisition with its counsel to be in compliance with the terms and conditions of the loan documentation relating only to the Company s acquisitions of complementary businesses and that Gold Bank s consent is not required with respect to an acquisition of this kind. In response to the Company s position, Gold Bank has reviewed the publicly announced proposed structure of the Acquisition and has indicated that there may be other covenants that it will interpret to be in default as a result of the closing of the Acquisition and that it has reserved its rights under the loan agreement. Gold Bank has also indicated to the Company its belief that its consent is required for Facility. As indicated above, the Facility has been terminated and the Company has entered into the Equity Line Agreement in a structure that the Company believes does not require Gold Bank s consent.

Item 9.01. Financial Statements and Exhibits.

In accordance with Form 8-K, the financial statements required to be filed pursuant to Form 8-K in connection with the Acquisition will be filed by an amendment to this Current Report by Friday, November 5, 2004.

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

2.1	Agreement and Plan of Merger and Reorganization, dated August 10, 2004, by and among the Company, Arius Acquisition Corp., Arius, Dr. Mark Sirgo and Dr. Andrew Finn. (1)
4.1	Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 20, 2004. (1)
4.2	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 25, 2004.
10.1	Facility Loan Agreement, dated August 2, 2004, by and between the Company and Hopkins Capital Group II, LLC. (2)
10.2	Binding Letter of Intent and Termination Agreement, dated August 23, 2004, between Hopkins Capital Group II, LLC and the Company.
10.3	Registration Rights Agreement, dated August 24, 2004, by and among the Company and the former stockholders of Arius.
10.4	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo.
10.5	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo.
10.6	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn.
10.7	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn.
10.8	Voting Agreement, dated August 24, 2004, by Mark A. Sirgo and Andrew L. Finn in favor of the Company.

10.9 Voting Agreement, dated August 24, 2004, by certain stockholders of the Company in favor of the Company, Mark A. Sirgo and Andrew L. Finn.

10.14 Loan Agreement, dated April 22, 2003, by and between the Company and Gold Bank.

10.15 Security Agreement, dated April 22, 2003, by and between the Company and Gold Bank.

10.16 Limited Waiver and Forbearance Agreement, dated effective May 14, 2004, by and between the Company and Gold Bank.

99.1 Press Release of the Company, dated August 24, 2004, with respect to the closing of the Arius transaction.

99.2 Press Release of the Company, dated August 24, 2004, with respect to the termination of the Facility and the Equity Line Agreement.

(1) Previously filed as (or as part of) an exhibit to the Company s Current Report on Form 8-K filed on August 12, 2004.
(2) Previously filed as an exhibit to the Company s Current Report on Form 8-K filed on August 6, 2004.

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, (i) statements about the benefits of the Company s Equity Line Agreement; (ii) statements with respect to Gold Bank and the GB Loan Agreement, (iii) statements with respect to the Company s plans, objectives, expectations and intentions; and (iv) other statements identified by words such as 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. 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).

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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.

August 26, 2004

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Francis E. O Donnell, Jr.
Name: Francis E. O Donnell, Jr.

Title: President and Chief Executive Officer