

BIODELIVERY SCIENCES INTERNATIONAL INC  
Form 8-K  
September 08, 2004

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**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 8, 2004 (August 31, 2004)

**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction

of incorporation)

**0-28931**  
(Commission

File Number)

**35-2089858**  
(IRS Employer

Identification No.)

**UMDNJ Medical School**

**185 South Orange Avenue, Bldg #4**

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

**07103**  
(Zip Code)

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

Not Applicable

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(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))
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**Item 1.01. Entry into a Material Definitive Agreement.**

On September 3, 2004, BioDelivery Sciences International, Inc. (the **Company**) entered into an Equity Line of Credit Agreement (the **Equity Line Agreement**) 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, President and CEO. The Equity Line Agreement further memorializes that certain Binding Letter of Intent and Termination Agreement, dated August 23, 2004, between the Company and HCG.

Pursuant to the Equity Line Agreement, HCG will, as requested by the Company, 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**). As of September 7, 2004, approximately \$1.25 million has been drawn under the Equity Line Agreement. 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 into shares of Company common stock (the **Common Stock**) at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to \$4.25 per share. The Series B Preferred ranks senior to shares of the Company's Common Stock and the Company's Series A Non-Voting Convertible Preferred Stock (the **Series A Preferred**) and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges.

Additionally, 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 and unpaid dividends thereon. HCG has no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

Finally, the Certificate of Designations for the Series B Preferred provides that without the prior approval of the Company's stockholders, in no event shall the Company issue shares of Common Stock at any time upon conversion of: (i) the first \$1.25 million face value of Series B Preferred (representing 294,117 shares of Series B Preferred), plus (ii) any additional shares of Series B Preferred, the proceeds from the sale of which are used by the Company in connection with the acquisition Arius Pharmaceuticals, Inc., a Delaware corporation ( **Arius** ) plus (iii) all shares of Series A Preferred (collectively, the **Aggregated Stock**) to the extent that the total aggregate number of shares of Common Stock issued or deemed to be issued at any time to any holder or all holders of the Aggregated Stock would exceed 19.99% of the issued and outstanding shares of Common Stock immediately prior to the effective time of the merger of Arius with and into Arius Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of the Company.

**Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.**

In two separate communications from the Nasdaq Stock Market ( **Nasdaq** ), dated August 31, 2004 and September 2, 2004, the Company received a formal notice of hearing and hearing memorandum as well as notices of additional listing deficiencies to be addressed in connection with the Company's upcoming delisting hearing (the **Hearing**) before a Nasdaq hearings panel on Thursday, September 9, 2004.

As previously announced, Nasdaq has initiated proceedings, subject to the Hearing, regarding the continued listing of the Company's common stock on the Nasdaq SmallCap Market for failure to meet the stockholders' equity, market value of listed securities, or net income from continuing operations requirement as set forth in Marketplace Rule 4310(c)(2)(B) ( **Point 1** ). The Company believes that it is

most likely to comply with this rule by achieving and maintaining a \$2.5 million level of stockholders' equity. The Company believes that it has undertaken several transactions (most notably the acquisition of Arius Pharmaceuticals, Inc. and the entry into the Equity Line Agreement) to directly and positively address the Company's level of stockholders' equity.

Additionally, in its more recent notices, the Nasdaq staff has alleged the following listing deficiencies: (1) failure to comply with stockholder approval requirements as set forth in Marketplace Rule 4350(i)(1)(C)(ii) ( **Point 2** ); (2) failure to obtain audit committee approval prior to entering into a related party transaction as required by Marketplace Rule 4350(h) ( **Point 3** ); (3) failure to file Notification: Listing of Additional Shares as required by Marketplace Rule 4310(c)(17)(D) ( **Point 4** ); and (4) the making of a material misrepresentation to Nasdaq in the course of responding to Nasdaq Staff comments in violation of Marketplace Rule 4330(c) ( **Point 5** ).

On September 7, 2004, the Company announced that it is prepared to address these additional points at the upcoming Hearing.

With respect to Points 2, 3 and 4 generally, the Company believes that, under the present facts and circumstances, these matters are more procedural in nature and are related ultimately to the Company's efforts to advance its business prospects and, in the process, substantively comply with Nasdaq's listing requirements by pursuing the options available to it and consummating those most likely to be beneficial to both the short and long term interests of the Company's stockholders, albeit in an expedited time frame.

With respect to Point 2, the Company believes that it has already complied with Nasdaq's concerns by including language, approved by the Nasdaq staff, in the Company's Series B Preferred Certificate of Designations and believes that this issue is now resolved.

With respect to Point 3, the Company believes that it has responsibly and promptly responded to an issue properly raised by the Nasdaq staff. The Company's independent audit committee has been and was fully aware of both the Series B Preferred financing (and its predecessor debt facility) and the related party nature of such transaction. Furthermore, the transaction was approved by a majority of BDSI's independent directors and otherwise in accordance with BDSI's publicly disclosed policies and procedures. Additionally, such independent directors and the board itself have approved the Series B Preferred transaction as being on terms no less favorable to BDSI and its stockholders than those obtainable in an arm's length transaction with a third party. The Company believes that the only open issue on Point 3 is a mere procedural one relating to the method by which approval was obtained. The Company believes that its audit committee has lawfully acted to approve the transaction via a fully executed written consent of all of the audit committee members.

With respect to Point 4, the Nasdaq staff has cited the Company for not providing Nasdaq with the required 15 days notice prior to effecting the Series B Preferred transaction. The Company believes that providing such notice was logistically impossible, given the timing of the transaction and the need to quickly restructure the Company's \$4 million debt facility with HCG in response to comments by the Company's secured equipment lender Gold Bank. The required notice was subsequently and promptly filed, which notice is presently under review. The Company believes that the restructuring of the debt facility into an equity line has already added an additional \$1.25 million to the Company's stockholders' equity, with up to an additional \$2.75 million of availability, which will only further add to stockholders' equity when drawn.

With respect to the Point 5, the Company strongly believes, without even addressing the level of materiality of the Nasdaq staff's assertion, that no misrepresentation was made to the Nasdaq staff. At

worst, the Company believes that there may have been a misunderstanding on a matter of procedure relating to the Company's efforts to remedy the alleged audit committee approval deficiency. The Company believes that it has had, both by itself and through counsel, full and fair discussions with the Nasdaq staff during the Hearing process and that all relevant information has been provided to the staff and that no information has been withheld.

**Item 9.01. Financial Statements and Exhibits.**

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

- 4.1 Certificate of Designations of the Series B Convertible Preferred Stock of the Company, dated September 3, 2004.
- 4.2 Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated September 2, 2004.
- 10.1 Equity Line of Credit Agreement, dated September 3, 2004, by and between the Company and Hopkins Capital Group II, LLC.
- 99.1 Press Release of the Company, dated September 7, 2004, with respect to the Equity Line Agreement and Nasdaq matters.

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 Company's Equity Line Agreement; (ii) statements with to the Company's delisting hearing with Nasdaq, (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, 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 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.

September 8, 2004

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ FRANCIS E. O DONNELL, JR.  
Name: **Francis E. O Donnell, Jr.**  
Title: **President and Chief Executive Officer**