

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

June 04, 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) June 4, 2004 (April 13, 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

07103

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185 South Orange Avenue, Bldg #4

Newark, New Jersey
(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)

Item 5. Other Events and Regulation FD Disclosure.

On April 13, 2004, BioDelivery Sciences International, Inc. (the "Company") announced that it licensed a topical formulation of its lead product, encochleated amphotericin B, to Accentia, Inc. ("Accentia"). Accentia, like the Company, is a portfolio company of Hopkins Capital Group, and is a privately-held, vertically-integrated specialty biopharmaceutical company that provides comprehensive biopharmaceutical services, including product commercialization, clinical manufacturing, contract sales and product distribution. Accentia is commercializing technology licensed from Mayo Foundation for Medical Education and Research ("Mayo") for the treatment of chronic rhinosinusitis ("CRS") in the U.S. and the European Union ("EU"). The technology consists of using low-dose topical antifungals to control the debilitating symptoms of CRS.

According to the terms of the license, Accentia will pay the Company a running royalty of 12-14% on net sales in the U.S. Accentia estimates that annual prescription cost will be approximately \$1,000/patient. Accentia is responsible for all expenses related to the development of an encochleated BioNasal (TM) amphotericin B for the indication of CRS in the U.S. and EU including the filing of an IND and clinical trials. The Company shall retain world-wide rights to the oral and intravenous formulations of encochleated amphotericin B and non-U.S. and non-EU rights to a topical formulation of BioNasal (TM) encochleated amphotericin B.

Effective June 1, 2004, the Company and Accentia amended their license agreement to make certain conforming changes as a result of Accentia's agreement with Mayo. Both the April 13, 2004 license agreement and the June 1, 2004 amendment, as well as the Company's April 13, 2004 press release, are attached as exhibits to this Current Report.

Item 7. Financial Statements and Exhibits.

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

- 10.1 License Agreement, dated effective April 12, 2004, between the Company and Accentia.
- 10.2 Amendment to License Agreement, dated effective June 1, 2004, between the Company and Accentia.
- 99.1 Press Release of the Company, dated April 13, 2004, relating to the license agreement with Accentia.

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 licensing arrangement with Accentia; (ii) statements with respect to the Company's plans, objectives, expectations and intentions; and (iii) 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.

June 4, 2004

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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

Name: Francis E. O Donnell, Jr.

Title: President and Chief Executive Officer