

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

(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 8, 2004, BioDelivery Sciences International, Inc. (the **Company**) announced that it entered into a definitive Asset Purchase Agreement (the **Asset Purchase Agreement**) with Accentia, Inc. (**Accentia**) pursuant to which the Company has sold to Accentia, effective September 8, 2004, an asset consisting of a royalty revenue stream in consideration of a one-time, irrevocable cash payment of \$2,500,000. Pursuant to the Asset Purchase Agreement, such cash payment is required to be made by Accentia by September 30, 2004, but the Company anticipates that payment will be received sooner than such date. Accentia's payment obligation is not subject to contingencies.

Accentia is a privately-held biopharmaceutical holding company partly-owned by Hopkins Capital Group, LLC, which is partly-owned and controlled by Francis E. O'Donnell, M.D., the Company's Chairman, President and Chief Executive Officer. The asset purchase transaction has been approved by the Company's board of directors and has separately been approved by the Company's audit committee in accordance with the rules of the Nasdaq Stock Market.

The Company and Accentia are also parties to a License Agreement, dated April 12, 2004 (the **License Agreement**) pursuant to which the Company has licensed a topical version of encochleated Amphotericin B to Accentia (the **Licensed Technology**). Using the Licensed Technology, Accentia intends to begin clinical trials for Amphotericin B, using patent rights licensed from the Mayo Foundation for Medical Education and Research, for using any antifungal agent used to treat chronic sinusitis topically (the **Application**). Under the terms of the License Agreement, Accentia is responsible for all development expenses including clinical trials and regulatory submissions.

Pursuant to the License Agreement, the Company is entitled to receive a twelve percent (12%) royalty fee with respect to the net sales of any and all products covered by the Licensed Technology and a fourteen percent (14%) royalty fee with respect to the net sales of an encochleated Amphotericin B with the approved indication for chronic rhinosinusitis in the United States (collectively, the **Royalty**). Pursuant to the Asset Purchase Agreement, the Company has sold to Accentia a fifty percent (50%) interest in the future Royalty (the **Royalty Stream**) for \$2,500,000. This will have the effect of reducing the Royalty to the Company by fifty percent (50%). The parties have agreed, however, that the future Royalty Stream sold to Accentia shall not include Royalty payments that are payable by Accentia under the License Agreement that are based on the sale of products exclusively intended to treat asthma, and the rights to such Royalty payments shall remain with the Company.

Pursuant to the Asset Purchase Agreement, the parties have also agreed to modify the terms of the License Agreement to grant Accentia a world-wide license to the Licensed Technology for use in the Application. Previously, the License Agreement provided for a territory consisting of the United States and the European Union only. The parties agreed that it would be mutually beneficial to extend the territory because of uncertainties in the marketplace related to the possibility of federally-sanctioned importation of prescription drugs from foreign markets into the United States.

Item 9.01. Financial Statements and Exhibits.

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

10.1 Asset Purchase Agreement, dated September 8 2004, by and between the Company and Accentia.

99.1 Press Release of the Company, dated September 8, 2004, with respect to the Accentia asset purchase transaction.

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).

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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