

BIODELIVERY SCIENCES INTERNATIONAL INC  
Form 8-K  
January 24, 2005

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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) January 24, 2005 (January 20, 2005)

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**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in its charter)

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**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)**

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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 8.01. Other Events**

On January 20, 2005, BioDelivery Sciences International, Inc. (the Company) announced that it signed a definitive licensing agreement with Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (Sigma-Tau Pharma) for the application of the Company's Biotrananocochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau Pharma. Sigma-Tau Pharma is an affiliate of The Sigma-Tau Group, one of Italy's leading pharmaceutical companies. Simultaneously with this licensing agreement, the Company announced that it entered into a stock purchase agreement with, and received a non-refundable upfront payment of US\$250,000 from, Sigma-Tau Finanziaria S.p.A. (Sigma-Tau), a holding company of The Sigma-Tau Group. This upfront payment was made in consideration of unregistered shares of the Company's common stock priced at \$4.25 a share.

The stock purchase agreement with Sigma-Tau provides for the acquisition by Sigma-Tau, upon the occurrence of specified developmental milestones associated with the license, of additional unregistered shares of Company common stock, up to an aggregate potential of \$1,500,000 worth of such shares. These milestones lead up to and include the filing of product INDs by Sigma-Tau Pharma for one or more of the four subject encochleated compounds. Such additional unregistered shares will be issued at the lesser of: (i) \$4.25 and (ii) the average of the closing trade price of the Company's common stock for the ten (10) trading days through and including the applicable payment date, with an absolute floor \$3.38 per share. Sigma-Tau, through other holding entities, is currently a stockholder of the Company. In addition to the milestone payments, the Company will receive a royalty on future sales of each of the four products which may arise from the encochleated compounds. Additional information about these transactions can be found in the agreements and press release attached as exhibits to this Form 8-K.

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

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

10.1 Licensing Agreement, dated January 20, 2005 (the Licensing Agreement), between the Company and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. **(confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2).**

10.2. Common Stock Purchase Agreement, dated January 20, 2005 (the Stock Purchase Agreement), between BDSI and Sigma Tau Finanziaria S.p.A. **(confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2).**

99.1 Press Release of the Company, dated January 20, 2005, with respect to the Licensing Agreement and the Stock Purchase Agreement.

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.

January 24, 2005

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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

Name: Francis E. O. Donnell, Jr.

Title: Chairman, President and Chief Executive Officer