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BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

January 07, 2003

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) December 16, 2002

BioDelivery Sciences International, Inc.

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(Exact name of registrant as specified in its charter)

Delaware

0-28931

35-2089858

-----  
(State or other jurisdiction  
of incorporation)

-----  
(Commission File Number)

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(IRS Employer  
Identification No.)

UMDNJ Medical School  
185 South Orange Avenue, Bldg #4  
Newark, New Jersey

07103

-----  
(Address of principal executive offices)

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(Zip Code)

Registrant's telephone number, including area code (813) 902-8980

Not Applicable

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(Former name or former address, if changed since last report)

Item 5. Other Events and Regulation FD Disclosure.

- (a) On December 31, 2002, BioDelivery Sciences International, Inc., a Delaware corporation (the "Company") entered into an agreement with Pharmaceutical Product Development, Inc, a North Carolina corporation ("PPDI"), pursuant to PPDI was granted a license to apply the Company's bioral nano-delivery technology to two therapeutic products. The terms of the license require one upfront royalty payment to the Company, additional royalty payments based on regulatory milestones and a running royalty rate based on worldwide sales.
- (b) As previously announced, the Company is a party to a license agreement

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with The University of Medicine and Dentistry of New Jersey and Albany Medical College (collectively, the "Universities") regarding certain of its technologies. On December 16, 2002, the Company and the Universities amended such agreement to provide for a decrease in the royalty payments to be paid to the Universities on sublicenses in consideration of an increase in the royalty on BDSI product sales and the issuance to the Universities of options to purchase shares of Company common stock.

- (c) On January 6, 2003, the Company announced that it entered into a confidential evaluation agreement with a major pharmaceutical company for encochleation of a proprietary antimicrobial. The Company will be paid for its services related to the evaluation. In exchange, the pharmaceutical company was granted an exclusive option to negotiate a license for application of the Bioral(TM) delivery technology to its antimicrobial pharmaceutical.

### Item 7. Financial Statements and Exhibits.

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

- 10.1 Sub-License Agreement, effective as of December 31, 2002, by and between the Company and Pharmaceutical Product Development, Inc. (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 6, 2003, relating to the license agreement between the Company and PPDI and confidential evaluation agreement.

### 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 7, 2003

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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

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Name: Francis E. O'Donnell, Jr.

Title: President and Chief Executive Officer