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BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

November 19, 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) November 19, 2003

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	0-28931	35-2089858
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(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

UMDNJ Medical School 185 South Orange Avenue, Bldg #4 Newark, New Jersey	07103
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(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 November 19, 2003, BioDelivery Sciences International, Inc. (the "Company") announced that it is intending to distribute to its stockholders 3,545,431 Class B Memberships Shares (the "Class B Shares"), or approximately 47% of the currently outstanding interests, of its subsidiary, Bioral Nutrient Delivery, LLC ("BND"). The Company previously announced that it would distribute rights to its stockholders to purchase up to 11,277,000 of such interests from the Company, both initially at \$0.01 per interest and then quarterly over of 3 year period at the then fair market value. The Company has decided to change the structure and distribute only 3,545,431 Class B Shares directly to Company stockholders of record on a pro-rata, one-time basis. Subject to compliance with

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applicable laws and the facts and circumstances at such time, the Company may elect to distribute additional Class B Shares in the future, although no assurances can be given that any such additional distributions will ever be undertaken. In February 2003, BND filed a registration statement on Form SB-1 with the Securities and Exchange Commission to register the rights and the underlying Class B Shares. Given the change in structure, such registration statement was withdrawn on November 18, 2003. Instead, on November 19, 2003, BND filed a registration statement on Form 10-SB covering the proposed, one-time distribution of 3,545,431 Class B Shares by the Company to its stockholders. Company stockholders will not be required to purchase Class B Shares in connection with the distribution.

In addition, the Company announced that it has amended its April 1, 2003 license agreement with BND to include personal care products. The original license gave BND rights to BioDelivery's licensed nano-encapsulation delivery technology to develop ways to deliver nutrients for non-pharmaceutical use in the processed food and beverage industries for both human and animal consumption. As amended, the license gives BND the right to exploit such technology in the personal care products sector as well. In addition, the Company announced that it has amended its March 31, 2003 management agreement with BND, pursuant to which the Company provides management and administrative services to BND at no cost, to extend the initial term of such agreement from March 31, 2004 to December 31, 2004.

The distribution of Class B Shares in BND will commence when the Form 10-SB becomes effective pursuant to SEC rules, which is anticipated to be 60 days from the date of filing. Following the distribution, BSDI stockholders will own approximately 47% of the currently outstanding economic interests in BND, and BND will be a separate reporting company with the SEC. However, such percentage will be subject to dilution based on a number of factors, including the possibility of new equity ownership interests being issued as BND pursues its licensing opportunities. Furthermore, the interests in BND will not, nor is it anticipated that they will be, publicly-traded and holders of such interests will be severely limited in their rights to transfer such interests. More information about the distribution, the Class B Shares and BND generally can be found in the registration statement on Form 10-SB filed by BND with the SEC, including the information statement attached thereto as an exhibit.

Item 7. Financial Statements and Exhibits.

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

- 10.1 Amended and Restated Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated October 1, 2003, by the Company, as Managing Member.
- 10.2 First Amendment to Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC.
- 10.3 First Amendment to Management Services and Administrative Agreement, dated effective April 1, 2003, by and between BioDelivery Sciences International, Inc. and Bioral Nutrient Delivery, LLC
- 10.4 Evaluation Agreement and Option to License, dated September 5, 2002 by and between BioDelivery Sciences International, Inc. and *****
(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 November 19, 2003, relating to the distribution of Class B Shares of BND.

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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 distribution of the Rights and the Additional Rights; (ii) statements with respect to the Company's plans, objectives, expectations and intentions with respect to BND; 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.

November 19, 2003

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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

Name: Francis E. O'Donnell, Jr.

Title: President and Chief Executive Officer