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BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

April 01, 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) March 28, 2003

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<br>of incorporation) | (Commission File Number) | (IRS Employer<br>Identification No.) |

|  |            |
|--|------------|
| UMDNJ Medical School<br>185 South Orange Avenue, Bldg #4<br>Newark, New Jersey | 7103       |
| -----  | -----      |
| (Address of principal executive offices)                                       | (Zip Code) |

Registrant's telephone number, including area code (973) 972-0015  
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Not Applicable

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

Items 9 and 12. Other Events and Regulation FD Disclosure; Results of Operation and Financial Condition.

On March 28, 2003, BioDelivery Sciences International, Inc., a Delaware corporation (the "Company"), filed its Annual Report on Form 10-KSB (the "10-KSB") with the Securities and Exchange Commission. On April 1, 2003, the Company issued a press release summarizing its financial and operational results for its fiscal year ended December 31, 2002.

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In footnote 2 to the financial statements appearing in the 10-KSB, the Company disclosed that it entered into a licensing agreement with a company (which is a shareholder), which license included an up-front non-refundable payment of \$2 million, which was received in January 2003. The Company has deferred the revenue and will recognize it over the period of the related research and development commitment. The agreement also provides for milestone payments. This license agreement was previously disclosed via a Current Report on Form 8-K, dated January 7, 2003, at which time the Company requested confidential treatment with respect to, among other matters, such \$2 million payment. Notwithstanding such confidential treatment request, the Company has disclosed such payment as part of its 10-KSB and this Current Report.

Item 7. Financial Statements and Exhibits.

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

99.1 Press Release of the Company, dated March 31, 2003, summarizing its financial and operational results for its fiscal year ended December 31, 2002.

# # #

### 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.

April 1, 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

EXHIBIT 99.1

BioDelivery Sciences Int., Inc.  
NASDAQ: BDSI

L. G. ZANGANI, LLC  
Nine Main Street, Flemington, NJ 08822  
(908) 788-9660 Fax: (908) 788-4024  
E-mail: office@zangani.com  
Web site: <http://www.zangani.com>

For Release: IMMEDIATELY

Contact: Francis E. O'Donnell, Jr., M.D.  
President and CEO

Susan Bonitz, Ph.D.  
LG Zangani, LLC

Kevin Nally  
L.G. Zangani, LLC

NEWS RELEASE

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BioDelivery Sciences International, Inc.  
Reports 2002 Results

Net loss per share for 2002 was \$.51, compared to \$1.15 in 2001.

Newark, New Jersey, April 1, 2003 - BioDelivery Sciences International, Inc. (NASDAQ:BDSI; BDSIW) today announced results for its fiscal year ended December 31, 2002.

In 2002, BDSI had sponsored research revenue of \$828,000, compared to \$478,000 in 2001. Virtually all revenue in both years was from a Small Business Innovation Research Grant from the National Institutes of Health.

In June, 2002, BDSI completed its initial public offering, resulting in approximately \$8.6 million, net of offering costs of approximately \$2.4 million.

At December 31, 2002, BDSI's financial condition includes cash and cash equivalents totaling approximately \$5.2 million, compared to approximately \$76,000 at December 31, 2001. In addition, the Company had a receivable of \$2 million from a sublicense agreement, which sublicense agreement the Company announced on January 7, 2003 and which was collected in January 2003.

James A. McNulty, BDSI's Chief Financial Officer, reported, "Our efforts in 2002 to advance our lead proprietary product, Bioral(TM) Amphotericin B are on target, with almost two years completed of the three-year NIH Grant. Our initial public offering was successful and our financial structure will finance our expected costs through 2004. Staffing at our Newark, New Jersey laboratory is in place. We are finalizing some laboratory improvements and needed scientific equipment purchases, with financing commitments currently in place, which improvements we expect to be finished by mid-2003. We will continue to manage costs and available resources as we pursue outlicensing of our delivery nanotechnology for applications in pharmaceuticals, vaccines, gene therapy, OTC drugs, nutraceuticals, supplements and, through our Bioral Nutrient Delivery, LLC subsidiary, processed food and beverages."

BioDelivery Sciences International, Inc. is a biotechnology company that is developing and seeking to commercialize a patented delivery technology designed for a potentially broad base of pharmaceuticals, vaccines, over-the-counter drugs, nutraceuticals and micronutrients in processed foods and beverages. Additional details relating to BDSI's financial and operational results for 2002 may be found in its Annual Report on Form 10-K for 2002, filed with the Securities and Exchange Commission on March 28, 2003. Such Report is available free of charge via EDGAR at the SEC's website, [www.sec.gov](http://www.sec.gov). and at BDSI's website, [www.bdsinternational.com](http://www.bdsinternational.com).  
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Note: Except for the historical information contained herein, this press release contains forward-looking statements that involve risks and uncertainties. Such statements are subject to certain factors, which may cause the Company's results to differ. Factors that may cause such differences include, but are not limited to, the Company's ability to accurately forecast the demand for each of its licensed technology and products associated therewith, the gross margins achieved from the sale of those products and the expenses and other cash needs for the upcoming periods, the Company's ability to obtain raw materials from its

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contract manufacturers on a timely basis if at all, the Company's need for additional funding, uncertainties regarding the Company's intellectual property and other research, development, marketing and regulatory risks and certain other factors that may affect future operating results and are detailed in the company's filings with the Securities and Exchange Commission.

L.G. Zangani, LLC provides financial public relations service to the Company. As such L.G. Zangani, LLC and/or its officers, agents and employees, receives remuneration for public relations and or other services in the form of monies, capital stock in the Company, warrants or options to purchase capital in the Company.