BIODELIVERY SCIENCES INTERNATIONAL INC
Form 424B3
March 06, 2006

PROSPECTUS SUPPLEMENT

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-126336

PROSPECTUS SUPPLEMENT NO. 2

(to Prospectus dated July 12, 2005)

BioDelivery Sciences International, Inc.

1,554,454 Shares of Common Stock

This prospectus supplement supplements, and should be read in conjunction with, the accompanying prospectus, dated June 20, 2005, as supplemented by Prospectus Supplement No. 1 thereto, dated December 16, 2005. The prospectus relates to the public sale, from time to time, of up to 1,554,454 shares of our common stock, par value $0.001 per share, by Laurus Master Fund, Ltd., for its own account.

The information attached to this supplement modifies and supersedes, in part, the information in the prospectus. Any information that is modified or superseded in the prospectus shall not be deemed to constitute a part of the prospectus except as modified or superseded by this prospectus supplement.

This prospectus supplement includes the attached Current Report on Form 8-K of BioDelivery Sciences International, Inc., filed with the Securities and Exchange Commission on March 2, 2006.

We may amend or supplement the prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

The date of this prospectus supplement is March 6, 2006

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 2, 2006 (March 1, 2006)

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

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

2501 Aerial Center Parkway, Suite 205

Morrisville, North Carolina	**07103**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (919) 653-5160

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))

Item 7.01. Regulation FD Disclosure.

On March 1, 2006, BioDelivery Sciences International, Inc. (the Company) issued a press release announcing that the Company had received a non-approvable letter from the Food and Drug Administration regarding the Company s Emezine® product. A copy of this press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

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

99.1 Press Release, dated March 1, 2006

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.

March 2, 2006

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo, Pharm.D.
Title: President & CEO

Exhibit 99.1

BioDelivery Sciences Receives Non-Approvable Notification

from FDA on Emezine®

Company Has Requested a Meeting with the FDA to Gain Clarity on Notification

MORRISVILLE, N.C March 1, 2006 - BioDelivery Sciences International, Inc. (NASDAQ:BDSI), a specialty biopharmaceutical company, has received a non-approvable letter from the U.S. Food and Drug Administration (FDA) for the company s new drug application (NDA) for Emezine®, a buccal tablet formulation of prochlorperazine maleate for the treatment of severe nausea and vomiting. The letter was received on February 28, 2006.

The non-approvable letter stated that additional information would be required to address remaining questions. BDSI has requested a meeting with the FDA regarding their notification and will use the outcome of this meeting to evaluate the direction it intends to pursue regarding Emezine®.

Dr. Mark A. Sirgo, President and CEO of BDSI, stated, We are extremely surprised and disappointed by the FDA s decision in light of the fact that we strictly adhered to the development program that was outlined in our pre-NDA meeting with FDA in March of 2004. It is clear based on FDA s comments that they are now, among other things and contrary to our previous expectations, seeking additional data on the product. We will take the next few days, in conjunction with our licensing and distribution partners, to consider our options in responding to and working with FDA on this matter. We have put in a meeting request today and plan to act quickly to resolve the situation. In the meantime, we will maintain focus on our flagship BEMA™ Fentanyl product, which is now progressing through Phase III, and on the other products and formulations in our pipeline.

Emezine® is an oral transmucosal (drug absorbed directly through the mucosa of the mouth) medication for the treatment of nausea and vomiting. The current alternatives to oral tablets are injections and suppositories. BDSI licenses Emezine® on an exclusive basis in the U.S. from Reckitt Benckiser Healthcare (UK) Limited. The Emezine® tablets are proposed to be manufactured for BDSI by Reckitt Benckiser, which currently distributes a similar product in the United Kingdom. TEAMM Pharmaceuticals, a subsidiary of Accentia Biopharmaceuticals, Inc. (NASDAQ:ABPI), has contracted to be BDSI s distribution partner for Emezine®.

BDSI is also working on BEMA Fentanyl, a treatment for breakthrough cancer pain, and expects to complete its Phase III BEMA Fentanyl trials during the second half of 2006. BEMA Fentanyl is an oral adhesive disc formulation of the narcotic fentanyl. Additionally, BDSI will be conducting Phase I trials with BEMA LA, its second analgesic in the BEMA technology, in the first quarter of 2006 and plans to initiate Phase III trials in the second half of 2006.

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. is a specialty biopharmaceutical company that is exploiting its licensed and patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, clinically-significant new formulations of proven therapeutics targeted at acute treatment opportunities such as pain, anxiety, nausea

and vomiting, and infections. The company s drug delivery technologies include: (i) the patented Bioral® nanocochleate technology, designed for a potentially broad base of applications, and (ii) the patented BEMA (transmucosal or mouth) drug delivery technology. The company s headquarters are located in Morrisville, North Carolina and its principal laboratory is located in Newark, New Jersey. For more information please visit www.bdsinternational.com.

Forward-Looking Statements

Note: Except for the historical information contained herein, this press release contains, among other things, certain forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. Such statement may include, 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 , 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, including those detailed in the Company s filings with the Securities and Exchange Commission. Actual results, including, without limitation, the results of additional clinical trials and FDA review of the Company s formulations and products, 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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