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 supplements 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 Any information that is modified or superseded in the prospectus shall not be deemed to constitute a part of the prospectus except as modified or superseded by this prospectus supplement.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 (State or other jurisdiction

0-28931 (Commission File Number) 35-2089858 (IRS Employer

of incorporation)

Identification No.)

2501 Aerial Center Parkway, Suite 205

Morrisville, North Carolina (Address of principal executive offices)

07103 (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<sup>®</sup>, 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<sup>®</sup>.

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<sup>TM</sup> 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. (NASDAO:ABPI), has contracted to be BDSI s distribution partner for Emezin®.

BDSI is also working on BEMA Fentanyl, a treatment for breakthrough cancer pain, and expects to complete its Phase III BEMFentanyl 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



Salvador Abady

37,231	
37,231 (21)	
0	
	0
Scot Jason Cohen	
11,819	
11,890 (22)	
0	
	0
Smithfield Fiduciary LLC	
132,108	
132,108 (23)	
0	
	0
Stanoff Corporation	
27,500	
27,500 (24)	

0	
	0
Steven and Adam Sprung	
37,231	
37,231 (25)	
0	
	0
Steven Landman	
6,607	
6,607 (26)	
0	
	0
Ted Struhl Family Partnership	
68,962	
68,962 (27)	
0	
	0

Vertical Ventures, LLC	
196,506	
196,506 (28)	
0	
	C
WEC Partners LLC	
26,422	
26,422 (29)	
0	
	C
William Castor	
11,000	
11,000 (30)	
0	
	C
* Represents less than 1%.	
(1)	

Percentage calculated on the basis of 7,728,174 shares of common stock outstanding on May 17, 2006.

- (2) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the selling stockholders are under no obligations known to us to sell any shares of common stock at this time.
- (3) Consists of shares of common stock issuable upon exercise of Reload Warrants. David Stone is the managing partner of Ajax Partners and has sole voting and investment power over the securities owned by Ajax Partners.
- (4) Consists of 52,844 shares of common stock issuable upon exercise of Reload Warrants and 2,579 shares of common stock issued upon exercise of the Bridge Warrants.

- (5) Consists of shares of common stock issuable upon exercise of Reload Warrants.
- (6) Consists of shares of common stock issued to Barretto Pacific Corporation. On December 13, 2004 we entered into a one-year term agreement with Barretto for the provision of investor relations consulting services. The agreement was for an aggregate cash amount of \$100,000. In connection with the agreement, we issued Barretto 7,800 shares of our common stock. Landon Barretto has sole voting and investment power over the shares owned by Barretto.
- (7) Consists of shares of common stock issued to Brainboost Partnership. On December 1, 2005 pursuant to a Purchase Agreement among us, Brainboost Partnership, a New York general partnership Assaf Rozenblatt, Edo Segal and Jon Medved, we purchased the entire limited liability interests of Brainboost Technology, LLC, a Delaware limited liability company ("Brainboost"). As a result of the acquisition, we took title to and possession of those certain assets owned by Brainboost, including, among other things, all intellectual property rights associated with a functionality known as the Brainboost Answer Engine, a cutting-edge Artificial Intelligence technology targeting natural language search on the World-Wide-Web. Pursuant to the Purchase Agreement, we paid Brainboost Partnership an aggregate of \$4,000,000 in cash and 439,000 shares of our common stock. Assaf Rozenblatt has sole voting and investment power over the shares owned by Brainboost Partnership.
- (8) Consists of shares of common stock issuable upon exercise of Reload Warrants.
- (9) Consists of shares of common stock issuable upon exercise of Reload Warrants.
- (10) Consists of 13,211 shares of common stock issuable upon exercise of Reload Warrants and 24,020 shares of common stock issued upon exercise of the Bridge Warrants.
- (11) Consists of shares of common stock issuable upon exercise of Reload Warrants.
- (12) Consists of shares of common stock issuable upon exercise of Reload Warrants.
- (13) Consists of 11,494 shares of common stock issuable upon exercise of Reload Warrants, 20,897 shares of common stock issued upon exercise of the Bridge Warrants and 5,800 shares of common stock issued upon conversion of the Bridge Notes.
- (14) Consists of 174,827 shares of common stock issuable upon exercise of Reload Warrants and 126,103 shares of common stock issuable upon exercise of the Bridge Warrants. Joshua Silverman is the managing partner of Iroquois Capital, L.P. and has sole voting and investment power over the shares owned by Iroquois Capital, L.P. Mr. Silverman disclaims beneficial ownership of the shares owned by Iroquois Capital, L.P.
- (15) Consists of 26,422 shares of common stock issuable upon exercise of Reload Warrants and 48,040 shares of common stock issued upon exercise of the Bridge Warrants.
- (16) Consists of 6,066 shares of common stock issuable upon exercise of Reload Warrants and 6,667 shares of common stock issued upon conversion of the Bridge Notes.
- (17) Consists of 97,496 shares of common stock issuable upon exercise of Reload Warrants and 47,534 shares of common stock issued upon conversion of the Bridge Notes. Of the 97,496 shares of common stock issuable upon exercise of Reload Warrants, 50,000 are owned by the Morton

Meyerson Family Foundation. Mr. Meyerson is the President of the Morton Meyerson Family Foundation and has voting and investment power over the 50,000 Reload Warrants.

- Consists of shares of common stock issuable upon exercise of Reload Warrants. Omicron Capital, (18)L.P. a Delaware limited partnership ("Omicron Capital"), serves as investment manager to Omicron Master Trust, a trust formed under the laws of Bermuda ("Omicron"), Omicron Capital, Inc., a Delaware corporation ("OCI"), serves as general partner of Omicron Capital, and Winchester Global Trust Company Limited ("Winchester") serves as the trustee of Omicron. By reason of such relationships, Omicron Capital and OCI may be deemed to share dispositive power over the shares of our common stock owned by Omicron, and Winchester may be deemed to share voting and dispositive power over the shares of our common stock owned by Omicron. Omicron Capital, OCI and Winchester disclaim beneficial ownership of such shares of our common stock. Omicron Capital has delegated authority from the board of directors of Winchester regarding the portfolio management decisions with respect to the shares of common stock owned by Omicron and as of March 15, 2006, Mr. Olivier H. Morali and Mr. Bruce T. Bernstein, officers of OCI, have delegated authority from the board of directors of OCI regarding the portfolio management decisions of Omicron Capital with respect to the shares of common stock owned by Omicron. By reason of such delegated authority, Messrs. Morali and Bernstein may be deemed to share dispositive power over the shares of our common stock owned by Omicron. Messrs. Morali and Bernstein disclaim beneficial ownership of such shares of our common stock and neither of such persons has any legal right to maintain such delegated authority. No other person has sole or shared voting or dispositive power with respect to the shares of our common stock being offered by Omicron, as those terms are used for purposes under Regulation 13D-G of the Securities Exchange Act of 1934, as amended. Omicron and Winchester are not "affiliates" of one another, as that term is used for purposes of the Securities Exchange Act of 1934, as amended, or of any other person named in this prospectus as a selling stockholder. No person or "group" (as that term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, or the SEC's Regulation 13D-G) controls Omicron and Winchester.
- (19) Consists of 5,867 shares of common stock issuable upon exercise of Reload Warrants and 24,020 shares of common stock issued upon exercise of Bridge Warrants. Florence Petrocellil has voting and/or dispositive power over the securities owned by Petrocelli Industries, Inc.

- (20) Consists of shares of common stock issuable upon exercise of stock options granted to Rivington Investments N.V. On April 27, 1999, we entered into a consulting agreement with Rivington pursuant to which agreement Rivington was retained to provide us with advisory services on strategic business planning and product critique. Pursuant to the consulting agreement, (i) Rivington was obligated to avail itself to our management team for a minimum of four (4) hours a month; (ii) we agreed to compensate Rivington in the form of the grant of a stock option to purchase 50,000 shares of our common stock at an exercise price of \$0.05 per share (it should be noted that following our 23.02:1 reverse stock split in January 2004, this option became an option to purchase 2,173 shares of our common stock at the exercise price of \$1.15); and (iii) the term of the option was ten (10) years subject to earlier termination pursuant to the terms of an option agreement entered into in conjunction with the consulting agreement. Professor Ehud Shapiro, Michelle Arnon and Elieser Kaplan share voting and/or dispositive power over the securities owned by Rivington.
- (21) Consists of 13,211 shares of common stock issuable upon exercise of Reload Warrants and 24,020 shares of common stock issued upon exercise of Bridge Warrants.
- (22) Consists of shares of common stock issuable upon exercise of Reload Warrants.
- (23) Consists of shares of common stock issuable upon exercise of Reload Warrants. Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and has voting control and investment direction over securities held by Smithfield Fiduciary LLC. Glenn Dubin and Henry Swieca control Highbridge Capital Management, LLC, Glenn Dubin and Henry Swieca disclaim beneficial ownership of the securities held by Smithfield Fiduciary LLC.
- (24) Consists of shares of common stock issuable upon exercise of Reload Warrants. Howard Weingrow as president and Robert Lifton as chairman of Stanoff Corporation have voting and investment power over the securities owned by Stanoff Corporation.
- (25) Consists of 13,211 shares of common stock issuable upon exercise of Reload Warrants and 24,020 shares of common stock issued upon exercise of Bridge Warrants.
- (26) Consists of shares of common stock issuable upon exercise of Reload Warrants.
- (27) Consists of 20,922 shares of common stock issuable upon exercise of Reload Warrants and 48,040 shares of common stock issued upon exercise of Bridge Warrants.
- (28) Consists of shares of common stock issuable upon exercise of Reload Warrants. Joshua Silverman is a managing partner of Vertical Ventures, LLC and has sole voting and investment power over the securities owned by Vertical Ventures, LLC. Mr. Silverman disclaims beneficial ownership of the securities owned by Vertical Ventures, LLC.
- (29) Consists of shares of common stock issuable upon exercise of Reload Warrants. Jaime Hartman, Daniel Saks and Ethan Benovitz share voting and investment power over the securities owned by WEC Partners, LLC.
- (30) Consists of 7,927 shares of common stock issuable upon exercise of Reload Warrants and 3,073 shares issued upon exercise of Bridge Warrants.

## PLAN OF DISTRIBUTION

The shares being offered by the selling stockholders will be sold from time to time in one or more transactions (which may involve block transactions) that may take place in The Nasdaq National Market, including ordinary brokers' transactions, privately negotiated transactions or through sales to one or more dealers for resale of such securities as principals, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling stockholders. The shares may also be sold pursuant to Rule 144 under the Securities Act. The selling stockholders have the sole and absolute discretion not to accept any purchase offer or make any sale of shares if they deem the purchase price to be unsatisfactory at any particular time.

The selling stockholders may also sell the shares directly to market makers acting as principals and/or broker-dealers acting as agents for themselves or their customers. Such broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principal, or both, which compensation as to a particular broker-dealer might be in excess of customary commissions. Market makers and block purchasers purchasing the shares will do so for their own account and at their own risk. It is possible that a selling stockholder will attempt to sell shares of common stock in block transactions to market makers or other purchasers at a price per share which may be below the then market price.

The selling stockholders and intermediaries through whom such securities are sold may be deemed "underwriters" within the meaning of the Securities Act, with respect to the securities offered hereby, and any profits realized or commissions received may be deemed underwriting compensation. We have agreed to indemnify the selling stockholders against certain liabilities, including liabilities under the Securities Act.

The selling stockholders, alternatively, may sell all or any part of the shares offered by this prospectus through an underwriter. To our knowledge, no selling stockholder has entered into an agreement with a prospective underwriter. If any selling stockholder notifies us that it has entered into an agreement or agreements with a broker-dealer or underwriter for the resale of the common stock, the relevant details will be set forth in a supplement or revision to this prospectus.

The selling stockholders and any other persons participating in the sale or distribution of the shares will be subject to applicable provisions of the Securities Exchange Act of 1934 and the rules and regulations thereunder, including, without limitation, Regulation M, which may restrict certain activities of, and limit the timing of purchases and sales of any of the shares by the selling stockholders or any other such person. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distributions, subject to specified exceptions or exemptions. All of these limitations may affect the marketability of the shares.

## **LEGAL MATTERS**

The validity of the common stock will be passed upon by our counsel, Sichenzia Ross Friedman Ference LLP, New York, New York.

## **EXPERTS**

The consolidated financial statements of Answers Corporation (formerly GuruNet Corporation) as of December 31, 2005 and 2004, and for each of the years in the two-year period ended December 31, 2005, have been incorporated by reference herein and in the registration statement in reliance upon the report of Somekh Chaikin, a member firm of KPMG International, an independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement that we filed on Form S-3 with the Securities and Exchange Commission or SEC. This prospectus does not contain all of the information in the registration statement and the exhibits and schedules that were filed with the registration statement. You should refer to the registration statement for additional information about us and the common stock being offered in this prospectus. Statements made in this prospectus regarding the contents of any contract, agreement or other document that is filed as an exhibit to the registration statement or any document incorporated by reference into the registration statement are not necessarily complete, and you should review the referenced document itself for a complete understanding of its terms.

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document that we file at the SEC's public reference facilities located at 100 F Street, NE, Washington, DC 20549. Copies of all or any part of the registration statement may be obtained from the SEC upon payment of the prescribed fee. Information regarding the operation of the public reference rooms may be obtained by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available to you free of charge at the SEC's web site at http://www.sec.gov.

## INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to 'incorporate by reference' the information into this prospectus. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information that we incorporate by reference is considered to be part of this prospectus. Because we are incorporating by reference our future filings with the SEC, this prospectus is continually updated and those future filings may modify or supersede some or all of the information included or incorporated in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until the selling stockholders sell all of our common stock registered under this prospectus.

Answers Corporation (File No. 001-32325)

- our annual report on Form 10-KSB for the fiscal year ended December 31, 2005 filed with the SEC on March 20, 2006;
- our annual report on Form 10-KSB/A for the fiscal year ended December 31, 2005 filed with the SEC on April 13, 2006;
- our annual report on Amendment No.2 to Form 10-KSB for the fiscal year ended December 31, 2005 filed with the SEC on May 19, 2006;
- our annual report on Amendment No. 3 to Form 10-KSB for the fiscal year ended December 31, 2005 filed with the SEC on June 7, 2006;
- our quarterly report on Form 10-QSB for the quarter ended March 31, 2006 filed with the SEC on May 12, 2006:
- our current report on Form 8-K filed on February 16, 2006; and
- the description of our common stock contained in Item 1 of our Registration Statement on Form 8-A, filed with the SEC on August 1, 2005.

The information about us contained in this prospectus should be read together with the information in the documents incorporated by reference. You may request a copy of any or all of these filings, at no cost, by writing or telephoning us at Jerusalem Technology Park, The Tower, Jerusalem 91481 Israel, +972-2-649-5000 or at 237 West 35 <sup>th</sup> Street, Suite 1101, New York, NY 10001, 646-502-4777.