### BIODELIVERY SCIENCES INTERNATIONAL INC Form 8-K

November 14, 2007

## **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 13, 2007 (November 9, 2007)

# **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.)** 

801 Corporate Center Drive, Suite #210

Raleigh, NC (Address of principal executive offices)

27607 (Zip Code)

Registrant s telephone number, including area code: 919-582-9050

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 4.02 Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

On November 9, 2007, the audit committee (the Committee ) of the Board of Directors of BioDelivery Sciences International, Inc. (the Company ), after discussions with the Company s independent registered public accounting firm, Aidman Piser & Company, P.A. (AP), concluded that a restatement of the Company s unaudited quarterly financial information and audited financial statements as previously reported as of and for the periods ended September 30, 2006 and December 31, 2006, respectively, was necessary as a result of a reevaluation by the Company and AP of the Company s revenue recognition policy relating to certain milestone payments previously received by the Company.

During the three months ended September 30, 2006, the Company licensed the European manufacturing and distribution rights for its BEMA<sup>TM</sup> Fentanyl product (BEMA Fentanyl) to Meda AB (Meda). In connection with this agreement, the Company received a \$2,500,000 initial non-refundable payment for delivery of the licensed technology and recognized that amount as revenue during the quarter ended September 30, 2006 since the Company believed that it had no significant continuing obligations with respect to the license delivery. The agreement provides for additional payments to the Company upon the achievement of certain milestones as well as payments for the Company s possible future manufacture of BEMA Fentanyl for Meda.

The Committee and AP have reevaluated the accounting for the \$2,500,000 payment based on the criteria of both SEC Staff Accounting Bulletin No. 104 and EITF 00-21 and determined that revenue recognition should have been deferred and recognized over the estimated term of the license (the term is expected to commence upon regulatory approval of BEMA Fentanyl in various European jurisdictions and generally terminates with the expiration of the patents underlying the licensed technology in the various European jurisdictions). As such, the unaudited quarterly financial information as previously reported as of and for the periods ended September 30, 2006 will be restated and should no longer be relied upon.

The Company is in the process of restating the financial statements contained in the Company s Form 10-QSB for the quarter ended September 30, 2006 as well as the financial statements for the Company s Form 10-KSB for year ended December 31, 2006. The restated balance sheet at September 30, 2006 and December 31, 2006, along with the statement of operations for the quarter and nine months ended September 30, 2006 will be presented in footnote 12 contained in the Company s Form 10-QSB for the quarter ended September 30, 2007. Restated annual information will be presented in an amendment to the Company s Form 10-KSB for the year ended December 31, 2006.

The Company believes that this restatement is not material to the Company s ongoing operations but that it affects the Company s revenue recognition both in the restated and future periods.

#### **Forward Looking Statement Disclaimer**

This Current Report on Form 8-K and the exhibits hereto 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, intends, plans 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.

November 13, 2007

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty Name: James A. McNulty

Title: Secretary, Treasurer and Chief Financial Officer