

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 8-K

February 28, 2013

**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): February 28, 2013 (February 25, 2013)

**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-31361**  
(Commission  
File Number)

**35-2089858**  
(IRS Employer

Identification No.)

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**801 Corporate Center Drive, Suite #210**

**Raleigh, NC**  
(Address of principal executive offices)

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

**27607**  
(Zip Code)

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

*Background and Overview*

As previously reported in the Quarterly Report on Form 10-Q of BioDelivery Sciences International, Inc. (the **Company**) for the period ended September 30, 2012, the Company has undertaken a review of its revenue recognition accounting with respect to certain non-refundable cash payments received during 2012 under its January 2012 license and commercialization agreement for BEMA<sup>®</sup> Buprenorphine for chronic pain with Endo Pharmaceuticals, Inc. (the **Endo Agreement**). Such review was undertaken following an initial comment letter on this topic received by the Company from the staff (the **Staff**) of the Securities and Exchange Commission (the **SEC**) on September 5, 2012.

Since its receipt of the Staff's initial comment letter, the Company has been engaged with the Staff in a steady and collaborative comment and reply process with related telephonic communications regarding this matter. Based on such process and related internal deliberations, and with input from outside consultants and representatives of Cherry Bekaert LLP, the Company's independent registered public accounting firm (**CB**), on February 25, 2013, the Audit Committee of the Board of Directors (the **Audit Committee**) and the executive management of the Company jointly determined that approximately \$14.4 million of the \$30 million non-refundable upfront license fee received by the Company under the Endo Agreement in January 2012 should not have been recognized as revenue at that time, but should instead be deferred. As such, a determination has been made that the Company's unaudited financial statements for each of the first three quarters of the Company's 2012 fiscal year require restatement solely with respect to such recognition of revenue under the Endo Agreement and therefore should not be relied upon. The restated financial information regarding such financial statements will be published in appropriate filings to be made to the SEC.

*Restatement Does Not Impact Company's Cash or Business Plans*

Importantly, the Company notes that the entire \$30 million of cash from the upfront license fee received in January 2012, as well as an additional \$15 million intellectual property-related milestone payment received in May 2012 under the Endo Agreement, are completely non-refundable and are being used to fund the Company's ongoing business. Furthermore, the Company's decision to restate its financial statements for the first three quarters of 2012 will have no impact on the Company's overall cash position or ability to progress its stated business plans. The aforementioned \$15 million intellectual property milestone will not be deferred as it was earned in the quarter ended June 30, 2012.

The Company further notes its view that this matter is based on an interpretation of relatively new and technical revenue recognition literature, in particular, the milestone method guidance promulgated in 2010 and revised guidance on multiple-deliverable arrangements promulgated in 2009. The Company's interactions with the Staff on this matter centered on the application of, and interplay between, the milestone method and multi-deliverable arrangement literature and related publicly available guidance to the particular facts and circumstances of the Endo Agreement (specifically, how and when revenue should be recognized when a party receives an upfront fee for an item with stand-alone value, but also has items (such as research and development services) to be provided over time, for which only milestone payments will be received upon successful outcomes). The Company believes that the interpretations of these pronouncements can be particularly unclear (and, to the Company's knowledge, are not uncommon) in the case of biopharmaceutical license and commercialization arrangements such as the Endo Agreement.

*Anticipated Impact of the Restatement*

In terms of the anticipated impact of the forthcoming restatement, and subject to audit procedures to be performed by CB, beginning with the quarterly period ended March 31, 2012, the Company anticipates deferring the recognition of an aggregate of approximately \$14.4 million of the non-refundable \$30 million dollar upfront license fee received under the Endo Agreement in January 2012. The Company had previously recognized such \$30 million in full during the quarterly period ended March 31, 2012.

The Company anticipates that approximately 40% of the deferred revenue amount will be recognized in 2012, with the remainder anticipated to be recognized in 2013 and 2014 as research and development services are performed and clinical trial materials delivered by the Company for the ongoing Phase 3 trials for BEMA<sup>®</sup> Buprenorphine as required under the Endo Agreement.

The restated unaudited financial statements and related footnotes for the impacted 2012 quarters, as well as the audited financial statements and related footnotes to be included in the Company's forthcoming Annual Report on Form 10-K for the fiscal year ended December 31, 2012 (the **2012 10-K**), will contain appropriate revisions and disclosures to reflect the foregoing.

The Company's management, Audit Committee and the Company's full Board of Directors have reviewed the effect of the pending restatement on the Company's internal controls over financial reporting and its disclosure controls and procedures. They have concluded that, although modifications have been discussed and implemented to the Company's internal controls and procedures with respect to revenue recognition (which modifications are expected to be disclosed in the forthcoming 2012 10-K), there were no material weaknesses in the Company's internal controls over financial reporting or disclosure controls and procedures as of December 31, 2012.

**Cautionary Note Regarding Forward-Looking Statements**

This Current Report on Form 8-K, the press release included herein, and any statements of representatives and partners of BioDelivery Sciences International, Inc. (the Company) related thereto contain, or may contain, among other things, certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as projects, may, will, could, would, should, believes, expects, anticipate, intends, plans, potential 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: (i) the timing for and results of the Company's pending restatement, including the actual amounts deferred and recognized once such amounts are subject to audit and (ii) the timing for future revenue recognition under the Endo Agreement) may differ significantly 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). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

**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.

February 28, 2013

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty

Name: James A. McNulty

Title: Secretary, Treasurer and Chief Financial Officer