BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K
January 23, 2009

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) January 23, 2009 (January 20, 2009)

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-31361**	**35-2089858**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

801 Corporate Center Drive, Suite #210

Raleigh, NC	**27607**
(Address of principal executive offices)	**(Zip Code)**

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

n/a

(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 1.01 Entry into a Material Definitive Agreement.

On January 20, 2009, BioDelivery Sciences International, Inc. (the Company), entered into a Research Collaboration and License Agreement (the Agreement) with The Drugs for Neglected Diseases initiative, a not-for-profit foundation organized under the laws of Geneva, Switzerland (DNDi) for the development and distribution of the Company s Bioral Amphotericin B product for certain targeted applications, specifically African Human Trypanosomiasis (HAT), Chagas disease and both visceral and cutaneous Leishmaniasis (the Target Applications).

Under the Agreement, the Company and DNDi will, on a non-exclusive basis, collaborate in assessing the efficacy of Bioral Amphotericin B in the Target Applications (the period of efficacy assessment collaboration being referred to herein as the Assessment Period). Following the Assessment Period, should efficacy be established, DNDi will be responsible for obtaining (including providing required funding to secure) regulatory approvals for the Target Applications in all countries of the world, but excluding Japan, Australia, New Zealand, Russia, CIS countries, China, and all countries in North America and any country in, or that joins, the European Union (the Territory), with the rights to non-Territory countries to remain with the Company. DNDi will also be responsible for conducting and funding the distribution of Bioral Amphotericin B through public sector non-profit or public benefit agencies for use in the Target Applications in the Territory (but excluding any military organization, branch, department or agency, the rights to which shall remain with the Company).

Under the Agreement, the Company has provided the necessary licenses to Bioral Amphotericin B intellectual property and clinical trial data and will also be responsible for providing clinical trial materials at the cost of the raw materials and production costs. In addition, the Company will provide commercial supplies of Bioral Amphotericin B to DNDi for its distribution at an agreed upon profit margin to the Company. The Company is not entitled to any royalties or similar payments under the Agreement

All data generated under the Agreement will be deemed the confidential information to be jointly owned by the Company and DNDi, and each of the Company and DNDi shall have unfettered rights to access and reference to the data in support of their clinical and regulatory activities.

The Agreement shall automatically terminate on the expiry of the last-to-expire United States patent forming part of the collaboration intellectual property, or the expiration of any data exclusivity awarded Bioral Amphotericin B in the United States, whichever is later. In addition: (i) DNDi, during the Assessment Period, may terminate the Agreement on 30 days written notice to the Company and (ii) either party may terminate the Agreement for breach of the Agreement after providing the other party 45 days to cure such breach.

Item 8.01. Other Information

On January 21, 2009, the Company issued a press release relating to its agreement with DNDi as described above. A copy of the press release is attached to this Current Report as Exhibit 99.1.

On January 22, 2009, the Company issued a press release relating to its filing of a universal shelf registration. A copy of the press release is attached to this Current Report as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

*10.1	Research Collaboration and License Agreement, dated January 20, 2009, between the Company and The Drugs for Neglected Diseases Initiative.
99.1	Press Release, dated January 21, 2009, regarding the Company s agreement with DNDi.
99.2	Press Release, dated January 22, 2009, regarding the Company s filing of a universal shelf registration.

* **Confidential treatment is requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.**

Cautionary Note on Forward-Looking Statements

This Current Report on Form 8-K and the exhibits hereto and the 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 , could , would , should , believes , expects , anticipates , esti 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: (i) actual sales results and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and the Company s need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s or other regulatory review and/or approval and commercial launch of the Company s formulations and products and regulatory filings related to the same, 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).

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.

January 23, 2009

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ James A. McNulty
Name: James A. McNulty
Title: Secretary, Treasurer and Chief Financial Officer