

BIODELIVERY SCIENCES INTERNATIONAL INC  
Form 8-K  
August 31, 2006

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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) August 31, 2006 (August 30, 2006)

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**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction

of incorporation)

**0-28931**  
(Commission File Number)

**35-2089858**  
(IRS Employer

Identification No.)

2501 Aerial Center Parkway, Suite 205

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

**27560**  
(Zip Code)

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

Not Applicable

(Former name or former address, if changed since last report)

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## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 8-K

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))
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**Items 1.02. and 7.01. Termination of a Material Definitive Agreement and Regulation FD Disclosure.**

On August 30, 2006, BioDelivery Sciences International, Inc. ( BDSI ) received written notice from CDC IV, LLC ( CDC ) of CDC 's claim of termination of the Clinical Development and License Agreement (the CDLA ), dated July 14, 2005, by and among BDSI, CDC and Arius Pharmaceuticals, Inc., a wholly-owned subsidiary of BDSI. A copy of such notice is attached hereto as Exhibit 10.1 and is incorporated herein by reference. BDSI disputes all of CDC 's claims and assertions contained within such notice and will vigorously defend itself against such claims and assertions.

Pursuant to the CDLA, CDC previously provided BDSI with funding for the clinical development of BDSI 's BEMAFentanyl product. In its notice, CDC alleges that BDSI breached the CDLA by violating certain notice and approval provisions and by failing to comply with applicable laws and protocols in California with respect to the clinical trials involving the BEMA Fentanyl product. BDSI is in the process of addressing this matter and believes it will be able to resolve the same in the ordinary course of conducting the BEMA Fentanyl program, consistent with the terms of the CDLA.

Pursuant to the CDLA, any claim of breach of material terms is subject to the dispute resolutions procedures, including arbitration, contained within the CDLA. A determination of breach not cured could require BDSI to transfer to CDC certain rights in the BEMA Fentanyl product. For more information regarding the terms of the CDLA, see BDSI 's current reports on Form 8-K, dated July 15, 2005 and May 16, 2006.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

10.1 Notice of Breach and Termination, received August 30, 2006, from CDC to BDSI

**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.

August 31, 2006

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo

Name: Mark A. Sirgo

Title: President and Chief Executive Officer