

BIODELIVERY SCIENCES INTERNATIONAL INC  
Form 10-Q  
May 15, 2008  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D. C. 20549

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2008

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-31361

**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in its charter)

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

**35-2089858**  
(I.R.S. Employer  
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**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of May 15, 2008, there were 19,166,037 shares of company common stock issued and 19,150,546 shares of company common stock outstanding.

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**BioDelivery Sciences International, Inc. and Subsidiaries**

**Form 10-Q**

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## BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

## ASSETS

	March 31, 2008 (Unaudited)	December 31, 2007
Current assets:		
Cash	\$ 9,970,400	\$ 13,797,093
Certificate of deposit		2,800,000
Accounts receivable	232,899	305,497
Due from related party		14,414
Prepaid expenses and other current assets	188,694	160,704
<b>Total current assets</b>	<b>10,391,993</b>	<b>17,077,708</b>
Equipment, net	207,433	222,806
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,709,488	1,755,977
Acquired product rights	4,598,211	4,711,986
<b>Total other intangible assets</b>	<b>6,307,699</b>	<b>6,467,963</b>
Deposits on equipment	1,366,851	1,344,311
Other assets	14,279	15,937
Restricted cash	144,000	144,000
<b>Total assets</b>	<b>\$ 21,147,255</b>	<b>\$ 27,987,725</b>

## LIABILITIES AND STOCKHOLDERS DEFICIT

Current liabilities:		
Notes payable, related party	\$	\$ 1,296,164
Notes payable	22,709	90,834
Accounts payable and accrued liabilities, other	452,034	1,535,077
Accounts payables and accrued liabilities, related party	169,732	166,219
Clinical trial payables and accrued liabilities, other	1,882,315	2,568,564
Clinical trial payables and accrued liabilities, related party	336,732	1,922,708
Deferred revenue, current	107,621	120,121
Derivative liability (Note 7)	4,307,097	6,543,571
<b>Total current liabilities</b>	<b>7,278,240</b>	<b>14,243,258</b>
Deferred revenue, long-term	35,050,559	32,532,252
<b>Total liabilities</b>	<b>42,328,799</b>	<b>46,775,510</b>
Commitments and contingencies (Notes 6 and 10)		
Stockholders deficit:		
Common stock, \$.001 par value; 45,000,000 shares authorized 19,166,037 and 19,101,037 shares issued; 19,150,546 and 19,085,546 shares outstanding in 2008 and 2007, respectively	19,166	19,101
Additional paid-in capital	56,516,087	56,267,563
Treasury stock, at cost, 15,491 shares, 2007 and 2006	(47,183)	(47,183)

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Accumulated deficit	(77,669,614)	(75,027,266)
Total stockholders' deficit	(21,181,544)	(18,787,785)
Total liabilities and stockholders' deficit	\$ 21,147,255	\$ 27,987,725

See notes to condensed consolidated financial statements

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## BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31, 2008</b>	<b>March 31, 2007</b>
<b>Revenues:</b>		
Royalty revenue, related party	\$ 19,748	\$ 18,130
Research fees	104,500	25,000
<b>Total revenues</b>	<b>124,248</b>	<b>43,130</b>
<b>Expenses:</b>		
<b>Research and development:</b>		
Related party	466,244	1,372,814
Other	2,594,215	1,862,822
<b>General and administrative:</b>		
Related party	15,300	3,900
Other	1,407,085	1,200,553
<b>Total expenses</b>	<b>4,482,844</b>	<b>4,440,089</b>
<b>Loss from operations</b>	<b>(4,358,596)</b>	<b>(4,396,959)</b>
Interest expense, net	(520,226)	(690,453)
Derivative gain (loss)	2,236,474	(7,768,113)
	1,716,248	(8,458,566)
<b>Net loss</b>	<b>(2,642,348)</b>	<b>(12,855,525)</b>
Constructive dividend-preferred stock		(3,870,588)
<b>Loss attributable to common stockholders</b>	<b>\$ (2,642,348)</b>	<b>\$ (16,726,113)</b>
<b>Per share amounts, basic and diluted:</b>		
<b>Loss attributable to common stockholders</b>	<b>\$ (0.14)</b>	<b>\$ (1.13)</b>
<b>Weighted average common stock shares outstanding basic and diluted</b>	<b>19,126,755</b>	<b>14,826,776</b>

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS DEFICIT

FOR THE THREE MONTHS ENDED MARCH 31, 2008

(Unaudited)

	Common Stock				Treasury Stock	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount	Additional Paid-In Capital				
Balances, January 1, 2008	19,101,037	\$ 19,101	\$ 56,267,563	\$ (47,183)	\$ (75,027,266)	\$ (18,787,785)	
Stock-based compensation			140,538			140,538	
Stock option exercises	65,000	65	107,986			108,051	
Net loss					(2,642,348)	(2,642,348)	
Balances, March 31, 2008	19,166,037	\$ 19,166	\$ 56,516,087	\$ (47,183)	\$ (77,669,614)	\$ (21,181,544)	

See notes to condensed consolidated financial statements

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## BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31, 2008</b>	<b>March 31, 2007</b>
<b>Operating activities:</b>		
Net loss	\$ (2,642,348)	\$ (12,855,525)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of common stock		147,875
Depreciation and amortization	201,081	157,971
Derivative (gain) loss	(2,236,474)	7,768,113
Accretion of interest on convertible debentures		205,648
Accretion of interest on notes payable, related party	603,836	
Stock-based compensation	140,538	207,413
Changes in assets and liabilities:		
Accounts receivable	72,598	17,118
Prepaid expenses and other current assets	(27,990)	376,039
Accounts payable and accrued expenses	(1,290,631)	1,815,782
Deferred revenue	2,505,807	
<b>Net cash flows from operating activities</b>	<b>(2,673,583)</b>	<b>(2,159,566)</b>
<b>Investing activities:</b>		
Redemption of certificate of deposit	2,800,000	
Purchase of equipment	(25,444)	(4,905)
Deposits on equipment	(630,305)	
<b>Net cash flows from investing activities</b>	<b>2,144,251</b>	<b>(4,905)</b>
<b>Financing activities:</b>		
Proceeds from issuance of common stock		250,000
Proceeds from exercise of stock options	108,051	
Proceeds from notes payable, related parties		2,900,000
Payment on notes payable, related parties	(1,968,124)	(1,000,000)
Repayment of related party borrowings, net	(1,437,288)	(808,623)
<b>Net cash flows from financing activities</b>	<b>(3,297,361)</b>	<b>1,341,377</b>
<b>Net change in cash</b>	<b>(3,826,693)</b>	<b>(823,094)</b>
<b>Cash at beginning of period</b>	<b>13,797,093</b>	<b>2,172,104</b>
<b>Cash at end of period</b>	<b>\$ 9,970,400</b>	<b>\$ 1,349,010</b>

See notes to condensed consolidated financial statements



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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

**SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION**

Non-cash investing and financing activities

The Company converted \$2,467,511 of convertible notes payable through the issuance of 997,193 shares of common stock in the first quarter of 2007. There were no such convertible notes payable in 2008.

The Company reclassified derivative liabilities of \$2,311,997 from debt to equity during the first quarter of 2007, as a result of the conversions of notes payable to which the derivative related. There were no such reclassifications during the first quarter of 2008.

The Company paid \$152,803 of accrued dividends payable through the issuance of 59,226 shares of common stock with a fair value of \$152,803 during the first quarter of 2007.

The Company recorded a constructive dividend of \$3,870,588 related to the redemption of Series A Non-Voting Convertible Preferred Stock ( Series A Preferred ) during the first quarter of 2007.

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2008 AND 2007

(Unaudited)

**1. Basis of presentation:**

The condensed consolidated balance sheet of BioDelivery Sciences International, Inc., together with its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. ( Arius One ) and Arius Two, Inc. ( Arius Two ) and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC ( BND and, collectively with Arius and Arius Two, the Company or we , us or similar terminology) as of March 31, 2008, and the condensed consolidated statements of operations for the three months ended March 31, 2008 and March 31, 2007 have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows at March 31, 2008 and for all periods presented, have been made. The accompanying consolidated financial statements include the accounts of BioDelivery Sciences International, Inc. and its subsidiaries, Arius One, Arius Two and BND. All intercompany accounts and transactions have been eliminated. BND became substantially inactive as of September 30, 2005.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to the Securities and Exchange Commission ( SEC ) rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2007, included in the Company s 2007 Annual Report on Form 10-K, filed with the SEC on March 7, 2008 (as amended, the 2007 Annual Report ). As used herein, the term Common Stock means the Company s common stock, par value \$.001 per share.

The results of operations for the three months ended March 31, 2008 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this report are encouraged to review the risk factors relating to the Company which are set forth in the 2007 Annual Report.

The Company currently generates revenue or deferred revenue from licensing, milestone payments and royalties. Ultimately, if approval of the Company s owned or licensed products is secured from the U.S. Food and Drug Administration ( FDA ), the Company s goal is to augment revenues or deferred revenues from sales of such products, on which royalties will be paid to licensors as applicable. The Company is also required to make certain license, royalty or similar payments (as the case may be) to such licensors or other third parties in accordance with applicable agreements.

*Revenue Recognition*

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements. When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represents separate units of accounting as defined in Emerging Issues Task Force ( EITF ) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether it is separable from the other aspects of the contractual relationship.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2008 AND 2007

(Unaudited)

**1. Basis of presentation (continued):**

*License Arrangements*

License arrangements may consist of non-refundable upfront license fees, data transfer fees, exclusive licensed rights to manufacture patented or patent pending products, technology access fees, various performance or sales milestones and future product royalty payments.

Non-refundable, upfront fees that are not contingent on any future performance by us, and require no consequential continuing involvement on the Company's part, are recognized as revenue over the established or estimated term of the license when the license arrangement commences and the licensed data, technology and/or product or supplies to manufacture the product is delivered. Such deliverables may include physical quantities of products, supplies, or design of the products, the conceptual framework and mechanism of actions taken by a third party, and rights to the patents or patents pending for such products.

The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology, know-how, rights, products or services conveyed in conjunction with the non-refundable fees have no utility to the licensee that could be considered separate and independent of the Company's performance under other elements of the arrangement. In addition, if the Company has continuing involvement through research an