

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 anEF 1 491700 TORONTO-DOMINION BANK PUT 891160509 52717 707400 PUT SH-DEF 1 707400 TORONTO-DOMINION BANK COM 891160509 835 11200 SH SOLE 11200 TORONTO-DOMINION BANK COM 891160509 66760 894733 SH SOLE 894733 TORONTO-DOMINION BANK COM 891160509 290792 3902068 SH SH-DEF 1 3902068 TORONTO-DOMINION BANK COM 891160509 57960 777750 SH SH-DEF 2 777750 TOTAL S.A. SPONSORED ADR COM 89151E109 2016 34740 SH SOLE 34740 TOWERSTREAM CORPORATION COM 892000100 702 467700 SH SOLE 467700 TOYOTA MOTOR CORP ADR COM 892331307 64 795 SH SOLE 795 TOYOTA MOTOR CORP -SPON ADR COM 892331307 72 900 SH SOLE 900 TRANSALTA CORP CALL 89346D107 2480 112100 CALL SOLE 112100 TRANSALTA CORP CALL 89346D107 4258 192500 CALL SH-DEF 1 192500 TRANSALTA CORP PUT 89346D107 841 38000 PUT SOLE 38000 TRANSALTA CORP PUT 89346D107 2995 135400 PUT SH-DEF 1 135400 TRANSALTA CORP COM 89346D107 31 1400 SH SOLE 1400 TRANSALTA CORP COM 89346D107 76384 3453068 SH SOLE 3453068 TRANSALTA CORP COM 89346D107 14600 660031 SH SH-DEF 1 660031 TRANSALTA CORPORATION COM 89346D107 9604 433615 SH SOLE 433615 TRANSCANADA CORP CALL 89353D107 2506 68400 CALL SH-DEF 1 68400 TRANSCANADA CORP PUT 89353D107 6680 182300 PUT SH-DEF 1 182300 TRANSCANADA CORP COM 89353D107 545648 14891693 SH SOLE 14891693 TRANSCANADA CORP COM 89353D107 6 164 SH SH-DEF 1 164 TRANSCANADA CORP COM 89353D107 14932 407517 SH SH-DEF 1 407517 TRANSCANADA CORP COM 89353D107 3645 99500 SH SH-DEF 1 99500 TRANSCANADA CORPORATION COM 89353D107 42797 1166567 SH SOLE 1166567 TRANSGLOBE ENERGY CORP COM 893662106 54 9300 SH SOLE 9300 TRANSGLOBE ENERGY CORP COM 893662106 1154 200000 SH SH-DEF 1 200000 TRAVELERS COMPANIES INC COM 89417E109 108 1994 SH SOLE 1994 TRAVELERS COS INC/THE COM 89417E109 0 1 SH SH-DEF 2 1 TSAKOS ENERGY NAVIGATION LTD COM G9108L108 252 17100 SH SOLE 17100 U S BANCORP COM 902973304 127 4900 SH SOLE 4900 U S GOLD CORP COM 912023207 0 47 SH SOLE 47 U.S. GEOTHERMAL INC RSTD COM 90338S102 188 207000 SH SOLE 207000 ULTRA PETROLEUM CORP COM 903914109 115 2460 SH SOLE 2460 UNILEVER N.V. NEW YORK SHARES COM 904784709 249 8263 SH SOLE 8263 UNILEVER PLC SPON ADR COM 904767704 248 8485 SH SOLE 8485 UNION PACIFIC CORPORATION COM 907818108 773 10550 SH SOLE 10550 UNITED PARCEL SERVICE INC CL B COM 911312106 90 1400 SH SOLE 1400 UNITED STATES OIL FUND LP COM 91232N108 165 4100 SH SOLE 4100 UNITED TECHNOLOGIES CORPORATION COM 913017109 6275 85245 SH SOLE 85245 UNITEDHEALTH GROUP INC COM 91324P102 1363 41715 SH SOLE 41715 UNUM GROUP COM 91529Y106 1164 47000 SH SOLE 47000 UR ENERGY INC COM 91688R108 84 101000 SH SOLE 101000 URS CORPORATION COM 903236107 193 3900 SH SOLE 3900 US BANCORP COM 902973304 331 12796 SH SOLE 12796 US NATURAL GAS FUND LP COM 912318102 1532 221700 SH SOLE 221700 VALE S.A SPON ADR COM 91912E105 2566 79710 SH SOLE 79710 VALE S.A. CLASS PFD ADR COM 91912E204 364 13100 SH SOLE 13100 VALE SA-SP ADR CALL 91912E105 1127 35000 CALL SOLE 35000 VALE SA-SP ADR PUT 91912E105 1127 35000 PUT SOLE 35000 VALERO ENERGY CORP COM 91913Y100 268 13600 SH SOLE 13600 VALUEVISION MEDIA INC CLASS A COM 92047K107 7 2000 SH SOLE 2000 VANGUARD EUROPE PACIFIC ETF COM 921943858 204 5900 SH SOLE 5900 VANGUARD TOTAL STOCK MARKET ETF COM

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922908769 51 850 SH SOLE 850 VANTAGE DRILLING CO COM G93205113 4 3000 SH SH-DEF 1 3000 VARIAN MEDICAL SYSTEMS INC COM 92220P105 4 75 SH SOLE 75 VEOLIA ENVIRONNEMENT SPON ADR COM 92334N103 34 975 SH SOLE 975 VERIZON COMMUNICATIONS INC COM 92343V104 6 200 SH SOLE 200 VERIZON COMMUNICATIONS INC COM 92343V104 791 25501 SH SOLE 25501 VERTEX PHARMACEUTICALS INC COM 92532F100 1181 28900 SH SOLE 28900 VIACOM INC CLASS B COM 92553P201 5 155 SH SOLE 155 VIRTUS INVESTMENT PARTNERS COM 92828Q109 898 43100 SH SOLE 43100 VISA INC- CLASS A SHARES COM 92826C839 246 2700 SH SOLE 2700 VISIONCHINA MEDIA INC COM 92833U103 235 50000 SH SOLE 50000 VISTA GOLD CORP COM 927926303 0 93 SH SOLE 93 VISTA GOLD CORP REORG SHS COM 927926303 324 161000 SH SOLE 161000 VODAFONE GROUP PLC COM 92857W209 3710 159303 SH SOLE 159303 WABCO HOLDINGS INC COM 92927K102 6 200 SH SOLE 200 WALGREEN CO COM 931422109 658 17740 SH SOLE 17740 WAL-MART STORES INC COM 931142103 5142 92478 SH SOLE 92478 WASHINGTON POST COMPANY CL B COM 939640108 109 245 SH SOLE 245 WASTE MANAGEMENT INC COM 94106L109 399 11575 SH SOLE 11575 WELLPOINT INC COM 94973V107 1494 23200 SH SOLE 23200 WELLS FARGO & CO COM 949746101 3894 125115 SH SOLE 125115 WELLS FARGO & CO COM 949746101 25866 831159 SH SH-DEF 2 831159 WESTERN UNION CO COM 959802109 333 19650 SH SOLE 19650 WESTPORT INNOVATIONS INC COM 960908309 5 286 SH SOLE 286 WESTPORT INNOVATIONS INC NEW COM 960908309 16 1000 SH SOLE 1000 WEYERHAEUSER CO COM 962166104 24 520 SH SOLE 520 WINDSTREAM CORPORATION COM 97381W104 2 200 SH SOLE 200 WINNEBAGO INDUSTRIES INC COM 974637100 18 1200 SH SOLE 1200 WPP PLC - SPONSORED ADR COM 92933H101 40 785 SH SOLE 785 WRIGHT EXPRESS CORP PUT 98233Q105 4593 152500 PUT SOLE 152500 WRIGHT EXPRESS CORP COM 98233Q105 105 3500 SH SOLE 3500 WTS-OILSANDS QUEST 12MY11 COM 678046129 107 670850 SH SH-DEF 1 670850 WYNN RESORTS LTD COM 983134107 303 4000 SH SOLE 4000 XEROX CORPORATION COM 984121103 33 3375 SH SOLE 3375 XTO ENERGY INC COM 98385X106 73 1555 SH SOLE 1555 YAMANA GOLD INC CALL 98462Y100 710 71800 CALL SH-DEF 1 71800 YAMANA GOLD INC CALL 98462Y100 879 89200 CALL SH-DEF 1 89200 YAMANA GOLD INC PUT 98462Y100 859 86800 PUT SH-DEF 1 86800 YAMANA GOLD INC COM 98462Y100 36 3642 SH SOLE 3642 YAMANA GOLD INC COM 98462Y100 79104 7995450 SH SOLE 7995450 YAMANA GOLD INC COM 98462Y100 1341 135419 SH SOLE 135419 YAMANA GOLD INC COM 98462Y100 7464 754386 SH SH-DEF 1 754386 YUM! BRANDS INC COM 988498101 138 3600 SH SOLE 3600 ZIMMER HOLDINGS INC COM 98956P102 966 16315 SH SOLE 16315