

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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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 and development services that are required because Company know-how and expertise related to the technology is proprietary to the Company, or can only be performed by the Company, then such upfront fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in research and development arrangements are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process. This includes the acceptance by the customer; no requirement by the Company for continued performance of future research and development services related to the milestone; the milestone payments are non-refundable, and substantive effort is involved in achieving the milestone. If any of these conditions are not met, the Company defers the milestone payments and recognizes them as revenue over the estimated period of performance under the contract as the Company completes its performance obligations.

Payment related to sales targets, whether or not referred to as milestones, specified in underlying sales and manufacturing agreements are recognized upon achievement of those targets as a performance bonus.

*Reclassification*

Certain amounts in the December 31, 2007 financial statements as previously reported have been reclassified to conform to the March 31, 2008 presentation. Such reclassifications had no impact on net income as previously reported.

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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)

**2. Liquidity and management's plans:**

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, and from funded research arrangements and milestone payments. The Company has not generated revenue from the sale of any product, but has generated deferred revenues from licensing arrangements, research fees and sponsored research in 2008 and 2007. The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock purchase warrants.

Significant financing or commitments in 2007 consisted of:

\$1,900,000 loan from CDC IV, LLC, a material stockholder of the Company ( CDC ) (which was repaid in March 2008, see Note 4);

\$1,000,000 loan from Hopkins Capital Group II, LLC, a material stockholder of the Company controlled by the Company's Chairman of the Board ( HCG II ) (which was repaid in 2007);

\$250,000 received from the sale of Common Stock to Sigma Tau Industrie Farmaceutiche Riunite S.p.A ( Sigma-Tau ) in January 2007 pursuant to a previously executed Stock Purchase Agreement;

Approximately \$693,000 from the exercise of Common Stock options;

Approximately \$3,200,000 from the exercise of Common Stock warrants held by Laurus Master Fund, Ltd. ( Laurus );

\$3,000,000 loan from Southwest Bank of St. Louis (which was repaid in September, 2007); and

\$30,000,000 up-front, non-refundable payment received in September 2007 under a License and Development Agreement (the Meda U.S. License ) with Meda AB, a Swedish company ( Meda ) relating to the commercialization rights for the Company's BEMA Fentanyl product ( BEMAM Fentanyl ) in the U.S., Mexico and Canada (see Note 6).

Significant financing or commitments during the three months ended March 31, 2008 consisted of:

Approximately \$108,000 from the exercise of Common Stock options; and

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\$2,500,000 milestone payment under a License and Development Agreement (the Meda European License ) with Meda relating to the commercialization rights for BEMA™ Fentanyl in Europe (see Note 6).

The Company's existing cash and cash equivalents are considered by management to be sufficient to finance the Company's operations, capital expenditures and debt obligations into the third quarter of 2008.

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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)

**2. Liquidity and management's plans (continued):**

While the Company expects that significant additional payments (aggregating an additional \$30,000,000) will be received in 2008 under the Meda U.S. License, the receipt of such payments is conditioned upon, among other things, FDA approval of the Company's FDA new drug application ( NDA ) for BEMA Fentanyl. As such, no assurance can be given that such payments will be received in 2008, if at all. Accordingly, and especially if such payments are not received, additional outside capital may be required in order to support the Company's 2008 operations, as well as future development activities around the Company's current pipeline of products in development or other initiatives that the Company may elect to pursue. The Company believes that it will be able to secure such funding at levels sufficient to support planned operations. However, there can be no assurance that additional capital will be available on favorable terms, if at all. If adequate outside funds are not available, the Company would likely be required to significantly reduce or refocus its planned expanded operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company's financial condition and viability.

The financial statements included in this Quarter Report do not include any adjustment that may arise as a result of these uncertainties.

**3. New accounting pronouncements:**

In March 2008, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities ( Statement No. 161 ), an amendment of SFAS No. 133 Accounting for Derivative Instruments and Hedging ( Statement No. 133 ). Statement No. 161 requires companies with derivative instruments to disclose information about how and why a company uses derivative instruments, how derivative instruments and related hedged items are accounted for under Statement No. 133, and how derivative instruments and related hedged items affect a company's financial position, financial performance, and cash flows. The required disclosures include the fair value of derivative instruments and their gains or losses in tabular format, information about credit-risk-related contingent features in derivative agreements, counterparty credit risk, and the company's strategies and objectives for using derivative instruments. Statement No. 161 expands the current disclosure framework in Statement No. 133. Statement 161 is effective prospectively for periods beginning on or after November 15, 2008. The Company plans to provide these additional disclosures in the first quarter of 2009.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141 (revised 2007), Business Combinations ( Statement No. 141(R) ). Statement No. 141(R) requires, among other things, the acquiring entity in a business combination to recognize the fair value of all the assets acquired and liabilities assumed, the recognition of acquisition-related costs in the statement of operations, the recognition of restructuring costs in the statement of operations for which the acquirer becomes obligated after the acquisition date, and contingent arrangements to be recognized at their fair values on the acquisition date with subsequent adjustments recognized in the statement of operations. Statement No. 141(R) is effective for annual periods beginning after December 15, 2008 and should be applied prospectively for all business combinations entered into after the date of adoption.

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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)

**3. New accounting pronouncements (continued):**

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 160, Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51 ( Statement No. 160 ). Statement No. 160 requires that noncontrolling interests be reported as a component of shareholders' equity; net income attributable to the parent and the noncontrolling interest be separately identified in the consolidated statement of operations; changes in a parent's ownership interest be treated as equity transactions if control is maintained; and upon a loss of control, any gain or loss on the interest be recognized in the statement of operations. Statement No. 160 also requires expanded disclosures to clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. Statement No. 160 is effective for annual periods beginning after December 15, 2008 and should be applied prospectively. However, the presentation and disclosure requirements of the statement shall be applied retrospectively for all periods presented. The adoption of the provisions of Statement No. 160 is not anticipated to materially impact the company's consolidated financial position.

In April 2008, FASB Staff Position No. 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3) was issued. This standard amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, Goodwill and Other Intangible Assets. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company has not determined the impact on its financial statements of this accounting standard.

*Fair value disclosure*

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements ( Statement No. 157 ) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. Statement No. 157 applies to other accounting pronouncements that require or permit fair value measurements and does not require any new fair value measurements.

In February 2008, the FASB issued FASB Staff Position 157-2, which provides for a one-year deferral of the provisions of Statement No. 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a non-recurring basis. The Company is currently evaluating the impact of adopting the provisions of Statement No. 157 for non-financial assets and liabilities that are recognized or disclosed on a non-recurring basis.

Effective January 1, 2008, the Company adopted the provisions of Statement No. 157 for financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis. The adoption of the provisions of Statement No. 157 related to financial assets and liabilities and other assets and liabilities that are carried at fair value on a recurring basis did not materially impact the Company's consolidated financial position and results of operations.

Statement No. 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Statement No. 157 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Statement No. 157 describes three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities





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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)

**3. New accounting pronouncements (continued):**

Level 2 quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

The following table summarizes liabilities measured at fair value on a recurring basis at March 31, 2008, as required by Statement No. 157:

Liabilities	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
Derivative liabilities	\$	\$ 4,307,097	\$	\$ 4,307,097

**4. Notes payable, related parties:**

Note payable, related party consists of the following:

	March 31, 2008	December 31, 2007
Note payable, CDC (stockholder) (1)		1,900,000
Less unamortized discount		(603,836)
Total fair value of note payable, related party	\$	\$ 1,296,164

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- (1) On March 12, 2007, the Company closed a one-year, unsecured loan from CDC for \$1.9 million, at 10.25% per annum due March 12, 2008 and a warrant to purchase 1 million shares of Common Stock with an exercise price of \$3.80 per share. The Company repaid this loan plus accrued interest in March 2008 and the warrant remains outstanding.

**5. Notes payable:**

Notes payable at March 31, 2008 and December 31, 2007, consist of insurance premium financing. The short-term financing from First Insurance Funding Corp., at 7.7% per annum is payable monthly through May 25, 2008.

**6. Acquired product rights and license agreement:**

*Acquired BEMA rights*

On September 5, 2007, the Company exercised a previously granted option and purchased from QLT USA, Inc. ( QLT ) the BEMA drug delivery technology and intellectual property assets specifically related to the development and commercialization of BEMA in the United States (the

BEMA U.S. Rights ). The Company had previously licensed the BEMA U.S. Rights from QLT.

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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)

**6. Acquired product rights and license agreement (continued):**

In consideration for the BEMA U.S. Rights, the Company agreed to pay QLT \$7 million, consisting of \$3 million in cash and a promissory note, secured by the purchased assets, in the principal amount of \$4 million. Payments under such note are due as follows: (i) \$2 million within ten (10) business days of FDA approval of a product based on the BEMA technology and (ii) \$2 million within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA -based products reach \$30 million.

The Company has recorded the \$3 million payment as additional acquired product rights in the accompanying March 31, 2008 consolidated balance sheet. Management deems the \$4 million balance a contingent liability and, therefore, will not record the \$4 million (or parts thereof) as a liability or intangible asset until such time as the conditions which trigger the payment obligation have been satisfied.

*Meda U.S. License*

On September 5, 2007, the Company entered into the Meda U.S. License with Meda and the Company's Arius subsidiary pursuant to which the Company and Arius agreed to grant to Meda an exclusive commercial license to manufacture, market, sell, and, following regulatory approval, continue development of BEMA Fentanyl product in the United States, Mexico and Canada.

Pursuant to the License Agreement, the Company did or will receive:

\$30 million milestone payment upon closing (which was received on September 14, 2007).

An additional \$30 million milestone payment concurrently with receipt of approval of BEMA Fentanyl by the FDA, unless the Company has not, at such time, manufactured stocks of BEMA Fentanyl, in bulk or finished form, sufficient for commercial launch of BEMA Fentanyl in the U.S., in which case \$15 million will be paid upon FDA approval and \$15 million will be paid upon the earlier of: (A) the date that such sufficient launch stocks are manufactured or (B) the first commercial sale of BEMA Fentanyl. The Company anticipates that it will have sufficient launch stocks of BEMA Fentanyl product concurrently with FDA approval of BEMA Fentanyl.

A significant double digit royalty on net sales of BEMA Fentanyl in the covered territories, subject to certain third party royalty adjustments and other adjustments in the event of certain specific supply disruptions. The Meda U.S. License provides for certain guaranteed minimum annual royalties to the Company during the second through seventh years following the product's first commercial sale.

Sales milestones: A total of \$30 million payable at:

\$10 million when and if annual sales exceeds \$75 million;



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(Unaudited)

**6. Acquired product rights and license agreement (continued):**

*Meda U.S. License (continued)*

\$10 million when and if annual sales exceeds \$125 million; and

\$10 million when and if annual sales exceeds \$175 million

Also, pursuant to the Meda U.S. License, the Company was granted certain rights to co-promote BEMA Fentanyl using its own sales force (which the Company does not currently have), with financial support by Meda for such efforts. Per the Meda U.S. License, this financial support will not begin for a period of time following FDA approval of BEMA Fentanyl. In addition, Meda is subject to certain minimum sales call and advertising and promotional expenditure requirements under the Meda U.S. License and has agreed to support all future costs of clinical development that do not involve studies in support of the NDA such as additional indications for BEMA Fentanyl. The Company announced the expansion of its clinical development program for BEMA Fentanyl in January 2008 to include a clinical development program to support a potential indication for breakthrough pain in opioid tolerant non-cancer patients.

The Company has recorded the September 2007 \$30 million payment received under the Meda U.S. License as deferred revenue.

*Meda European License*

In August 2006, the Company entered into the Meda European License with Meda to develop and commercialize BEMA Fentanyl in Europe. Under terms of the Meda European License, the Company granted Meda rights to the European development and commercialization of BEMA Fentanyl, in exchange for an upfront fee to the Company, certain milestone payments and double digit royalties to be received by the Company on product sales. The Company received a non-refundable up-front payment of \$2.5 million upon signing the Meda European License. On March 31, 2008, the Company received a second non-refundable development milestone payment of \$2.5 million from Meda. This milestone was by providing certain clinical study reports to Meda required as part of their European regulatory submission for the use of BEMA<sup>TM</sup> Fentanyl for the treatment of cancer breakthrough pain in opioid tolerant patients. Each of the \$2.5 million payments were recorded as deferred revenue in the accompanying financial statements. An additional \$5 million in milestone payments is still achievable under the terms of the Meda European License if certain development milestones are met.

Meda will manage the clinical development and regulatory submissions in Europe. Upon regulatory approval, Meda will exclusively commercialize BEMA Fentanyl in Europe. The Company retains all development and commercial rights to BEMA Fentanyl in Japan, Australia and other territories outside of Europe, the U.S., Mexico and Canada.

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(Unaudited)

**7. Derivative Financial Instruments:**

The Company generally does not use derivative instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. However, certain other financial instruments, such as warrants and embedded conversion features that are indexed to the Company's Common Stock, are classified as liabilities when either (a) the holder possesses rights to net-cash settlement or (b) physical or net-share settlement is not within the control of the Company. In such instances, net-cash settlement is assumed for financial accounting and reporting, even when the terms of the underlying contracts do not provide for net-cash settlement. Such financial instruments are initially recorded at fair value estimated on the settlement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate, and then adjusted to fair value at the close of each reporting period.

The following tabular presentation reflects the components of derivative financial instruments as of the three months ended March 31, 2008 and the year ended December 31, 2007;

	March 31, 2008	December 31, 2007
Free standing warrants	\$ 4,307,097	\$ 6,543,571

**Shares into which derivative liability can be settled:**

	March 31, 2008	December 31, 2007
Free standing warrants	4,622,265	4,622,265

The following tabular presentation reflects the components of derivative financial instruments as of the three months ended March 31, 2008 and 2007;

**Derivative income (expense) in the accompanying statements of operations is related to the individual derivatives as follows:**

	March 31, 2008	March 31, 2007
Embedded derivative instruments	\$	\$ (2,797,706)
Free standing derivatives (principally warrants)	2,236,474	(4,970,407)
Total	\$ 2,236,474	\$ (7,768,113)

**8. Stockholders equity:**

*Stock-based compensation:*

During the three months ended March 31, 2008, options were granted to certain employees at prices equal to the market value of the Common Stock on the dates the options were granted. A total of 339,247 options have been granted at a fair market value of \$967,155. The options granted have a term of 10 years from the grant date and vest either immediately or ratably over a three year period, depending on the terms. The fair value of each option is amortized into compensation expense as vesting milestones are achieved. The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility,

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(Unaudited)

**8. Stockholders equity (continued):**

expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from traded options on the Common Stock, historical volatility of the Common Stock, and other factors estimated over the expected term of the options.

The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term.

The weighted average for key assumptions used in determining the fair value of options granted during the three months ended March 31, 2008 follows:

Expected price volatility	54.41%-87.13%
Risk-free interest rate	2.67%-3.88%
Weighted average expected life in years	6-10 years
Dividend yield	

Option activity during the three months ended March 31, 2008 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2008	2,695,904	\$ 3.95	
Granted	339,247	2.85	
Exercised	(65,000)	1.66	
Forfeitures	(121,117)	3.61	
Outstanding at March 31, 2008	2,849,034	\$ 3.88	\$ 82,621

Options outstanding at March 31, 2008 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 1.00 5.00	2,116,015	8.02	\$ 2.96	
\$ 5.01 10.00	733,019	9.04	\$ 6.53	



2,849,034

\$ 82,621

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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)

**8. Stockholders equity (continued):**

Options exercisable at March 31, 2008 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 1.00 5.00	1,492,324	7.52	\$ 3.02	
\$ 5.01 10.00	9,637	9.16	\$ 5.22	
	1,501,961			\$ 64,030

The weighted average grant date fair value of options granted during the three months ended March 31, 2008 whose exercise price is equal to the market price of the stock at the grant date was \$2.99. There were no options granted during the three months ended March 31, 2008 whose exercise price is greater or lower than the estimated market price of the stock at the grant date.

A summary of the status of the Company's nonvested stock options as of January 1, 2008, and changes during the three months ended March 31, 2008 is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Intrinsic Value
Nonvested at January 1, 2008	1,178,696		
Granted	339,247		
Vested	(88,505)		
Forfeited	(82,365)		
Nonvested at March 31, 2008	1,347,073	\$ 4.83	\$ 18,590

As of March 31, 2008, there was approximately \$3.5 million of unrecognized compensation cost related to unvested shares-based compensation awards granted. These costs will be expensed over the next three years.

*Warrants:*

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements.



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(Unaudited)

**8. Stockholders equity (continued):**

Warrants outstanding at March 31, 2008 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 0.00 5.00	5,186,757	5.22	\$ 3.42	
\$ 5.01 10.00	700,000	3.59	\$ 5.45	
	5,886,757			\$ 229,930

Warrants exercisable at March 31, 2008 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 0.00 5.00	5,186,757	5.22	\$ 3.42	
\$ 5.01 10.00	700,000	3.59	\$ 5.45	
	5,886,757			\$ 229,930

**9. Net loss per common share:**

The following table reconciles the numerators and denominators of the basic and diluted loss per share computations.

	Three Months Ended March 31,	
	2008	2007
Net loss attributable to common stockholder (numerator)	\$ (2,642,348)	\$ (16,726,113)
Basic:		
Weighted average shares outstanding (denominator)	19,126,755	14,826,776

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Net loss per common share	basic	\$	(0.14)	(1.13)
<b>Diluted:</b>				
Weighted average shares outstanding			19,126,755	14,826,776
Effect of dilutive securities				
Adjusted weighted average shares (denominator)			19,126,755	14,826,776
Net loss per common share	diluted	\$	(0.14)	\$ (1.13)

The effects of all stock options and warrants outstanding have been excluded from Common Stock equivalents because their effect would be anti-dilutive.

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(Unaudited)

**10. Commitments and Contingencies:**

*Litigation*

On or about April 19, 2004, the Company was named as the defendant in an action commenced by MAS Capital in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff sought monetary damages from the Company in the amount of \$1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company provided MAS Capital's counsel with copies of documents executed by MAS Capital and its affiliates that the Company alleged fully release them. Upon MAS Capital's refusal to dismiss the action, notwithstanding the documents that fully release all parties, the Company filed an Amended Answer asserting a claim for attorneys' fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. The Company also filed a motion for summary judgment on June 9, 2005 and on August 25, 2006, the U.S. District Court granted the motion for summary judgment on all of MAS Capital's claims for relief. Accordingly, the parties were to proceed until resolution of the Company's counterclaim for attorneys' fees and costs and either party could appeal at that point in time. On August 6, 2007, the U.S. District Court entered a final judgment on the Company's counterclaim pursuant to the parties' stipulation of dismissal. MAS Capital filed its appeal of the entry of summary judgment against it with the Seventh Circuit Court of Appeals. On May 1, 2008, the Seventh Circuit affirmed the district court decision and has given MAS Capital 14 days to show cause as to why it should not be sanctioned for the frivolous appeal.

*Certain Rights of CDC*

The Company and CDC are parties to a Clinical Development and License Agreement, dated July 15, 2005 (as amended, the "CDLA") pursuant to which CDC has previously provided funds to the Company for the development of the Company's BEMA Fentanyl product. Pursuant to the CDLA, in February 2006 the Company entered into a Security Agreement (the "Security Agreement") under which it granted CDC a security interest in the Company's assets related to BEMA Fentanyl. The Security Agreement terminates at the time of FDA approval of BEMA Fentanyl. As such, until such approval, CDC retains the right to reclaim the BEMA Fentanyl-related assets in the event of a default by the Company under the CDLA. Events of default include: (i) failure to pay royalties, (ii) acceleration of a debt in excess of \$1.0 million and the Company's failure to pay such debt, (iii) judgment of \$500,000 and the Company's failure to satisfy such judgments, or (iv) the Company's insolvency, among other things.

In September 2007, in connection with CDC's consent to the Meda transaction, the Company, among other transactions with CDC, granted CDC a 1% royalty on sales of the next BEMA product, including an active pharmaceutical ingredient other than fentanyl, to receive FDA approval (the "Next BEMA Product"). In connection with the 1% royalty grant: (i) CDC shall have the option to exchange its royalty rights to the Next BEMA Product in favor of royalty rights to a substitute BEMA product, (ii) the Company shall have the right, no earlier than six (6) months prior to the initial commercial launch of the Next BEMA Product, to propose in writing and negotiate the key terms pursuant to which it would repurchase the royalty from CDC, (iii) CDC's right to the royalty shall immediately terminate at any time if annual net sales of the Next BEMA Product equal less than seven \$7.5 million in any calendar year following the third (3rd) anniversary of initial launch of the product and CDC receives \$18,750 in three (3) consecutive quarters as payment for CDC's one percent (1%) royalty during such calendar year and (iv) CDC shall have certain information rights with respect to the Next BEMA Product.

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(Unaudited)

**10. Commitments and Contingencies (continued):**

The amount of royalties which the Company may be required to pay for the Next BEMA Product (including estimates of the minimum royalties) is not presently determinable because product sales estimates cannot be reasonably determined and the regulatory approvals of the product for sale is not possible to predict. As such, the Company expects to record such royalties, if any, as cost of sales when and if such sales occur.

*BEMA Fentanyl Supplier Concentration*

Key components used in the manufacture of the Company's BEMA Fentanyl product are currently provided by sole or limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs. The reliance on a sole or limited number of suppliers could potentially result in the Company's inability to timely obtain an adequate supply of required components and could result in reduced control over pricing, quality and timely delivery. Except for the Company's agreement with Aveva Drug Delivery Systems, Inc. (Aveva), the manufacturer of the BEMA Fentanyl product, by distribution in the U.S. under the Company's distribution agreement with Meda, the Company does not have long-term agreements with any of its suppliers and, therefore, the supply of a particular component could be terminated without penalty to the supplier. Any interruption in the supply of components from Aveva or other third party suppliers could cause the Company to seek alternative sources of supply. If the supply of any components is interrupted, components from alternative suppliers may not be available in sufficient volumes within required time frames, if at all, to meet the Company's needs. This could delay Aveva's ability to timely produce supplies for commercial sale, which could delay commercialization or decrease sales by Meda and therefore could cause the Company to lose royalty revenues or incur additional costs, affect the royalty rates payable by Meda, or potentially harm the Company's reputation.

*Doyen Medipharm*

On August 28, 2007, the Company agreed with Doyen Medipharm Inc. to purchase a BEMA related pharmaceutical device production machine. The Company has made payment of approximately \$1,400,000 pursuant to a purchase order (included in deposits on equipment in the accompanying financial statements) towards the total cost, which is approximately \$2,400,000. Payments will be made in separate increments during the production of the equipment.

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### **Item 2. Management's Discussion and Analysis or Plan of Operation.**

The following discussion and analysis should be read in conjunction with the Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Form 10-Q. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company's actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Form 10-Q.

#### **For the Three Months Ended March 31, 2008 Compared to the Three Months Ended March 31, 2007**

**Research Fee Revenues.** During the three-month periods ending March 31, 2008 and March 31, 2007 we reported research revenues of \$0.1 million and \$0.025 million respectively. The increase is due to increased business development and collaboration activity in our Newark laboratory.

**Royalty Revenues.** During each of the three-month periods ending March 31, 2008 and March 31, 2007, we reported \$0.02 million of royalty revenue from a related company.

**Research and Development.** Research and development expenses of approximately \$3.1 million and \$3.2 million were incurred during the respective three-month periods ended March 31, 2008 and 2007. These aforementioned amounts included \$0.5 million and \$1.4 million, respectively, paid to a contract research organization that is a stockholder of the Company. Our scientific staff continued to work toward increased development and application of our BEMA and Biora® technologies and other drug-related areas. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA and Biora® drug delivery technologies.

**General and Administrative Expenses including Stock-based Compensation.** General and administrative expenses of approximately \$1.4 million and \$1.2 million were incurred in the three-month periods ended March 31, 2008 and 2007, respectively. These expenses are principally composed of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries, and other business development costs. The Company granted employees stock based compensation of \$0.1 million and \$0.2 million during the three months ended March 31, 2008 and 2007 respectively.

**Interest Expense Net.** Interest expense for the periods ended March 31, 2008 and 2007 was principally composed of interest expense for amortization of deferred loan costs and notes payable discount amortization, net of interest earnings on invested cash.

**Derivative gain (Loss).** Derivative loss during 2008 and 2007 is related to the adjustment of derivative liabilities to fair value. These derivatives relate to prior financings with CDC, Laurus and HCG. The change in derivative gain (loss) is attributed to the decrease in the stock price of the Company and the interest rate from the period ended March 31, 2008 and 2007.

**Income Taxes.** While net operating losses were generated during the three months ended March 31, 2008 and 2007, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved.



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### **Liquidity and Capital Resources**

From inception through April 2008, we financed our operations primarily from the private sales of our convertible preferred stock, convertible debt and common stock, our initial public offering in 2002 and follow-on public offering in 2005, exercise of options, various strategic and licensing agreements (including the CDLA and our Meda agreements), NIH grants, bank financing, and through the sale of a royalty stream asset.

In September 2004, we entered into an Equity Line of Credit Agreement with HCG II, an affiliated entity which is controlled and partially-owned by our Chairman. Pursuant to the Equity Line Agreement, as amended March 30, 2006, HCG II was obligated, as requested by us, to invest up to \$4.0 million in our company from through December 31, 2006, in consideration of shares of our Series B Convertible Preferred Stock. As of December 31, 2006, \$1.45 million was drawn under the Equity Line Agreement. The holders of the Series B Preferred were entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred were convertible into shares of our common stock at a price equal to \$4.25 per share, at any time as of or after April 1, 2006, or earlier upon a change of control of our company. On January 10, 2007, HCG II converted all 341,176 shares of Series B Convertible Preferred Stock of our company into 341,176 shares of common stock. No other consideration was paid. HCG II also acquired 59,226 shares of common stock pursuant to the conversion of accrued and unpaid dividends on the Series B Preferred Stock.

In January 2005, we signed a definitive licensing agreement with Sigma-Tau Pharma for the application of our Bioral<sup>®</sup> nanocochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau Pharma. Simultaneously with this licensing agreement, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of \$0.25 million from another Sigma Tau-related entity. This upfront payment was made in consideration of unregistered shares of our common stock priced at \$4.25 a share. The stock purchase agreement with Sigma-Tau provides for the acquisition by Sigma-Tau, upon the occurrence of specified developmental milestones associated with the license, of additional unregistered shares of our common stock, up to an aggregate potential of \$1.5 million worth of such shares. Such additional unregistered shares will be issued at the lesser of: (i) \$4.25 and (ii) the average of the closing trade price of our Common Stock for the ten (10) trading days through and including the applicable payment date, with an absolute floor \$3.38 per share. In January 2007, under our development agreement with Sigma Tau, we were paid a milestone payment of \$250,000 for which we issued 73,964 shares of Common Stock at \$3.38. Sigma-Tau, through other holding entities, is currently a stockholder of our Company. In addition to the milestone payments, we will receive a royalty on future sales of each of the four products which may arise from the encochleated compounds.

In March 2007, we entered into a \$1.9 million financing with CDC. This financing involved a one-year, 10.25% loan from CDC and a warrant to purchase 1 million shares of our common stock with an exercise price of \$3.80. On March 12, 2008, we repaid the loan in full plus interest due to CDC.

In September 2007, we received an up-front non-refundable payment in connection with our U.S commercialization agreement with Meda of \$30.0 million.

At March 31, 2008, we had cash and cash equivalents of approximately \$9.97 million. The adequacy of cash for our operations and continued research is dependent on, among other things, licensing and milestone payments, and additional equity or debt financing opportunities that we are able to negotiate in the coming year. We used \$2.7 million of cash for operations for the three months ended March 31, 2008. This resulted from a net loss of \$2.6 million, which included net non-cash charges of \$3.9 million, as well as a \$2.5 million additional up-front payment from Meda (which was recorded as deferred revenue) and a decrease in our accounts payable and accrued liabilities of \$1.3 million.

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We have incurred significant net losses and negative cash flows from operations since our inception. As of March 31, 2008, we had stockholders deficit of \$21.2 million, versus \$18.8 million at December 31, 2007.

We anticipate that cash used in operations and our investment in facilities will continue beyond our BEMA Fentanyl agreements with Meda, as we research, develop, and, potentially, manufacture and commercialize additional drug formulations with our BEMA and Bioral technologies. While we believe further application of our BEMA and Bioral cochleate technologies to other drugs will result in license agreements with additional pharmaceutical manufacturers, our plan of operations for the foreseeable future will be focused on our further development of the BEMA and Bioral cochleate technologies and their use in a limited number of applications. Such focus will not be on the marketing, production or sale of FDA approved products.

Until FDA approval, we are required under our Meda agreement to pay certain chemistry, manufacturing and control, as well as clinical and regulatory costs associated with the NDA, as well as manufacturing and packaging equipment costs for BEMA Fentanyl. Our agreement with Meda requires all pre-launch marketing and commercialization costs for BEMA Fentanyl to be paid by Meda, as well as all required clinical costs associated with BEMA Fentanyl after FDA approval. Meda will pay for costs of Phase III-b and Phase IV studies which, although not required as part of our BEMA Fentanyl NDA, may be done to support the program with additional market data.

Our existing cash and cash equivalents, is considered by our management to be sufficient to finance the planned basic operations (minimal research and development activities beyond those covered under our Meda agreement) debt repayment obligations and capital expenditures into approximately the third quarter of 2008.

Under our existing Meda agreements, we expect to receive additional payments aggregating \$30.0 million upon FDA approval and launch of BEMA Fentanyl, for which we have a Prescription Drug User Fee Act ( PDUFA ) date of August 31, 2008. However, there can be no assurances that we will receive FDA approval or the timing of such approval, if received. Additional capital may be required in order to proceed with our support of the launch of BEMA Fentanyl, clinical development programs for other products in our pipeline, such as BEMA Buprenorphine and Bioral Amphotericin B (the scale of which is dependent in part on the success of BEMA Fentanyl and on the results from our Phase I studies for each of these products), and for general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

public equity markets;

private equity financings;

collaborative arrangements;

grants and new license revenues;

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bank loans;

public or private debt; and

exercise of existing warrants.

There can be no assurance that additional capital will be available on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations in 2008 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

### ***Revenue Recognition***

The Company recognizes revenue in accordance with the 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 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. See Note 1 to our condensed consolidated financial statements for further discussion regarding revenue recognition. Ultimately, the objective of our analysis of each customer contract based on the aforementioned criteria is to determine the amount and appropriate accounting period in which revenue should be recognized. To date our primary source of revenue has been the issuance of European and U.S. licensing rights to BEMA Fentanyl and related formulations. All amounts received have currently been recorded as deferred revenue in our financial statements.

### ***Valuation of Goodwill and Intangible Assets***

Our intangible assets include goodwill, product rights, and licenses, all of which are accounted for based on Financial Accounting Standard Statement No. 142 Goodwill and Other Intangible Assets ( FAS 142 ). As described below, goodwill is not amortized but is tested at least annually for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with limited useful lives are amortized using the straight-line method over their estimated period of benefit, ranging from eleven to thirteen years.

Our carrying value of goodwill at March 31, 2008 was \$2.715 million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements or the underlying patents. Our carrying value of other, amortizing intangible assets at March 31, 2008 was \$6.3 million, net of accumulated amortization of \$1.1 million. We begin amortizing capitalized intangibles on their date of acquisition.

### ***Impairment Testing***

Our goodwill impairment testing is calculated at the reporting unit level. Our annual impairment test has two steps. The first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired and the second step is not necessary. If the carrying value exceeds the fair value, the second step calculates the

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possible impairment loss by comparing the implied fair value of goodwill with the carrying amount. If the implied fair value of goodwill is less than the carrying amount, a write-down is recorded. No goodwill impairment charges have resulted from this analysis for 2008 or 2007.

In accordance with SFAS 144, which relates to impairment of long-lived assets other than goodwill (our other amortizing intangibles), impairment exists if the sum of the future estimated undiscounted cash flows related to the asset is less than the carrying amount of the intangible asset or to its related group of assets. In that circumstance, then an impairment charge is recorded for the excess of the carrying amount of the intangible over the estimated discounted future cash flows related to the asset.

In making this assessment, we predominately use a discounted cash flow model derived from internal budgets in assessing fair values for our impairment testing. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. In addition, selection of a risk-adjusted discount rate on the estimated undiscounted cash flows is susceptible to future changes in market conditions, and when unfavorable, can adversely affect our original estimates of fair values. In the event that our management determines that the value of intangible assets have become impaired using this approach, we will record an accounting charge for the amount of the impairment. No impairment charges have been recorded to other amortizing intangibles in either 2008 or 2007.

### ***Stock-Based Compensation and other stock based valuation issues (derivative accounting)***

We account for stock-based awards to employees and non-employees using the accounting provisions of SFAS 123R Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of the Company's common stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide the service in exchange for the award. We use the Black-Scholes options-pricing model to determine the fair value of stock option and warrant grants. We also use the Black Scholes option pricing model as the primary basis for valuing our derivative liabilities at each reporting date (both embedded and free-standing derivatives). The underlying assumptions used in this determination are primarily the same as are used in the determination of stock-based compensation discussed in the previous paragraph except contractual lives of the derivative instruments are utilized rather than expected option terms as discussed in the previous paragraph.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

### **Item 4T. Controls and Procedures**

#### ***Evaluation of Disclosure Controls and Procedures***

As of the end of the period covered by this Quarterly Report, the Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer (the Certifying Officers), conducted evaluations of the Company's disclosure controls and procedures. As defined under Sections 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act), the term disclosure controls and procedures means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports

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that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, included the Certifying Officers, to allow timely decisions regarding required disclosures.

Based on this evaluation, the Certifying Officers have concluded that the Company's disclosure controls and procedures were effective to ensure that material information is recorded, processed, summarized and reported by management of the Company on a timely basis in order to comply with the Company's disclosure obligations under the Exchange Act and the rules and regulations promulgated thereunder.

This Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the company to provide only management's report in this report.

### *Changes in Internal Control over Financial Reporting*

Further, there were no changes in the Company's internal control over financial reporting during the Company's first fiscal quarter of 2008 that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### *Limitations on the Effectiveness of Internal Controls*

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

## **NOTE ON FORWARD-LOOKING STATEMENTS**

The information set forth in this Report on Form 10-Q under the Sections Management's Discussion and Analysis or Plan of Operation, Management's plans regarding liquidity and capital resources and elsewhere relate to future events and expectations and as such constitute Forward-Looking Statement within the meaning of the Private Securities Litigation 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, anticipates, estimates, intends, 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

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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 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. Such forward-looking statements also involve other factors which may cause the actual results, performance or achievements of the Company to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1 of the 2007 Annual Report and other factors detailed from time to time in the Company's other filings with the Securities and Exchange Commission. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Report.

**Table of Contents****PART II. OTHER INFORMATION****Item 1. Legal Proceedings.**

On or about April 19, 2004, the Company was named as the defendant in an action commenced by MAS Capital in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff sought monetary damages from the Company in the amount of \$1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company provided MAS Capital's counsel with copies of documents executed by MAS Capital and its affiliates that the Company alleged fully release them. Upon MAS Capital's refusal to dismiss the action, notwithstanding the documents that fully release all parties, the Company filed an Amended Answer asserting a claim for attorneys' fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. The Company also filed a motion for summary judgment on June 9, 2005 and on August 25, 2006, the U.S. District Court granted the motion for summary judgment on all of MAS Capital's claims for relief. Accordingly, the parties were to proceed until resolution of the Company's counterclaim for attorneys' fees and costs and either party could appeal at that point in time. On August 6, 2007, the U.S. District Court entered a final judgment on the Company's counterclaim pursuant to the parties' stipulation of dismissal. MAS Capital filed its appeal of the entry of summary judgment against it with the Seventh Circuit Court of Appeals. On May 1, 2008, the Seventh Circuit affirmed the district court decision and has given MAS Capital 14 days to show cause as to why it should not be sanctioned for the frivolous appeal.

**Item 6. Exhibits.**

<b>Number</b>	<b>Description</b>
31.1	Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302
31.2	Certification of Chief Financial Officer Pursuant To Sarbanes-Oxley Section 302
32.1	Certification Pursuant To 18 U.S.C. Section 1350 (*)
32.2	Certification Pursuant To 18 U.S.C. Section 1350 (*)

\* A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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**SIGNATURES**

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 15, 2008

By: /s/ Mark A. Sirgo  
Mark A. Sirgo, President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 15, 2008

By: /s/ James A. McNulty  
James A. McNulty, Secretary, Treasurer and Chief Financial Officer  
(Principal Financial Officer)

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