BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
August 14, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 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)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

801 Corporate Center Drive, Suite #210

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

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

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 x 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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of August 14, 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

	June 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash	$ 6,121,415	$ 13,797,093
Certificate of deposit		2,800,000
Accounts receivable	326,703	305,497
Due from related party		14,414
Prepaid expenses and other current assets	104,486	160,704
Deferred income taxes	2,000,000	
Total current assets	8,552,604	17,077,708
Equipment, net	168,718	222,806
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,662,999	1,755,977
Acquired product rights	4,484,437	4,711,986
Total other intangible assets	6,147,436	6,467,963
Deposits on equipment	1,949,073	1,344,311
Other assets	12,666	15,937
Restricted cash	144,000	144,000
Total assets	$ 19,689,497	$ 27,987,725
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Notes payable, related party	$	$ 1,296,164
Notes payable		90,834
Accounts payable and accrued liabilities, other	547,079	1,535,077
Accounts payable and accrued liabilities, related party	169,604	166,219
Clinical trial payables and accrued liabilities, other	1,961,215	2,568,564
Clinical trial payables and accrued liabilities, related party	19,560	1,922,708
Deferred revenue, current	95,121	120,121
Derivative liability (Note 7)	4,259,997	6,543,571
Total current liabilities	7,052,576	14,243,258
Deferred revenue, long-term	35,032,052	32,532,252
Total liabilities	42,084,628	46,775,510
Commitments and contingencies (Notes 6 and 12)		
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	57,731,578	56,267,563
Treasury stock, at cost, 15,491 shares, 2008 and 2007	(47,183)	(47,183)
Accumulated deficit	(80,098,692)	(75,027,266)

Total stockholders deficit	(22,395,131)	(18,787,785)
Total liabilities and stockholders deficit	$ 19,689,497	$ 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Royalties, related parties	$ 15,488	$ 19,540	$ 35,236	$ 37,670
Research fees/consulting	12,500		117,000	25,000
Research and development services	829,995		1,448,269	
	857,983	19,540	1,600,505	62,670
Expenses:				
Research and development:				
Related party	70,914	1,685,854	537,158	3,058,668
Other	2,637,182	1,349,167	5,849,671	3,211,989
General and administrative:				
Related party	15,000	4,402	30,300	8,302
Other	2,645,292	1,010,550	4,055,725	2,211,102
Total expenses	5,368,388	4,049,973	10,472,854	8,490,061
Loss from operations	(4,510,405)	(4,030,433)	(8,872,349)	(8,427,391)
Interest income (expense), net	34,226	(646,005)	(482,651)	(1,336,458)
Derivative gain (loss)	47,100	4,090,612	2,283,574	(3,677,501)
Loss on extinguishment of debt		(3,595,169)		(3,595,169)
Loss before income taxes	(4,429,079)	(4,180,995)	(7,071,426)	(17,036,519)
Deferred income tax benefit	2,000,000		2,000,000	
Net loss	(2,429,079)	(4,180,995)	(5,071,426)	(17,036,519)
Constructive dividends				(3,870,588)
Loss attributable to common stockholders	$ (2,429,079)	$ (4,180.995)	$ (5,071,426)	$ (20,907,107)
Per share amounts, basic and diluted:				
Loss attributable to common stockholders	$ (0.13)	$ (0.22)	$ (0.26)	$ (1.24)
Weighted average common stock shares outstanding basic and diluted	19,150,546	19,001,041	19,138,650	16,925,440

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 SIX MONTHS ENDED JUNE 30, 2008

(Unaudited)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount				
Balances, January 1, 2008	19,101,037	$ 19,101	$ 56,267,563	$ (47,183)	$ (75,027,266)	$ (18,787,785)
Stock-based compensation			1,356,029			1,356,029
Stock option exercises	65,000	65	107,986			108,051
Net loss					(5,071,426)	(5,071,426)
Balances, June 30, 2008	19,166,037	$ 19,166	$ 57,731,578	$ (47,183)	$ (80,098,692)	$ (22,395,131)

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended	
	June 30, 2008	**June 30, 2007**
Operating activities:		
Net loss	$ (5,071,426)	$ (17,036,519)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of common stock		201,154
Depreciation and amortization	401,531	315,426
Derivative (gain) loss	(2,283,574)	3,677,501
Loss on extinguishment of debt		3,595,169
Accretion of interest on convertible debentures	603,836	680,647
Stock-based compensation	1,356,029	207,413
Changes in assets and liabilities:		
Accounts receivable	(21,206)	(10,033)
Prepaid expenses and other current assets	59,210	522,557
Accounts payable and accrued expenses	(1,118,152)	(238,734)
Deferred revenue	2,474,801	
Deferred income tax asset	(2,000,000)	
Net cash flows from operating activities	(5,598,951)	(8,085,419)
Investing activities:		
Purchase of equipment	(26,827)	(8,107)
Deposits on equipment	(1,212,528)	
Net cash flows from investing activities	(1,239,355)	(8,107)
Financing activities:		
Proceeds from issuance of common stock		250,000
Proceeds from exercise of stock options	108,051	521,392
Proceeds from notes payable and warrants sale, related parties		2,900.000
Payment on notes payable, related parties	(1,900,000)	(1,000,000)
Payment of other notes payable	(90,835)	
Proceeds from exercise of common stock warrants		3,235,420
(Repayment of) proceeds from related party borrowings, net	(1,754,588)	1,662,632
Net cash flows from financing activities	(3,637,372)	7,569,444
Net change in cash and cash equivalents	(10,475,678)	(524,082)
Cash and cash equivalents at beginning of period	16,597,093	2,172,104
Cash and cash equivalents at end of period	$ 6,121,415	$ 1,648,022

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 $4,057,401 of convertible notes payable through the issuance of 1,757,454 shares of common stock during the six months ended June 30, 2007.

The Company converted $201,154 of interest payable through the issuance of common stock to Laurus Master Fund Ltd. during the six months ended June 30, 2007.

The Company reclassified derivative liabilities of $5,175,701 from debt to equity during the six months ended June 30, 2007, as a result of the conversions of notes payable to which the derivative related.

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 six months ended June 30, 2007.

The Company recorded a constructive dividend of $3,870,588 related to the redemption of Series A Non-Voting Convertible Preferred Stock during the six months ended June 30, 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 SIX MONTHS ENDED JUNE 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation:

Overview

The accompanying unaudited condensed consolidated financial statements 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) 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 June 30, 2008 and for all periods presented, have been made. 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 (GAAP) have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. These unaudited 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). The accompanying condensed unaudited balance sheet at December 31, 2007 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements. As used herein, the term Common Stock means the Company s common stock, par value $.001 per share.

The results of operations for the six months ended June 30, 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, research and development services 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

Multiple Deliverable Arrangements

The Company s license, development and commercial product supply agreements (particularly, and presently, with respect to the Company s lead product, BEMA™ Fentanyl (BEMA™ Fentanyl)) contain multiple elements, including non-refundable upfront fees; payments for ongoing research and development services; payments associated with achieving specific performance-based milestones; payments related to manufacturing or supplying product; and royalties based on specified percentages of net product revenues earned by the licensee, if any. The Company applies

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

Revenue recognition (continued):

the guidance established by EITF Issue 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-2) in order to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and to address how arrangement consideration should be measured and allocated. The Company applies the revenue recognition criteria outlined in Staff Accounting Bulletin Topic 13, *Revenue Recognition* (SAB Topic 13) to determine if the criteria for revenue recognition have been met under the appropriate revenue recognition conventions.

Pursuant to EITF 00-21, consideration is allocated to a delivered product or service when all of the following criteria are met: (1) the delivered item has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item; and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company s control. The Company performs this analysis at the inception of the arrangement and as each substantive product or service is delivered. When a delivered product or service (or group of delivered products or services) meets the criteria for separation as established in EITF 00-21, the Company allocates consideration based upon the relative fair values of each element. The Company determines the fair value of a separate deliverable using either prices charged to other customers when that product or service is sold separately or in instances where the Company does not sell the product or service separately, third-party evidence of fair value is obtained. In applying the criteria of EITF 00-21, the Company considers a variety of factors in determining the appropriate separation of units of accounting and method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract. The application of these standards requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

The Company considers licensed rights to have standalone value to the licensees if the Company or others have sold such rights separately or licensees can sell such rights or technology separately without the need for the Company s continuing involvement. Non-refundable, up-front fees that are not contingent on any future performance by the Company, and require no consequential continuing involvement on the Company s part, are recognized as revenue when the license term commences and the licensed data and/or technology is delivered. The Company defers recognition of non-refundable upfront fees if continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of the Company s performance under the other elements of the arrangement. In addition, if the arrangement includes continuing involvement through research and development services which require the Company to provide these services because the know-how and expertise related to the technology is proprietary to the Company, or can only be performed by the Company s personnel, then such up-front fees are deferred and recognized over the related performance period.

Payments related to substantive, performance-based milestones are recognized as revenue upon the achievement of the milestones as specified in the agreements when they represent the culmination of an earnings process. The Company believes that a milestone represents the culmination of a

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

Revenue recognition (continued):

distinct earnings process when it is not associated with ongoing research, development or other performance on the Company s part. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product or technology, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company considers the nature, timing, and value of significant achievements in the development of the product; the relative level of effort required to achieve the milestone; and the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing products or technology in a drug development program and in ultimately attaining an approved drug product. The Company recognizes such performance-based milestones as revenue when they become due and collection is reasonably assured. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period. Deferred revenue will be recognized over the performance period.

Research and development services

The Company provides research and development services based on various fixed-price and time and materials contracts with third parties. Revenues earned from fixed-price contracts are recognized based on percentage of completion of the contract terms. Revenues from time and materials contracts are recognized as revenue when the services are performed.

The Company enters into license and development agreements which include research and development services requirements and have varying arrangements as to which parties perform these services and bear the costs of these activities. When the Company is entitled to reimbursement of all or a portion of the research and development services costs incurred under an arrangement and these services represent separate units of accounting, these reimbursable amounts are recognized as Research and Development Services revenue as the services are provided and the costs are incurred by the Company.

Royalty and Contract Revenues

Royalty revenue amounts are recognized as revenue on a monthly basis based on net sales under the Company s license agreement with Accentia Biopharmaceuticals, Inc. (Accentia) relating to chronic rhinosinusitis (CRS). This is shown as royalty revenue, related party on the accompanying condensed consolidated statements of operations. Royalty revenues associated with

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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FOR THE SIX MONTHS ENDED JUNE 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

Revenue recognition (continued):

the BEMA Fentanyl License and Development agreements between the Company and Meda AB, a Swedish company (Meda) will be recognized on a monthly basis based on net sales, as defined, made by Meda.

Reimbursement of Direct Out-of-Pocket Costs

The Company pays on behalf of its partners certain fees to regulatory agencies and other out-of-pocket costs for which the Company is reimbursed at cost, without mark-up or profit. Revenues derived from reimbursement of these direct out-of-pocket costs associated with research and development services are presented in the accompanying consolidated financial statements based on EITF Issue 99-19, Reporting Revenue Gross as a Principal Versus Net as an Agent (EITF 99-19) and EITF Issue 01-14, Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses Incurred (EITF 01-14). According to the criteria established by these EITF Issues, in transactions where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, revenue should be presented at the gross amount of the reimbursement in the statement of operations. The Company has included the revenue associated with these reimbursed costs in Research and Development Services revenue in the accompanying 2008 consolidated statement of operations. The expenses associated with these reimbursements are reflected as a component of research and development expense in the accompanying 2008 consolidated statements of operations.

Reclassification

Reclassification of December 31, 2007 balance sheet:

Clinical trial payables, other and related party of $2.57 million and $1.9 million, respectively, which were previously included in accrued liabilities in the December 31, 2007 balance sheet, have been reclassified as a separate line item in the accompanying December 31, 2007 balance sheet to conform to the March 31, 2008 presentation.

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 revenue and deferred revenues from licensing arrangements, including research and development services, 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

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(Unaudited)

2. Liquidity and management s plans (continued):

Significant financing or commitments in 2007 consisted of:

- $1.9 million loan from CDC IV, LLC, a material stockholder of the Company (CDC) (which was repaid in March 2008, see Note 4);
- $1.0 million 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 September 2007);
- $0.250 million 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 $0.693 million from the exercise of Common Stock options;
- Approximately $3.2 million from the exercise of Common Stock warrants held by Laurus Master Fund, Ltd. (Laurus);
- $3.0 million loan from Southwest Bank of St. Louis (which was repaid in September 2007); and
- $30 million up-front, non-refundable payment received in September 2007 under a License and Development Agreement (the Meda U.S. License) with Meda relating to the licensing rights for BEMA™ Fentanyl in the U.S., Mexico and Canada (see Note 6).

Significant financing or commitments during the six months ended June 30, 2008 consisted of;

- Approximately $0.108 million from the exercise of Common Stock options; and
- $2.5 million milestone payment received in March 2008, under a License and Development Agreement (the Meda European License) with Meda relating to the licensing rights for BEMA™ Fentanyl product in Europe (see Note 6).

Company management believes that the Company s existing cash and cash equivalents are sufficient to finance planned basic operations (minimal research and development activities beyond those covered under the Company s Meda and related agreements) into approximately the fourth quarter of 2008.

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 agreement, the receipt of such payments is conditional 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 will 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2008 AND 2007

(Unaudited)

2. Liquidity and management s plans (continued):

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 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 condensed consolidated financial statements included in this Quarterly 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.

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2008 AND 2007

(Unaudited)

3. New accounting pronouncements (continued):

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 statements.

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 six levels of inputs that may be used to measure fair value:

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2008 AND 2007

(Unaudited)

3. New accounting pronouncements (continued):

The following table summarizes liabilities measured at fair value on a recurring basis at June 30, 2008, as required by Statement No. 157:

	Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Derivative liabilities	$	$ 4,259,997	$	$ 4,259,997

4. Notes payable, related parties:

Note payable, related party consists of the following:

	June 30, 2008	**December 31, 2007**
Note payable, CDC (stockholder)		1,900,000
Less unamortized discount		(603,836)
Total fair value of note payable, related party	$	$ 1,296,164

On March 12, 2007, the Company closed on 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 December 31, 2007 consist of insurance premium financing. Such short-term financing from First Insurance Funding Corp., was at 7.7% per annum and payable monthly through April 25, 2008. The Company paid this financing in full as of April 24, 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.

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.

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(Unaudited)

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

The Company recorded the $3 million payment as additional acquired product rights in the accompanying 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.

Additional aggregate milestone payments of $30 million, of which a $15 million milestone payment will be paid concurrently with receipt of approval of BEMA Fentanyl by the FDA and $15 million 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 by the time of the expected launch of the approved product, but not concurrently with FDA approval of BEMA Fentanyl if the PDUFA date (August 31, 2008) is met.

A significant double digit royalty on net sales to Meda s customers 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 exceed $75 million;

$10 million when and if annual sales exceed $125 million; and

$10 million when and if annual sales exceed $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, such as additional indications for BEMA Fentanyl, that do not involve studies in support of the original NDA. The Company announced the expansion of its clinical development program for

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

Meda U.S. License (continued)

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 receipt 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 payment 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 generated as the result of The Company providing certain clinical study reports to Meda required as part of their European regulatory submission for the use of BEMA™ 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 remain 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.

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 and for the three and six months ended June 30, 2008 and as of December 31, 2007;

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(Unaudited)

7. Derivative Financial Instruments (continued):

	June 30, 2008	December 31, 2007
Free standing warrants	$ 4,259,997	$ 6,543,571

	June 30, 2008	December 31, 2007
Shares into which derivative liability can be settled:		
Free standing warrants	4,622,265	4,622,265

The following tabular presentation reflects the components of derivative financial instruments as of the three and six months ended June 30, 2008 and 2007;

	3 months ending Jun 30, 2008	3 months ending Jun 30, 2007	6 months ending Jun 30, 2008	6 months ending Jun 30, 2007
Derivative income (expense) in the accompanying statement of operations is related to the individual derivatives as follows:				
Embedded derivative instruments	$ 0	$ (567,033)	$ 0	$ (3,430,698)
Free standing derivatives (principally warrants)	47,100	4,657,645	2,283,574	(246,803)
Total	$ 47,100	$ 4,090,612	$ 2,283,574	$ (3,677,501)

8. Stockholders equity:

Stock-based compensation:

During the six months ended June 30, 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 about $0.967 million. 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 evenly through the vesting period. 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, 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.

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8. Stockholders equity (continued):

The weighted average for key assumptions used in determining the fair value of options granted during the six months ended June 30, 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 six months ended June 30, 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 June 30, 2008	2,849,034	$ 3.88	$ 77,838

Options outstanding at June 30, 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	7.77	$ 2.96	
$ 5.01 10.00	733,019	7.51	$ 6.53	
	2,849,034			$ 77,838

Options exercisable at June 30, 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	1,495,090	7.27	$ 4.91	
$ 5.01 10.00	257,190	7.58	$ 6.46	
	1,752,280			$ 59,911

The weighted average grant date fair value of options granted during the six months ended June 30, 2008 whose exercise price is equal to the market price of the stock at the grant date was $2.85.

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8. Stockholders equity (continued):

There were no options granted during the six months ended June 30, 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 six months ended June 30, 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	(362,195)		
Forfeited	(58,994)		
Nonvested at June 30, 2008	1,096,754	$ 4.45	$ 17,927

As of June 30, 2008, there was approximately $2.2 million of unrecognized compensation cost related to unvested shares-based compensation awards granted. These costs will be expensed over the next two years.

Warrants:

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

Warrants outstanding at June 30, 2008, all of which are exercisable are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.00 5.00	5,186,757	4.97	$ 3.42	
$ 5.01 10.00	700,000	3.34	$ 5.45	
	5,886,757			$ 228,357

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(Unaudited)

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 June 30,		Six months ended June 30,	
	2008	**2007**	**2008**	**2007**
Loss attributable to common stockholders	$ (2,429,079)	$ (4,180,995)	$ (5,071,426)	$ (20,907,107)
Basic:				
Weighted average shares outstanding (denominator)	19,150,546	19,001,041	19,138,650	16,925,440
Net loss per common share basic	$ (0.13)	$ (0.22)	$ (0.26)	$ (1.24)
Diluted:				
Weighted average shares outstanding	19,150,546	19,001,041	19,138,650	16,925,440
Net loss per common share diluted	$ (0.13)	$ (0.22)	$ (0.26)	$ (1.24)

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

10. Income tax benefit:

The Company has recognized a $2.0 million deferred tax benefit related to the loss incurred for the six months ended June 30, 2008. This is based upon the expectation that it is more likely than not that there will be taxable income for the year ended December 31, 2008 because approximately $30.0 million of revenues which are currently deferred for financial reporting purpose will become taxable in 2008, notwithstanding the Company s financial accounting with regard to this item (previously, the Company was not able to make this more likely than not determination, and as such, no tax benefits associated with losses were recognized). Therefore, since the 2008 loss to date is expected to offset, in part, the taxable income, a deferred tax asset is being recorded for the tax benefit of the current loss.

The following is a reconciliation of the expected federal rate to the effective rate recognized in the accompanying financial statements for the periods ended June 30, 2008.

	Three months ended June 30, 2008	**Six months ended June 30, 2008**
Expected rate (tax benefit)	(34.0%)	(34.0%)
State taxes, net	(3.4)	(3.4)
Permanent difference	7.9	8.0

Effect of recognition of tax benefit of first quarter 2008 losses in second quarter	(18.0)	
Other	2.4	1.2
Effective rate (tax benefit)	(45.1%)	(28.2%)

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11. Reclassification of Research and Development Services Revenue and Expenses:

The Company incorrectly previously reported Research and Development Services revenue of approximately $0.6 million as an offset to Research and Development Expense, Other for the three months ended March 31, 2008. Pursuant to guidance under EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19) and EITF Issue 01-14, *Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses Incurred* (EITF 01-14) the Company should have recorded these amounts, based on the gross amount of the reimbursements received for services provided and out-of-pocket expenses incurred, as Research and Development Services revenue as the Company acts as a principal, has discretion to choose suppliers and bears credit risk in the transactions. Following is the reclassification to the Statement of Operations for the three months ended March 31, 2008:

	For the three months ended March 31, 2008		
	As previously reported	Reclassification	As restated
Royalty revenue, related party	$ 19,748		$ 19,748
Research fees/consulting	104,500		104,500
Research and development services		618,274	618,274
Total revenue	124,248	618,274	742,522
Expenses:			
Research and development:			
Related party	466,244		466,244
Other	2,594,215	618,274	3,212,489
General and administrative:	15,300		15,300
Related party	1,407,085		1,407,085
Other			
Total Expenses:	4,482,844	618,274	5,101,118
Loss from operations	(4,358,596)		(4,358,596)
Non-operating income	1,716,248		1,716,248
Net loss	$ (2,642,348)		$ (2,642,348)

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12. 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 (Case 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. In 2008, the final resolution of the case resulted in no liability by the Company and a judgment in favor of the Company of $0.021 million related to recovery of legal fees incurred during the appeal process.

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 $0.5 million 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 discussed in Note 6, 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 six (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.

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.

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12. Commitments and Contingencies (continued):

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 payments or has accrued approximately $1.9 million pursuant to a purchase order (included in deposits on equipment in the accompanying condensed consolidated financial statements) toward the total cost, which is approximately $2.8 million. Payments are being 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 June 30, 2008 compared to the three months ended June 30, 2007

Royalty Revenues. For both of the three-month periods ended June 30, 2008 and 2007, the Company reported $0.02 million in royalty revenue from a related company.

Research and development services. For the three-month periods ended June 30, 2008 and 2007, the Company reported $0.8 million and $0.0, respectively, in research and development services. The increased revenues were earned as reimbursements of costs incurred under the Meda License and Development agreement for research and development services performed on the Non-cancer indication of BEMA Fentanyl.

Research and Development. Research and development expenses of approximately $2.7 million and $3.0 million were incurred during the three-month periods ended June 30, 2008 and 2007, respectively. These aforementioned amounts included $0.07 million and $1.7 million, respectively, paid to a contract research organization, which is a shareholder. The Company s scientific staff continued to work toward increased development and application of our BEMA and Bioral® 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 Bioral® drug delivery technologies.

General and Administrative Expenses. General and administrative expenses of approximately $2.6 million and $1.0 million were incurred in the three-month periods ended June 30, 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 recorded stock based compensation of $1.2 million during the three months ended June 30, 2008. No such expenses were recorded for the three months ended June 30, 2007.

Interest Income (expense). Interest expense for the periods ended June 30, 2008 and 2007 was principally composed of expense incurred which was derived from the amortization of deferred loan costs and notes payable discount amortization, net of interest earnings on invested cash.

Derivative Gain (Loss). Derivative gain (loss) during 2008 and 2007 is related to the adjustment of related derivative liabilities to fair value. These derivatives relate to warrants and certain embedded instruments associated with previous financings (see Note 7 to the condensed consolidated financial statements).

Income Taxes. The Company has recognized a $2.0 million deferred tax benefit related to the loss incurred for the three months ended June 30, 2008. This is based upon the expectation that it is more likely than not that there will be taxable income for the year ended December 31, 2008 because approximately $30.0 million of revenues which are currently deferred for financial reporting purpose will become taxable in 2008, notwithstanding the Company s financial accounting with regard to this item. Therefore since the 2008 loss to date is expected to offset the taxable income, a deferred tax asset is being recorded for the tax benefit of the current loss.

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For the Six Months Ended June 30, 2008 Compared to the Six Months Ended June 30, 2007

Royalty Revenues. During both of the six-month periods ending June 30, 2008 and June 30, 2007, we reported $0.04 million of royalty revenue from a related company.

Research and development services. During the six-month periods ending June 30, 2008 and June 30, 2007, we reported $1.6 million and $0.0 million, respectively, of research and development services. The increased revenues were earned under the Meda License and Development Agreement for research and development services performed on the non-cancer indication of BEMA™ Fentanyl.

Research and Development. Research and development expenses of approximately $6.4 million and $6.3 million were incurred during the respective six-month periods ended June 30, 2008 and 2007. These aforementioned amounts included $0.5 million and $3.0 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 Bioral® 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 Bioral® drug delivery technologies.

General and Administrative Expenses including Stock-based Compensation. General and administrative expenses of approximately $4.1 million and $2.2 million were incurred in the six-month periods ended June 30, 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 recorded stock based compensation of $1.3 million and $0.2 million during the six months ended June 30, 2008 and 2007, respectively.

Interest Expense Net. Interest expense for the periods ended June 30, 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. The relatively high level of expense in 2007 resulted from the write-off of deferred loan costs associated with the principal reduction on the Laurus debt conversions, as Laurus exercised its right to convert the debt to Common Stock.

Derivative Gain (Loss). Derivative gain (loss) during 2008 and 2007 is related to the adjustment of derivative liabilities to fair value. These derivatives relate to warrants and certain embedded instruments associated with previous financings (see Note 7 to the financial statements).

Income Taxes. The Company has recognized a $2.0 million deferred tax benefit related to the loss incurred for the six months ended June 30, 2008. This is based upon the expectation that it is more likely than not that there will be taxable income for the year ended December 31, 2008 because approximately $30.0 million of revenues which are currently deferred for financial reporting purpose will become taxable in 2008, notwithstanding the Company s financial accounting with regard to this item. Therefore since the 2008 loss to date is expected to offset the taxable income, a deferred tax asset is being recorded for the tax benefit of the current loss.

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Liquidity and Capital Resources

From inception through July 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 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® 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 June 30, 2008, we had cash and cash equivalents of approximately $6.1 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 $5.6 million of cash for operations for the six months ended June 30, 2008. This resulted from a net loss of $5.1 million (which included a derivative gain of $2.3 million), offset by stock-based compensation of $1.4 million, other non-cash charges of $1.0 million, a

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decrease in our related party accounts receivable (primarily Meda) of $0.02 million and a decrease in our accounts payable and accrued liabilities of $1.1 million. We received a $2.5 million additional up-front payment from Meda, which was recorded as deferred revenue. In addition we recorded a deferred tax asset of $2.0 million at June 30, 2008, based on our expectation of income tax that we will incur on the $30.0 million up-front payment that we received in 2007 which is taxable for the year ended December 31, 2008.

We have incurred significant net losses and negative cash flows from operations since our inception. As of June 30, 2008, we had stockholders deficit of $22.4 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 to further develop our BEMA and Bioral® cochleate technologies for 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 and 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. In addition, Meda is paying for the development costs for BEMA Fentanyl in non-cancer breakthrough pain.

Our existing cash and cash equivalents are believed by our management to be sufficient to finance planned basic operations (minimal research and development activities beyond those covered under our Meda and our related agreement(s)) into approximately the fourth 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 will 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;

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grants and new license revenues;

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

Multiple Deliverable Arrangements

Our license, development and commercial product supply agreements contain multiple elements, including non-refundable upfront fees; payments for ongoing research and development services; payments associated with achieving specific performance-based milestones; payment related to manufacturing or supplying product; and royalties based on specified percentages of net product revenues earned by the licensee, if any. We apply the guidance established by EITF Issue 00-21, *Revenue Arrangements with Multiple Deliverables*(EITF 00-2) in order to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and to address how arrangement consideration should be measured and allocated. We apply the revenue recognition criteria outlined in Staff Accounting Bulletin Topic 13, *Revenue Recognition* (SAB Topic 13) to determine if the criteria for revenue recognition have been met under the appropriate revenue recognition conventions.

Pursuant to EITF 00-21, consideration is allocated to a delivered product or service when all of the following criteria are met: (1) the delivered item has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item; and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company s control. We perform this analysis at the inception of the arrangement and as each substantive product or service is delivered. When a delivered product or service (or group of delivered products or services) meets the criteria for separation as established in EITF 00-21, we allocate consideration based upon the relative fair values of each element. We determine the fair value of a separate deliverable using either prices charged to other customers when that product or service is sold separately or in instances where we do not sell the product or service separately, third-party evidence of fair value is obtained. In applying the criteria of EITF 00-21, we consider a variety of factors in determining the appropriate separation of units of accounting and method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

The application of these standards requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship. Although there are risks, both within and outside of our control, that could impact our ability to assess such individual elements and their separability from

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other aspects of the contractual relationship in questions, we believe that our management and board of directors have sufficient experience to manage our ability to asses and implement our contractual obligations.

We consider licensed rights to have standalone value to the customers if we or others have sold such rights separately or customers can sell such rights or technology separately without the need for our continuing involvement. Non-refundable, up-front fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue when the license term commences and the licensed data and/or technology is delivered. We defer recognition of non-refundable upfront fees if continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of our performance under the other elements of the arrangement. In addition, if the arrangement includes continuing involvement through research and development services which require us to provide these services because the know-how and expertise related to the technology is proprietary to us, or can only be performed by our personnel, then such up-front fees are deferred and recognized over the related performance period.

Payments related to substantive, performance-based milestones are recognized as revenue upon the achievement of the milestones as specified in the agreements when they represent the culmination of an earnings process. We believe that a milestone represents the culmination of a distinct earnings process when it is not associated with ongoing research, development or other performance on our part. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product or technology, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we consider the nature, timing, and value of significant achievements in the development of the product; the relative level of effort required to achieve the milestone; and the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing products or technology in a drug development program and in ultimately attaining an approved drug product. We recognize such performance-based milestones as revenue when they become due and collection is reasonably assured. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period. Deferred revenue will be recognized over the performance period.

Should the FDA or other regulatory agencies require additional data or information, we adjust the performance estimates accordingly. Changes in estimates of total expected performance are accounted for prospectively as a change in estimate. To date, the Company has not recognized any revenues utilizing the proportional performance model.

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 June 30, 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

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underlying patents. Our carrying value of other, amortizing intangible assets at June 30, 2008 was $6.1 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 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 except contractual lives of the derivative instruments are utilized rather than expected option terms as discussed in the previous paragraph.

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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 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 second 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.

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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 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.

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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. In 2008 the final resolution of the case resulted in no liability by the Company and a judgment of $21,000 related to legal fees in the appeal process was awarded by the courts to the Company based on the frivolous nature of the lawsuit.

Item 6. Exhibits.

Number	Description
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: August 14, 2008

By: /s/ Mark A. Sirgo
Mark A. Sirgo,

President and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2008

By: /s/ James A. McNulty
James A. McNulty,

Secretary, Treasurer and Chief Financial Officer
(Principal Financial Officer)

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