BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
May 15, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-QSB

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2007

¨ 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 0-28931

BioDelivery Sciences International, Inc.

(Exact name of small business issuer as specified in its charter)

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

2501 Aerial Center Parkway Suite 205

Morrisville, NC 27560

(Address of principal executive offices)

(919) 653-5160

(Issuer s telephone number)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

State the number of shares outstanding of each of the issuer s classes of common equity, as of the latest practicable date: The Issuer had 18,842,340 shares of common stock issued and 18,826,849 shares of common stock outstanding as of May 15, 2007.

Transitional Small Business Disclosure Format (Check one): Yes ¨ No x

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BioDelivery Sciences International, Inc. and Subsidiaries

Form 10-QSB

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2007 (Unaudited)	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,349,010	$ 2,172,104
Accounts receivable	41,073	42,118
Due from related party	6,526	8,523
Prepaid expenses and other current assets	170,265	180,863
Total current assets	1,566,874	2,403,608
Equipment, net	318,157	379,654
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,895,454	1,941,942
Acquired product rights	1,893,381	1,938,462
Total other intangible assets	3,788,835	3,880,404
Deferred loan costs	97,827	463,268
Total assets	$ 8,486,693	$ 9,841,934
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Notes payable	$	$ 1,000,000
Notes payable, related parties	1,000,000	
Accounts payable and accrued liabilities	1,980,566	2,032,765
Due to related parties	2,074,611	1,001,177
Deferred revenue	70,360	70,360
Dividends payable		152,803
Derivative liability	15,152,047	7,795,931
Total current liabilities	20,277,584	12,053,036
Convertible notes payable, less current maturities	1,741,387	4,003,250
Total liabilities	22,018,971	16,056,286
Commitments and contingencies (Note 10)		
Stockholders deficit:		
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 0 and 1,647,059 shares issued and outstanding in 2007 and 2006, respectively		3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 0 and 341,176 shares issued and outstanding in 2007 and 2006, respectively		1,450,000
Series C Preferred stock, $.001 par value; 1,647,059 shares designated, 1,647,059 and 0 issued and outstanding in 2007 and 2006, respectively	7,576,471	
	15,564	14,049

Common stock, $.001 par value; 45,000,000 shares authorized, 15,563,864 and 14,048,637 shares issued; 15,548,373 and 14,033,146 shares outstanding in 2007 and 2006, respectively		
Additional paid-in capital	39,118,693	32,132,609
Treasury stock, at cost, 15,491 shares, 2007 and 2006	(47,183)	(47,183)

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2007 (Unaudited)	December 31, 2006
Accumulated deficit	(60,195,823)	(43,469,710)
Total stockholders deficit	(13,532,278)	(6,214,352)
Total liabilities and stockholders deficit	$ 8,486,693	$ 9,841,934

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006

	Three Months Ended	
	March 31, 2007	March 31, 2006
Revenues:		
Sponsored research revenues	$	$ 17,153
Royalty revenue, related party	18,130	20,813
Research fees	25,000	10,000
Total revenues	43,130	47,966
Expenses:		
Research and development:		
Related party	1,372,814	1,117,854
Other	1,862,822	1,923,227
Product development costs		746,591
General and administrative:		
Related party	3,900	19,903
Other	1,200,553	785,547
Total expenses	4,440,089	4,593,122
Loss from operations	(4,396,959)	(4,545,156)
Interest expense, net	(690,453)	(547,895)
Derivative loss	(7,768,113)	(583,659)
	(8,458,566)	(1,131,554)
Net loss	(12,855,525)	(5,676,710)
Preferred stock dividends		(16,089)
Constructive dividend-preferred stock	(3,870,588)	
Loss attributable to common stockholders	$ (16,726,113)	$ (5,692,799)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (1.13)	$ (0.48)
Weighted average common stock shares outstanding basic and diluted	14,826,776	11,870,813

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS DEFICIT

FOR THE THREE MONTHS ENDED MARCH 31, 2007

(Unaudited)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Deficit
Balances, January 1, 2007	1,647,059	$ 3,705,883	341,176	$ 1,450,000			14,048,637	$ 14,049	$ 32,132,609	$ (47,183)	$ (43,469,710)	$ (6,214,352)
Stock-based compensation									207,413			207,413
Shares issued for cash							73,964	74	249,926			250,000
Conversion of notes payable to common stock							997,193	997	2,466,514			2,467,511
Payment of interest with common stock							43,668	44	147,831			147,875
Reclassification of derivative liability to equity									2,311,997			2,311,997
Conversion of Series A to Series C Preferred stock	(1,647,059)	(3,705,883)			1,647,059	7,576,471						3,870,588
Conversion of Series B Preferred stock to common stock			(341,176)	(1,450,000)			341,176	341	1,449,659			0
Payment of accrued dividends with common stock							59,226	59	152,744			152,803
Constructive dividends											(3,870,588)	(3,870,588)
Net loss											(12,855,525)	(12,855,525)
Balances, March 31, 2007	0	$ 0	0	$ 0	1,647,059	$ 7,576,471	15,563,864	$ 15,564	$ 39,118,693	$ (47,183)	$ (60,195,823)	$ (13,532,278)

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended	
	March 31,2007	**March 31, 2006**
Operating activities:		
Net loss	$ (12,855,525)	$ (5,676,710)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of common stock	147,875	16,261
Expenses paid through the issuance of warrants		746,591
Depreciation and amortization	157,971	178,693
Derivative loss	7,768,113	583,659
Accretion of interest on convertible debentures	205,648	465,259
Stock-based compensation	207,413	50,291
Changes in assets and liabilities:		
Accounts receivable	17,118	
Prepaid expenses and other current assets	10,598	31,263
Accounts payable and accrued expenses	1,815,783	262,525
Other assets	365,441	
Net cash flows from operating activities	(2,159,565)	(3,342,168)
Investing activities:		
Purchase of equipment	(4,905)	(4,598)
Net cash flows from investing activities	(4,905)	(4,598)
Financing activities:		
Proceeds from deposits		2,416,667
Proceeds from issuance of common stock	250,000	
Proceeds from notes payable, related parties	2,900,000	
Payment on notes payable	(1,000,000)	
Proceeds from related party borrowings, net	(808,623)	274,220
Net cash flows from financing activities	1,341,377	2,690,887
Net change in cash and cash equivalents	(823,093)	(655,879)
Cash and cash equivalents at beginning of period	2,172,104	4,914,735
Cash and cash equivalents at end of period	$ 1,349,010	$ 4,258,856

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 accrued $16,089 in annual cumulative dividends in connection with its Series B Preferred stock during the first quarter of 2006. No such dividends were accrued during the first quarter of 2007.

The Company converted $2,467,511 and $265,488 of convertible notes payable through the issuance of 997,193 and 108,363 shares of common stock in the first quarter of 2007 and 2006, respectively.

The Company reclassified derivative liabilities of $2,311,997 and $119,210 from debt to equity during the first quarter of 2007 and 2006, respectively, 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 first quarter of 2007.

The Company recorded a constructive dividend of $3,870,588 related to the redemption of Series A Non-Voting Convertible Preferred Stock (Series A Preferred) during the first quarter of 2007 (see Note 8).

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006

(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheet of BioDelivery Sciences International, Inc., together with its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. (Arius One) and Arius Two, Inc. (Arius Two) and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (BND and, collectively with Arius and Arius Two, the Company or we , us or similar terminology) as of March 31, 2007, and the condensed consolidated statements of operations for the three months ended March 31, 2007 and 2006 have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows at March 31, 2007 and for all periods presented, have been made. The accompanying consolidated financial statements include the accounts of BioDelivery Sciences International, Inc. and its subsidiaries, Arius One, Arius Two and BND. All intercompany accounts and transactions have been eliminated. BND became substantially inactive as of September 30, 2005.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2006, included in the Company s 2006 Annual Report on Form 10-KSB, filed with the SEC on April 17, 2007 (2006 Annual Report). As used herein, the term Common Stock means the Company s common stock, per value $.001 per share.

The results of operations for the three months ended March 31, 2007 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 2006 Annual Report.

The Company currently generates revenue from licensing, milestone payments and royalties, as well as from grants. Ultimately, if approval of licensed products and formulations is secured from the U.S. Food and Drug Administration (FDA), the Company s goal is to augment these revenues from sales of such products and formulations, on which royalties will be paid to licensors. The Company is also required to make certain license payments to such licensors in accordance with applicable agreements.

2. New accounting pronouncements:

The Financial Accounting Standards Board (FASB) has announced a new interpretation, FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which is effective for fiscal year 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes . FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN 48 did not result in any changes to the beginning stockholders deficit (January 1, 2007) and the Company s financial position.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006

(Unaudited)

2. New accounting pronouncements (continued):

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157). SFAS 157 clarifies the definition of fair value, describes methods used to appropriately measure fair value, and expands fair value disclosure requirements. This statement is effective for fiscal year beginning after November 15, 2007. The Company is currently in the process of assessing the impact that SFAS 157 will have on the consolidated financial statements.

In February 2007, the FASB issued SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities . SFAS 159 permits entities to choose to measure financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The decision to elect the fair value option may be applied instrument by instrument, is irrevocable, and is applied to the entire instrument and not to only specified risks, specific cash flows or portions of that instrument. An entity is restricted in choosing the dates to elect the fair value option for an eligible item. Adoption of SFAS 159 is effective for the Company on January 1, 2008. Early adoption is permitted, provided the entity also elects to apply the provisions of SFAS 157, Fair Value Measurements . Management of the Company is currently evaluating the potential impact of SFAS 159 on the Company s financial condition, results of operations, and liquidity.

In September, 2006 the SEC staff issued Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 provides guidance on the process of quantifying financial statement misstatements, advising companies to use both a balance sheet (iron curtain) and an income statement (rollover) approach when quantifying and evaluating the materiality of a misstatement. The iron curtain approach quantifies a misstatement based on the effects of correcting the misstatement existing in the balance sheet at the end of the reporting period. The rollover approach quantifies a misstatement based on the amount of the error originating in the current period income statement, including the reversing effect of prior year misstatements. The use of this method can lead to the accumulation of misstatements in the balance sheet. Under the guidance of SAB 108, companies will be required to adjust their financial statements if either the iron curtain or rollover approach results in the quantification of a material misstatement. Previously filed reports would not be amended, but would be corrected the next time the company files prior year financial statements. Companies are allowed to record a one-time cumulative effect adjustment to correct errors in prior years that previously had been considered immaterial based on their previous approach. SAB 108 is effective for the Company upon issuance of its Fiscal 2007 annual financial statements. However, early application of SAB 108 is permitted for interim periods prior to the issuance of the annual financial statements. The Company does not believe this standard will have any effect on its financial statements.

3. 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. The Company has not generated revenue from the sale of any product but has generated revenues from licensing arrangements, research fees and sponsored research in 2007 and 2006. The Company intends to finance its research and development efforts and its working capital needs from existing cash, anticipated exercises of warrants, new sources of financing and licensing agreements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006

(Unaudited)

3. Liquidity and management s plans (continued):

Significant fundings in 2005 and 2006 have consisted of:

Proceeds from an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC (HCG), a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman. Pursuant to the Equity Line Agreement as amended, HCG, at the Company s request, was to invest up to $4.0 million in the Company from August 23, 2004 through December 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock (Series B Preferred). As of December 31, 2006, the Equity Line Agreement terminated with $1.45 million having been drawn thereunder. On January 10, 2007, HCG converted 341,176 shares of Series B Preferred (consisting of all said Series B Preferred then outstanding) into 341,176 shares of Common Stock. No other consideration was paid. HCG also acquired 59,226 shares of Common Stock pursuant to the payment of $152,803 accrued and unpaid dividends on the Series B Preferred;

$5,000,000 secured convertible debt financings with Laurus Master Fund, Ltd. (Laurus) (see Note 6); and

$7,000,000 sale of Common Stock in 2006, consisting of 2 million shares of Common Stock issued to CDC IV, LLC, as successor in interest to Clinical Development Capital, LLC (collectively CDC), $2,416,667 of which had been received and recorded as a deposit during the first quarter of 2006 pursuant to a Clinical Development and License Agreement, dated July 15, 2005, between the Company and CDC (the CDLA) relating to the development of the Company s BEMA® fentayl product.

The Company secured additional financings or commitments during the three months ended March 31, 2007 as follows:

$1,900,000 loan from CDC (see Note 5);

$1,000,000 loan from HCG (see Note 5); and

Obtained $5 million commitment from HCG to purchase (prior to September 30, 2007) certain royalty rights (see Note 5).

Finally, as discussed in Note 11, the Company secured additional funding and additional events occurred during the quarter ended and subsequent to March 31, 2007 to further improve the Company s liquidity position as follows:

Received $250,000 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;

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

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(Unaudited)

3. Liquidity and management s plans (continued):

Received proceeds of approximately $3,200,000 from the exercise of Common Stock warrants held by Laurus; and

Laurus converted all debt remaining under its February and May 2005 convertible notes with the Company into shares of Common Stock.

The Company s existing cash and cash equivalents together with subsequent funding and available financings are considered by management to be sufficient to finance the Company s basic operations (minimal research and development activities), capital expenditures and debt obligations into approximately the second quarter of 2008.

Additional capital will be required in order to proceed with the Company s planned expanded development activities around the Company s lead product, BEMA Fentanyl. Management is currently negotiating with a number of funding sources, including potential commercial partners in regard to the U.S. distribution rights for BEMA Fentanyl, and believes that the Company will be able to secure such funding at levels sufficient to support planned expanded operations. However, there can be no assurance that additional capital will be available on favorable terms, if at all. Management believes that should a distribution partnership be consummated, the costs for the continuing BEMA Fentanyl program would be paid in full or in material part by the distribution partner. However, there can be no assurance that the Company will be able to secure a commercial partner for BEMA Fentanyl. If adequate funds either through a financial or distribution partner are not available, the Company would be required to significantly reduce or refocus its planned expanded operations (conduct only the basic operations as discussed in the preceding paragraph) 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 in 2008 and beyond.

4. Deferred loan costs:

Deferred loan costs are being amortized over the life of the related debt.

Estimated future amortization expense is as follows;

Year ending December 31	
2007	$ 67,561
2008	30,266
	$ 97,827

5. Notes payable; related parties:

Notes payable, related parties at March 31, 2007 consists of the following:

Note payable, HCG (1)	$ 1,000,000
Note payable, CDC (stockholder) (2)	1,900,000
Less unamortized discount (see Note 7)	(1,900,000)
Total at March 31, 2007	$ 1,000,000

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NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006

(Unaudited)

5. Notes payable; related parties (continued):

(1) On March 30, 2007, HCG funded a $1.0 million unsecured, non-interest bearing note, due June 30, 2007. As consideration for the loan made by HCG, the Company granted HCG the right, for a period of six months, to participate in and enter into a royalty purchase agreement. The consideration to be paid upon exercise of the right, which can be demanded by either the Company or HCG at any time before September 30, 2007, is $5.0 million. The royalty is to be paid based on a low, single digit tiered percentage of net sales of the BEMA Fentanyl once the product is approved and commercial sales begin. In addition, if the royalty purchase agreement is entered into, the Company would issue a warrant to HCG to purchase 475,000 shares of Common Stock at $5.55 per share (the closing price on April 2, 2007). No assurances can be given that either the Company or HCG will elect to enter into the royalty purchase agreement.

(2) On March 12, 2007, the Company secured a loan from CDC which involves a one-year $1.9 million unsecured 10.25% loan from CDC due March 12, 2008 and a warrant (the New CDC Warrant) to purchase 1 million shares of Common Stock with an exercise price of $3.80. The Company is not required to file a registration statement with the Securities and Exchange Commission to register the shares of Common Stock underlying the New CDC Warrant for a period of one year (i.e., a registration statement must be filed by March 12, 2008). CDC was also granted piggyback registration rights with respect to such shares of Common Stock which come into effect only after March 12, 2008. The New CDC Warrant contains weighted average anti-dilution protection.

6. Convertible notes payable:

Activity with respect to the Company s February and May 2005 convertible notes payable with Laurus during the three months ended March 31, 2007 was as follows:

Carrying value at January 1, 2007	$ 4,003,250
Conversion of debt to equity through March 31, 2007	(2,467,511)
Accretion of discount	205,648
Carrying value at March 31, 2007	$ 1,741,387

The Laurus convertible notes were collateralized by all assets of the Company. From April 1 through April 25, 2007, all remaining convertible debt and accrued interest under the Laurus notes was converted by Laurus into shares of Common Stock such that, as of the date of this Report, the Company has no further obligations to Laurus under the February and May 2005 convertible notes and related security agreements.

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006

(Unaudited)

7. Derivative Financial Instruments (continued):

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 and subsequently adjusted to fair value at the close of each reporting period.

Significant new derivatives instruments (liability) issued during the three months ended March 31, 2007 consisted of 1,000,000 Common Stock warrants issued to CDC in connection with a $1.9 million note payable to CDC (see Note 5). This warrant had a fair value of approximately $3.3 million which resulted in the debt being completely discounted and the approximately $1.4 million excess of the fair value of the warrant over the debt discount was charged to derivative loss in the statement of operations.

The derivative liability is composed of the following:	**March 31, 2007**	**December 31, 2006**
Embedded beneficial conversion option in the Laurus convertible debt	$ 2,479,364	$ 1,993,655
Free standing warrants	12,672,683	5,802,276
Total	$ 15,152,047	$ 7,795,931

Shares into which derivative liability can be settled:	**March 31, 2007**	**December 31, 2006**
Embedded beneficial conversion option	760,261	1,862,331
Free standing warrants	3,313,394	69,274
Total	4,073,655	1,931,605

	Three Months Ended	
Derivative loss in the accompanying statement of operations is related to the individual derivatives as follows:	**March 31, 2007**	**March 31, 2006**
Embedded beneficial conversion option	$ (2,797,706)	$ (567,033)
Free standing warrants	(4,970,407)	(16,626)
Total	$ (7,768,113)	$ (583,659)

8. Stockholders equity:

Common stock:

During the first quarter of 2007, under its convertible debt arrangements with Laurus, the debt holder converted $2,467,511 of debt into 997,193 shares of Common Stock and was paid accrued interest of $147,875 with 43,668 shares of Common Stock.

On January 24, 2007, Sigma Tau acquired 73,964 shares of Common Stock at a price of $3.38 per share for aggregate proceeds to the Company of $0.25 million in accordance with their Stock Purchase Agreement. The Stock Purchase Agreement dated January 20, 2005 provides for certain development milestones and purchases of stock thereof. No other consideration was paid.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006

(Unaudited)

8. Stockholders equity (continued):

On February 22, 2007, all 1,647,059 shares of the Company s Series A Preferred (which were issued to the former stockholders of Arius Pharmaceuticals upon the Company s acquisition of such company in August 2004) were exchanged with the holders thereof via redemption for an identical number of shares of newly designated Series C Non-Voting Convertible Preferred Stock (Series C Preferred). The rights associated with the Series C Preferred Stock are identical to those associated with the Series A Preferred in all material respects except that the Series C Preferred has different terms of conversion into shares of Common Stock. The rights relating to Series C Preferred are as follows:

Dividend Rights. Holders of Series C Preferred shall be entitled to receive, pari passu with holders of Common Stock all cash or in-kind dividends or distributions on an as converted basis from time to time at any time declared, set aside, or paid by the Company in an amount that would have been received by the holders of Series C Preferred (assuming, for purposes of the calculation, that the holders of Series C Preferred had lawfully converted such Series C Preferred into shares of Common Stock immediately prior to the record date for determining the holders of Common Stock entitled to receive such distribution at the then-applicable Series C Stock Conversion Rate (as defined in the Certificate of Designations for the Series C Preferred (the Series C Certificate of Designations)), in each case only when, as and if declared by the Board of Directors of the Company, and, in the case of cash dividends, only out of funds that are legally available therefore. Such dividends shall be non-cumulative.

Voting Rights. The holders of shares of Series C Preferred shall not have any voting or approval rights whatsoever except as expressly set forth herein. Notwithstanding the foregoing, the Company shall not amend or modify the Series C Certificate of Designations without the prior written consent of the holders of a majority of the then outstanding shares of Series C Preferred.

Liquidation Rights. Upon any Liquidation Event (as defined in the Series C Certificate of Designations), subject to the rights and preferences of any shares of the Company s preferred stock having liquidation rights senior to those of the Series C Preferred, the assets and funds of the Company legally available for distribution to its stockholders shall be distributed ratably (the Liquidation Event Distribution) among the holders of the Common Stock and Series C Preferred as if such shares of Series C Preferred had been converted into Common Stock at the then-applicable Series C Stock Conversion Rate immediately prior to such distribution, without any further action by the holders of such shares; provided, however, that all declared and unpaid dividends, if any, shall be paid to holders of Series C Preferred in cash or, to the extent sufficient funds are not then legally available therefore, in Common Stock (at the Common Stock s fair market value determined by the Company s Board of Directors as of the date of such payment); provided further, however, that the Company s obligations with respect to the Liquidation Event Distribution shall be contingent upon the delivery of the certificates evidencing such shares of Series C Preferred to the Company or its transfer agent as provided below, or the notification by the holder to the Company or its transfer agent that such certificates have been lost, stolen or destroyed and execution of an agreement satisfactory to the Company to indemnify the Company from any loss incurred by it in connection with such certificates.

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FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006

(Unaudited)

8. Stockholders equity (continued):

Conversion Rights. Shares of Series C Preferred are convertible into shares of the Common Stock upon the earlier to occur of: (i) the public announcement by the Company of a positive outcome of the Company s Phase III efficacy trial (FEN - 201) for its BEMA Fentanyl product, with the term positive outcome meaning a statistically significant difference (p less than or equal to 0.05) in the primary efficacy endpoint comparing active to placebo; or (ii) August 24, 2009.

The Company made a public announcement of a positive outcome of the Phase III efficacy trial for BEMA Fentanyl on April 25, 2007. As a result, Dr. Mark Sirgo and Dr. Andrew Finn, each executive officers and the holders, collectively, of approximately 97% of the shares of Series C Preferred, converted an aggregate of 1,594,826 shares of Series C Preferred into a like number of shares of Common Stock. See Subsequent Events (Note 11) below.

The Company has recorded the excess of the fair value of the Series C Preferred (based upon the fair value of the underlying Common shares into which the Series C Preferred was convertible) over the carrying value of the Series A Preferred stock redeemed as a preferred stock constructive dividend.

Stock-based compensation:

As of March 31, 2007, there was approximately $800,000 of unrecognized compensation cost related to unvested share-based compensation awards granted. That cost is expected to be recognized over the next three years.

Options were granted to certain employees during the first quarter of 2007 at prices equal to the market value of the Common Stock on the dates the options were granted. The options granted have a term of 10 years from the grant date and vest ratably over a two or three year period. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date and each vesting date. The fair value of each option award is estimated on the date of grant issue 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 Company s Common Stock, historical volatility of the Common Stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average for key assumptions used in determining the fair value of options granted during the three months ended March 31, 2007 follows:

Expected price volatility	50.43 %
Risk-free interest rate	4.87 %
Weighted average expected life in years	6 years
Dividend yield	0

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(Unaudited)

8. Stockholders equity (continued):

Option activity during the first quarter of 2007 was as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Yrs)
Outstanding at January 1, 2007	2,023,704	$ 3.04	6.51
Forfeited	(179,945)	$ 4.01	
Exercised			
Granted	302,925	$ 2.46	9.82
Outstanding at March 31, 2007	2,146,684	$ 2.87	6.94
Exercisable at March 31, 2007	1,661,427	$ 2.96	6.94

The fair market value of options granted in the first quarter of 2007 was $761,000.

Options outstanding at March 31, 2007 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	2,074,522	7.13	$ 2.69	
$ 5.01 10.00	55,000	1.47	$ 6.18	
$10.01 15.00	8,581	0.63	$ 11.80	
$15.01 20.00	8,581	0.63	$ 17.48	
	2,146,684			$ 5,442,673

Options exercisable at March 31, 2007 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	1,595,265	7.13	$ 2.73	
$ 5.01 10.00	49,000	1.47	$ 6.27	
$10.01 15.00	8,581	0.63	$ 11.80	
$15.01 20.00	8,581	0.63	$ 17.48	
	1,661,427			$ 4,117,357

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8. Stockholders equity (continued):

Warrants outstanding at March 31, 2007 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	5,270,765	5.95	$ 3.24	
$ 5.01 10.00	2,310,000	0.43	$ 6.11	
	7,580,765			$ 9,410,583

Warrants exercisable at March 31, 2007 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	5,245,765	5.95	$ 3.25	
$ 5.01 $ 10.00	2,310,000	0.43	$ 6.11	
	7,555,765			$ 9,323,333

9. Net loss per common share:

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

	Three Months Ended March 31,	
	2007	2006
Net loss attributable to common stockholder (numerator)	$ (16,726,113)	$ (5,692,799)

Basic:		
Weighted average shares outstanding (denominator)	14,826,776	11,870,813
Net loss per common share basic	$ (1.13)	$ (.48)
Diluted:		
Weighted average shares outstanding	14,826,776	11,870,813
Effect of dilutive securities		
Adjusted weighted average shares (denominator)	14,826,776	11,870,813
Net loss per common share diluted	$ (1.13)	$ (.48)

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

10. **Commitments and Contingencies:**

On or about April 19, 2004, the Company was named as the defendant in an action commenced by MAS Capital Inc. in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff seeks

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(Unaudited)

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

monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company has provided MAS Capital s counsel with copies of documents executed by MAS Capital and its affiliates that the Company alleges fully release the Company. Upon MAS Capital s refusal to dismiss the action, notwithstanding the documents that fully release the Company, BDSI filed an Amended Answer asserting a claim for attorneys fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. The Company also filed a motion for summary judgment on June 9, 2005 and on August 25, 2006, the U.S. District Court granted the motion for summary judgment on all of MAS Capital s claims for relief. On September 6, 2006, the parties, by their respective counsel, appeared before the Judge for a settlement conference on the Company s claim for attorneys fees and costs, but were unable to resolve in light of MAS Capital s intent to appeal the summary judgment order. MAS Capital subsequently filed its Motion for Certificate of Appealability of Interlocutory Order requesting the Judge certify the case for interlocutory appeal, which would allow MAS Capital to appeal the summary judgment order at this time rather than once the entire case had yet to be decided on the merits. The Judge denied the Motion. Accordingly, the parties are to proceed until resolution of the Company s counterclaim for attorneys fees and costs and either party could appeal at that point in time. The parties are in the discovery phase with regard to the counterclaim for attorneys fees and costs and no hearing date has yet to be scheduled on said counterclaim. The Company believes that the plaintiff s claims are without merit and intends to continue to vigorously defend the lawsuit. No liability, if any that may result from this matter has been recorded in the financial statements.

On October 17, 2006, CDC filed an action in New York State Supreme Court against the Company seeking to enjoin the Company from entering into a financing transaction with a third party pursuant to a purported right of first negotiation provision granted to CDC under the Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC. On October 26, 2006, the Company entered into a stipulation with CDC to settle this case without prejudice pursuant to which BDSI and CDC agreed to follow a procedure regarding the right of first negotiation as modified by the stipulation.

On March 12, 2007, the Company entered into a Dispute Resolution Agreement (the DRA) with CDC. Pursuant to the DRA, the Company and CDC have terminated the previously instituted dispute resolution procedures between the parties relating to the allegations and demands made by the parties against each other in August 2006 (the Disputed Matters). The effect of the DRA is that CDC has withdrawn its August 2006 claims to ownership of the Company s BEMA Fentanyl asset, which had been asserted by CDC as part of the Disputed Matters, and the Company has withdrawn its claims against CDC. The Company has previously rejected CDC s August 2006 allegations and demands. The resolution of the disputes under the DRA is without prejudice to the Disputed Matters of both the Company and CDC. As such, no assurance can be given that CDC will not make similar or additional claims against the Company. Simultaneously with the Company and CDC s entry into the DRA, the Company and CDC entered into an amendment to the CDLA. The purpose of the amendment to the CDLA is to clarify certain reporting and other obligations between the parties regarding the development and commercialization of BEMA Fentanyl. Under the CDLA, the Company must meet certain conditions or CDC can assume control of the BEMA Fentanyl project and

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(Unaudited)

10. Commitments and Contingencies (continued):

related intellectual property assets. Concurrently with the parties negotiation of the DRA, CDC alleged that the Company had violated CDC s financing right of first refusal (as amended, the ROFN) provided for in the May 2006 Securities Purchase Agreement between the parties. Specifically, in January 2007, CDC alleged by written notice that the Company s December 2006 note deferral agreements with Laurus Master Fund Ltd. (the Laurus Deferral Transaction) triggered the ROFN provisions.

In order for the Company to avoid CDC s continued assertion of its alleged ROFN with respect to the Laurus Deferral Transaction, and in order to enter into the DRA with the resulting resolution of the August 2006 disputes, CDC required that, simultaneously with the entry into the DRA, the Company enter into to a $1.9 million financing with CDC (the New CDC Financing). The New CDC Financing is intended to resolve CDC s January 2007 ROFN claims, notwithstanding the Company s rejection of CDC s assertion that the ROFN was triggered by the Laurus Deferral Transaction.

The New CDC Financing involves a one-year, $1.9 million, 10.25% loan from CDC and a warrant (the New CDC Warrant) to purchase 1 million shares of Common Stock with an exercise price of $3.80. The Company is not required to file a registration statement with the SEC to register the shares of Common Stock underlying the New CDC Warrant for a period of one year (i.e., a registration statement must be filed by March 12, 2008). CDC was also granted piggyback registration rights with respect to such shares of Common Stock which come into effect only after March 12, 2008. The New CDC Warrant contains weighted average anti-dilution protection. The proceeds from the New CDC Financing will be used for general corporate purposes and for the continued development of BEMA Fentanyl. See Note 5 for a description of the New CDC Financing.

The Company is contingently liable for a $1,000,000 payment related to the purchase of intellectual property rights related to its BEMA technology for territories outside of the United States. The payment is due within 10 days of initial non-U.S. approval of any BEMA product. Management deems this $1.0 million payment a contingent liability and therefore will not record the $1.0 million as a liability or intangible asset until the conditions occur which would trigger the requirement to make this payment. In addition to the purchased BEMA intellectual property rights, the Company has the option, for a period of 12 months, to purchase the intellectual property rights related to BEMA technology for the United States territory. If such option is exercised, the purchase price for the United States territory would be $7.0 million, which would be paid over time. The initial payment of $3.0 million would be due August 1, 2007.

11. Subsequent events:

On April 10, 2007, the Company entered into a fifth amendment to the May 2005 convertible note with Laurus. Pursuant to the fifth amendment, Laurus agreed: (i) to exercise an aggregate of 833,871 warrants previously issued to Laurus to purchase a like number of shares of Common Stock, resulting in cash proceeds of approximately $3.2 million to the Company and (ii) to defer all principal payments under the Company s May 2005 note with Laurus to July 1, 2008. In consideration of these agreements, the Company issued to Laurus a new warrant to purchase 833,871 shares of Common Stock at $5.00 per share. The Company

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(Unaudited)

11. Subsequent events (continued):

agreed to file a registration statement registering the shares underlying such warrant, together with certain other shares of Common Stock beneficially held by Laurus, by May 25, 2007. Subsequent to the conclusion of the first quarter 2007, Laurus similarly converted all outstanding principal and interest under its May 2005 note into shares of Common Stock. As a result, as of the date of this Report, all principal and interest under the Company s February and May 2005 convertible notes with Laurus has been either paid or fully converted into shares of Common Stock.

On April 13, 2007, the Compensation Committee of the Company s board of directors awarded the following options to the following senior executives of the Company: Mark Sirgo: 434,000 options; James McNulty: 100,000 options; and Andrew Finn 100,000 options. All of the foregoing options vest in three equal installments beginning on the first anniversary of the grant date (April 13, 2008) and have an exercise price of $6.63 per option share.

As a result of certain previous issuances by the Company of its securities at prices below the then current market price of the Common Stock (including a warrant issued to Laurus in April 2007 as described above), the exercise price of the Company s publicly-traded warrants was, effective April 10, 2007, adjusted downward from $6.30 to $6.11 pursuant to the terms of the warrant agreement entered into in connection with the Company s June 2002 initial public offering. The Company s publicly-traded warrants expire on June 24, 2007.

On April 25, 2007, the Company issued a press release relating to BDSI s announcement of top line efficacy results from the Company s Phase III clinical trial regarding BEMA Fentanyl. The results are based on achievement of the primary efficacy endpoint of the trial, Summary of Pain Intensity Difference (SPID), compared to placebo. The results demonstrated that patients treated with BEMA Fentanyl showed a statistically significant improvement on the primary efficacy endpoint at 30 minutes (SPID 30) compared to placebo (p less than 0.004), meaning a greater reduction in pain. Eighty (80) patients participated in the double-blind, placebo-controlled portion of the study. BEMA Fentanyl consists of a small, dissolvable polymer disc, formulated with the opioid narcotic fentanyl, for application to the buccal (inner lining of cheek) membranes. Upon administration, BEMA Fentanyl is designed to deliver a rapid, reliable dose of drug across mucous membranes.

On May 1, 2007, Mark Sirgo, the Company s Chief Executive Officer and President, and Andrew Finn, the Company s Executive Vice President of Product Development, elected to convert an aggregate of 1,594,826 shares of Series C Preferred Stock held by them into shares of Common Stock. Pursuant to its terms, the Series C Preferred Stock was convertible on a one-for-one basis into shares of Common Stock upon the Company s announcement of a positive outcome of the Company s Phase III efficacy trial (FEN-201) for BEMA Fentanyl, with the term positive outcome meaning a statistically significant difference (p less than or equal to 0.05) in the primary efficacy endpoint comparing active to placebo. As discussed in the proceeding paragraph, the Company made such an announcement on April 25, 2007.

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ITEM 2. Management s Discussion and Analysis of Financial Condition and Plan of Operations

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-QSB. 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-QSB.

For the Three Months Ended March 31, 2007 Compared to the Three Months Ended March 31, 2006

Sponsored Research Revenue. During the three-month periods ending March 31, 2007 and March 31, 2006, we reported $0.0 million and $0.02 million respectively of sponsored research revenues from a grant from the National Institutes of Health.

Research Fee Revenues. During the three-month periods ending March 31, 2007 and March 31, 2006 we reported research revenues of $0.025 million and $0.01 million respectively.

Royalty Revenues. During each of the three-month periods ending March 31, 2007 and March 31, 2006, we reported $0.02 million of royalty revenue from a related company.

Research and Development. Research and development expenses of approximately $3.2 million and $3.0 million were incurred during the respective three-month periods ended March 31, 2007 and 2006. These aforementioned amounts included $1.4 million and $1.1 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 $1.2 million and $0.8 million were incurred in the three-month periods ended March 31, 2007 and 2006, respectively. These expenses are principally composed of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries, and other business development costs. The Company granted employees stock based compensation of $0.2 million and $0.05 million during the three months ended March 31, 2007 and 2006 respectively.

Interest Expense Net. Interest expense for the periods ended March 31, 2007 and 2006 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 increase in 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 Loss*.** Derivative loss during 2007 and 2006 is related to the adjustment of derivative liabilities to fair value. These derivatives relate to the Laurus financing and the CDC warrants (see Notes 5, 6, and 7 to the financial statements).

***Income Taxes*.** While net operating losses were generated during the three months ended March 31, 2007 and 2006, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting

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Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon available data, which includes historical operating performance and reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Liquidity and Capital Resources

Since inception, we financed our operations primarily from the private sales of our convertible preferred stock, convertible debt and common stock, our initial public offering, the follow-on offering in 2005, exercise of options and warrants, various strategic and licensing agreements (including the CDLA), NIH grants, bank financing, and through the sale of a royalty stream asset to Accentia Biopharmaceuticals, Inc, (a related party). At March 31, 2007, we had cash and cash equivalents of $1.3 million. We subsequently received approximately $3.2 million from the exercise of warrants. The adequacy of cash for our operations in continued research is dependent on, among other things, warrant exercises (including the public warrants issued in our 2002 IPO, which expire June 24, 2007), licensing and additional equity or debt financing opportunities we are able to negotiate in the coming year.

We have incurred significant net losses and negative cash flows from operations since our inception. As of March 31, 2007, we had stockholders deficit of $13.5 million, versus a deficit of $6.2 million at December 31, 2006.

We used $2.2 million of cash for operations during the three months ended March 31, 2007. The net loss for the three month period ended March 31, 2007 of $12.8 million included non-cash charges of $8.5 million, primarily related to the cost of warrants issued and accounting requirements related to derivatives.

On September 3, 2004, we entered into an Equity Line of Credit Agreement with HCG, a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman. Pursuant to the Equity Line Agreement as amended, HCG was to, at our request, invest up to $4.0 million in the Company from August 23, 2004 through December 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock, or Series B Preferred. As of December 31, 2006, when the Equity Line expired, $1.45 million had been drawn under the Equity Line Agreement. On January 10, 2007, HCG converted 341,176 shares of Series B Convertible Preferred Stock of BDSI (consisting of all said Series B Preferred Shares outstanding) into 341,176 shares of Common Stock. No other consideration was paid. HCG also acquired 59,226 shares of Common Stock pursuant to the conversion of accrued and unpaid dividends on the Series B Convertible Preferred Stock.

In February and May 2005, we consummated two separate $2.5 million secured convertible debt financings from Laurus. Net proceeds from the financing were used primarily to retire a secured equipment loan and were used to support research and development opportunities and for general working capital purposes.

On May 16, 2006, we consummated a transaction with CDC pursuant to which $7 million in funds previously committed by CDC under the CDLA to fund our clinical development of BEMA Fentanyl was converted into shares of our common stock at a value of $3.50 per share. As a result of this transaction, CDC was issued 2 million shares of our common stock and 904,000 common stock warrants at $3.00 each in return for accelerating the funding of the aggregate commitment under the CDLA and for eliminating the $7 million milestone payable to CDC upon the approval by the FDA of BEMA Fentanyl which had been required under the CDLA.

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On January 24, 2007, Sigma Tau acquired for $0.25 million 73,964 shares of our Common Stock at a price of $3.38 per share in accordance with their Stock Purchase Agreement. The Stock Purchase Agreement dated January 20, 2005 provides for certain development milestones and purchases of stock thereof. No other consideration was paid.

On February 22, 2007, all 1,647,059 shares of our Series A Preferred Stock were exchanged with the holders thereof for an identical number of shares of newly designated Series C Non-Voting Convertible Preferred Stock. The rights associated with the Series C Preferred Stock are identical to those associated with the Series A Preferred Stock in all material respects except that the Series C Preferred Stock has different terms of conversion into shares of Common Stock.

On March 12, 2007, CDC funded a one-year, $1.9 million loan which accrues interest at 10.25%. In connection with this loan, we issued CDC a warrant to purchase 1 million shares of Common Stock with an exercise price of $3.80. We are not required to file a registration statement with the SEC to register the shares of Common Stock underlying such warrant for a period of one year (i.e., a registration statement must be filed by March 12, 2008). CDC was also granted piggyback registration rights with respect to such shares of Common Stock which come into effect only after March 12, 2008. The warrant contains weighted average anti-dilution protection. The proceeds from this loan were used for general corporate purposes and for the continued development of BEMA Fentanyl.

On March 30, 2007, HCG funded a $1.0 million unsecured, non-interest bearing note, due June 30, 2007. As consideration for the loan made by HCG, we granted HCG the right, for a period of six months, to participate in and enter into a royalty purchase agreement. The consideration to be paid upon exercise of the right, which can be demanded by either BDSI or HCG at any time before September 30, 2007, is $5.0 million. The royalty is to be paid based on a low, single digit tiered percentage of net sales of the BEMA Fentanyl once the product is approved and commercial sales begin. In addition, if the royalty purchase agreement is entered into, we would issue a warrant to HCG to purchase 475,000 shares of Common Stock at $5.55 per share (the closing price on April 2, 2007). No assurances can be given that either we or HCG will elect to enter into the royalty purchase agreement.

On April 10, 2007, we entered into a fifth amendment to the May 2005 convertible note with Laurus. Pursuant to the fifth amendment, Laurus agreed: (i) to exercise an aggregate of 833,871 warrants previously issued to Laurus to purchase a like number of shares of Common Stock, resulting in cash proceeds of approximately $3.2 million to BDSI and (ii) to defer all principal payments under our May 2005 note with Laurus (which remaining balance has been converted as of April 25, 2007) to July 1, 2008. In consideration of these agreements, the Company issued to Laurus a new warrant to purchase 833,871 shares of Common Stock at $5.00 per share. We agreed to file a registration statement registering the shares underlying such warrant by July 31, 2007.

Finally, Laurus converted the remaining balance of the notes of approximately $4.31 million of principal of its convertible notes and $0.129 million of interest into common stock from January through April 2007.

Our existing cash and cash equivalents together with available financing and common stock sale proceeds discussed in the preceding paragraphs are considered by management to be sufficient to finance our basic operations (minimal research and development activities), capital expenditures and debt obligations into approximately the second quarter of 2008.

Additional capital will be required in order to proceed with our planned expanded development activities around our lead product, BEMA Fentanyl. Management is currently negotiating with a number of funding sources, including potential commercial partners in regard to the U.S. distribution rights for BEMA Fentanyl, and management believes that the Company will be able to secure

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such funding at levels sufficient to support planned expanded operations. However, there can be no assurance that additional capital will be available on favorable terms, if at all. Management believes that should a distribution partnership be consummated, the costs for the continuing BEMA Fentanyl program would be paid in full or in material part by the distribution partner. However, there can be no assurance that we will be able to secure a commercial partner for BEMA Fentanyl. If adequate funds either through a financial or distribution partner are not available, we would be required to significantly reduce or refocus our planned expanded operations (conduct only the basic operations as discussed in the preceding paragraph) 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 our financial condition in 2008 and beyond.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. We believe that the following are some of the more critical judgment areas in the application of our accounting policies that affect our financial condition and results of operations. We have discussed the application of these critical accounting policies with our Board of Directors and our Audit Committee.

Valuation of Goodwill and Intangible Assets

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

Our carrying value of goodwill at March 31, 2007 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. Our carrying value of other, amortizing intangible assets at March 31, 2007 was $3.78 million, net of accumulated amortization of $.6 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 2007 or 2006.

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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 intangible in either 2006 or 2005.

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 service in exchange for the award.

We use the Black-Scholes options-pricing model to determine the fair value of stock option and warrant grants. We also use the Black Scholes option pricing model as the primary basis for valuing our derivative liabilities at each reporting date (both embedded and free-standing derivatives). The underlying assumptions used in this determination are primarily the same as are used in the determination of stock-based compensation discussed in the previous paragraph except contractual lives of the derivative instruments are utilized rather than expected option terms as discussed in the previous paragraph.

ITEM 3. Controls and Procedures

The Company s Chief Executive Officer and Chief Financial Officer (collectively, the Certifying Officers) are responsible for establishing and maintaining disclosure controls and procedures for the Company. Such officers have concluded (based on their evaluation of these controls and procedures as of a date within 90 days of the filing of this report) that the Company s disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in this report is accumulated and communicated to the Company s management, including its principal executive officers as appropriate, to allow timely decisions regarding required disclosures.

The Certifying Officers also have indicated that there were no significant changes in the Company s internal controls or other factors that could significantly affect such controls subsequent to the date of their evaluation, and there were no corrective actions with regard to significant deficiencies and material weaknesses.

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NOTE ON FORWARD-LOOKING STATEMENTS

The information set forth in this Report on Form 10-QSB 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. The words believes, anticipates, plans, expec and similar expressions in this report are intended to identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties, and 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 2006 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 Inc. in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff seeks monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company has provided MAS Capital s counsel with copies of documents executed by MAS Capital and its affiliates that the Company alleges fully release them. Upon MAS Capital s refusal to dismiss the action, notwithstanding the documents that fully release the Company; BDSI filed an Amended Answer asserting a claim for attorneys fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. The Company also filed a motion for summary judgment on June 9, 2005 and on August 25, 2006, the U.S. District Court granted the motion for summary judgment on all of MAS Capital s claims for relief. On September 6, 2006, the parties, by their respective counsel, appeared before the Judge for a settlement conference on the Company s claim for attorneys fees and costs, but were unable to resolve in light of MAS Capital s intent to appeal the summary judgment order. MAS Capital subsequently filed its Motion for Certificate of Appealability of Interlocutory Order requesting the Judge certify the case for interlocutory appeal, which would allow MAS Capital to appeal the summary judgment order at this time rather than once the entire case had yet to be decided on the merits. The Judge denied the Motion. Accordingly, the parties are to proceed until resolution of the Company s counterclaim for attorneys fees and costs and either party could appeal at that point in time. The parties are in the discovery phase with regard to the counterclaim for attorneys fees and costs and no hearing date has yet to be scheduled on said counterclaim. The Company believes that the plaintiff s claims are without merit and intends to continue to vigorously defend the lawsuit. No liability, if any that may result from this matter has been recorded in the financial statements.

On October 17, 2006, CDC filed an action in New York State Supreme Court against the Company seeking to enjoin the Company from entering into a financing transaction with a third party pursuant to a purported right of first negotiation provision granted to CDC under the Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC. On October 26, 2006, the Company entered into a stipulation with CDC to settle this case without prejudice pursuant to which BDSI and CDC agreed to follow a procedure regarding the right of first negotiation as modified by the stipulation. On March 12, 2007, the Company entered into a Dispute Resolution Agreement (the DRA) with CDC IV, LLC. Pursuant to the DRA, the Company and CDC have terminated the previously instituted dispute resolution procedures between the parties relating to the allegations and demands made by the parties against each other in August 2006 (the Disputed Matters). The effect of the DRA is that CDC has withdrawn its claims to ownership of the Company s BEMA Fentanyl asset, which had been asserted by CDC as part of the Disputed Matters, and the Company has withdrawn its claims against CDC. The Company has previously rejected CDC s August 2006 allegations and demands. The resolution of the disputes under the DRA is without prejudice to the Disputed Matters of both the Company and CDC. As such, no assurance can be given that CDC will not make similar or additional claims against the Company. Simultaneously with the Company and CDC s entry into the DRA, the Company and CDC entered into an amendment to their Clinical Development and License Agreement, dated July 14, 2005 (as amended, the CDLA). The purpose of the amendment to the CDLA is to clarify certain reporting and other obligations between the parties regarding the development and commercialization of BEMA Fentanyl. Under the CDLA, the Company must meet certain conditions or CDC can assume control of the BEMA Fentanyl project and related intellectual property assets. Concurrently with the parties negotiation of the DRA, CDC alleged that the Company had violated CDC s financing right of first refusal (as amended, the ROFN) provided for in the May 2006 Securities Purchase Agreement between the parties. Specifically, in January 2007, CDC alleged by written notice that the Company s December 2006 note deferral agreements with Laurus Master Fund Ltd. (the Laurus Deferral Transaction) triggered the ROFN provisions.

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In order for the Company to avoid CDC s continued assertion of its alleged ROFN with respect to the Laurus Deferral Transaction, and in order to enter into the DRA with the resulting resolution of the August 2006 disputes, CDC required that, simultaneously with the entry into the DRA, the Company enter into to a $1.9 million financing with CDC (the New CDC Financing). The New CDC Financing is intended to resolve CDC s January 2007 ROFN claims, notwithstanding the Company s rejection of CDC s assertion that the ROFN was triggered by the Laurus Deferral Transaction.

The New CDC Financing involves a one-year, 10.25% loan from CDC and a warrant (the New CDC Warrant) to purchase 1 million shares of Company common stock with an exercise price of $3.80. The Company is not required to file a registration statement with the Securities and Exchange Commission to register the shares of Company common stock underlying the New CDC Warrant for a period of one year (i.e., a registration statement must be filed by March 12, 2008). CDC was also granted piggyback registration rights with respect to such shares of common stock which come into effect only after March 12, 2008. The New CDC Warrant contains weighted average anti-dilution protection. The proceeds from the New CDC Financing will be used for general corporate purposes and for the continued development of BEMA Fentanyl.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On January 24, 2007, under the Company s development agreement with Sigma Tau, the Company was paid a milestone payment of $0.25 million for which the Company issued 73,964 shares of unregistered Common Stock at value equal to $3.38. The proceeds of this issuance to Sigma Tau were used for general corporate and working capital purposes.

On March 12, 2007, the Company entered into the New CDC Financing. See Part II, Item 1 above. The proceeds of the New CDC Financing were used for general corporate and working capital purposes.

On March 30, 2007, HCG funded a $1.0 million unsecured, non-interest bearing note, due June 30, 2007. As consideration for the loan made by HCG, the Company granted HCG the right, for a period of six months, to participate in and enter into a royalty purchase agreement. The consideration to be paid upon exercise of the right, which can be demanded by either the Company or HCG at any time before September 30, 2007, is $5.0 million. The royalty is to be paid based on a low, single digit tiered percentage of net sales of the BEMA Fentanyl once the product is approved and commercial sales begin. In addition, if the royalty purchase agreement is entered into, the Company would issue a warrant to HCG to purchase 475,000 shares of Common Stock at $5.55 per share (the closing price on April 2, 2007). No assurances can be given that either the Company or HCG will elect to enter into the royalty purchase agreement.

The proceeds of the HCG note were used for the payment of $1.0 million to QLT USA, Inc. (QLT) under the Company s August 2006 intellectual property purchase agreement with QLT and for general corporate and working capital purposes.

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Item 6. Exhibits.

(a) Exhibits

Exhibit

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Number	**Description**
31.1	Certification Pursuant To Sarbanes-Oxley Section 302
31.2	Certification Pursuant To Sarbanes-Oxley Section 302
32.1	Certification Pursuant To 18 U.S.C. Section 1350 (*)
32.2	Certification Pursuant To 18 U.S.C. Section 1350 (*)

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

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SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 15, 2007

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

Date: May 15, 2007

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