BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
May 17, 2006
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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, 2006

¨ 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 11,963,637 shares of common stock issued and 11,948,146 shares of common stock outstanding as of May 15, 2006.

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

AS OF MARCH 31, 2006 AND DECEMBER 31, 2005

	March 31, 2006 (unaudited)	December 31, 2005	Proforma March 31, 2006 (unaudited) See Note 11
ASSETS			
Current assets:			
Cash and cash equivalents	$ 4,258,856	$ 4,914,735	$ 8,842,189
Due from related party	80,582	59,038	80,582
Prepaid expenses and other current assets	180,181	211,445	180,181
Total current assets	4,519,619	5,185,218	9,102,951
Equipment, net	582,569	647,677	582,569
Goodwill	2,715,000	2,715,000	2,715,000
Other intangible assets:			
Licenses	2,442,171	2,442,171	2,442,171
Non-compete agreements	500,000	500,000	500,000
Accumulated amortization	(756,594)	(647,608)	(756,594)
Total other intangible assets	2,185,577	2,294,563	2,185,577
Other assets	749,573	844,430	749,573
Total assets	$ 10,752,338	$ 11,686,888	$ 15,335,670
LIABILITIES AND STOCKHOLDERS EQUITY			
Current liabilities:			
Current maturities of convertible notes payable	$ 2,169,446	$ 1,638,763	$ 2,169,446
Accounts payable and accrued expenses	1,457,322	1,194,797	1,457,322
Due to related parties	333,432	37,668	333,432
Deferred revenue	70,360	70,360	70,360
Dividends payable	103,642	87,553	103,642
Derivative liability	2,151,475	1,687,026	2,151,475
Total current liabilities	6,285,677	4,716,167	6,285,677
Convertible notes payable, less current maturities	1,167,756	1,595,525	1,167,756
Deposits	2,416,667		
Total liabilities	9,870,100	6,311,692	7,453,432
Stockholders equity:			
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 1,647,059 issued and outstanding	3,705,883	3,705,883	3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000	1,450,000	1,450,000

Common stock, $.001 par value; 45,000,000 shares authorized, 11,943,637 issued; 11,928,146 outstanding	11,944	11,829	13,944
Additional paid-in capital	25,012,805	23,599,632	32,010,805
Treasury stock, at cost, 15,491 shares	(47,183)	(47,183)	(47,183)
Accumulated deficit	(29,251,211)	(23,344,965)	(29,251,211)
Total stockholders equity	882,238	5,375,196	7,882,238
Total liabilities and stockholders equity	$ 10,752,338	$ 11,686,888	$ 15,335,670

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

	Three Months Ended	
	March 31, 2006	**March 31, 2005 (as restated)**
Sponsored research revenues	$ 17,153	$ 73,412
Royalty revenue, related party	20,813	14,389
Research fees	10,000	
Total Revenues	47,966	87,801
Expenses:		
Research and development:		
Related Party	1,117,854	58,224
Other	1,923,227	953,247
Product development costs	746,591	
General and administrative:		
Stock-based compensation	50,291	26,980
Related party	19,903	8,590
Other	735,256	972,616
Total expenses	4,593,122	2,019,657
Loss from operations	(4,545,156)	(1,931,856)
Interest expense, net	(547,894)	(81,868)
Derivative loss	(583,659)	(19,988)
Loss before income taxes	(5,676,710)	(2,033,712)
Income tax benefit		
Net loss	(5,676,710)	(2,033,712)
Preferred stock dividends	(16,089)	(16,089)
Loss attributable to common stockholders	$ (5,692,799)	$ (2,049,801)
Per share amounts, basic and diluted:		
Loss attributed to common stockholders	$ (0.48)	$ (0.28)
Weighted average common stock shares outstanding basic and diluted	11,870,813	7,204,517

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

FOR THE THREE MONTHS ENDED MARCH 31, 2006

(Unaudited)

	Series A Preferred Stock		Series B Preferred stock		Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity
Balances, January 1, 2006	1,647,059	$ 3,705,883	341,176	$ 1,450,000	11,828,637	$ 11,829	$ 23,831,168	($ 47,183)	($ 23,574,501)	$ 5,377,196
Stock-based compensation							50,291			50,291
Issuance of warrants for product development							746,591			746,591
Conversion of notes payable to common stock					108,363	108	265,380			265,488
Payment of interest with common stock					6,637	7	16,254			16,261
Reclassification of derivative liability to equity							119,210			119,210
Series B Preferred Dividends							(16,089)			(16,089)
Net loss									(5,676,710)	(5,676,710)
Balances, March 31, 2006	1,647,059	$ 3,705,883	341,176	$ 1,450,000	11,943,637	$ 11,944	$ 25,012,805	($ 47,183)	($ 29,251,211)	$ 882,238(1)

(1) See Proforma Balance Sheet and Note 11.

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

	Three Months Ended	
	March 31,2006	**March 31, 2005 (as restated)**
Operating activities:		
Net loss	$ (5,676,710)	$ (2,033,612)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of treasury stock		20,000
Expenses paid through the issuance of common stock	16,261	
Expenses paid through the issuance of warrants	746,591	
Depreciation	69,706	70,824
Amortization	108,986	108,513
Derivative loss	583,659	19,888
Accretion of interest on convertible debentures	465,259	60,971
Stock-based compensation	50,291	6,980
Changes in assets and liabilities:		
Accounts receivable		(3,079)
Prepaid expenses and other assets	31,263	(284,134)
Accounts payable and accrued liabilities	262,525	228,674
Net cash flows from operating activities	(3,342,168)	(1,804,975)
Investing activities:		
Purchase of equipment	(4,598)	(9,507)
Net cash flows from investing activities	(4,598)	(9,507)
Financing activities:		
Proceeds from deposits	2,416,667	
Proceeds from issuance of common stock		250,000
Proceeds from convertible debentures		2,500,000
Proceeds from related party borrowings	274,220	(48,523)
Payment on notes payable		(333,333)
Net cash flows from financing activities	2,690,887	2,368,144
Net change in cash and cash equivalents	(655,879)	553,662
Cash and cash equivalents at beginning of period	4,914,735	749,932
Cash and cash equivalents at end of period	$ 4,258,856	$ 1,303,594

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

The Company paid cash in payment of interest expense in the amounts of $109,896 and $19,965 during the first quarter of 2006 and 2005, respectively.

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 and 2005.

The Company converted $265,488 of convertible note payable through the issuance of 108,363 shares of common stock in the first quarter of 2006.

The Company reclassified in the first quarter of 2006 derivative liabilities of $119,210 from debt to equity as a result of the Company converting a portion of notes payable to which the derivative related.

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheet of BioDelivery Sciences International, Inc., together with its wholly-owned subsidiary, Arius Pharmaceuticals, Inc. (Arius), and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (BND and, collectively with Arius, the Company or we, us or similar terminology) as of March 31, 2006, and the condensed consolidated statements of operations for the three months ended March 31, 2006 and 2005 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, 2006 and for all periods presented, have been made.

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, 2005, included in the Company s 2005 Annual Report on Form 10-KSB, filed with the SEC on April 1, 2006 (2005 Annual Report).

The results of operations for the three months ended March 31, 2006, are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

The accompanying consolidated financial statements include the accounts of BioDelivery Sciences International, Inc. and its subsidiaries, Arius and BND. All intercompany accounts and transactions have been eliminated. BND became substantially inactive as of September 30, 2005.

2. Summary of significant accounting policies:

General:

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

2. Summary of significant accounting policies (continued):

Revenue Recognition:

Royalties are recognized as earned.

Sponsored research amounts are recognized as revenue when the research underlying such payments has been performed or when the funds have otherwise been utilized, such as for the purchase of operating assets. Grant revenue is recognized to the extent provided for under the related grant or collaborative research agreement. Research and development expenses are charged to operations as incurred.

License fees are payments for the initial license of and access to the Company s technology. For nonrefundable license fees received at the initiation of license agreements for which the Company has an ongoing research and development commitment, the Company defers these fees and recognizes them ratably over the period of the related research and development. For nonrefundable license fees received under license agreements where the continued performance of future research and development services is not required, the Company recognizes revenues upon delivery of the technology. There were no license fees recognized during either the three months ended March 31, 2006 or 2005.

In addition to license fees, the Company may also generate revenue from time to time in the form of milestone payments. Milestone payments are only received and recognized as revenues if the specified milestone is achieved and accepted by the customer and continued performance of future research and development services related to that milestone are not required. The Company, for arrangements where non-refundable upfront fees exist and there are further payments due upon achieving certain milestones, recognizes such revenue pursuant to Emerging Issues Task Force 00-21, Revenue Arrangements with Multiple Deliverables, whereby multiple deliverables are evaluated to determine whether such deliverables should be considered a single unit of accounting. No milestone payments were received or recognized as revenue during either the three months ended March 31, 2006 or 2005.

Other assets:

Other assets consist principally of deferred loan costs, which are being amortized over the life of the related debt.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

2. Summary of significant accounting policies (continued):

Stock-based compensation:

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (FAS 123(R)) using the modified-prospective-transition method. Under this transition method, compensation cost in 2006 includes cost for options granted prior to but not vested as of December 31, 2005, and options vested in 2006. Therefore results for prior periods have not been restated.

The adoption of SFAS No. 123(R) lowered net income by approximately $0.03 million for the three months ended March 31, 2006, compared to continued accounting for share-based compensation using the intrinsic value method under APB No. 25, Accounting For Stock Issued to Employees.

The following table illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of SFAS No. 123 during the period ended March 31, 2005. For the purposes of this pro forma disclosure, the value of the options is estimated using a Black-Scholes option-pricing model and amortized to expense over the options vesting periods.

	March 31, 2005
Loss-attributable to common stockholders, as reported	$ (2,049,701)
Stock-based employee compensation, as reported	$ 6,980
Stock-based employee compensation under fair value method	$ 58,374
Pro forma loss attributable to common stockholders under fair value method	$ (2,101,095)
Loss attributable to common stockholders basic and diluted:	
As reported	$ (0.28)
Pro forma under fair value method	$ (0.29)

As of March 31, 2006, there was approximately $937,000 of unrecognized compensation cost related to unvested share-based compensation awards granted. That cost is expected to be recognized over the next four years.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

2. Summary of significant accounting policies (continued):

Options were granted to certain employees during the first quarter of 2006 at prices equal to the market value of the stock on the dates the options were granted. The options granted have a term of 10 years from the grant date and granted options for employees vest ratably over a three year period. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the option and each vesting date. The Company has estimated the fair value of all stock option awards as of the date of the grant by applying the Black-Scholes pricing valuation model. The application of this valuation model involves assumptions that are judgmental and sensitive in the determination of compensation expense. The weighted average for key assumptions used in determining the fair value of options granted during the three months ended March 31, 2006 follows:

Expected price volatility	54.5%
Risk-free interest rate	4.32%
Weighted average expected life in years	10 years
Dividend yield	0

Option activity during the first quarter of 2006 was as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Yrs)
Outstanding at January 1, 2006	2,198,562	$ 4.41	5.08
Forfeited	(42,036)	$ 3.23	
Exercised			
Granted (unvested)	100,000	$ 2.69	9.78
Outstanding at March 31, 2006	2,256,526	$ 4.34	5.07
Exercisable at March 31, 2006	1,847,064	$ 4.62	5.07

The fair market value of options granted in the first quarter of 2006 was $185,700.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

2. Summary of significant accounting policies (continued):

New accounting pronouncements:

In February 2006, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 155 (SFAS No. 155), ACCOUNTING FOR CERTAIN HYBRID FINANCIAL INSTRUMENTS AN AMENDMENT OF FASB STATEMENTS NO. 133 AND 140, to simplify and make more consistent the accounting for certain financial instruments. Specifically, SFAS No. 155 amends SFAS No. 133, ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES, to permit fair value remeasurement for any hybrid financial instrument with an embedded derivative that otherwise would require bifurcation, provided that the whole instrument is accounted for on a fair value basis. Prior to fair value measurement, however, interests in securitized financial assets must be evaluated to identify interests containing embedded derivatives requiring bifurcation. The amendments to SFAS No. 133 also clarify that interest-only and principal-only strips are not subject to the requirements of the SFAS, and that concentrations of credit risk in the form of subordination are not embedded derivatives. Finally, SFAS No. 155 amends SFAS No. 140, ACCOUNTING FOR THE IMPAIRMENT OR DISPOSAL OF LONG-LIVED ASSETS, to allow a qualifying special-purpose entity (SPE) to hold a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. SFAS No. 155 applies to all financial instruments acquired or issued after the beginning of an entity s first fiscal year that begins after September 15, 2006, with earlier application allowed. The Company does not anticipate that the adoption of this statement to have a material impact on its consolidated financial statements.

3. Liquidity and management s plans:

Since inception, the Company has financed its operations primarily from the sale of its securities and loans from third parties. From inception through March 31, 2006, the Company has raised approximately $31.1 million, net of issuance costs, through these issuances. At March 31, 2006, the Company had $4.3 million in cash. The adequacy of cash for the Company s operations and continued research is dependent on, among other things, licensing opportunities the Company is seeking to enter into in the coming year, as well as the funding of the Company s equity line of credit, also further described below, which had an available balance remaining of $2.6 million at March 31, 2006, milestone payments, commercialization licenses and product development agreements and private or public financings, including potential offerings of common stock such as the Company s October 2005 offering.

On September 3, 2004, the Company entered into 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 on March 30, 2006, HCG will, at the Company s request, invest up to $4.0 million in the Company through December 31, 2006 in consideration of shares of

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

3. Liquidity and management s plans (continued):

Series B Convertible Preferred Stock of the Company (Series B Preferred). The Series B Preferred is convertible at any time as of or after April 1, 2006 at a price equal to $4.25 per share. Except for the extension of the commitment period, no other terms or conditions of equity line of credit were amended.

As of March 31, 2006, $1.45 million had been drawn under the Equity Line Agreement.

On July 15, 2005, the Company entered into a clinical development and license agreement with Clinical Development Capital, LLC (CDC) pursuant to which CDC was to provide up to $7 million in funding, (including a $2 million upfront payment received in February 2006 and subsequent monthly payments) for the clinical development of the Company s BEMA Fentanyl product. All funds made available under the transaction with CDC were to be repaid to CDC within 60 days of FDA approval of BEMA Fentanyl and therefore were accounted for as a refundable deposit. As part of the July 2005 transaction with CDC, the Company issued a warrant to CDC in February 2006 to purchase 601,120 shares of Common Stock at $2.91 per share (originally 500,000 shares at $3.50, which number of shares and exercise price was adjusted as a result of the pricing of the Company s October 2005 public financing). Such warrant contains certain antidilution provisions with respect to certain issuances of stock (or issuance of securities convertible into stock) at a price per share less than the exercise price stated in the warrant during the six months following its issuance. Also, the number of shares for which the warrant may be exercised is subject to adjustment based on the amount of funding provided by CDC, provided the warrant shall not, in any event, be exercisable for less than 100,000 shares of Common Stock. Finally, such warrant expires after the earlier of: (i) the second anniversary of the approval by the FDA of the first NDA relating to BEMA Fentanyl, (ii) the closing of a sale of all or substantially all of the Company s assets or the acquisition of the Company by another entity by means of merger or other transaction as a result of which the Company s stockholders immediately prior to such acquisition possess a minority of the voting power of the acquiring entity immediately following such acquisition, or (iii) any liquidation or winding up of the Company. Additionally, CDC will receive royalties based on net sales of BEMA Fentanyl (including minimum royalties).

In May 2006, the Company and CDC entered into several related agreements to convert the CDC refundable funding commitment to an equity investment, as further described in Footnote 11.

The Company s existing cash and cash equivalents, together with available financing, including proceeds from the October 2005 public offering, the remaining balances of the Company s equity line of credit, the May 2006 funding from CDC, the remaining balance of the Company s NIH grant, and potential new license revenue is considered by management to be sufficient to finance planned operations and capital expenditures through

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

3. Liquidity and management s plans (continued):

at least the second quarter of 2007, assuming that the Company does not accelerate the development of other opportunities available to it, engage in an extraordinary transaction or otherwise face unexpected expenses, events or contingencies, any of which could effect the Company s cash requirements. Additionally, available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, the Company anticipates it will likely be required to raise additional capital through one or more of a variety of potential sources, including:

Private equity financings

Collaborative agreements;

Grants and new license revenues;

Bank loans;

Public or private debt; and

Redemption and/or exercise of existing public warrants.

There can be no assurance that additional capital will be available on favorable terms, if at all. If adequate funds are not available, the Company may be required to significantly reduce or refocus its operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, any of which could have a material adverse effect on the Company, financial condition and results of operations. 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.

4. Convertible notes payable:

On February 22 and May 31, 2005, the Company entered into two separate $2.5 million convertible note and warrant financings with Laurus Master Fund, Ltd. (Laurus). The notes have 3-year terms and are each payable in monthly installments of $75,758 plus interest at prime plus 2%, with a floor of 7.5%. The notes are convertible, under certain conditions, into shares of Common Stock at a price equal to $2.45 per share (originally $3.10 per share, which conversion price was adjusted downward as a result of the pricing of the Company s October 2005 public offering).

In connection with these financings, the Company also issued Laurus two Common Stock purchase warrants to purchase up to an aggregate of 833,871 shares of Common Stock at a price equal to $3.88 per share. Registration statements were filed with the SEC to register the shares of Common Stock underlying the Laurus notes and warrants.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

4. Convertible notes payable (continued):

In addition, on June 29, 2005 and December 30, 2005 the Company entered into amendments to the February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by the Company of principal under the Laurus notes until July 1, 2006. In consideration of Laurus agreement, the Company issued to Laurus four warrants to purchase an aggregate of 99,274 shares of common stock at an exercise price of $.001 per share, with the last warrant expiring on December 28, 2012. The shares of Common Stock underlying all of such warrants have been registered with the SEC.

The Laurus financings included registration rights related to share settlement of the embedded conversion features and the warrants that the Company has determined not to be within its control. In addition, certain features associated with the financings, such as anti-dilution protection afforded to Laurus render the number of shares issuable under the financings to be variable (only when and if the Company sells stock for an amount less than the otherwise fixed conversion price). In these instances, EITF 00-19 Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock , requires allocation of the proceeds between the various instruments and the derivative elements carried at fair value. From December 2005 through March 31, 2006, Laurus converted approximately $0.4 million of debt to equity at $2.45 per share.

The following tabular presentation reflects the allocation of the proceeds of the financing:

Principal balance of notes	$ 5,000,000
Less reduction for:	
Fair value of beneficial conversion option	(1,450,404)
Fair value of warrants	(993,501)
Recorded at closing	2,556,095
Accretion of discount (interest expense) through March 31, 2006	
using effective interest method	1,218,096
Conversion of debt to equity	(436,989)
Carrying value at March 31, 2006	$ 3,337,202
As presented on balance sheet:	
Current maturities of convertible notes payable	$ 2,169,446
Convertible notes payable, less current maturities	1,167,756
	$ 3,337,202

The discount to the debt instruments resulting from the aforementioned allocation is being amortized through periodic charges to interest expense using the effective interest method. Effective interest rates used to amortize the Laurus financing discounts amounted to 33.3%, and 46.6% for the February and May financings, respectively.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

4. Convertible notes payable (continued):

Future maturities of convertible note payable are as follows:

Year Ended March 31,	
2007	$ 2,934,186
2008	1,477,501
2009	151,324
	4,563,011
Less unamortized discount	(1,225,809)
	$ 3,337,202

5. 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 (assumed under the Laurus registration rights obligations) or (b) physical or net-share settlement is not within the control of the Company (assumed when and if the Company sells Common Stock for amounts less than Laurus conversion price). 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 and subsequently adjusted to fair value at the close of each reporting period.

As of March 31, 2006, the derivative liability is composed of the following:

		Number of shares into which derivative liability can be settled
Free standing warrants	$ 190,441	69,274
Embedded beneficial conversion option	1,961,034	1,862,331
	$ 2,151,475	1,931,605

Derivative loss in the accompanying 2006 statement of operation is related to the individual derivatives as follows:

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

5. Derivative Financial Instruments (continued):

Free standing warrants	$ (16,626)
Embedded beneficial conversion option	(567,033)
	$ (583,659)

6. Stockholders equity:

Common stock:

During the first quarter of 2006, under its convertible debt arrangements with Laurus, the Company issued 6,637 shares of Common Stock with a share price of $2.45 for payment of $16,261 of interest, and 108,363 shares for payment of $265,489 of principal.

Warrants:

During the first quarter of 2006, the Company issued 601,120 warrants with a fair value of $746,591 to purchase shares of Common Stock at a price of $2.91, in connection with a product development agreement.

7. 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,	
	2006	**2005**
Net loss attributable to common stockholder (numerator)	$ (5,692,799)	$ (2,049,801)
Basic:		
Weighted average shares outstanding (denominator)	11,870,813	7,204,517
Net loss per common share basic	$ (.48)	$ (.28)
Diluted:		
Weighted average shares outstanding	11,870,813	7,204,517
Effect of dilutive securities		

Adjusted weighted average shares (denominator)	11,870,813	7,204,517
Net loss per common share diluted	$ (.48)	$ (.28)

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NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

7. Net loss per common share (continued):

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.

8. National Institutes of Health Grant:

In 2001, the National Institutes of Health (NIH) awarded the Company a Small Business Innovation Research Grant (the SBIR), which has been utilized in research and development efforts. The grant consisted of a 2003 grant of $1.0 million, a 2002 grant of $0.8 million and a 2001 grant of $0.9 million, a total of approximately $2.7 million related to its initial application for the grant through August 2004. All available funds have been funded through August 2004.

The grant is subject to provisions for monitoring set forth in NIH Guide for Grants and Contracts dated February 24, 2000, (specifically, the NIAID Policy on Monitoring Grants Supporting Clinical Trials and Studies).

In August 2002, the NIH awarded the Company a second grant for $0.6 million over two years. The Company incurred approximately $0.01 million and $0.04 million of costs related to this agreement for the three months ended March 31, 2006 and 2005, respectively. During the three months ended March 31, 2006 and 2005, the Company received $0.02 million and $0.07 million respectively, and recognized revenue of $0.02 million and $0.07 million, respectively, from this grant.

9. Restatement of previously reported quarterly information:

During the fourth quarter of 2005, the Company reevaluated its accounting for the convertible note financing transaction with Laurus discussed in Note 4. During the three months ended March 31, 2005, the Company accounted for its freestanding warrants and embedded beneficial conversion option associated with the convertible notes as equity. During the fourth quarter of 2005, management determined that these derivatives should be recorded as liabilities at fair value and thereafter adjusted to fair value at each subsequent reporting period until certain conditions are met, at which time such derivative liabilities will be reclassified into equity. As such, the unaudited quarterly financial information as previously reported for March 31, 2005, has been restated. More information can be found regarding such restatement in Note 14 to the audited financial statements appearing in the 2005 Annual Report.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2006 AND 2005

(Unaudited)

10. 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 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 us through an initial public offering. The Company has provided MAS Capital s counsel with copies of documents executed by either MAS Capital or its affiliates that we allege fully release the Company. Upon MAS Capital s refusal to dismiss the action notwithstanding the documents that the Company alleges fully release it, the Company has 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 filed a motion for summary judgment on June 9, 2005, and expect a ruling thereon in the second quarter of 2006. The Company believes that the plaintiff s claims are without merit and the Company intends to continue to vigorously defend the lawsuit.

11. Subsequent event:

On May 16, 2006 the Company closed a transaction with CDC pursuant to which $7.0 million in funds previously committed by CDC to fund the clinical development of the Company s BEMÆntanyl product were converted into shares of Common Stock at at premium to the market price of the Company s Common Stock. Pursuant to this transaction, $2.8 million of funds previously funded to the Company in calendar 2006 under the July 2005 CDC agreement have been converted into shares of Common Stock, and approximately $4.2 million in cash has been funded to the Company in consideration of shares of Common Stock, in each case at $3.50 per share. As a result, the Company has, as of the closing and funding of the transaction, a cash position of approximately $7.4 million and stockholders equity was increased by $7.0 million. Pursuant to this transaction, the Company has also: (i) issued CDC an additional warrant to purchase 904,000 shares of Common Stock at $3.00 and (ii) made certain amendments with CDC to the July 2005 agreements.

The above transaction is reflected in these financial statements on a pro-forma basis as if the transaction had occurred on March 31, 2006.

For further background on the CDC transaction, please see Note 3.

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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, 2006 Compared to the Three Months Ended March 31, 2005

Sponsored Research Revenue. During the three-month periods ending March 31, 2006 and March 31, 2005, the Company reported $0.02 million and $0.07 million respectively of sponsored research revenues from a grant from the National Institutes of Health.

Research Fee Revenues. During the three-month period ending March 31, 2006, the Company reported $0.01 million of research revenues. No research revenue was reported during the three-month period ended March 31, 2005.

Royalty Revenues. During the three-month periods ending March 31, 2006 and March 31, 2005, the Company reported $0.02 million and $0.01 million respectively of royalty revenue from a related company.

Research and Development. Research and development expenses of approximately $3.8 million and $1.0 million were incurred during the three-month periods ended March 31, 2006 and 2005, respectively. The Company s scientific staff continued to work toward increased development and application of the Company s BEMA and Bioral® drug delivery technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue and funding provided by the equity line of credit from HCG, the Laurus financings, the October 2005 public offering and the initial funds received from CDC development agreement. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead expenses and other costs directly related to the development and application of the BEMA and Bioral® drug delivery technologies. In February 2006, the Company received the first payment pursuant to a July 2005 development agreement of $2.0 million of a total $7.0 million commitment from CDC.

General and Administrative Expense. General and administrative expenses of approximately $0.8 million and $1.0 million were incurred in the three-month periods ended March 31, 2006 and 2005, 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. Stock-based compensation cost of $0.05 million in 2006 and $0.03 million in 2005 was associated with options issued during the period. Effective January 1, 2006 employees stock option grants are treated under FAS 123R for new options granted to employees.

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Interest Expense, Net. Interest expense for the periods ended March 31, 2006 and 2005 was principally composed of earnings from invested cash offset by interest expense for deferred loan costs and notes payable discount amortization.

***Derivative Loss*.** Derivative loss during 2006 and 2005 is related to the adjustment of derivative liabilities to fair value. These derivatives relate to the Laurus financing (see Note 5 to the financial statements).

***Income Taxes*.** While net operating losses were generated during the three months ended March 31, 2006 and 2005, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting 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

Our operations since inception have been financed primarily from the sale of securities and loans from third parties. From inception through March 31, 2006, approximately $31.1 million, net of issuance costs, has been raised through these issuances. At March 31, 2006, we had $4.3 million in cash. The adequacy of cash for operations and continued research is dependent on, among other things, licensing opportunities and product development agreements such as CDC that we are able to negotiate in the coming year, as well as the funding of our equity line of credit, which had an available balance remaining of $2.6 million at March 31, 2006, and a variety of other funding sources further described below.

Our working capital deficit was ($1.8) million at March 31, 2006.

We have incurred significant net losses and negative cash flows from operations since our inception. As of March 31, 2006, we had an accumulated deficit of $29.3 million and total stockholders equity of $.9 million. At December 31, 2005, our accumulated deficit was $23.3 million and our stockholders equity was approximately $5.4 million. On a pro-forma basis, which includes the closing of the CDC transaction on May 15, 2006, our working capital at March 31, 2006 was approximately $2.8 million and stockholders equity was approximately $7.9 million.

We anticipate that cash used in operations and our investment in facilities will increase significantly in the future as we research, develop, and, potentially, manufacture our proposed drug formulations. While we believe further application of our BEMA and Bioral® drug delivery technologies to other drugs will result in license agreements with manufacturers of generic and over-the-counter drugs, our plan of operations for the foreseeable future will be focused on our

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further development of the BEMA and Biora® technologies and their use in a limited number of applications, and not on the marketing, production or sale of FDA approved products.

Our existing cash and cash equivalents, together with available financing, including proceeds from the October 2005 public offering, the remaining balances of our equity line of credit, the May 2006 funding from CDC, the remaining balance of the Company s NIH grant, and potential new license revenue is considered by our management to be sufficient to finance the planned operations and capital expenditures into approximately the second quarter of 2007. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

- public equity markets;
- private equity financings;
- collaborative arrangements;
- grants and new license revenues;
- bank loans;
- public or private debt; and
- redemption and/or exercise of existing public 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. 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.

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 its Audit Committee.

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Revenue recognition:

License fee revenue is recognized over the life of the respective agreements. Royalties are recognized as earned. Milestone payments are recognized as income in the period the payments are earned and received. We have not received any milestone payments through March 31, 2006.

Stock-based compensation:

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (FAS 123(R)) using the modified-prospective-transition method. Under this transition method, compensation cost in 2006 includes cost for options granted prior to but not vested as of December 31, 2005, and options vested in 2006. Therefore results for prior periods have not been restated

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.

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

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others, those listed under Item 1 of the 2005 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, we were 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 us in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for us through an initial public offering. We have provided MAS Capital s counsel with copies of documents executed by either MAS Capital or its affiliates that we allege fully release our company. Upon MAS Capital s refusal to dismiss the action notwithstanding the documents that we allege fully release us, we have filed an Amended Answer asserting a claim for our attorneys fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. We filed a motion for summary judgment on June 9, 2005, and we presently expect a ruling thereon in the second quarter of 2006. We believe that the plaintiff s claims are without merit and we intend to continue to vigorously defend the lawsuit.

The Company may, from time to time, be involved in actual or potential legal proceedings that the Company considers to be in the normal course of business. The Company does not believe that any of these proceedings will have a material adverse effect on its business.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits

Exhibit Index

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.

(b) Reports on Form 8-K

On January 3, 2006, the Company filed a Current Report on Form 8-K regarding an amendment to financing agreements with Laurus its postponed principal payments due under such agreements until July 1, 2006.

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On March 6, 2006, the Company filed a Current Report on Form 8-K regarding its receipt of a non-approvable letter from the Food and Drug Administration regarding the Company s Emezine® product.

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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 17, 2006

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

Date: May 17, 2006

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

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