BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
May 16, 2005
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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, 2005

¨ 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

(State or other jurisdiction of incorporation or organization)

35-2089858

(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)

The Issuer had 7,304,687 shares of common stock issued and 7,269,197 shares of common stock outstanding as of March 31, 2005.

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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, 2005 AND DECEMBER 31, 2004

	March 31, 2005 (unaudited)	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,305,594	$ 749,932
Accounts receivable	30,224	27,145
Due from related party	21,868	9,290
Prepaid expenses and other current assets	217,233	242,849
Total current assets	1,574,919	1,029,216
Equipment, net	833,977	895,294
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	2,417,445	2,417,445
Non-compete agreements	500,000	500,000
Accumulated amortization	(320,171)	(211,658)
Total other intangible assets	2,597,274	2,705,787
Other assets	615,821	24,726
Total assets	$ 8,336,991	$ 7,370,023
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current maturities of note payable	$ 757,580	$ 333,333
Accounts payable and accrued liabilities	902,983	758,220
Due to related parties	135,382	171,327
Deferred revenue	123,311	123,311
Total current liabilities	1,919,256	1,386,191
Note payable	821,159	
Total liabilities	2,740,415	1,386,191
Commitments (Note 10)		
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
Series B Preferred stock, $.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000	1,450,000
Common stock, $.001 par value; 45,000,000 shares authorized, 7,304,687 and 7,245,863 shares issued; 7,269,197 and 7,145,863 shares outstanding in 2005 and 2004, respectively	7,305	7,246
Additional paid-in capital	16,126,597	14,619,701

Treasury stock, at cost, 35,490 and 100,000 shares, 2005 and 2004, respectively	(107,783)	(303,894)
Accumulated deficit	(15,585,426)	(13,495,104)
Total stockholders equity	5,596,576	5,983,832
Total liabilities and stockholders equity	$ 8,336,991	$ 7,370,023

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, 2005 AND 2004

(Unaudited)

	Three Months Ended March 31,	
	2005	**2004**
Sponsored research revenues	$ 73,412	$ 271,312
Royalty revenue, related party	14,389	
	87,801	271,312
Expenses:		
Research and development	1,011,471	699,115
General and administrative	981,206	670,069
Stock-based compensation	26,980	32,862
Total expenses	2,019,657	1,402,046
Interest income (expense), net	(158,466)	5,791
Loss before income taxes	(2,090,322)	(1,124,943)
Income tax benefit		
Net loss	(2,090,322)	(1,124,943)
Preferred stock dividends	(16,089)	
Loss attributable to common stockholders	$ (2,106,411)	$ (1,124,943)
Per share amounts, basic and diluted:		
Loss attributed to common stockholders	$ (0.29)	$ (0.16)
Weighted average common stock shares outstanding basic and diluted	7,204,517	6,985,863

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STOCKHOLDERS EQUITY

FOR THE THREE MONTHS ENDED MARCH 31, 2005

(Unaudited)

	Series A Preferred Stock		Series B Preferred stock		Common Stock		Additional	Treasury	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Shares	Amount	Paid-In Capital	Stock	Deficit	Equity
Balances, January 1, 2005	1,647,059	$ 3,705,883	341,176	$ 1,450,000	7,245,863	$ 7,246	$ 14,619,701	$ (303,894)	$ (13,495,104)	$ 5,983,832
Stock-based compensation							6,980			6,980
Issuance of common stock					58,824	59	249,941			250,000
Issuance of treasury stock							(76,111)	196,111		120,000
Beneficial conversion feature of convertible debentures							481,955			481,955
Issuance of warrants with convertible debentures							554,535			554,535
Issuance of Warrants for financing costs							305,685			305,685
Series B Preferred Dividends							(16,089)			(16,089)
Net loss									(2,090,322)	(2,090,322)
Balances, March 31, 2005	1,647,059	$ 3,705,883	341,176	$ 1,450,000	7,304,687	$ 7,305	$ 16,126,597	$ (107,783)	$ (5,585,426)	$ 5,596,576

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

CONDENSED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

	Three Months Ended March 31,	
	2005	**2004**
Operating activities:		
Net loss	$ (2,090,322)	$ (1,124,943)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of treasury stock	20,000	
Depreciation	70,824	70,708
Amortization	132,853	9,950
Accretion of interest on convertible debentures	115,229	
Loss on sale of marketable securities		7,297
Stock-based compensation	6,980	32,862
Changes in assets and liabilities:		
Accounts receivable	(3,079)	(23,532)
Prepaid expenses and other assets	(284,134)	(37,803)
Accounts payable and accrued liabilities	228,674	44,472
Deferred revenue		(23,974)
Net cash flows from operating activities	(1,802,975)	(1,044,963)
Investing activities:		
Purchase of equipment	(9,507)	(43,074)
Investments, net		975,355
Net cash flows net from investing activities	(9,507)	932,281
Financing activities:		
Proceeds from issuance of common stock	250,000	
Proceeds from convertible debentures	2,500,000	
Repayment of borrowings from related parties	(48,523)	(61,836)
Payment on notes and capital leases	(333,333)	(63,685)
Net cash flows from financing activities	(2,368,144)	(125,521)
Net change in cash and cash equivalents	555,662	(238,203)
Cash and cash equivalents at beginning of period	749,932	525,670
Cash and cash equivalents at end of period	$ 1,305,594	$ 287,467

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

CONDENSED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Non-cash investing and financing activities:

The Company issued 64,510 shares of treasury stock in payment of legal fees during the first quarter of 2005.

The Company accrued $16,089 in annual cumulative dividends in connection with its Series B Preferred stock during the first quarter of 2005.

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, 2005 AND 2004

(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheets 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) as of March 31, 2005, and the condensed consolidated statements of operations for the three months ended March 31, 2005 and 2004 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, 2005 and for all periods presented, have been made. The condensed consolidated balance sheet at December 31, 2004, has been derived from the Company s audited consolidated financial statements at that date.

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, 2004, included in the Company s 2004 Annual Report on Form 10-KSB/A, filed with the SEC on April 29, 2005 (2004 Annual Report).

The results of operations for the three months ended March 31, 2005, 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.

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 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.

Revenue recognition:

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

2. Summary of significant accounting policies (continued):

Revenue recognition (continued):

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.

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. There have been no milestone payments earned or received through March 31, 2005.

3. Corporate structure:

On August 24, 2004, the Company completed the acquisition of all of the capital stock of Arius. The transaction was structured as a reorganization of Arius with and into a newly formed, wholly-owned subsidiary of the Company. As part of the transaction, the Company issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of a newly designated, non-voting and non-interest bearing, series of convertible preferred stock, designated as Series A Non-Voting Convertible Preferred Stock (the Series A Preferred). The Series A Preferred will be convertible (upon the satisfaction of certain conditions) into shares of Company common stock (Common Stock) on a one for one basis. The Series A Preferred is eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first product or (ii) five years from the closing date. The Series A Preferred enjoys certain other rights and privileges.

The Company engaged a valuation firm to prepare a valuation of the Series A Preferred issued, and the intangibles acquired, in connection with the Arius transaction. The Series A Preferred has been valued at $2.25, which includes a 30% discount. Cash acquired in the transaction of $57,675 was recorded at cost, as were the liabilities assumed of $1,417,041. Intangibles which were subject to purchase price allocation of $5,315,249, included a license agreement, non-compete agreements with the principals of Arius, in process research and development, and goodwill.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

3. Corporate structure (continued):

On January 8, 2003, the Company formed BND as a majority-owned subsidiary. BND presently has two classes of equity interests: Class A Shares and Class B Shares. As of the date of this report, BDSI owns approximately 94.5% of BND s Class B Shares and all 708,587 of BND s Class A Shares.

During 2003, BND filed a registration statement on Form SB-1 on behalf of BDSI. In connection therewith, the Company made plans to distribute to BDSI stockholders 3,545,431 of BND s Class B Shares, or approximately 43% of BND s outstanding equity interests, including the Class A Shares. After having reevaluated this strategic opportunity, the Company decided in early 2005 to forego the planned distribution of Class B Shares and presently has no intention of effecting any such distribution. BND is substantially inactive at March 31, 2005.

4. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, through short-term borrowings, which were subsequently repaid, and from funded research arrangements. The Company has not generated revenue from the sale of any product but has generated revenues from licensing arrangements and the sale of royalty rights in 2004. The Company intends to finance its research and development efforts and its working capital needs from existing cash, new sources of financing and licensing agreements.

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 and CEO. Pursuant to the Equity Line Agreement, HCG will, at the Company s request, invest up to $4.0 million in the Company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock (Series B Preferred). The Series B Preferred will be convertible at any time as of or after April 1, 2006 at a price equal to $4.25 per share. As of March 31, 2005, $1.45 million has been drawn under the Equity Line Agreement.

On February 22, 2005, the Company consummated a three year $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., a Cayman Islands corporation (Laurus). The Laurus investment takes the form of a convertible note secured by certain assets of the Company, Arius and BND. Net proceeds from the financing were used primarily to retire the Company s $1.0 million secured equipment loan with Gold Bank (on which approximately $300,000 was owed and was paid at the closing of the Laurus transaction) and will be used to support research and development opportunities and for general working capital purposes.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

4. Liquidity and management s plans (continued):

In connection with the financing, Laurus was issued a Common Stock purchase warrant to purchase up to 350,000 shares of Common Stock at a price equal to $3.88 per share. The note bears interest at the prime rate plus 2% (7.5% at February 22, 2005), but not less than 7.5%, and is payable in monthly principal and interest installments of $75,758 beginning June 1, 2005. The note is convertible, under certain conditions, into shares of Common Stock at a price equal to $3.10 per share. The Company agreed, pursuant to a registration rights agreement, to register the shares of Common Stock underlying the Laurus note and the warrant.

The Company s existing cash and cash equivalents, together with available financing, including the remaining balances of the Company s equity line of credit and the remaining balance of our NIH grant, and potential new license revenue is considered by management to be sufficient to finance the planned operations and capital expenditures through at least December 2005. Based on product development timelines and agreements with the Company s 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, the Company anticipates it may be required to raise additional capital through a variety of sources, including:

The public equity markets;

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, either 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.

5. Goodwill and other intangible assets:

Estimated aggregate future amortization expense for other intangible assets for each of the next five years is as follows:

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

5. Goodwill and other intangible assets:

Year ending March 31	
2006	$ 435,948
2007	290,123
2008	185,952
2009	185,952
2010	185,952
Thereafter	1,313,347
	$ 2,597,274

6. Note payable:

On February 22, 2005, the Company consummated a three year $2.5 million secured convertible debt financing from Laurus. The Laurus investment takes the form of a convertible note secured by certain assets of the Company.

The Laurus financing is shown on the balance sheet under the following accounts:

Principal balance of note	$ 2,500,000
Less reduction for:	
Beneficial conversion feature of warrants	(481,955)
Value of warrants	(554,535)
Recorded at closing	$ 1,463,510
Add accretion (interest expense) through March 31, 2005	115,229
Balance at March 31, 2005	$ 1,578,739
Reflected on balance sheet:	
Current maturity of note payable	$ 757,580
Note payable	821,159
	$ 1,578,739

7. Stockholders equity:

Common stock:

During the first quarter of 2005, the Company issued 58,824 shares of Common Stock with a per share price of $4.25 for $250,000 in connection with a transaction with a strategic partner.

Treasury stock:

During the first quarter of 2005, the Company issued 64,510 shares of Treasury Stock with a per share price between $2.04 and $3.00 and a total value of $196,110. These shares satisfied $170,000 in legal fees to the Company s attorneys.

Warrants:

The Company issued to Laurus a Common Stock purchase warrant to purchase 350,000 shares of Common Stock in connection with the convertible note described in Note 6. The warrant has a seven-year term and can be exercised at a price of $3.88.

The Company also issued a warrant to Ferris Baker Watts (FBW), an investment banking firm, in connection with the Laurus financing to purchase 225,000 shares of Common Stock. This warrant has a four-year term and can be exercised at a price of $5.25.

The fair value of these warrants, determined using the Black-Scholes model, was $554,535 for Laurus and $305,865 for FBW. The beneficial conversion feature allocation for the Laurus note was $481,955. These amounts have been accounted for as deferred financing costs, and will be recognized over the term of the warrants.

8. Net loss per common share:

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

8. Net loss per common share (continued):

	Three Months Ended March 31,	
	2005	**2004**
Net loss (numerator)	$ (2,090,322)	$ (1,124,943)
Basic:		
Weighted average shares outstanding (denominator)	7,204,517	6,985,863
Net loss per common share basic	$ (.29)	$ (.16)
Diluted:		
Weighted average shares outstanding	7,204,517	6,985,863
Effect of dilutive securities		
Adjusted weighted average shares (denominator)	7,204,517	6,985,863
Net loss per common share diluted	$ (.29)	$ (.16)

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

9. Stock-based compensation:

The Company follows Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation (SFAS 123), which establishes a fair value based method of accounting for stock-based employee compensation plans; however, the Company has elected to account for its employee stock compensation plans using the intrinsic value method under Accounting Principles Board Opinion No. 25 with pro forma disclosures of net earnings and earnings per share, as if the fair value based method of accounting defined in SFAS 123 had been applied.

The following table reflects supplemental financial information related to stock-based employee compensation, as required by Statement of Financial Accounting Standards No. 148, ACCOUNTING FOR STOCK-BASED COMPENSATION TRANSITION AND DISCLOSURE.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

9. Stock-based compensation (continued):

	March 31, 2005	March 31, 2004
Loss-attributable to common stockholders, as reported	$ (2,090,322)	$ (1,124,943)
Stock-based compensation, as reported	$ 6,980	$ 32,862
Stock-based compensation under fair value method	$ 58,374	$ 53,228
Pro forma loss attributable to common stockholders under fair value method	$ (2,141,716)	$ (1,145,309)
Loss attributable to common stockholders basic and diluted:		
As reported	$ (.29)	$ (.16)
Pro forma under fair value method	$ (.30)	$ (.16)

10. 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 (which was fully-funded through August 2004), 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.

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). The Company incurred approximately $250,785 and $183,000 of costs related to this agreement for the three months ended March 31, 2005 and 2004, respectively.

During the three months ended March 31, 2005 and 2004, the Company received $0 and $247,000 respectively, and recognized revenue of $0 and $271,000, respectively, from this grant. These amounts are included in sponsored research revenues in the accompanying statements of operations. The grant provides for reimbursement of or advances for future research and development efforts. Upon receiving funding under the grant and utilizing the funds as specified, no amounts are refundable.

In August 2002, the NIH awarded the Company a second grant for $0.6 million over two years. The Company incurred approximately $0.1 million and $0 of costs related to this agreement for the three months ended March 31, 2005 and 2004, respectively. During the three months ended March 31, 2005 and 2004, the Company received $0.1 million and $0 respectively, and recognized revenue of $0.1 million and $0, respectively, from this grant.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004

(Unaudited)

11. Subsequent event:

Effective April 14, 2005, the Company s Vice President and Director of Innovation and Discovery, resigned from the Company. Previously, in November 2004, she accepted a permanent employment position at UMDNJ. Simultaneously with the resignation, the Company agreed to terminate such officer s employment agreement with the Company, and in connection therewith, the Company entered into a termination agreement and release with her and made a one-time payment to her of $7,708. In addition, the Company entered into a consulting agreement pursuant to which, through November 15, 2005, she will continue to consult with the Company on matters relating to the Company s patent estate. Finally, the Company terminated the 58,057 of Company incentive stock options she held and granted her 58,057 non-qualified options (at the same exercise prices as the former incentive stock options), which options terminate on November 15, 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, 2005 Compared to the Three Months Ended March 31, 2004

Sponsored Research Revenue. During the three-month period ended March 31, 2005, the Company reported $0.1 million of sponsored research revenues from a grant from the National Institutes of Health. Revenue aggregating $0.3 million in the three months ended March 31, 2004 was derived from an SBIR grant, which was fully funded in August 2004.

License Fee Revenues. There were no licensing revenues for the three months period ended March 31, 2005 nor in 2004.

Royalty Revenues. During the three-month period ended March 31, 2005, the Company reported $0.01 million of royalty revenue from a related company. There were no such royalties in the prior year.

Research and Development. Research and development expenses of approximately $1.0 million and $0.7 million were incurred during the three-month periods ended March 31, 2005 and 2004, respectively. The Company s scientific staff continued to work toward increased development and application of our BEMA and Bioral® cochleate technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options by directors, and funding of an equity line of credit from HCG. 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 Expense. General and administrative expenses of approximately $1.0 million and $0.7 million were incurred in the three-month periods ended March 31, 2005 and 2004, respectively. These expenses are principally composed of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries, website update and development, and other business development costs. Furthermore, expenses include approximately $0.03 million and $0.1 million of expenses related to BND operating activities in the three months ended March 31, 20005 and 2004, respectively. Stock-based compensation costs of $0.03 million in 2005 were associated with options issued during the period. Employees stock option grants are treated under APB 25 through December 31, 2004. The Company intends to adopt FAS 123 in 2005 for new options granted to

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employees. The increase in general and administrative expenses in 2005 is primarily due to increased staffing following the acquisition of Arius, and additional patent costs, partially offset by reduced costs associated with BND.

Interest Income (Expense). Interest income (expense) for the periods ended March 31, 2005 and 2004 was principally composed of earnings from invested cash offset by interest expense on the line of credit, notes payable and capital leases payable. Interest expense in 2005 also includes amortization of loan costs associated with warrants issued to the Company s investment banker of $0.01 million and amortization of the Laurus discount of $0.09 million.

Income Taxes. While net operating losses were generated during the three month period ended March 31, 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 our historical operating performance and our 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 have financed our operations primarily from the sale of our securities and loans from third parties. From inception through March 31, 2005, we raised approximately $18.4 million, net of issuance costs, through these issuances. At March 31, 2005, we had $1.3 million in cash and investments. At December 31, 2004, we had cash and investments totaling approximately $0.8 million. The adequacy of cash for our operations in continued research is dependent on, among other things, licensing opportunities we are able to negotiate in the coming year, as well as the funding of our equity line of credit, which had a balance remaining of $2.6 million at March 31, 2005.

Our working capital deficit was $0.3 million and $0.4 million at March 31, 2005 and December 31, 2004, respectively.

We have incurred significant net losses and negative cash flows from operations since our inception. As of March 31, 2005, we had an accumulated deficit of $15.6 million and total stockholders equity of $5.6 million. At December 31, 2004, our accumulated deficit was $13.5 million and our stockholders equity was approximately $6.0 million.

We anticipate that cash used in operations will increase significantly in the future as we research, develop, and, potentially, manufacture, distribute and/or sell our proposed drug formulations and products. While we believe further application of our BEMA and Bioral® cochleate technologies to other drugs will result in license agreements with manufacturers of generic and

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over-the-counter drugs, our plan of operations for the next 24 months will be focused primarily on the further development of the Emezine® formulation and the BEMA and Bioral® technologies, and the application of such technologies to a limited number of pharmaceutical products, and not on the marketing, production or sale of FDA approved products.

Our existing cash and cash equivalents, together with available financing, including the remaining balances of our existing equity line of credit and grant, and potential new license revenue, is considered by our management to be sufficient to finance the planned operations and capital expenditures through at least December 31, 2005. 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:

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. 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. There have been no milestone payments earned or received through March 31, 2005.

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 others, those listed under Item 1 of the 2004 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 $1.6 million based upon the allegation that MAS Capital, at the request of the Company, 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. The Company has filed an Amended Answer asserting a claim for the Company s attorneys fees and costs expended to defend the case. The matter is in the discovery stage and it is the Company s plan to file a motion for summary judgment. The deadline for filing a motion for summary judgment is currently June 9, 2005. The Company believes that plaintiff s claims are without merit and intends 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
10.1	Consulting Agreement, executed as of April 14, 2005, by and between the Company and Susan Gould-Fogerite (+)
10.2	Termination Agreement and Release, dated April 14, 2005, by and between the Company and Susan Gould-Fogerite (+)
10.3	Non-Qualified Stock Option Agreement, dated April 14, 2005, between the Company and Susan Gould-Fogerite (+)
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 (*)

+ Previously filed with the Company s Registration Statement on Form SB-2/A, dated April 29, 2005.

* 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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(b) Reports on Form 8-K

On February 25, 2005, the Company filed a Current Report on Form 8-K regarding the Company s $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd.

On February 2, 2005, the Company filed a Current Report on Form 8-K regarding the appointment of Mark A. Sirgo as President of the Company and an amendment to the employment agreement of Francis E. O Donnell, Jr., M.D., the Company s Chairman and Chief Executive Officer.

On January 24, 2005, the Company filed a Current Report on Form 8-K regarding its licensing and stock purchase transaction with Sigma Tau.

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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 16, 2005

By: /s/ Francis E. O Donnell, Jr.

Francis E. O Donnell, Jr., Chief Executive Officer
and Chairman
(Principal Executive Officer)

Date: May 16, 2005

By: /s/ James A. McNulty

James A. McNulty, Secretary, Treasurer and
Chief Financial Officer
(Principal Financial Officer)

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