BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
August 14, 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 June 30, 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

(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)

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

The Issuer had 13,953,637 shares of common stock issued and 13,938,146 shares of common stock outstanding as of June 30, 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 JUNE 30, 2006 AND DECEMBER 31, 2005

	June 30, 2006 (Unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,236,929	$ 4,914,735
Due from related party	99,903	59,038
Prepaid expenses and other current assets	120,656	211,445
Total current assets	5,457,488	5,185,218
Equipment, net	515,061	647,677
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	2,442,171	2,442,171
Non-compete agreements	500,000	500,000
Accumulated amortization	(865,582)	(647,608)
Total other intangible assets	2,076,589	2,294,563
Other assets	654,423	844,430
Total assets	$ 11,418,561	$ 11,686,888
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current maturities of notes payable	$ 2,744,072	$ 1,609,144
Accounts payable and accrued liabilities	1,133,508	1,194,797
Due to related parties	303,087	37,668
Deferred revenue	70,360	70,360
Dividends payable	119,910	87,553
Derivative liability	1,004,619	1,687,026
Total current liabilities	5, 375,556	4,686,548
Notes payable	896,762	1,623,144
Total liabilities	6,272,318	6,309,692
Commitments and Contingencies		
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, 13,953,637 and 11,828,637 shares issued; 13,938,146 and 11,813,146 shares outstanding in 2006 and 2005, respectively	13,954	11,829
Additional paid-in capital	32,260,071	23,831,168
Treasury stock, at cost, 15,491 shares, 2006 and 2005	(47,183)	(47,183)
Accumulated deficit	(32,236,482)	(23,574,501)

Total stockholders equity	5,146,243	5,377,196
Total liabilities and stockholders equity	$ 11,418,561	$ 11,686,888

See notes to condensed financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005 (Restated)	2006	2005 (Restated)
Sponsored research revenues	$ 7,196	$ 116,204	$ 24,349	$ 189,616
License fees and royalties, related parties	17,792	369,464	38,605	383,853
Research fees		24,995	10,000	24,995
	24,988	510,663	72,954	598,464
Expenses:				
Research and development	2,242,805	1,500,446	4,166,032	2,454,593
Related party research and development	331,847	364,321	1,449,701	421,645
Product development costs			746,591	
General and administrative	840,377	1,132,815	1,633,583	2,131,511
Related party general and administrative	25,386	3,900	45,289	13,390
Total expenses	3,440,415	3,001,482	8,041,196	5,021,139
Other income, net			7,663	
Interest expense, net	(551,879)	(314,667)	(1,099,773)	(396,535)
Derivative gain	982,030	937,436	398,371	917,548
Loss before income taxes	(2,985,276)	(1,868,050)	(8,661,981)	(3,901,662)
Income tax benefit (expense)				
Net loss	(2,985,276)	(1,868,050)	(8,661,981)	(3,901,662)
Preferred stock dividends	(16,268)	(16,268)	(32,357)	(32,357)
Loss attributable to common stockholders	$ (3,001,544)	$ (1,884.318)	$ (8,694,338)	$ (3,934,019)
Per share amounts, basic and diluted:				
Loss attributable to common stockholders	$ (0.23)	$ (0.26)	$ (0.70)	$ (0.54)
Weighted average common stock shares outstanding basic and diluted	12,945,838	7,269,196	12,415,936	7,236,856

See notes to condensed financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STOCKHOLDERS EQUITY

FOR THE SIX MONTHS ENDED JUNE 30, 2006

(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, 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 common stock and warrants, net of offering costs					2,000,000	2,000	6,973,900			6,975,900
Issuance of warrants for product development costs							797,796			797,796
Issuance of warrants for financing costs							32,485			32,485
Conversion of notes payable to common stock					118,363	118	289,870			289,988
Payment of interest with common stock					6,637	7	16,254			16,261
Reclassification of derivative liability to equity							300,664			300,664
Series B Preferred Dividends							(32,357)			(32,357)
Net loss									(8,661,981)	(8,661,981)
Balances, June 30, 2006	1,647,059	$ 3,705,883	341,176	$ 1,450,000	13,953,637	$ 13,954	$ 32,260,071	$ (47,183)	$ (32,236,482)	$ 5,146,243

See notes to condensed financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

	Six Months Ended June 30, 2006	(restated) 2005
Operating activities:		
Net loss	$ (8,661,981)	$ (3,901,662)
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	830,281	84,573
Depreciation	139,475	141,638
Amortization	217,974	295,310
Derivative gain	(398,371)	(917,548)
Accretion of interest on convertible debentures	715,160	206,278
Stock-based compensation	50,291	8,715
Changes in assets and liabilities:		
Accounts receivable	(40,865)	(303,152)
Prepaid expenses	280,796	49,589
Accounts payable and accrued liabilities	(61,288)	1,148,068
Deferred revenue		(52,950)
Net cash flows from operating activities	(6,912,267)	(3,221,141)
Investing activities:		
Purchase of equipment	(6,859)	(14,750)
Net cash flows from investing activities	(6,859)	(14,750)
Financing activities:		
Proceeds from issuance of common stock	6,975,900	250,000
Proceeds from convertible debentures		5,000,000
Change in amounts due to related parties	265,419	(45,547)
Payment on notes payable		(333,333)
Cash paid for loan costs		(595,000)
Net cash flows from financing activities	7,241,319	4,276,120
Net change in cash and cash equivalents	322,194	1,040,229
Cash and cash equivalents at beginning of period	4,914,735	749,932
Cash and cash equivalents at end of period	$ 5,236,929	$ 1,790,161

See notes to condensed financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

The Company paid cash for interest expense in the amounts of $211,137 and $86,632 during the six months ended June 30, 2006 and 2005, respectively.

Non-cash investing and financing activities:

The Company accrued $32,357 in annual cumulative dividends in connection with its Series B Preferred stock during the six months ended June 30, 2006 and 2005, respectively.

The Company converted $289,988 of its convertible note payable to 118,363 shares of common stock in the six months ended June 30, 2006.

The Company reclassified derivative liabilities of $300,664 in the six months ended June 30, 3006, from debt to equity as a result of the conversion of a portion of notes payable to which the derivative related.

See notes to condensed financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 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), (collectively, the Company or we , us similar terminology) as of June 30, 2006, and the condensed consolidated statements of operations for the six and three months ended June 30, 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 June 30, 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 six months ended June 30, 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 certain 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 FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

2. Summary of certain 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 six months ended June 30, 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.

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 $0.1 million for the six months ended June 30, 2006, compared to continued accounting for share-based compensation using the intrinsic value method under APB No. 25, Accounting for Stock Issued to Employees.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

2. Summary of certain significant accounting policies (continued):

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 three and six months ended June 30, 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.

	Three months ended June 30, 2005	Six months ended June 30, 2005
Loss-attributable to common stockholders, as reported	$ (1,884,318)	$ (3,934,019)
Stock-based employee compensation, as reported	1,735	28,715
Stock-based employee compensation under fair value method	(65,952)	$ (124,326)
Pro forma loss attributable to common stockholders under fair value method	$ (1,948,535)	$ (4,029,630)
Loss attributable to common stockholders basic and diluted:		
As reported	$ (.26)	$ (.54)
Pro forma under fair value method	$ (.27)	$ (.56)

As of June 30, 2006, there was approximately $951,000 of unrecognized compensation cost related to unvested share-based compensation awards granted. That cost is expected to be recognized over the next four years.

Options were granted to certain employees during January, 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 period ended June 30, 2006 follows:

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

2. Summary of certain significant accounting policies (continued):

Option activity during the period ending June 30, 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	(51,717)	$ 3.34	
Exercised			
Granted (unvested)	100,000	$ 2.69	9.53
Outstanding at June 30, 2006	2,246,845	$ 4.34	4.81
Exercisable at June 30, 2006	1,837,383	$ 4.63	4.80

The fair value of each option award is estimated on the date of grant issue using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from traded options on the Company s stock, historical volatility of the Company s stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term.

Options outstanding at June 30, 2006 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	1,838,980	5.73	$ 2.91	
$ 5.01 10.00	177,889	1.12	$ 5.85	
$10.01 15.00	114,988	0.34	$ 11.80	
$15.01 20.00	114,988	0.34	$ 17.48	
	2,246,845			$ 57,160

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

2. Summary of certain significant accounting policies (continued):

Options exercisable at June 30, 2006 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	1,435,518	5.73	$ 2.91	
$ 5.01 10.00	171,889	1.12	$ 5.85	
$10.01 15.00	114,988	0.34	$ 11.80	
$15.01 20.00	114,988	0.34	$ 17.48	
	1,837,383			$ 53,400

The fair market value of options granted during the period ended June 30, 2006 was $185,700.

Warrants outstanding at June 30, 2006 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	2,660,765	6.49	$ 3.15	
$ 5.01 10.00	2,310,000	1.18	$ 6.20	
	4,970,765			$ 231,218

Warrants exercisable at June 30, 2006 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	2,635,765	6.49	$ 3.16	
$ 5.01 10.00	2,310,000	1.18	$ 6.20	
	4,945,765			$ 223,968

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 re-measurement 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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

2. Summary of certain significant accounting policies (continued):

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.

The Financial Accounting Standards Board (FASB) has recently announced a new interpretation, FASB Interpretation no. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which will be effective for fiscal years beginning after December 15, 2006, FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB statement No. 109, Accounting for Income Taxes . FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company has not determined the impact of the adoption of FIN 48 on its consolidated financial statements.

Reclassifications

Certain prior period amounts have been reclassified to conform to current period presentation.

3. Liquidity and management s plans:

The company has financed its operations primarily from the sale of its securities and loans from third parties. From inception through June 30, 2006, the company has raised approximately $38.1 million, net of issuance costs, through these issuances. At June 30, 2006, the company had $5.2 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 may negotiate in the coming year, milestone payments, commercialization licenses and product development agreements and private or public financings, including potential offerings of common stock, and the funding of the Company s equity line of credit, further described below, which had an available balance remaining of $2.6 million at June 30, 2006.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

3. Liquidity and management s plans (continued):

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 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 June 30, 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 BEMÆFentanyl product. All funds made available under the transaction with CDC were originally 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. Such warrant contains certain anti-dilution 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).

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 BEMÆFentanyl product (as discussed in the previous paragraph) were converted into shares of Common Stock at premium to the market price of the Company s Common Stock. Pursuant to this transaction, $2.8 million of funds previously received by the Company in calendar 2006 (and recorded as a deposit liability) under the July 2005 CDC agreement

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

3. Liquidity and management s plans (continued):

and approximately $4.2 million in cash received by the Company were in consideration for shares of Common Stock, at $3.50 per share. As a result, the Company s 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 Company s existing cash and cash equivalents, 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 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 affect 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

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.

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.

On July 31, 2006, the Company entered into two separate third amendments to the Company s February and May 2005 financing agreements with Laurus. Such financing agreements and the initial two amendments thereto are filed as exhibits to the Company s Current Reports on Form 8-K dated, respectively, February 25, 2005, June 3, 2005, June 30, 2005 and January 3, 2006. Under the third amendments, Laurus has agreed to defer payments by the Company of certain monthly principal amounts under the Company s February and May 2005 Convertible Notes with Laurus ($909,096 in the aggregate), as well as certain other previously postponed principal amounts due under such notes ($1,280,945 in the aggregate), until the first business day of January 2007.

In consideration of Laurus agreement to enter into the third amendments, the Company issued to Laurus two warrants, one to purchase 62,887 shares of Company common stock (in connection with the February amendment) and a second to purchase 47,113 shares of Company common stock (in connection with the May amendment) (such warrants collectively, the July 2006 Warrants). In each case, the July 2006 Warrants are exercisable into shares of Company common stock at an exercise price of $3.00 per share and expire on July 31, 2013. Except for the exercise price of the warrants, the July 2006 Warrants are substantially similar to the warrants issued to Laurus on February 22, 2005, May 31, 2005, June 29, 2005 and December 28, 2005.

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(Unaudited)

4. Convertible notes payable (continued):

The following tabular presentation reflects the allocation of the proceeds of Laurus financings:

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 June 30, 2006 using effective interest method	1,578,966
Conversion of debt to equity	(494,227)
Carrying value at June 30, 2006	$ 3,640,834
As presented on balance sheet:	
Current maturities of convertible notes payable	$ 2,744,072
Convertible notes payable, less current maturities	896,762
	$ 3,640,834

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.

Future maturities of convertible note payable are as follows:

Year Ended June 30,	
2007	$ 3,388,734
2008	1,149,777
	4,538,511
Less unamortized discount	(897,677)
	$ 3,640,834

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

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(Unaudited)

4. Derivative Financial Instruments: (continued):

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 June 30, 2006, the derivative liability is composed of the following:

	Amount	Number of shares into which derivative liability can be settled
Embedded beneficial conversion option	$ 1,004,619	1,852,453

Derivative gain in the accompanying condensed consolidated statements of operation is related to the individual derivatives as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Free standing warrants	$ 17,285	$ 388,162	$ 693	$ 309,161
Embedded beneficial conversion option	964,745	549,274	397,678	608,387
	$ 982,030	$ 937,436	$ 398,371	$ 917,548

6. Stockholders equity:

*Stock options***:**

The Company s Amended and Restated 2001 Stock Incentive Plan (the Plan) covers a total of 3,500,000 shares of Common Stock (amended from 2,100,000 and approved by the Company stockholders at the Company s 2006 annual meeting in July, 2006). Options may be awarded during the ten-year term of the Plan to Company employees, directors, consultants and other affiliates.

Common stock:

During the six months ended June 30, 2006, under its convertible debt arrangements with Laurus, the Company issued 118,363 shares of Common Stock with a share price of $2.45 for payment of $289,988 of principal.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

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FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

6. Stockholders equity (continued):

Warrants:

See Note 3 regarding warrants issued in connection with the CDC transaction.

The Company issued warrants to purchase 33,000 shares of Common Stock at a price of $3.50, for financing costs. The warrants had a fair value of $32,485 at the date of the grant.

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 June 30,		Six months ended June 30,	
	2006	**2005**	**2006**	**2005**
Loss attributable to common stockholders	$ (3,001,544)	$ (1,884,318)	$ (8,694,338)	$ (3,934,019)
Basic:				
Weighted average shares outstanding (denominator)	12,945,838	7,269,196	12,415,936	7,236,856
Net loss per common share basic	$ (0.23)	$ (0.26)	$ (0.70)	$ (0.54)
Diluted:				
Weighted average shares outstanding	12,945,838	7,269,196	12,415,936	7,125,856
Net loss per common share diluted	$ (0.23)	$ (0.26)	$ (0.70)	$ (0.54)

The effect of Common Stock equivalents are not considered in the calculation of diluted loss per share because the effect would be anti-dilutive. They are as follows at June 30, 2006 and 2005:

	2006	**2005**
Options and warrants to purchase common stock	7,217,610	4,976,126
Preferred stock (convertible to common stock)	1,988,235	1,988,235
Shares issuable for convertible debt	1,852,454	1,612,904

8. Restatement of previously reported June 30, 2005 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 six months ended June 30, 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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

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FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

8. Restatement of previously reported June 30, 2005 quarterly information (continued):

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 June 30, 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.

9. 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 expects a ruling thereon in the third 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. As such, no liability, if any, associated with this matter have been included in the financial statements.

10. Subsequent events:

On August 2, 2006, Arius Two, Inc. (Arius Two), a newly formed, wholly-owned subsidiary of the Company, entered into an Intellectual Property Assignment Agreement and related agreements with QLT USA, Inc. (QLT) pursuant to which Arius Two purchased intellectual property rights owned by QLT related to its BEMA technology for territories located outside of the United States. The Company, through its Arius subsidiary, previously licensed exclusive rights to the BEMA technology for such territories. Arius Two paid $3.0 million for the acquired intellectual property rights, consisting of $1.0 million in cash and a promissory note, secured by the purchased assets, for $2.0 million. Payments under such note are due as follows: (i) $1.0 million on March 31, 2007 and (ii) $1.0 million within 10 business days of initial non-U.S. approval of any BEMA product. In addition to the purchased BEMA intellectual property rights, QLT granted to BDSI the option, for a period of 12 months, to purchase the intellectual property rights owned by QLT related to its BEMA technology for the United States territory. If such option is exercised, the purchase price for the United States territory would be $7.0 million, which would be paid over time.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2006 AND 2005

(Unaudited)

10. Subsequent events (continued):

On August 2, 2006, the Company, Arius and Meda AB, a Swedish corporation (Meda), entered into a License and Development Agreement (the License Agreement) pursuant to which the Company and Arius granted Meda an exclusive license to develop and sell the Company s BEMA Fentanyl product in Europe in exchange for an upfront payment of $2.5 million, milestone payments, and a double digit royalty on sales. Milestone payments, totaling an additional $7.5 million, shall be received by the Company upon the achievement of certain milestones. As part of this transaction, Meda, the Company and Arius have also entered into a BEMA Fentanyl Supply Agreement pursuant to which Meda shall acquire, and the Company and Arius shall supply (directly or indirectly through third party contractors), all of Meda s requirements of BEMA Fentanyl product.

In connection with the above referenced transactions, certain consents and agreements were required of CDC and Laurus. The Company is a party to several existing agreements with CDC pursuant to which CDC has funded the development of the Company s BEMA Fentanyl product and is also a party to two separate $2.5 million secured convertible promissory notes and related agreements, as amended, with Laurus entered into in February 2005 and May 2005, respectively. Each of CDC and Laurus entered into agreements with the Company as of August 2, 2006 wherein they granted the required consents to the structure and payment schedule of the non-U.S. BEMA purchase transaction between Arius Two and QLT. In addition, CDC granted the required consent to the structure and payment schedule of the License Agreement with Meda.

On July 31, 2006, the Company entered into two separate third amendments to the Company s February and May 2005 financing agreements with Laurus. Such financing agreements and the initial two amendments thereto are filed as exhibits to the Company s Current Reports on Form 8-K dated February 25, 2005, June 3, 2005, June 30, 2005 and January 3, 2006, respectively. Under the third amendments, Laurus has agreed to defer payments by the Company of certain monthly principal amounts under the Company s February and May 2005 Convertible Notes with Laurus ($909,096 in the aggregate), as well as certain other previously postponed principal amounts due under such notes ($1,280,945 in the aggregate) until the first business day of January 2007. In consideration of Laurus agreement enter into the third amendments, the Company issued to Laurus two warrants, one to purchase 62,887 shares of Company common stock (in connection with the February amendment) and a second to purchase 47,113 shares of Company common stock (in connection with the May amendment) (such warrants collectively, the July 2006 Warrants). In each case, the July 2006 Warrants are exercisable into shares of Company common stock at an exercise price of $3.00 per share and expire on July 31, 2013. Except for the exercise price of the warrants, the July Warrants are substantially similar to the warrants issued to Laurus on February 22, 2005, May 31, 2005, June 29, 2005 and December 28, 2005. The Company has agreed to register the shares of common stock underlying the July Warrants with the Securities and Exchange Commission pursuant to a registration statement required to be filed by no later than July 31, 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 June 30, 2006 compared to the three months ended June 30, 2005

Sponsored Research Revenue. For the three-months ended June 30, 2006, the Company reported $0.01 million of sponsored research revenues from a grant from the National Institutes of Health, compared to such revenue aggregating $0.1 million during the same period in 2005.

License Fees and Milestone Revenues. During the three-months ended June 30, 2006 the Company reported zero license or milestone revenue. whereas $0.3 million of milestone revenue was reported from a related company for the same period last year.

Royalty Revenues. For the three-month periods ended June 30, 2006 and 2005, the Company reported $0.02 million and $0.07 million, respectively, in royalty revenue from a related company.

Research Fee Revenues. From time to time the company earns fees from collaborative research projects with third parties. During the three-months ended June 30, 2006, the Company did not report any such revenue, whereas $0.03 million of like revenue was recorded in the same period of last year.

Research and Development. Research and development expenses of approximately $2.6 million and $1.9 million were incurred during the three-month periods ended June 30, 2006 and 2005. These aforementioned amounts included $0.3 million and $0.4 million, respectively, paid to a contract research organization, which is a shareholder. The Company s scientific staff continued to work toward increased development and application of our BEMA and Bioral® technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options in 2004 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 Expenses. General and administrative expenses of approximately $0.9 million and $1.1 million were incurred in the three-month periods ended June 30, 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. Nominal stock-based compensation costs in 2005 were associated with vested options during the period. Employees stock option grants were treated under APB 25 through December 31, 2005. The Company has adopted FAS 123 beginning in 2006 for new options granted to employees.

Interest Income (Expense). Interest income (expense) for the periods ended June 30, 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 Gain. Derivative Gain during 2006 and 2005 is related to the adjustment of related 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 month period ended June 30, 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 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.

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Interest Income (Expense). Interest income (expense) for the periods ended June 30, 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 Gain. Derivative gain during 2006 and 2005 is related to the adjustment of related derivative liabilities to fair value. These derivatives relate to the Laurus financing (see Note 5 to the condensed consolidated financial statements).

***Income Taxes*.** While net operating losses were generated during the three month period ended June 30, 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 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.

For the six months ended June 30, 2006 compared to the six months ended June 30, 2005

Sponsored Research Revenue. During the six-months ended June 30, 2006, the Company reported $.02 million of sponsored research revenues from a grant from the National Institutes of Health. In the corresponding prior year period, revenue aggregating $0.2 million was recognized from an SBIR grant.

License Fee and Milestone Revenues. During the six-months ended June 30, 2006, the Company had no licensing or milestone revenue, whereas related party milestone revenue aggregating $0.3 million was recorded in the year-ago six month period.

Royalty Revenues. For the six-month periods ended June 30, 2006 and 2005, the Company reported $.04 million and $.08 million, respectively, of royalty revenue from a related company.

Research Fee Revenues. From time to time the company earns fees from collaborative research projects with third parties. During the six-months ended June 30, 2006, the Company reported $.01 million of research fee revenue, compared to a corresponding prior year amount of $.02 million.

Research and Development. Research and development expenses of approximately $5.6 million and $2.9 million were incurred during the six-months ended June 30, 2006 and 2005, respectively. Included in the before-described amounts were $1.4 million and $0.4 million, respectively, paid to a contract research organization, which is a stockholder. The Company s scientific staff continued to work toward increased development and application of our BEMA and Bioral® technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options in 2004 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.

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General and Administrative Expenses. General and administrative expenses of approximately $1.6 million and $2.1 million were incurred in the six-months ended June 30, 2006 and 2005, respectively. These expenses are principally comprised 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 costs of $.05 million in 2006 were associated with vested options during the period. Employees stock option grants were treated under APB 25 through December 31, 2005. The Company has adopted FAS 123 beginning in 2006 for new options granted to employees.

Interest Income (Expense). Interest income (expense) for the periods ended June 30, 2006 and 2005 was principally composed of earnings from invested cash offset by interest expense for deferred loan costs and notes payable discount amortization.

***Income Taxes*.** While net operating losses were generated during the six month period ended June 30, 2006, 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

We have financed our operations primarily from the sale of our securities and loans from third parties. From inception through June 30, 2006, we raised approximately $38.1 million, net of issuance costs, through these avenues. At June 30, 2006, we had $5.2 million in cash and at December 31, 2005, we had cash totaling approximately $4.9 million. The adequacy of cash for our operations in continued research is dependent on, among other things, licensing opportunities 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 June 30, 2006.

Our working capital was $0.1 million and $0.5 million at June 30, 2006 and December 31, 2005, respectively.

We have incurred significant net losses and negative cash flows from operations since our inception. As of June 30, 2006, we had an accumulated deficit of $32.2 million and total stockholders equity of $5.1 million. At December 31, 2005, the corresponding amounts were $23.6 million and approximately $5.4 million, respectively.

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. 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 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, the BEMA and Bioral® technologies, and the application of such technologies to a limited number of pharmaceutical products. Marketing, production or sale of FDA approved products will not receive our primary emphasis.

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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 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 the Company 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 June 30, 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 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, the Company was named as the defendant in an action commenced by MAS Capital Inc. in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff seeks monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company has provided MAS Capital s counsel with copies of documents executed by MAS Capital and its affiliates that the Company alleges fully release the Company. Upon MAS Capital s refusal to dismiss the action notwithstanding the documents that fully release the Company, the Company filed an Amended Answer asserting a claim for attorneys fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. The Company also filed a motion for summary judgment on June 9, 2005, with a ruling thereon expected in the third 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 4. Submission of Matters to a Vote of Security Holders

On July 27, 2006, the Company held its annual meeting of stockholders (the Annual Meeting). At the Annual Meeting, all proposals presented were approved by the Company s stockholders. The following is a tabulation of the voting on the proposals presented at the Annual Meeting:

Proposal 1: The following nominees were elected as directors of the Company, to serve until the 2007 Annual Meeting of Stockholders and until his successor has been duly elected and qualified.

Name	Shares Voted For	Shares Withheld
Francis E. O Donnell, Jr.	11,928,083	53,089
Mark A. Sirgo	11,934,018	47,154
Raphael J. Mannino	11,929,203	51,969
William B. Stone	11,935,718	45,454
L.M. Stephenson	11,934,468	46,704
John J. Shea	11,930,003	51,169
William S. Poole	11,934,818	46,354

Proposal 2: A proposal to amend the Company s Amended and Restated 2001 Incentive Plan to increase the number of shares of common stock reserved for issuance under such plan from 2,100,000 to 3,500,000 was approved as follows:

Shares Voted For	Shares Withheld	Shares Abstaining
7,004,666	137,785	13,786

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Proposal 3: A proposal to approve and ratify the terms of the issuance by the Company of 2,000,000 shares of Company common stock and a warrant to purchase 904,000 shares common stock issued to CDC IV, LLC on May 16, 2006 (aggregated with a previously warrant to purchase 601,120 shares of common stock issued to CDC IV, LLC on July 15, 2005) in accordance with NASDAQ Marketplace Rule 4350(i)(1)(D)(ii) was approved as follows:

Shares Voted For	Shares Withheld	Shares Abstaining
7,031,512	105,210	19,516

Proposal 4: A proposal to ratify the appointment by the Audit Committee of the Company s Board of Directors of Aidman Piser & Company, P.A. as the Company s independent auditors for the fiscal year ending December 31, 2006 was approved as follows:

Shares Voted For	Shares Withheld	Shares Abstaining
11,969,662	3,330	8,180

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 May 22, 2006, the Company filed a Current Report on Form 8-K regarding the entry into a material definitive agreement with CDC IV, LLC.

On April 3, 2006, the Company filed a Current Report on Form 8-K regarding: (i) the extension of its equity line of credit with Hopkins Capital Group II, LLC through December 31, 2006 and (ii) restatement of certain financial results as more fully described in Note 8 in this Quarterly Report on Form 10-QSB.

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SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: August 14, 2006

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

Date: August 14, 2006

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

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