BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB/A
September 02, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-QSB/A

(Amendment No. 2)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2004

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 0-28931

BioDelivery Sciences International, Inc.

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

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

185 South Orange Avenue, Administrative Building 4

Newark, New Jersey 07103

(Address of principal executive offices)

(973) 972-0015

(Issuer s telephone number)

The Issuer had 7,085,863 shares of common stock issued and 6,985,863 shares of common stock outstanding as of June 30, 2004.

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INTRODUCTORY NOTE

This Amendment No. 2 to the Quarterly Report on Form 10-QSB (the **Form10-QSB/A-2**) of BioDelivery Sciences International, Inc. (the **Company**) for the quarterly period ended June 30, 2004, as filed with the Securities and Exchange Commission (**SEC**) on August 18, 2004 (such quarterly report, the **Original Form 10-QSB**), is being filed solely for the purpose of amending Exhibits 31.1 and 31.2 thereto. The amendment to such exhibits is to correct a clerical error included in the original exhibit filing.

This Form 10-QSB/A-2 is being filed at the request of the Nasdaq SmallCap Stock Market to correct the Company s Amendment No. 1 to the Original Form 10-QSB, as filed with the SEC on August 30, 2004, by adding the entire text of the Original Form 10-QSB to such amendment.

This Form 10-QSB/A-2 does not reflect events occurring after the filing of the Original Form 10-QSB, or modify or update the disclosures contained in the Original Form 10-QSB in any way other than as required to reflect the amendment set forth above. The filing of this Form 10-QSB/A-2 shall not be deemed an admission that the Original Form 10-QSB, when made, included any untrue statement of a material fact or omitted to state a material fact necessary to make a statement not misleading.

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BioDelivery Sciences International, Inc. and Subsidiary

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF JUNE 30, 2004 AND DECEMBER 31, 2003

ASSETS	June 30, 2004 (unaudited)	December 31, 2003
Current assets:		
Cash and cash equivalents	$ 142,807	$ 525,670
Investments	285,000	2,027,652
Accounts receivable	27,145	-
Prepaid expenses and other current assets	153,262	222,490
Total current assets	608,214	2,775,812
Equipment, net	985,769	1,067,596
Licenses	458,691	477,641
Other assets, net	26,002	26,953
Total assets	$ 2,078,676	$ 4,348,002
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current maturities of note payable, bank	$ 246,813	$ 225,979
Accounts payable and accrued liabilities	474,205	158,148
Due to related parties	-	61,836
Deferred revenue	-	23,974
Capital lease obligation	2,371	4,742
Total current liabilities	723,389	474,679
Note payable, bank	586,521	732,354
Total liabilities	1,309,910	1,207,033
Commitments and contingencies	-	-
Stockholders equity:		
Preferred stock, $.001 par value, 20,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, $.001 par value 80,000,000 shares authorized, 7,085,863 issued, 6,985,863 outstanding in 2004	7,086	7,086
Additional paid-in capital	14,184,324	14,106,366
Treasury stock, at cost, 100,000 shares	(303,894)	(303,894)
Accumulated deficit	(13,119,844)	(10,668,589)
Accumulated other comprehensive gain	1,094	-
Total stockholders equity	768,766	3,140,969
Total liabilities and stockholders equity	$ 2,078,676	$ 4,348,002

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Sponsored research revenues	$ 247,338	$ 255,125	$ 518,650	$ 510,250
License fees	-	600,000	-	1,200,000
	247,338	855,125	518,650	1,710,250
Expenses:				
Research and development	826,499	642,672	1,525,614	1,286,167
General and administrative	671,198	533,847	1,341,267	1,334,375
Stock-based compensation	45,096	9,730	77,958	23,222
Total expenses	1,542,793	1,186,249	2,944,839	2,643,764
Interest income (expense), net	(30,856)	23,994	(25,066)	54,477
Loss before income taxes	(1,326,311)	(307,130)	(2,451,255)	(879,037)
Income tax benefit (expense)	-	-	-	-
Net loss	($ 1,326,311)	($ 307,130)	($ 2,451,255)	($ 879,037)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable equity securities	1,094	(7,203)	1,094	(7,203)
Comprehensive loss	($ 1,325,217)	($ 314,333)	($ 2,450,161)	($ 886,240)
Note: Accumulated comprehensive loss consists exclusively of unrealized losses on marketable equity securities.				
Net loss per common share:				
Basic and diluted	($ 19)	($ 04)	($ 35)	($ 12)
Weighted average common stock shares outstanding basic and diluted	6,985,863	7,010,566	6,985,863	7,048,007

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STOCKHOLDERS EQUITY

FOR THE SIX MONTHS ENDED JUNE 30, 2004

(Unaudited)

	Preferred Stock		Common Stock		Treasury Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders Equity
	Shares	Amount	Shares	Amount					
Balance, December 31, 2003	-	$ -	7,085,863	$ 7,086	($ 303,894)	$ 14,106,366	($ 10,668,589)	$ -	$ 3,140,969
Issuance of common stock options	-	-	-	-	-	77,958	-	-	77,958
Unrealized gain on marketable securities		-	-	-	-	-	-	1,094	1,094
Net loss	-	-	-	-	-	-	(2,451,255)	-	(2,451,255)
Balance, March 31, 2004 (unaudited)	-	$ -	7,085,863	$ 7,086	($ 303,894)	$ 14,184,324	($ 13,119,844)	$ 1,094	$ 768,767

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

C ONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003

(Unaudited)

	Six Months Ended June 30,	
	2004	2003
Operating activities:		
Net loss	($ 2,451,255)	($ 879,037)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	162,016	83,696
Loss on sale of marketable securities	9,483	
Stock-based compensation	77,958	23,222
Changes in assets and liabilities:		
Accounts receivable	(27,145)	2,000,000
Prepaid expenses and other current assets	(69,288)	87,058
Accounts payable and accrued liabilities	316,057	(249,994)
Deferred revenue	(23,974)	(1,200,000)
Net cash flows from operating activities	(1,867,632)	(135,055)
Investing activities:		
Purchase of equipment	(60,288)	(361,998)
Investments, net	1,734,263	(2,479,665)
Net cash flows net from investing activities	1,673,975	(2,841,663)
Financing activities:		
Repayment of borrowings from related parties	(61,836)	298,676
Payment on notes and capital leases payable	(127,370)	(6,389)
Net cash flows from financing activities	(189,206)	292,287
Net change in cash and cash equivalents	(382,863)	(2,684,431)
Cash and cash equivalents at beginning of period	525,670	5,207,303
Cash and cash equivalents at end of period	$ 142,807	$ 2,522,872
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Non-cash investing and financing activities:		
Unrealized gain (loss) on marketable equity securities	$ 1,094	($ 7,203)
Net loss	($ 2,451,255)	($ 879,037)

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003

(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheets of BioDelivery Sciences International, Inc. and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (collectively the Company) as of June 30, 2004, and the condensed consolidated statements of operations for the three and six months ended June 30, 2004 and 2003 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, 2004 and for all periods presented, have been made. The condensed consolidated balance sheet at December 31, 2003, 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, 2003, included in the Company s 2003 Annual Report on Form 10-KSB filed with the SEC on March 30, 2004 (2003 Annual Report).

The results of operations for the three and six months ended June 30, 2004, 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 majority-owned subsidiary, Bioral Nutrient Delivery, LLC. All intercompany accounts and transactions have been eliminated.

2. Summary of significant accounting policies:

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. 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. Research and development expenses principally include, among other things, consulting fees and cost reimbursements to the University of Medicine and Dentistry of New Jersey (UMDNJ), testing of compounds under investigation, and salaries and benefits of employees engaged in research and development activities.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003

(Unaudited)

2. Summary of significant accounting policies (continued):

Revenue recognition (continued):

License fees are up-front 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. To date, no milestone payments have been received.

3. Subsidiary corporate structure:

On January 8, 2003, the Company formed Bioral Nutrient Delivery, LLC, a Delaware limited liability company (BND) as a majority-owned subsidiary.

Effective April 1, 2003, the Company entered into a perpetual world-wide exclusive sublicense with BND for all opportunities in the processed food and beverage industry for both human and non-human use. Such sublicense was subsequently amended to include personal care products. BND intends to identify licensees who will apply the Company s encochleating technology to processed foods, including snacks such as chips, candies, breads, canned goods, packaged meals (such as microwaveable entrees), pet foods and pet treats, cheeses, cereals, soups, popcorn, pretzels and condiments. BND further believes the technology might be applied to beverages, including sports drinks, enhanced waters, carbonated beverages, infant formulas, milk, juices, beer and wine, as well as personal care products. BND will seek to commercialize the delivery technology through a combination of licensing programs to manufacturing, marketing and distribution companies within these industries.

BND has filed a registration statement on Form SB-1 on behalf of BDSI. BDSI, as issuing security holder, may distribute as a dividend to its stockholders, upon the effectiveness of such registration statement, 3,545,431 of the Company s Class B Membership Shares (Class B Shares) currently held by BDSI. The Class B Shares neither are presently nor will be listed on any exchange and will not be publicly-traded securities. No such Class B Shares have been distributed by BDSI to its stockholders as of June 30, 2004, and no assurances can be given that any distribution of Class B Shares will ever occur. Because the Company will receive no proceeds from the offering, offering costs aggregating approximately $258,000 have been expensed in the accompanying statements of operations. Total offering costs are estimated to be $350,000.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003

(Unaudited)

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 in 2003. The Company intends to finance its research and development efforts and its working capital needs from existing cash, investments, new sources of financing and licensing agreements.

In July and August 2004, certain directors of the Company exercised certain of their options to acquire shares of Company common stock and, as a result, funded approximately $275,000.

The Company is in negotiations to finalize a $1 million license agreement with Sigma-Tau S.p.A., a stockholder of the Company, which agreement shall include a $250,000 up-front payment (expected in August 2004), and the balance in milestone payments, all of which is expected to be earned in calendar 2004.

Pursuant to a license agreement, dated April 12, 2004 (the License Agreement), by and between the Company and Accentia, Inc. (Accentia), the Company has licensed a topical version of encochleated Amphotericin B to Accentia (the Licensed Technology). Accentia is another pharmaceutical holding company concern partly-owned by Hopkins Capital Group, LLC, which is owned and controlled by Francis E. O Donnell, M.D., the Company s Chairman, President and Chief Executive Officer. Using the Licensed Technology, Accentia intends to begin clinical trials for Amphotericin B, using patent rights, licensed from the Mayo Foundation for Medical Education and Research, for using any antifungal agent used to treat chronic sinusitis topically (the Patent Rights). Pursuant to the License Agreement, the Company is entitled to receive a twelve (12%) royalty fee (the Royalty) with respect to the net sales of any and all products covered by the Patent Rights and a fourteen (14%) royalty fee with respect to the net sales of an encochleated Amphotericin B with the approved indication for chronic rhinosinusitis in the USA. The Company is in discussions with Accentia for the possible purchase by Accentia of fifty (50%) of the Royalty (the Royalty Acquisition) in consideration of an irrevocable, one-time, up-front payment in the amount of $2.5 million. As a result, if this transaction were consummated as described above, the Company s royalties under the License Agreement would be reduced by 50%.

Readers are cautioned that, as of the date of this Report, no definitive documentation has been entered into by the Company with respect to either the Sigma Tau or Royalty Acquisition transactions and the Company s board of directors has not formally approved these transactions. As a result, no assurances can be given that these transactions will actually be consummated.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003

(Unaudited)

5. Licenses:

Licenses consist of the following:

	June 30, 2004	December 31, 2003
Licensing costs	$ 517,445	$ 517,445
Less accumulated amortization	(58,754)	(39,804)
	$ 458,691	$ 477,641

Estimated aggregate future amortization expense for each of the next five years and thereafter is as follows:

Year ending June 30,	
2005	$ 34,496
2006	34,496
2007	34,496
2008	34,496
2009	34,496
Thereafter	286,211
	$ 458,691

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003

(Unaudited)

6. Net loss per common share:

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

	Three Months Ended March 31,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss (numerator)	($ 1,326,311)	($ 307,130)	($ 2,451,255)	($ 879,037)
Basic:				
Weighted average shares outstanding (denominator)	6,985,863	7,010,566	6,985,863	7,048,007
Net loss per common share basic	($ 0.19)	($ 0.04)	($ 0.35)	($ 0.12)
Diluted:				
Weighted average shares outstanding	6,985,863	7,010,566	6,985,863	7,048,007
Effect of dilutive securities				
Adjusted weighted average shares (denominator)	6,985,863	7,010,566	6,985,863	7,048,007
Net loss per common share diluted	($ 0.19)	($ 0.04)	($ 0.35)	($ 0.12)

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

7. 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003

(Unaudited)

7. Stock-based compensation (continued):

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.

	June 30, 2004	June 30, 2003
Net loss, as reported	($ 2,451,255)	($ 879,037)
Stock-based compensation, as reported	$ 77,958	23,222
Stock-based compensation under fair value method	$ 157,250	99,788
Pro-forma net loss under fair value method	($ 2,530,547)	($ 955,603)
Net loss per share, as reported	($ 0.35)	($ 0.12)
Proforma net loss per share under fair value method	($ 0.36)	($ 0.13)

8. National Institutes of Health Grant:

In 2001, the National Institutes of Health (NIH) awarded the Company a Small Business Innovation Research Grant (the SBIR), which will be utilized in research and development efforts. NIH has formally awarded the Company a 2003 grant of $989,000, 2002 grant of $814,000 and a 2001 grant of $883,972. Therefore, the Company expects to receive a total of approximately $2.8 million related to its initial application for the grant through August 2004. The initial application was for approximately $3.0 million. Due to the expected purchase of certain materials from sources outside the United States, the funding was reduced since the SBIR requires that materials be purchased from U.S. suppliers.

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 $643,000 and $279,000 of costs related to this agreement for the six months ended June 30, 2004 and 2003, respectively.

During the six-month period ended June 30, 2004 and 2003, the Company received $495,000 and $444,000, respectively, and recognized revenue of $519,000 and $444,000, respectively, from this grant. As awarded on September 19, 2001, the grant provided 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.

9. Subsequent Events:

In July and August 2004, certain directors of the Company exercised certain of their options to acquire shares of Company common stock and, as a result, funded approximately $275,000. Such directors, as a condition of their exercise, have agreed not to sell such shares of common stock for a minimum of six months from the date of exercise.

On August 3, 2004, the Company announced that it entered into a credit facility of up to $4 million (the Facility) with Hopkins Capital Group II, LLC (HCG II). The Facility allows the Company to make drawdowns when needed, and Facility proceeds may be used by the Company in its discretion, including for general corporate purposes. Pursuant to the terms of the Facility, HCG II may convert, at maturity of the Facility or thereafter, any amount of principal and accrued interest outstanding under the Facility into shares of Company common stock at $4.25 per share.

On August 10, 2004, the Company announced that it entered into a definitive agreement to acquire all of the capital stock of Arius Pharmaceuticals, Inc., a Delaware corporation (Arius). As part of the transaction, the Company will issue 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.

At conversion, the preferred shares will be converted to Company common stock. The closing of the acquisition of Arius is subject to customary and certain other specific conditions set forth in the agreement and plan of merger and reorganization and is expected to occur by August 24, 2004.

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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 Six Months Ended June 30, 2004 Compared to the Six Months Ended June 30, 2003

Sponsored Research Revenue. During the six-month period ended June 30, 2004, we reported $519,000 of sponsored research revenues from a grant from the National Institutes of Health. In the prior year, revenue aggregating $444,000 was derived from the grant and $66,250 from a collaborative research agreement.

License Fee Revenues. During December 2002, the Company entered into a licensing agreement with a company (which is a shareholder), which included an up-front non-refundable payment of $2 million, which was received in January 2003. The Company deferred the revenue and recognized $1.2 million over the first six months of 2003 and the balance through October 2003. There were no licensing revenues in 2004.

Research and Development. Research and development expenses of approximately $1,526,000 and $1,286,000 were incurred during the six-month periods ended June 30, 2004 and 2003, respectively. Research and development expenses generally include: salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation, a portion of overhead operating expenses and other costs directly related to the development and application of the Bioral cochleate drug delivery technology.

General and Administrative Expense. General and administrative expenses of approximately $1,341,000 and $1,334,000 were incurred in the six-month periods ended June 30, 2004 and 2003, respectively. These expenses are principally comprised 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 $147,000 and $180,000 of expenses related to BND operating activities including offering costs. Stock-based compensation costs of approximately $78,000 in 2004 were associated with options issued during the period.

Interest Income (Expense). Interest income (expense) for the periods ended June 30, 2004 and 2003 was principally comprised of earnings from invested cash offset by interest expense on the equipment note payable and capital leases payable.

Income Taxes. While net operating losses were generated during the six month periods ended June 30, 2004 and 2003, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting Standard 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

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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.

Other comprehensive loss Other comprehensive loss in 2003 consists exclusively of unrealized losses on marketable equity securities held for sale. At June 2004 all marketable equity securities had been substantially sold and minimal unrealized gains existed at that date.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily from the sale of our securities. From inception through June 30, 2004, we raised approximately $14.1 million, net of issuance costs, through these issuances. At June 30, 2004 we had cash and cash equivalents of $428,000. At December 31, 2003, we had cash and investments totaling approximately $2.5 million. At June 30, 2003, we had approximately $5.0 million cash and (equivalents) investments.

Working capital (and working capital deficit) was approximately ($115,000) and $2,300,000 at June 30, 2004 and December 31, 2003, respectively.

In July and August 2004, certain directors exercised options to acquire 160,000 shares common stock, with net proceeds of approximately $275,000.

On August 3, 2004, the Company announced that it entered into a Facility with an affiliated entity of the Company which is controlled and partially-owned by Dr. Francis E. O Donnell, Jr., the Company s Chairman and CEO. The Facility allows the Company to make drawdowns when needed, and Facility proceeds may be used by the Company in its discretion, including for general corporate purposes. All debt funded from time to time under the Facility will have a stated maturity of March 31, 2006. The Company will be obligated to pay interest at the prime rate per annum on the aggregate amount of principal outstanding under the Facility. Pursuant to the terms of the Facility, HCG II may convert, at maturity of the Facility or thereafter, any amount of principal and accrued interest outstanding under the Facility into shares of Company common stock at $4.25 per share. The Facility will be subordinate to BDSI s existing funded debt.

We have incurred significant net losses and negative cash flows from operations since our inception. As of June 30, 2004, we had an accumulated deficit of approximately $13.1 million and total stockholders equity of approximately $769,000 At December 31, 2003, our accumulated deficit was approximately $10.7 million and our stockholders equity was approximately $3.1 million.

We anticipate that cash used in operations and our investment in facilities will continue in the future as we research, develop, and, potentially, manufacture our drugs. While we believe further application of our Bioral cochleate technology to other drugs will result in license agreements with manufacturers of generic and over-the-counter drugs, our plan of operations in the next 18 months is focused on our further development of the Bioral cochleate technology itself, as well as the development of the BEMA technology to be acquired in the acquisition of Arius Pharmaceuticals, Inc. (expected to close in late August) as further described below, and the use of the technologies in a limited number of applications. Such plans do not include the marketing, production or sale of FDA approved products.

Pursuant to a license agreement, dated April 12, 2004, by and between the Company and Accentia, the Company has licensed a topical version of encochleated Amphotericin B to Accentia. Using the Licensed Technology, Accentia intends to begin clinical trials for Amphotericin B, using patent rights, licensed from the Mayo Foundation for Medical Education and Research, for using any antifungal agent used to treat chronic sinusitis topically. Pursuant to the License Agreement, the Company is entitled to receive a twelve percent (12%) royalty fee with respect to the net sales of any and all products covered by the Patent Rights and a fourteen percent (14%) royalty fee with respect to the net sales of an encochleated Amphotericin B with the approved indication for chronic rhinosinusitis in the United States. The Company is in discussions with Accentia regarding the possible Royalty Acquisition in consideration for an irrevocable, one-time, up-front payment in the amount of $2.5 million (See Note 4 above). As a result, if this transaction were consummated as described above, the Company s royalties under the License Agreement would be reduced by 50%. Readers are cautioned that, as of the date of this Report, no definitive documentation has been entered into by the Company with respect to this transaction and the Company s board of directors has not formally approved this transaction. As a result, no assurances can be given that this transaction will actually be consummated.

On August 10, 2004, the Company announced that it entered into a definitive agreement to acquire all of the capital stock of Arius. The transaction is being 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 will issue 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. The newly-created preferred stock will be convertible (upon the satisfaction of certain conditions) into shares of Company common stock on a one for one basis. The value of the transaction was established was established based upon the $4.25 per share of the Company s initial public offering. The preferred stock 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 preferred stock enjoys certain other rights and privileges. The closing of the acquisition of Arius is subject to customary and certain other specific conditions set forth in the agreement and plan of merger and reorganization and is expected to occur by August 24, 2004.

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We may refinance our existing equipment debt facility with Gold Bank to a more favorable rate and extended term.

We believe that our existing cash and investments, our $4 million line of credit with Hopkins Capital Group and the proceeds from the recent exercise of director options and will be sufficient to finance our planned operations and capital expenditures through at least the next 12 months and likely longer if the acquisition of Arius is not consummated.

In addition, we believe that the cash which may be generated from the Royalty Acquisition, together with a contemplated equipment financing, pending and potential license agreements, and the net proceeds of potential equity or debt financings will allow us to potentially continue the financing of our operations. However, none of these transactions have been consummated as of the date of this Report and no assurances can be given that any such transactions will ever occur.

As a result, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we may be required to raise additional capital through a variety of sources, including:

the public equity market;
private equity financing;
collaborative arrangements;
grants;
public or private debt; and
redemption and exercise of 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 of our drugs, technologies or potential markets, either of which could have a material adverse effect on our business, 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 our 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.

Revenue recognition:

License fee revenue is recognized over the life of the respective agreements.

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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 and elsewhere in this Report 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, expects, 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 Form 10-KSB 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.

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 $1,575,000 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 filed for the removal of the action from the Indiana state court to the U.S. District Court for the Southern District of Indiana. The Company has also answered the complaint, denying the material allegations asserted by the plaintiff, and the Company believes that plaintiff s claims are without merit and intends to vigorously defend the lawsuit.

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

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

(a) Exhibits

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

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

(b) Reports on Form 8-K

On June 4, 2004, the Company filed a Current Report on Form 8-K regarding its license agreement with Accentia, Inc.

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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: September 2, 2004

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

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

Date: September 2, 2004

By: /s/ James A. McNulty

James A. McNulty,

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

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