BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
November 12, 2004

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 September 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

(State or other jurisdiction of

incorporation or organization)

35-2089858

(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 7,245,863 shares of common stock issued and 7,145,863 shares of common stock outstanding as of September 30, 2004.

BioDelivery Sciences International, Inc. and Subsidiaries

Form 10-QSB

Index

	Page
Part I. Financial Information	
Item 1. Financial Statements	
Condensed Consolidated Balance Sheets as of September 30, 2004 (unaudited) and December 31, 2003	2
Condensed Consolidated Statements of Income and Comprehensive Loss for the three and nine months ended September 30, 2004 and 2003 (unaudited)	3
Condensed Consolidated Statement of Stockholders Equity for the nine months ended September 30, 2004 (unaudited)	4
Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2004 and 2003 (unaudited)	5
Notes to Condensed Consolidated Financial Statements (unaudited)	7
Item 2. Management s Discussion and Analysis or Plan of Operation	14
Item 3. Controls and Procedures	19
Part II. Other Information	
Item 1. Legal Proceedings	20
Item 6. Exhibits and Reports on Form 8-K	20
Signatures	S-1
Certifications	

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF SEPTEMBER 30, 2004 AND DECEMBER 31, 2003

	September 30, 2004 (unaudited)	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,140,362	$ 525,670
Investments		2,027,652
Accounts receivable, including $500,000 due from related company	527,145	
Prepaid expenses and other current assets	217,938	222,490
Total current assets	2,885,445	2,775,812
Equipment, net	922,946	1,067,596
Licenses	449,215	477,641
Intangibles subject to Purchase Price Allocation	5,295,001	
Other assets, net	25,527	26,953
Total assets	$ 9,578,134	$ 4,348,002
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current maturities of note payable, bank	$ 246,813	$ 225,979
Accounts payable and accrued liabilities	1,569,247	158,148
Due to related parties		61,836
Deferred revenue		23,974
Capital lease obligation	1,185	4,742
Total current liabilities	1,817,245	474,679
Note payable, bank	524,021	732,354
Total liabilities	2,341,266	1,207,033
Commitments and contingencies		
Stockholders equity:		
Series A Preferred Stock, $.001 par value, 1,647,059 shares designated, issued and outstanding 2004	3,705,883	
Series B Preferred Stock, $.001 par value, 941,177 designated, 341,176 shares issued and outstanding 2004	1,450,000	
Common stock, $.001 par value 45,000,000 shares authorized, 7,245,863 and 5,770,677 shares issued, 7,145,863 shares outstanding in 2004 and 2003	7,246	7,086
Additional paid-in capital	14,490,021	14,106,366
Treasury stock, at cost, 100,000 shares	(303,894)	(303,894)
Accumulated deficit	(12,113,482)	(10,668,589)
Accumulated other comprehensive gain	1,094	
Total stockholders equity	7,236,868	3,140,969
Total liabilities and stockholders equity	$ 9,578,134	$ 4,348,002

See notes to condensed consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE LOSS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Sponsored research revenues	$ 164,892	$ 179,617	$ 683,542	$ 689,867
Development cost reimbursement	500,000		500,000	
License fees, related party		600,000		1,800,000
	664,892	779,617	1,183,542	2,489,867
Expenses:				
Research and development	1,366,882	700,027	2,882,089	1,986,194
General and administrative	741,275	552,994	2,092,949	1,887,369
Stock-based compensation	33,858	13,492	111,816	36,714
Total expenses	2,142,015	1,266,513	5,086,854	3,910,277
Other income (expense):				
Sale of future revenue stream	2,500,000		2,500,000	
Interest income (expense), net	(14,115)	(1,452)	(39,181)	53,025
Gain (loss) before income taxes	1,008,762	(488,348)	(1,442,493)	(1,367,385)
Income tax expense	(2,400)		(2,400)	
Net income (loss)	$ 1,006,362	($488,348)	($1,444,893)	($1,367,385)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable equity securities			1,094	6,125
Comprehensive income (loss)	$ 1,006,362	($488,348)	($1,443,799)	($1,361,260)
Net income (loss) per common share:				
Basic and diluted	$ .14	($.07)	($.21)	($.19)
Weighted average common shares outstanding basic and diluted	7,098,635	6,985,863	7,023,728	7,027,064

Note: Other comprehensive gain (loss) consists exclusively of unrealized gain (loss) on marketable equity securities.

See notes to condensed consolidated financial statements.

3

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STOCKHOLDERS EQUITY

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004

(Unaudited)

	Preferred Stock		Common Stock		Treasury	Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Income	Equity
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						111,815			111,815
Unrealized loss on marketable securities								1,094	1,094
Exercise of stock options			160,000	160		271,840			272,000
Issuance of Series A Preferred Stock for business acquisition	1,647,059	3,705,883							3,705,883
Issuance of Series B Preferred Stock for equity line draws	341,176	1,450,000							1,450,000
Net loss							(1,444,893)		(1,444,893)
Balance, September 30, 2004 (unaudited)	2,011,655	$ 5,155,883	7,245,863	$ 7,246	($ 303,894)	$ 14,490,021	($ 12,113,482)	$ 1,094	$ 7,236,868

See notes to condensed consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

	Nine Months Ended September 30,	
	2004	**2003**
Operating activities:		
Net loss	($1,444,893)	($1,367,385)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	242,945	155,221
Loss on sale of marketable securities	10,993	
Stock-based compensation	111,816	36,714
Expense in-process R&D from acquisition	100,000	
Changes in assets and liabilities:		
Accounts receivable	(527,145)	2,000,000
Grants receivable, prepaid expenses and other current assets	4,552	(110,251)
Other assets	20,000	
Accounts payable and accrued liabilities	(355,693)	(346,056)
Deferred revenue	(23,974)	(1,800,000)
Net cash flows from operating activities	(1,861,399)	(1,431,757)
Investing activities:		
Purchase of equipment	(68,444)	(771,753)
Cash acquired through acquisition	57,675	
Investments, net	2,017,753	(2,479,665)
Net cash flows from investing activities	2,006,984	(3,251,418)
Financing activities:		
Issuance of common stock	272,000	
Issuance of Series B Preferred Stock	1,450,000	
Net change in short-term borrowings		1,000,000
Purchase of treasury stock		(303,894)
Repayments of related party borrowings	(61,836)	(51,725)
Payments on notes and capital lease obligations	(191,056)	(9,583)
Net cash flows from financing activities	1,469,107	634,798
Net change in cash and cash equivalents	1,614,692	(4,048,377)
Cash and cash equivalents at beginning of period	525,670	5,207,303
Cash and cash equivalents at end of period	$ 2,140,362	$ 1,158,926

See notes to condensed consolidated financial statements.

5

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Non-cash investing and financing activities:

	Nine Months Ended September 30,	
	2004	**2003**
Acquisition of Arius with issuance of preferred stock	$ 3,705,883	
Unrealized gain on marketable equity securities	1,094	6,125
	$ 3,706,977	$ 6,125
Interest paid during the period	$ 50,122	$ 20,374

See notes to condensed consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheets of BioDelivery Sciences International, Inc., together with its wholly-owned subsidiary, Arius Pharmaceuticals, Inc. (Arius), and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (BND and, collectively with Arius, the Company) as of September 30, 2004, and the condensed consolidated statements of operations for the three and nine months ended September 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 September 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 nine months ended September 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 subsidiaries, Arius and BND. All intercompany accounts and transactions have been eliminated.

The accompanying financial statements reflect the disclosure of the authorized shares of Company common stock of 45,000,000. In previous filings, the authorized shares were shown as 80,000,000 authorized. This presentation correction has no accounting effect or financial impact.

2. Summary of significant accounting policies:

Revenue recognition:

Sponsored research revenues are recognized 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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

2. Summary of significant accounting policies (continued):

Revenue recognition (continued):

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.

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.

In April 2004, the Company entered into a sublicensing agreement (the Accentia License Agreement) with Accentia Biopharmaceuticals, Inc., f/k/a Accentia, Inc. (Accentia), a related company, pursuant to which the Company was entitled to a 12% to 14% royalty stream from an oral compound for the treatment of chronic rhinosinusitis. Under the terms of the Accentia License Agreement, all development costs are paid by Accentia. The Company is entitled to that royalty stream based on its application of encochleated technology to licensed drugs. In September 2004, in part to address the Company s liquidity, the Company entered into an asset purchase agreement with Accentia whereby the Company sold to Accentia an asset consisting of 50% of the future revenue stream under the Accentia License Agreement (and a resulting reduction of future royalty payments) for a one-time non-refundable payment of $2.5 million, which was paid in September and which is recognized as other income in the financial statements contained in this Report.

License fee revenue in Arius is recognized over the life of the respective agreements. The Company recognizes revenue pursuant to licensing agreements over the term of the licensing agreement in proportion to milestones achieved. For arrangements where non-refundable upfront fees exist and there are further payments due upon achieving certain milestones, the Company recognizes such revenue pursuant to Emerging Issues Task Force 00-21, *Revenue Arrangements with Multiple Deliverables,* whereby multiple deliverables

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

2. Summary of significant accounting policies (continued):

are evaluated to determine whether such deliverables should be considered a single unit of accounting. BND has not recognized revenue to date.

3. Subsidiary corporate structure:

In January, 2003, the Company formed 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. The 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 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 are not presently, nor will they 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 September 30, 2004, and no assurances can be given that any distribution of Class B Shares will ever occur. The Company s is presently re-evaluating the potential distribution of Class B Shares. Because the Company, if the distribution of Class B Shares ever occurs, would receive no proceeds from such distribution, offering costs aggregating approximately $258,000 have been expensed in the statements of operations contained in this Report. Total costs associated with the potential distribution are estimated to be $350,000.

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 and the sale of a revenue stream in 2004. 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

4. Liquidity and management s plans (continued):

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, $272,000 has been reported as funded equity in the financial statements included in this Report.

The Company is in negotiations to finalize a $1 million license agreement with Sigma-Tau S.p.A., an entity which controls a material stockholder of the Company, which agreement is expected to include a $250,000 up-front payment (expected in late 2004) with the balance in milestone payments, which are expected to be earned in calendar 2005. Readers are cautioned that, as of the date of this Report, no definitive documentation has been entered into by the Company with respect to the Sigma Tau transaction. As a result, no assurances can be given that this transaction will actually be consummated.

Pursuant to the Accentia License Agreement, the Company has licensed a topical version of encochleated Amphotericin B to Accentia (the Licensed Technology). Accentia is a pharmaceutical holding company concern partly-owned by Hopkins Capital Group, LLC, which is owned and controlled by the Company s Chairman, President and Chief Executive Officer. During 2004, using the Licensed Technology, Accentia began the process of evaluating clinical applications of 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 Accentia License Agreement, the Company was 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 encochleated Amphotericin B with the approved indication for chronic rhinosinusitis in the USA. As described in Note 2 above, and in part to address the Company s liquidity, in September 2004, the Company sold to Accentia 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, the Company s royalties under the License Agreement will be reduced by 50%.

5. Business acquisition:

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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

5. Business acquisition (continued):

occur of: (i) FDA approval of Arius first product or (ii) five years from the closing date. The Series A Preferred enjoys certain other rights and privileges.

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

6. Licenses and other intangibles:

Licenses consist of the following:

	September 30, 2004	December 31, 2003
Licensing costs	$ 517,445	$ 517,445
Less accumulated amortization	(68,230)	(39,804)
	$ 449,215	$ 477,641

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

Year ending September 30,	
2005	$ 34,496
2006	34,496
2007	34,496
2008	34,496
2009	34,496
Thereafter	276,735

	$ 449,215

Intangibles Subject to Purchase Price Allocation have been recorded in connection with the acquisition of Arius. in the amount of $5,315,267.

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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

7. Stock-based compensation (continued):

intrinsic value method under Accounting Principles Board Opinion No. 25 with pro forma disclosures of net earnings and earnings per share, as if the fair value based method of accounting defined in SFAS 123 had been applied.

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

	September 30, 2004	September 30, 2003
Net loss, as reported	($1,444,893)	($1,367,385)
Stock-based compensation, as reported	$ 111,816	36,714
Stock-based compensation under fair value method	$ 550,112	113,280
Pro-forma net loss under fair value method	($1,883,189)	($1,443,951)
Net loss per share, as reported	($.21)	($.19)
Proforma net loss per share under fair value method	($.27)	($.21)

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 awarded the Company a 2003 grant of $989,000, 2002 grant of $814,000 and a 2001 grant of $883,972. Therefore, the Company received 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 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 $845,000 and $379,000 of costs related to this agreement for the nine months ended September 30, 2004 and 2003, respectively.

During the nine-month period ended September 30, 2004 and 2003, the Company received $660,000 and $600,844, respectively, and recognized revenue of $684,000 and $600,844, 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(Unaudited)

9. Equity Line Agreement:

On August 23, 2004, the Company entered into a private, unregistered Equity Line Agreement with Hopkins Capital Group II, LLC (HCG) whereby HCG will, as requested by the Company, invest up to $4,000,000 in the Company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock of BDSI (the Series B Preferred). As of September 30, 2004, $1.45 million has been drawn under the Equity Line Agreement. The holders of the Series B Preferred are entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred is convertible into shares of Company common stock (the Common Stock) at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to $4.25 per share. The Series B Preferred ranks senior to shares of the Company s Common Stock and the Series A Preferred and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. HCG is an affiliated entity of the Company which is controlled and partially-owned by Dr. Francis E. O Donnell, Jr., the Company s Chairman, President and CEO.

Additionally, the Company has the right, in its discretion at any time, to redeem the shares of Series B Preferred stock for cash equal to the amount invested under the Equity Line Agreement plus accrued and unpaid dividends thereon. Furthermore, the Certificate of Designations for the Series B Preferred provides for certain limitations on the conversion of the Series B Preferred into shares of Common Stock without the prior approval of the Company s stockholders. Finally, HCG has no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

10. Subsequent events:

On October 13, 2004, the Company was notified by a hearing panel of the NASDAQ Stock Market that the Company had been granted an exception to the requirement that the Company maintain a minimum of $2.5 million in stockholder s equity as of June 30, 2004, subject to the Company demonstrating compliance with this requirement for the quarter ended September 30, 2004. This exception was issued by a NASDAQ hearing panel which, at the Company s request, held a formal hearing regarding the Company s continued listing on September 9, 2004. As of the date of this Report, the Company s stock remains trading under the symbol BDSIC until NASDAQ, pending its review of the Company s stockholders equity level as of the quarter ended September 30, 2004. The Company believes that, as of the date of this Report, it has met all requirements for continued listing on the NASDAQ SmallCap Market.

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 Nine months Ended September 30, 2004 Compared to the Nine months Ended September 30, 2003

Sponsored Research Revenue. During the nine-month period ended September 30, 2004, the Company reported $684,000 of sponsored research revenues from a grant from the National Institutes of Health. In the prior year, revenue aggregating $624,000 was derived from the grant and $66,000 from a collaborative research agreement.

License Fee Revenues. During December 2002, the Company entered into a licensing agreement with a company (which is also a Company stockholder), which included an up-front non-refundable payment of $2 million, which was received in January 2003. The Company deferred the revenue and recognized $2 million over the first ten months of 2003.

Development cost reimbursement. The Company has an agreement whereby it is reimbursed by Accentia for expenses associated with the development of certain of its technology applications. During the quarter ended September 30, 2004, $500,000 is shown as development cost reimbursement in the Company s subsidiary, Arius. The associated expenses are included in research and development expenses as incurred.

Research and Development. Research and development expenses of approximately $2.9 million and $2 million were incurred during the nine-month periods ended September 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. The period ended September 30, 2004 also includes $100,000 of in-process research and development associated with an acquisition as described below.

In-Process Research and Development. In connection with the August 2004 acquisition of Arius, the Company acquired a product in development that meets the tests for classification as In Process Research and Development. In accordance with valuation criteria and generally accepted accounting principles, the cost allocated to the product of $100,000 was expensed immediately after the acquisition.

General and Administrative Expense. General and administrative expenses of approximately $2.1 million and $1.9 million were incurred in the nine-month periods ended September 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, such expenses include approximately $193,000 and $388,000, respectively, of expenses related to BND operating activities including offering costs. Stock-based compensation costs of approximately $112,000 and $37,000 in 2004 and 2003, respectively, were associated with options issued in prior periods. This cost is being amortized over the appropriate vest periods.

Interest Income (Expense). Net Interest income (expense) for the periods ended September 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.

Other Income. In April 2004, the Company entered into a sublicensing agreement with Accentia pursuant to which the Company was entitled to a 12% to 14% royalty stream. In September 2004, in part to address the Company s liquidity, the Company sold to Accentia fifty (50%) of the Royalty in consideration of an irrevocable, one-time, up-front payment in the amount of $2.5 million. As a result, the Company s royalties under the License Agreement will be reduced by 50%. The $2.5 million cash receipt is reflected in Other income in the financial statements contained in this Report.

Income Taxes. While net operating losses were generated during the nine month periods ended September 30, 2004 and 2003, the Company 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 the Company s historical operating performance and its reported cumulative net losses in prior years, the Company has provided a full valuation allowance against the Company s net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Other comprehensive gain (loss). Other comprehensive gain or loss in 2004 and 2003 consists exclusively of unrealized gains and losses on marketable equity securities held for sale. At September 30, 2004 all marketable equity securities had been substantially sold and minimal unrealized gains existed at that date.

Liquidity and Capital Resources

Since inception, the Company has financed operations primarily from the sale of its securities. From inception through September 30, 2004, the Company raised approximately $18.6 million, net of issuance costs, through these issuances. At September 30, 2004, the Company had cash and cash equivalents of $2.14 million. At December 31, 2003, the Company had cash and investments totaling approximately $2.5 million. At September 30, 2003, the Company had approximately $5.0 million cash and (equivalents) investments.

Working capital (and working capital deficit) was approximately $1.1 million and $2.3 million at September 30, 2004 and December 31, 2003, respectively.

In July and August 2004, certain Company directors exercised options to acquire 160,000 shares common stock, with net proceeds of $272,000.

On August 23, 2004 (with subsequent additional definitive documentation entered into on September 3, 2004), the Company entered into an Equity Line Agreement with HCG pursuant to which HCG will, as requested by the Company, invest up to $4,000,000 in the Company from August 23, 2004 through March 31, 2006 in consideration of shares of Series B Preferred. HCG is controlled by the Company s Chairman, President and CEO. As of September 30, 2004, $1.45 million has been drawn under the Equity Line Agreement. The holders of the Series B Preferred are entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred is convertible into shares of Common Stock at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to $4.25 per share. The Series B Preferred ranks senior to shares of the Company s Common Stock and the Company s Series A Preferred and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges.

Additionally, the Company has the right, in its discretion at any time, to redeem the shares of Series B Preferred stock for cash equal to the amount invested under the Equity Line Agreement plus accrued and unpaid dividends thereon. Furthermore, the Certificate of Designations for the Series B Preferred provides for certain limitations on the conversion of the Series B Preferred into shares of Common Stock without the prior approval of the Company s stockholders. Finally, HCG has no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

The Company has incurred significant net losses and negative cash flows from operations since inception. As of September 30, 2004, the Company had an accumulated deficit of approximately $12 million and total stockholders equity of approximately $7.2 million. At December 31, 2003, the Company had an accumulated deficit of approximately $10.7 million and stockholders equity was approximately $3.1 million.

The Company anticipates that cash used in operations and investment in facilities will continue in the future as the Company researches, develops, and, potentially, manufactures its delivery technologies and proposed products. While the Company believes further application of its licensed Bioral cochleate technology to other drugs will result in license agreements with manufacturers of generic and over-the-counter drugs, the Company s plan of operations in the next 18 months is focused on further development of the Bioral cochleate technology itself. The Company also plans to develop the BEMA technology acquired in the acquisition of Arius for use in a limited number of applications. Such plans do not include the marketing, production or sale of FDA approved products.

Pursuant to the Accentia License Agreement, the Company licensed to Accentia its encochleation technology (Licensed Technology) for use in a topical version of encochleated Amphotericin B. During 2004, using the Licensed Technology, Accentia began the process of evaluating clinical applications of 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 Accentia License Agreement, the Company was 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. However, in September 2004, and in part to address the Company s liquidity, the Company consummated the sale to Accentia of an asset consisting of 50% of the royalty revenue stream under the Accentia License Agreement in consideration for an irrevocable, one-time, up-front payment in the amount of $2.5 million (See Note 4 above). As a result, the Company s royalties under the License Agreement will be reduced by fifty percent (50%).

On August 24, 2004, the Company acquired all of the capital stock of Arius. The transaction was structured as a reorganization of Arius with and into a newly formed, wholly-owned subsidiary of the Company. As part of the transaction, the Company issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of Series A Preferred, a newly designated, non-voting and non-interest bearing, series of convertible preferred stock. The Series A Preferred is convertible (upon the satisfaction of certain conditions) into shares of Common Stock on a one for one basis. The Series A Preferred is eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first product or (ii) five years from the closing date. The Series A Preferred enjoys certain other rights and privileges. In connection with the acquisition of Arius, the Company had an independent valuation of intangibles prepared in accordance with SFAS 141.

The assets acquired were as follows:

Fair value of Series A Convertible Preferred Stock	$ 3,705,883
Liabilities assumed	1,417,041
Acquisition costs	250,000
Fair value of assets acquired	5,372,924
Less cash	(57,675)
Fair value of assets to be allocated	5,315,249

Since May 2004, the Company has been operating under a limited waiver and forbearance agreement (the Forbearance Agreement) with Gold Bank, the Company s equipment lender. Gold Bank made a $1 million four-year term loan to the Company in April 2003 secured by the equipment in the Company s Newark facility. The Forbearance Agreement was required because the Company was out of compliance with the cash to total liabilities ratio covenant contained in the Gold Bank loan agreement. Pursuant to such the Forbearance Agreement, Gold Bank agreed, in consideration of a $10,000 fee payment from the Company, to waive compliance with the cash to liabilities covenant through June 30, 2004, which forbearance period was been extended to September 30, 2004 by the payment of subsequent $5,000 monthly payments.

However, in August 2004, Gold Bank indicated to the Company its belief that the acquisition of Arius and associated transactions required Gold Bank s consent. The Company believes that it has structured the acquisition with its counsel to be in compliance with the terms and conditions of the loan documentation relating only to the Company s acquisitions of complementary businesses and that Gold Bank s consent is not required with respect to an acquisition of this kind. In response to the Company s position, Gold Bank reviewed the publicly announced

proposed structure of the Arius acquisition and indicated that there may be other covenants that it will interpret to be in default as a result of the closing of the acquisition and that it has reserved its rights under the loan agreement. Gold Bank has also indicated to the Company its belief that its consent is required for the Company s now terminated debt facility with HCG (which facility was replaced by the Equity Line Agreement). The Company believes that the Equity Line Agreement does not require Gold Bank s consent.

The Gold Bank loan was been paid down to approximately $750,000 through September 30, 2004, at which time the Company arranged to further pay down the loan, in order to maintain its financial covenants with the bank as the Company seeks to refinance the loan with another lender. On October 15, 2004, the Company reduced the outstanding principal under the loan by 50%, or $375,000, and the Company is presently negotiating a $1 million equipment line of credit with a new lender. The Company has a signed term sheet from the new lender, and due diligence by the new lender is ongoing as of the date of this Report. The Company expects to close the loan in the fourth quarter of 2004, although no assurances can be given that the Company will be able to obtain such financing. Furthermore, no assurances can be given that Gold Bank will refrain from alleging other breaches of covenants and agreements contained in the loan documentation.

The Company believes that existing cash and investments (including cash generated from the Royalty Acquisition with Accentia, less a 5% royalty on such amount which the Company will pay to the universities who licensed the Company its cochleate technology), the $4 million equity line of credit, the expected equipment loan refinancing proceeds, and the proceeds from the recent exercise of director options will be sufficient to finance planned operations and capital expenditures through at least the next 12 months. The Company also may seek to pursue an equity financing in early to mid-2005. However, no assurances can be given that the Company will be able to obtain such financing on satisfactory terms or at all.

The Company may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, the Company 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, the Company may be required to significantly reduce or refocus its operations or to obtain funds through arrangements that may require the Company to relinquish rights to certain of its drugs, technologies or potential products and markets, either of which could have a material adverse effect on the Company s 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 the Company s 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. Company management has discussed the application of these critical accounting policies with the Company s Board of Directors and its Audit Committee.

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 Quarterly Report on Form 10-QSB under the Sections Management s Discussion and Analysis or Plan of Operation , Liquidity and management s plans 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, 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 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 answered the complaint, denying the material allegations asserted by plaintiff, and the Company believes that plaintiff s claims are without merit and intends to vigorously defend the lawsuit.

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

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

(a) Exhibits

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

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

(b) Reports on Form 8-K

On August 6, 2004, the Company filed a Current Report on Form 8-K regarding a credit facility entered into with Hopkins Capital Group II, LLC. This line of credit has been superseded by the Equity Line Agreement entered into on September 3, 2004.

On August 12, 2004, the Company filed a Current Report on Form 8-K regarding a definitive merger agreement entered into with Arius.

On August 26, 2004, the Company filed a Current Report on Form 8-K regarding the completion of its acquisition of Arius and certain matters relating to the Company s equipment lender.

On September 8, 2004, the Company filed a Current Report on Form 8-K regarding its entry into a material definitive agreement with Accentia regarding the sale of an asset consisting of a royalty revenue stream.

On September 8, 2004, the Company filed a Current Report on Form 8-K regarding its entry into a the Equity Line Agreement with Hopkins Capital Group II, LLC and certain matters relating to the Company s listing on the Nasdaq SmallCap Market.

On September 15, 2004, the Company filed a Current Report on Form 8-K regarding the appointment of three officers to the Company and resignation of Mr. James R. Butler from the Board of Directors due to a conflict of interest and appointment of Mr. L.M. Stephenson, an existing director to replace Mr. Butler on the Audit Committee.

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: November 12, 2004

By: /s/ FRANCIS E. O DONNELL, JR.
Francis E. O Donnell, Jr., President and

Chief Executive Officer

(Principal Executive Officer)

Date: November 12, 2004

By: /s/ JAMES A. MCNULTY
James A. McNulty, Secretary, Treasurer and

Chief Financial Officer

(Principal Financial Officer)