BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
May 17, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-QSB

(Mark One)

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

For the quarterly period ended March 31, 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)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

The Issuer had 7,085,863 shares of common stock issued and 6,985,863 shares of common stock outstanding as of May 14, 2004.

Transitional Small Business Disclosure Format (Check one): Yes ¨ No x

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NOTE ON FORWARD-LOOKING STATEMENTS

The information set forth in this Report on Form 10-QSB under the Sections Management s Discussion and Analysis or Plan of Operation , Management s plans regarding liquidity and capital resources and elsewhere relate to future events and expectations and as such constitute Forward-Looking Statement within the meaning of the Private Securities Litigation Act of 1995. The words believes, anticipates, plans, expec and similar expressions in this report are intended to identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors which may cause the actual results, performance or achievements of the Company to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include those detailed from time to time in the Company s filings with the Securities and Exchange Commission. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this report.

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BioDelivery Sciences International, Inc. and Subsidiary

Form 10-QSB

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See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF MARCH 31, 2004 AND DECEMBER 31, 2003

ASSETS

	March 31, 2004 (unaudited)	December 31, 2003
Current assets:		
Cash and cash equivalents	$ 287,467	$ 525,670
Investments	1,045,000	2,027,652
Accounts receivable	23,532	
Prepaid expenses and other current assets	260,293	222,490
Total current assets	1,616,292	2,775,812
Equipment, net	1,039,962	1,067,596
Licenses	468,166	477,641
Other assets, net	26,478	26,953
Total assets	$ 3,150,898	$ 4,348,002

LIABILITIES AND STOCKHOLDERS EQUITY

Current liabilities:		
Current maturities of note payable, bank	$ 246,813	$ 225,979
Accounts payable and accrued liabilities	202,620	158,148
Due to related parties		61,836
Deferred revenue		23,974
Capital lease obligation	3,556	4,742
Total current liabilities	452,989	474,679
Notes payable, bank	649,021	732,354
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 shares issued, 6,985,763 shares outstanding	7,086	7,086
Additional paid-in capital	14,139,228	14,106,366
Treasury stock, at cost, 100,000 shares	(303,894)	(303,894)
Accumulated deficit	(11,793,532)	(10,668,589)
Total stockholders equity	2,048,888	3,140,969

Total liabilities and stockholders equity	$ 3,150,898	$ 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 THREE MONTHS ENDED MARCH 31, 2004 AND 2003

(Unaudited)

	Three Months Ended March 31,	
	2004	**2003**
Sponsored research revenues	$ 271,312	$ 255,125
License fees		600,000
	271,312	855,125
Expenses:		
Research and development	699,115	643,495
General and administrative	670,069	814,020
Stock based compensation	32,862	
Total expenses	1,402,046	1,457,515
Interest income (expense), net	5,791	30,483
Loss before income taxes	(1,124,943)	(571,907)
Income tax benefit		
Net loss	($ 1,124,943)	($ 571,907)
Net loss per common share:		
Basic and diluted	($ 0.16)	($ 08)
Weighted average common stock shares outstanding basic and diluted	6,985,863	6,985,863

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STOCKHOLDERS EQUITY

FOR THE THREE MONTHS ENDED MARCH 31, 2004

(Unaudited)

	Preferred Stock		Common Stock		Treasury	Additional Paid-In	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	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						32,862		32,862
Net loss							(1,124,943)	(1,124,943)
Balance, March 31, 2004 (unaudited)			7,085,863	$ 7,086	($ 303,894)	$ 14,139,228	($ 11,793,532)	$ 2,048,888

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003

(Unaudited)

	Three Months Ended March 31,	
	2004	**2003**
Operating activities:		
Net loss	($ 1,124,943)	($ 571,907)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	80,658	71,638
Loss on sale of marketable securities	7,297	
Stock-based compensation	32,862	9,730
Changes in assets and liabilities:		
Accounts receivable	(23,532)	1,994,961
Prepaid expenses and other assets	(37,803)	(611)
Accounts payable and accrued liabilities	44,472	74,440
Deferred revenue	(23,974)	(566,875)
Net cash flows provided by (used in) operating activities	(1,044,963)	1,011,376
Investing activities:		
Purchase of equipment	(43,074)	(321,665)
Investments, net	975,355	(3,500,000)
Net cash flows provided by (used in) investing activities	932,281	(3,821,665)
Financing activities:		
Repayment of borrowings from related parties	(61,836)	(51,725)
Payment on notes and capital leases payable	(63,685)	(3,196)
Net cash flows provided by (used in) financing activities	(125,521)	(54,921)
Net change in cash and cash equivalents	(238,203)	(2,865,210)
Cash and cash equivalents at beginning of period	525,670	5,207,303
Cash and cash equivalents at end of period	$ 287,467	$ 2,342,093
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Non-cash investing and financing activities:		
Unrealized losses on marketable equity securities	$	$ 110,810

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003

(Unaudited)

	2004	2003
Net loss	($ 1,124,943)	($ 571,907)
Other comprehensive gain (loss):		
Unrealized gain (loss) on marketable equity securities		(110,810)
Comprehensive loss	($ 1,124,943)	($ 682,717)

Note: Accumulated comprehensive loss consists exclusively of unrealized losses on marketable equity securities.

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 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 March 31, 2004, and the condensed consolidated statements of operations for the three months ended March 31, 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 March 31, 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.

The results of operations for the three months ended March 31, 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, 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 THREE MONTHS ENDED MARCH 31, 2004 AND 2003 (Continued)

(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. BND is governed by a limited liability company operating agreement, dated January 8, 2003, as amended and restated. The agreement was executed by the Company as the holder of 708,586 of BND s Class A Membership Shares (which gives the Company the right to act as the sole managing member of BND) and 8,600,000 Class B Membership Shares (Class B Shares) and certain other individuals and entities (as the holders of an aggregate of 412,500 Class B Shares). The holders of such 412,500 Class B Shares are: Dr. Raphael Mannino (125,000 Class B Shares); Susan Gould-Fogerite, Ph.D. (75,000 Class B Shares); Donald L. Ferguson (75,000 Class B Shares); Ellenoff Grossman & Schole LLP (37,500 Class B Shares); James A. McNulty (20,000 Class B Shares); Susan G. Bonitz, Ph.D. (20,000 Class B Shares); Mauro Bove (20,000 Class B Shares); Christopher Chapman, M.D. (20,000 Class B Shares); and Samuel S. Duffey, Esq. (20,000 Class B Shares). These holders have no cost basis in their BND Class B Shares and no obligation to fund deficits; therefore, no minority interest has been recorded. All of these holders are either officers or directors of, or outside counsel to, the Company, BND or their affiliates.

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003 (Continued)

(Unaudited)

3. Subsidiary corporate structure (continued):

BND has filed a registration statement on Form SB-1 on behalf of BDSI. BDSI, as issuing security holder, intends initially to 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 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 March 31, 2004. Because the Company will receive no proceeds from the offering as these rights are distributed as dividends, offering costs aggregating $258,201 have been expensed in the accompanying statements of operations. Total offering costs are estimated to be $275,000.

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 nor from royalty payments but has generated revenues from licensing arrangements in 2003. The Company intends to continue to finance its research and development efforts and its working capital needs from existing cash, investments, new sources of financing and licensing agreements. The Company was granted approximately $2.7 million from the National Institutes of Health to fund specific research efforts conducted by the Company through June 2004, of which $2.3 million has been received through March 31, 2004.

We believe that our existing cash and investments, together with available financing and the net proceeds of the potential license agreements, both of which are currently under negotiation, will be sufficient to finance our planned operations and capital expenditures through at least the next 18 months. 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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003 (Continued)

(Unaudited)

sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

5. Licenses:

Licenses consist of the following:

	March 31, 2004	December 31, 2003
Licensing costs	$ 517,445	$ 517,445
Less accumulated amortization	(49,279)	(39,804)
	$ 468,166	$ 477,641

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

Year ending March 31,	
2005	$ 34,496
2006	34,496
2007	34,496
2008	34,496
2009	34,496
Thereafter	295,686
	$ 468,166

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003 (Continued)

(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,	
	2004	**2003**
Net loss (numerator)	($ 1,124,943)	($ 571,907)
Basic:		
Weighted average shares outstanding (denominator)	6,985,863	7,085,863
Net loss per common share basic	($ .16)	($ .08)
Diluted:		
Weighted average shares outstanding	6,985,863	7,085,863
Effect of dilutive securities		
Adjusted weighted average shares (denominator)	6,985,863	7,085,863
Net loss per common share diluted	($ .16)	($ .08)

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.

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003 (Continued)

(Unaudited)

7. Stock-based compensation (continued):

	March 31, 2004	March 31, 2003
Net loss, as reported	($ 1,124,943)	($ 571,907)
Stock-based compensation, as reported	$ 32,862	9,730
Stock-based compensation under fair value method	$ 53,228	111,339
Pro-forma net loss under fair value method	($ 1,145,309)	($ 673,516)
Net loss per share, as reported	($ .16)	($ .08)
Proforma net loss per share under fair value method	($ .16)	($ .10)

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, a 2002 grant of $814,000 and a 2001 grant of $884,000. Therefore, the Company expects to receive a total of approximately $2.7 million related to its initial application for the grant through June 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. If NIH believes that satisfactory progress is not achieved, the 2003 amount noted above may be reduced or eliminated. The Company incurred approximately $183,000 and $144,000 of costs related to this agreement for the three months ended March 31, 2004 and 2003, respectively.

During the three-month period ended March 31, 2004 and 2003, the Company received $247,000 and $222,000, respectively, and recognized revenue of $271,000 and $222,000, 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.

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I TEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Form 10-QSB. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company s actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Form 10-QSB.

For the Three Months Ended March 31, 2004 Compared to the Three Months Ended March 31, 2003

Sponsored Research Revenue. During the three-month period ended March 31, 2004, we reported $271,312 of sponsored research revenues from a grant from the National Institutes of Health. In the prior year, revenue aggregating $222,000 was derived from the grant and $33,125 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 $600,000 over the first three 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 $700,000 and $643,000 were incurred during the three-month periods ended March 31, 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 $670,000 and $814,000 were incurred in the three-month periods ended March 31, 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 $87,000 and $180,000 of expenses related to BND operating activities including offering costs during the quarters ended on March 31, 2004 and 2003 respectively. Stock-based costs of $33,000 in 2004 were associated with options issued during the period.

Interest Income (Expense). Interest income (expense) for the periods ended March 31, 2004 and 2003 was principally comprised of earnings from invested cash, offset by interest expense on the line of credit, notes payable and capital leases payable.

Income Taxes. While net operating losses were generated during the three month period ended March 31, 2004, we did not recognize any benefit associated with these losses, as all related

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deferred tax assets have been fully reserved. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Other comprehensive loss. Other comprehensive loss in 2004 and 2003 consists exclusively of unrealized losses on marketable equity securities held for sale. At March 2004 all marketable equity securities had been sold.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily from the sale of our securities and the initial licensing agreement signed in December, 2002 and funded the next month. From inception through March 31, 2004, we raised approximately $14.1 million, net of issuance costs, through securities issuances, with an additional $2.0 million in license agreement fees. At December 31, 2003, we had cash and investments totaling approximately $2.5 million. At March 31, 2004, we had approximately $1.3 million in cash and investments.

Working capital was approximately $1.2 million and $2.3 million at March 31, 2004 and December 31, 2003, respectively.

We have incurred significant net losses and negative cash flows from operations since our inception. As of March 31, 2004, we had an accumulated deficit of $11.8 million and total stockholders equity of approximately $2.0 million. At December 31, 2003, our accumulated deficit was $10.7 million and our stockholders equity was approximately $3.1 million.

We anticipate that cash used in operations will continue in the future as we research, develop, and, potentially, manufacture our drugs. While we believe further application of our licensed 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 and its use in a limited number of applications. Such plans do not include the marketing, production or sale of FDA approved products. In the event we sign additional licensing agreements, we expect the negotiated terms to include the costs of marketing, production, and sales to be borne by the licensee.

We believe that our existing cash and investments, together with available financing and the net proceeds of the potential license agreements, both of which are currently under negotiation, will be sufficient to finance our planned operations and capital expenditures through at least the next 18 months. 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;

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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 our recognition of revenue is the only critical judgment area in the application of our accounting policies that affects our financial condition and results of operations. We have discussed the application of this critical accounting policy with our Board of Directors and its Audit Committee.

Revenue recognition:

We recognize license fee revenue over the life of a license agreement. License fees are up-front payments for the initial license of and access to our technology. For nonrefundable license fees received at the initiation of license agreements for which we have an ongoing research and development commitment, we defer these fees and recognize 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, we recognize revenues upon delivery of the technology.

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I TEM 3. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Our management, with the participation of our Chief Executive Officer and Chief Financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) pursuant to Rule 13a-15(b) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-QSB. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable SEC rules and forms.

Changes in Internal Control Over Financial Reporting. There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-QSB that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings.

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. None.

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SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 17, 2004 By: /s/ Francis E. O Donnell, Jr.

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

Date: May 17, 2004 By: /s/ James A. McNulty

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