BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
May 16, 2003

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

FORM 10-QSB

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

For the quarterly period ended March 31, 2003

[ ] 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 7,085,863 shares of common stock issued and outstanding as of May 15, 2003.

BioDelivery Sciences International, Inc. and Subsidiary
Form 10-QSB

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
AS OF MARCH 31, 2003 AND DECEMBER 31, 2002

ASSETS

	March 31, 2003 (unaudited)	December 31, 2002
Current assets:		
Cash and cash equivalents	$ 2,342,093	$ 5,207,3
Marketable equity securities, available for sale	3,389,190	
Accounts receivable	5,039	2,000,0
Prepaid expenses and other assets	202,129	201,5
Total current assets	5,938,451	7,408,8

Equipment, net	694,188	435,0
Licenses	508,821	517,4
Other assets, net	28,379	28,8
Total assets	$ 7,169,839	$ 8,390,1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 612,450	$ 538,0
Due to related parties	-	51,7
Deferred revenue	1,433,125	2,000,0
Current maturities of capital lease payable	14,321	12,7
Total current liabilities	2,059,896	2,602,5
Capital lease payable, less current maturities	-	4,7
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 and 5,770,677 shares issued and outstanding in 2003 and 2002, respectively	7,086	7,0
Additional paid-in capital	13,966,057	13,956,3
Accumulated deficit	(8,752,390)	(8,180,4
Accumulated other comprehensive loss	(110,810)	
Total stockholders' equity	5,109,943	5,782,9
Total liabilities and stockholders' equity	$ 7,169,839	$ 8,390,1

The accompanying notes are an integral part of these financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(Unaudited)

	Three Months Ended March 31,	
	2003	2002
Sponsored research revenues	$ 255,125	$ 275,000
License fees	600,000	-

	855,125	275,000
Expenses:		
Research and development	643,495	450,475
General and administrative	814,020	205,768
Total expenses	1,457,515	656,243
Interest income (expense), net	30,483	(9,814)
Loss before income taxes	(571,907)	(391,057)
Income tax benefit	-	95,843
Net loss	($ 571,907)	($ 295,214)
Net loss per common share:		
Basic and diluted	($ .08)	($ .06)
Weighted average common stock shares outstanding - basic and diluted	7,085,863	5,000,863

The accompanying notes are an integral part of these financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS ENDED MARCH 31, 2003
(Unaudited)

	Preferred Stock		Common Stock		Additional	Accumu
	Shares	Amount	Shares	Amount	Paid-In Capital	Defi
Balance, December 31, 2002	-	$ -	7,085,863	$ 7,086	$ 13,956,327	($ 8,180
Issuance of common stock options	-	-	-	-	9,730	
Unrealized loss on marketable equity						

securities	-	-	-	-	-	
Net loss	-	-	-	-	-	(571
Balance, March 31, 2003 (unaudited)	-	$ -	7,085,863	$ 7,086	$ 13,966,057	($ 8,752

The accompanying notes are an integral part of these financial state

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(Unaudited)

	Three Months Ended March 31,	
	2003	2002
Operating activities:		
Net loss	($ 571,907)	($ 295,214)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	71,638	40,358
Stock-based compensation	9,730	-
Changes in assets and liabilities:		
Accounts receivable	1,994,961	-
Prepaid expenses and other assets	(611)	(135,869)
Other assets	-	(232,682)
Accounts payable and accrued liabilities	74,440	271,459
Deferred revenue	(566,875)	(37,000)
Net cash flows from operating activities	1,011,376	(388,948)
Investing activities:		
Purchase of equipment	(321,665)	-
Purchase of marketable equity securities	(3,500,000)	-
Net cash flows from investing activities	(3,821,665)	-
Financing activities:		
Issuance of Common Stock	-	336,205
(Payments on) borrowings from related parties	(51,725)	32,277
Payment on notes and capital leases payable	(3,196)	(55,047)
Net cash flows from financing activities	(54,921)	313,435

Net change in cash and cash equivalents	(2,865,210)	(75,513)
Cash and cash equivalents at beginning of period	5,207,303	75,513
Cash and cash equivalents at end of period	$ 2,342,093	$ -

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Non-cash investing and financing activities:

Unrealized losses on marketable equity securities	$ 110,810	$ -

The accompanying notes are an integral part of these financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(Unaudited)

	2003	2002
Net loss	($ 571,907)	($ 295,214)
Other comprehensive loss:		
Unrealized loss on marketable equity securities	(110,810)	-
Comprehensive loss	($ 682,717)	($ 295,214)

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

The accompanying notes are an integral part of these financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(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, 2003, and the condensed consolidated statements of operations for the three months ended March 31, 2003 and 2002 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, 2003 and for all periods presented, have been made. The condensed consolidated balance sheet at December 31, 2002, 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, 2002, included in the Company's 2002 Annual Report on Form 10-KSB filed with the SEC on March 28, 2003 ("2002 Annual Report").

The results of operations for the three months ended March 31, 2003, 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:

Marketable securities:

Marketable equity securities are recorded at fair value. Unrealized losses on these securities are recorded as other comprehensive income as a component of equity.

Revenue recognition:

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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(Unaudited)

3. Corporate structure:

On January 8, 2003, the Company formed Bioral Nutrient Delivery, LLC, a Delaware limited liability company ("BND") as a majority-owned subsidiary. The Company intends to grant to BND an exclusive worldwide perpetual sub-license to the Company's proprietary encochleation drug delivery technology for non-pharmaceutical use in the processed food and beverage industries for both human and animal consumption. BND is governed by a limited liability company operating agreement, dated January 8, 2003. The agreement was executed by the Company (as the managing member and a holder of 708,586 of BND's Class A Membership Shares, or Class A Shares, and

8,600,000 Class B Shares) and certain other individuals and entities (as the holders of an aggregate of 412,500 Class B Shares). These individuals have no cost basis in this subsidiary and no obligation to fund deficits, therefore, no minority interest has been recorded.

Upon the granting of the license, 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. BND will seek to commercialize the delivery technology through a combination of licensing programs to manufacturing, marketing and distribution companies within these industries.

In February 2003, BND filed a registration statement with the SEC to distribute as a dividend to the Company's stockholders an aggregate of 3,545,431 rights to purchase a corresponding number of Class B Membership Shares, which rights are exercisable for $0.01. Such registration statement has not been approved by the SEC as of the date of this report, is in the midst of the registration process and there can be no assurances given that the registration statement will be declared effective or that the distribution of rights will be effected.

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. For instance, 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 $1,475,972 has been received through March 31, 2003. It was also awarded a second NIH grant in August 2002, for $600,000 over 2 years.

In the first quarter of 2003, the Company received a commitment for a $1 million bank line of credit, to be converted to a four year term loan, with a 75% loan to value ratio, at an interest rate of 7.5%, to be used in the purchase of laboratory and other equipment and facilities improvements in the Newark lab. The collateral will be all equipment owned. The loan was closed in April, 2003 with an initial draw of $650,000, which covered expenditures in the fourth quarter of 2002 of approximately $325,000 and in the first quarter of 2003 of $322,000.

On June 24, 2002, the Securities and Exchange Commission declared effective the Company's Registration Statement on Form SB-2, Registration No. 333-72877. Commencing on June 25, 2002, and pursuant to such Registration

Statement, the Company conducted an offering consisting of 2,000,000 unitswith each unit consisting of (i) one share of common stock, par value $.001 per share, and (ii) one Class A common stock purchase warrant. Each warrant entitles the owner to purchase one share of Company common stock at a price of $6.30 for a period of four years commencing on June 24, 2003. Refer to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2002 for further detail relating to this offering.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(Unaudited)

5. Marketable equity securities:

Marketable equity securities consist of corporate fixed income bonds and money market fund shares. The Company's marketable securities have been classified as available-for-sale and are recorded at current market value with changes in the difference between market value and cost recorded as an adjustment to stockholders' equity. The investment in marketable securities was made in February 2003 and gross unrealized holding losses aggregated $110,810 at March 31, 2003. Interest income is recorded on the accrual basis. Dividends are recorded on the ex-dividend date.

6. Licenses:

Licenses consist of the following:

	March 31, 2003	December 31, 2002
Licensing costs	$ 517,445	$ 517,445
Less accumulated amortization	(8,624)	(-)
	$ 508,821	$ 517,445

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

Year ending March 31,	
2004	$ 34,496
2005	34,496
2006	34,496
2007	34,496
2008	34,496
Thereafter	336,341
	$ 508,821

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY

NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(Unaudited)

7. Net loss per common share:

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

	Three Months Ended March 31, 2003	Three Months Ended March 31, 2002
Net loss - (numerator)	($ 571,907)	($ 295,214)
Basic:		
Weighted average shares outstanding (denominator)	7,085,863	5,000,863
Net loss per common share - basic	($ .08)	($ .06)
Diluted:		
Weighted average shares outstanding	7,085,863	5,000,863
Effect of dilutive securities	-	-
Adjusted weighted average shares (denominator)	7,085,863	5,000,863
Net loss per common share - diluted	($ .08)	($ .06)

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

8. Stock-based compensation:

The Company accounts for compensation costs associated with stock options issued to employees under the provisions of Accounting Principles Board Opinion No. 25 ("APB 25") whereby compensation is recognized to the extent the market price of the underlying stock at the date of grant exceeds the exercise price of the option granted. Stock-based compensation to non-employees is accounted for using the fair-value based method prescribed by Financial Accounting Standard No. 123 ("FAS 123").

During the three months ended March 31, 2003, the Company issued 60,000 shares of common stock options to an employee as compensation for services. In accordance with APB 23, there was no stock-based compensation expense recognized in conjunction with these common stock options. These options fully vested upon issuance but are subject to stockholder approval.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(Unaudited)

8. Stock-based compensation (continued):

During the three months ended March 31, 2003, the Company issued 45,000 shares of common stock options to a consultant and an aggregate 20,000 shares of common stock options to two members of the Company's Scientific Advisory Board as compensation for services. The common stock options, which vest over three years, were valued based upon the trading market prices on the dates of issuance, or $61,443 and $13,914, respectively.

The Company used the Black-Scholes options-pricing model to determine the fair value of each option grant as of the date of grant for consulting expense incurred and for the or the purpose of the following pro forma presentation. The following assumptions were used for grants in 2003: No dividend yield, expected volatility of 73%; risk-free interest rates of 2.62% and 3.62% and expected lives of 10 years. The share price on the date of grant for the 2003 grants range between $1.85 and $2.18 and the exercise price of the grants range between $1.63 and $5.50.

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.

	March 31, 2003	March 31, 2002
Net loss, as reported	($ 571,907)	($ 295,21
Stock-based compensation, as reported	$ 9,730	
Stock-based compensation under fair value method	$ 76,566	
Pro-forma net loss under fair value method	($ 648,473)	($ 295,21
Net loss per share, as reported	($ .08)	($ .0
Proforma net loss per share under fair value method	($ .09)	($ .0

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2003 AND 2002
(Unaudited)

9. 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 2002 grant of $814,398 and a 2001 grant of $883,972. Additionally, this award refers to funding levels of $989,352 that the Company expects to be awarded in 2003, subject to availability and satisfactory progress of the project. 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. However, due to the expected purchase of certain materials from sources outside the United States, the expected funding was accordingly 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 $126,000 and $260,000 of costs related to this agreement for the three months ended March 31, 2003 and 2002, respectively.

During the three-month period ended March 31, 2003 and 2002, the Company received $222,000 and $148,000, respectively, and recognized revenue of $222,000 and $259,000, 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.

In addition, in August of 2002, the NIH awarded a second grant for $600,000 over two years. The second grant is expected to begin funding in the second quarter of 2003.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY

ITEM 2. Management's Discussion and Analysis of Financial Condition and Plan of Operations

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

For the Three Months Ended March 31, 2003 Compared to the Three Months Ended March 31, 2002

Sponsored Research Revenue. During the three-month period ended March 31, 2003, we reported $255,125 of sponsored research revenues. Of this amount , $222,000 was from a grant from the National Institutes of Health, and $33,125 was from a collaborative research agreement. In the prior year, all revenue aggregating $275,000 was derived from the grant.

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 has deferred the revenue and will recognize it over the period of the related research and development commitment. The agreement also provides for milestone payments.

Research and Development. Research and development expenses of approximately $643,000 and $450,000 were incurred during the three-month periods ended March 31, 2003 and 2002, 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(TM) cochleate drug delivery technology.

General and Administrative Expense. General and administrative expenses of approximately $814,000 and $206,000 were incurred in the three-month periods ended March 31, 2003 and 2002, 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, 2003 expenses include approximately $180,000 related to BND operating activities that commenced in 2003.

Interest Income (Expense). Interest income (expense) for the periods ended March 31, 2003 and 2002 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, 2003, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. However, in March 2002, a new tax law changed the carryback period from two to five years, which allowed us to carryback prior losses to 1996 and 1997, resulting in a tax benefit of $95,843 in 2002. 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 consists exclusively of unrealized losses on marketable equity securities held for sale. These securities were purchased in the first quarter of 2003.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily from the sale of our securities. From inception through March 31, 2003, we raised approximately $10.4 million, net of issuance costs, through these issuances. At December 31, 2002, we had cash and cash equivalents totaling approximately $5,200,000. At March 31, 2003, we had $5,731,000 cash and cash equivalents. The operations of BioDelivery Sciences, Inc., prior to our acquisition of a controlling interest on October 10, 2000, were financed primarily through funded research agreements. In 2001, the National Institutes of Health awarded to us a three-year Small Business Innovation Research Grant (SBIR), to be utilized in our research and development efforts.

The NIH award consisted of a 2001 grant of $883,972 (of which we recognized approximately 50% in 2001 and the remainder in 2002) and a 2002 grant of $814,398 (of which $370,000 was recognized in 2002, with the balance to be recognized through June 30, 2003). Additionally, this award refers to funding levels of $989,000 we expect to be awarded in 2003, subject to availability and satisfactory progress of the project. We expect to receive a total of approximately $2.7 million related to all NIH grants through June 2004. The grants are 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.

In the first quarter of 2003, we received a commitment for a $1 million bank line of credit, to be converted to a four year term loan, with a 75% loan to value ratio, at an interest rate of 7.5%, to be used in the purchase of laboratory and other equipment and facilities improvements in our Newark lab. The collateral will be all equipment owned by us. The loan was closed in April, 2003 with an initial draw of $650,000,

which covered our expenditures in the fourth quarter of 2002 of approximately $325,000 and in the first quarter of 2003 of $322,000.

Working capital was $3,879,000 and $3,878,555 at March 31, 2003 and December 31, 2002, respectively. At March 31, 2002, the working capital deficit was $1,698,000.

From our inception through March 31, 2003, we have incurred approximately $4.2 million of research and development expenses. Additionally, during the period March 28, 1995 (date of BioDelivery Sciences, Inc.'s incorporation) through the acquisition of a controlling interest in BioDelivery Sciences, Inc., we incurred approximately $6.8 million of research and development expenses.

We have incurred significant net losses and negative cash flows from operations since our inception. As of March 31, 2003, we had an accumulated deficit of $8.7 million and total stockholders' equity of $5.1 million. At March 31, 2002, our accumulated deficit was $5.4 million and our stockholders' deficit was approximately $500,000.

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 (TM) 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(TM) 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.

We believe that our existing cash and cash equivalents, together with available equipment financing and the net proceeds of the pending offering will be sufficient to finance our planned operations and capital expenditures through at least the next 12 to 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 sale of equity or

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

During June 2002, our existing line-of-credit terminated and the balance was repaid from the proceeds of our common stock offering.

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.

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.

Prior its dismissal on April 18, 2003, the Company's former independent auditor, Grant Thornton LLP ("GT"), has advised the Audit Committee of the Company's board of directors and the Company's management that GT noted a lack of segregation of accounting and financial reporting duties as a result of the Company's small size, which condition GT considered to be reportable under standards established by the American Institute of Certified Public Accountants. The Company believes this matter is not reportable under Regulation S-B since, among other factors, the noted issue did not preclude the Company from developing reliable financial statements as contemplated by Item 304(a)(1)(iv)(B)(1) of Regulation S-B. In its Current Report on Form 8-K, dated April 25, 2003, wherein the Company announced the dismissal of GT, the Company voluntarily made the disclosure of GT's notations as an accommodation to its former independent auditor. The Company has taken GT's notation under advisement but believes its internal accounting controls are sufficient in order to allow the Company to develop reliable financial statements. The Company will continue to monitor and assess the costs and benefits of additional staffing in the accounting area in conjunction with its newly appointed independent accountants.

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," "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.

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
99.1	Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 Of The Sarbanes-Oxley Act Of 2002(*)
99.2	Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 Of The Sarbanes-Oxley Act Of 2002(*)

* 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 April 25, 2003, the Company filed a report on Form 8-K regarding a change in the Company's certifying accountants.

On April 1, 2003, the Company filed a report on Form 8-K regarding its Annual Report on Form 10-K and certain matters contained therein.

On February 26, 2003, the Company filed a report on Form 8-K regarding the formation of its subsidiary, Bioral Nutrient Delivery, LLC

On January 7, 2003, the Company filed a report on Form 8-K regarding its license agreement with Pharmaceutical Product Development, Inc.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY

SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 15, 2003 By: /s/ Francis E. O'Donnell, Jr.

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

Date: May 15, 2003 By: /s/ James A. McNulty

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

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CERTIFICATION

I, Francis E. O'Donnell, Jr., certify that:

1. I have reviewed this quarterly report on Form 10-QSB of BioDelivery Sciences International, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The Registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and I have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others, particularly during the period in which this quarterly report is being prepared;
(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The Registrant's other certifying officer and I have disclosed, based on my most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors;

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The Registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/s/ Francis E. O'Donnell, Jr.

Francis E. O'Donnell, Jr.
President and Chief Executive Officer

CERTIFICATION

I, James A. McNulty, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of BioDelivery Sciences International, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and I have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others, particularly during the period in which this quarterly report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. I have disclosed, based on my most recent evaluation, to the registrant's

auditors and the audit committee of registrant's board of directors;

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/s/ James A. McNulty

James A. McNulty

Secretary, Treasurer and Chief Financial Officer