BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
August 14, 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 June 30, 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 6,985,863 shares of common stock outstanding as of June 30, 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 JUNE 30, 2003 AND DECEMBER 31, 2002

ASSETS

	June 30, 2003 (unaudited)	December 31, 2002
Current assets:		
Cash and cash equivalents	$ 2,522,872	$ 5,207,303
Marketable equity securities, available for sale	549,025	--
Investments	1,923,437	--
Accounts receivable	--	2,000,000
Prepaid expenses and other current assets	114,460	201,518
Total current assets	5,109,794	7,408,821

Equipment, net	731,562	435,061
Licenses	500,197	517,445
Other assets, net	27,904	28,855
Total assets	$ 6,369,457	$ 8,390,182
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current maturities of note payable, bank	$ 95,925	$ --
Accounts payable and accrued liabilities	288,016	538,010
Due to related parties	--	51,725
Deferred revenue	800,000	2,000,000
Current maturities of capital lease obligation	11,128	12,775
Total current liabilities	1,195,069	2,602,510
Capital lease obligation, less current maturities	--	4,742
Note payable, bank, less current maturities	558,370	--
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; 6,985,863 and 7,085,863 outstanding in 2003 and 2002, respectively	7,086	7,086
Additional paid-in capital	13,979,549	13,956,327
Treasury stock, at cost, 100,000 shares	(303,894)	--
Accumulated deficit	(9,059,520)	(8,180,483)
Accumulated other comprehensive loss	(7,203)	--
Total stockholders' equity	4,616,018	5,782,930
Total liabilities and stockholders' equity	$ 6,369,457	$ 8,390,182

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

	Three Months Ended June 30,	Six Months Ended June 30,

	2003	2002	2003	2002
Sponsored research revenues	$ 255,000	$ 182,972	$ 510,250	$ 457,972
License fees, related party	600,000	--	1,200,000	--
	855,125	182,972	1,710,250	457,972
Expenses:				
Research and development	642,672	459,078	1,286,167	909,553
General and administrative	543,577	195,038	1,357,597	400,806
Total expenses	1,186,249	654,116	2,643,764	1,310,359
Interest income (expense), net	23,994	(25,949)	54,477	(35,763)
Loss before income taxes	(307,130)	(497,093)	(879,037)	(888,150)
Income tax benefit (expense)	--	(40,879)	--	54,964
Net loss	$ (307,130)	$ (537,972)	$ (879,037)	$ (833,186)
Net loss per common share:				
Basic and diluted	$ (0.04)	$ (0.11)	$ (0.12)	$ (0.17)
Weighted average common stock shares outstanding - basic and diluted	7,010,566	5,066,796	7,048,007	5,034,011

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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STOCKHOLDERS' EQUITY
FOR THE SIX MONTHS ENDED JUNE 30, 2003
(Unaudited)

Preferred Stock		Common Stock		Additional		
				Paid-In	Treasury	A
Shares	Amount	Shares	Amount	Capital	Stock	

Balance at December 31, 2002	--	$ --	7,085,863	$ 7,086	$13,956,327	$ --	$
Issuance of common stock options	--	--	--	--	23,222	--	
Unrealized loss on marketable equity securities	--	--	--	--	--	--	
Repurchase of treasury stock	--	--	--	--	--	(303,894)	
Net loss	--	--	--	--	--	--	
Balance at June 30, 2003	--	$ --	7,085,863	$ 7,086	$13,979,549	$ (303,894)	$

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 SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002
Operating activities:		
Net loss	$ (879,037)	$ (833,186)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	83,696	60,137
Stock-based compensation	23,222	--
Changes in assets and liabilities:		
Accounts receivable	2,000,000	--
Prepaid expenses and other current assets	87,058	(405,516)
Accounts payable and accrued liabilities	(249,994)	548,802
Deferred revenue	(1,200,000)	(37,000)

Net cash flows from operating activities	(135,055)	(617,209)
Investing activities:		
Purchase of equipment	(361,998)	(608)
Net purchase of marketable equity securities and investments	(2,479,665)	--
Net cash flows from investing activities	(2,841,663)	(608)
Financing activities:		
Issuance of common stock	--	8,647,933
Net change in short-term borrowings	654,295	(282,527)
Repurchase of treasury stock	(303,894)	--
(Payments on) borrowings from related parties	(51,725)	49,554
Payment on notes and capital leases payable	(6,389)	(104,611)
Net cash flows from financing activities	292,287	8,260,795
Net change in cash and cash equivalents	(2,684,431)	7,642,978
Cash and cash equivalents at beginning of period	5,207,303	75,513
Cash and cash equivalents at end of period	$ 2,522,872	$ 7,718,491

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Non-cash investing and financing activities:		
Unrealized losses on marketable equity securities	$ (7,203)	$ --
Net loss	($ 879,037)	$ (833,186)
Other comprehensive loss:		
Unrealized loss on marketable equity securities	(7,203)	--
Comprehensive loss	$ (886,240)	$ (833,186)

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 SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheets of BioDelivery Sciences

International, Inc. and its wholly-owned subsidiary, Bioral Nutrient Delivery, LLC (collectively the "Company") as of June 30, 2003, and the condensed consolidated statements of operations for the three and six months ended June 30, 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 June 30, 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 and six months ended June 30, 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 wholly-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 loss as a component of equity. Proceeds and gross realized losses from the sale of these securities was $3,498,314 and ($1,685), respectively, for the six months ended June 30, 2003.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

2. Summary of significant accounting policies (continued):

Investments:

Investments consist of certificates of deposit with an original maturity in excess of 3 months and are recorded at cost plus interest thereon.

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.

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 revenue 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.

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.

2. Summary of significant accounting policies (continued):

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

	June 30, 2003	June 30, 2002
Net loss, as reported	$ (879,037)	$ (833,186)
Stock-based compensation, as reported	$ 23,222	-
Stock-based compensation under fair value method	$ 99,788	-
Pro-forma net loss under fair value method	$ (955,603)	$ (833,186)

Net loss per share, as reported	$ (0.12)	$ (0.17)
Pro-forma net loss per share under fair value method	$ (0.13)	$ (0.17)

Recent accounting pronouncements:

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. The statement amends and clarifies accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and hedging activities. This statement is designed to improve financial reporting such that contracts with comparable characteristics are accounted for similarly. The statement, which is generally effective for contracts entered into or modified after June 30, 2003, is not anticipated to have a significant effect on the Company's financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the first interim period beginning after June 15, 2003. The Company currently has no such financial instruments outstanding or under consideration and therefore adoption of this standard currently has no financial reporting implications.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

2. Summary of significant accounting policies (continued):

Recent accounting pronouncements (continued):

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Valuable Interest Entities. This interpretation clarifies rules relating to consolidation where entities are controlled by means other than a majority voting interest and instances in which equity investors do not bear the residual economic risks. This interpretation is effective immediately for variable interest entities created after January 31, 2003 and for interim periods beginning after June 15, 2003 for interests acquired prior to February 1, 2003. The Company currently has no ownership in variable interest entities and therefore adoption of this standard currently has no financial reporting implications.

3. Subsidiary corporate structure:

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

3. Subsidiary corporate structure (continued):

BND has filed a registration statement on Form SB-2 on behalf of BDSI. BDSI, as selling security holder, intends initially to distribute as a dividend to its current and future stockholders rights to purchase an aggregate of 11,277,000 of the Company's Class B Membership Shares. Such rights to purchase such amount of Class B Shares are referred to herein as the "Rights."

Neither the Rights nor equity interests (including the Class B Shares which will be received upon the exercise of the Rights) are or will be listed on any exchange and will not be publicly-traded securities. No such rights have been distributed by BDSI to its stockholders as of June 30, 2003.

Because the Company will receive no proceeds from the offering as these rights are distributed as dividends, offering costs aggregating $148,039 have been expensed in the accompanying statement of operations. Total offering costs are estimated to be $225,000.

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, some of 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, exercise of rights to purchase interests in its subsidiary 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 $1.9 million has been received through June 30, 2003, and the balance of $800,000, which has been approved for funding through August 2004. It was also awarded a second NIH grant in August 2002, for $600,000 over 2 years.

In the second quarter of 2003, the Company closed a $1 million, four year bank 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. The loan was fully funded in July 2003.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

4. Liquidity and management's plans :

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 units with 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. No warrants have been exercised as of June 30, 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.

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 $7,203 at June 30, 2003. Interest income is recorded on the accrual basis. Dividends are recorded on the ex-dividend date.

6. Licenses:

Licenses consist of the following:

	June 30, 2003	December 31, 2002
Licensing costs	$ 517,445	$ 517,445
Less accumulated amortization	(17,248)	-
	$ 500,197	$ 517,445

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

6. Licenses (continued):

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

Year ending June 30,	
2004	$ 34,496
2005	34,496
2006	34,496
2007	34,496
2008	34,496
Thereafter	327,717
	$ 500,197

7. Note payable, bank:

Note payable, bank consists of borrowings under a $1,000,000 four year team loan with interest only payable monthly at 7.50% through October 2003 and interest and principal payable monthly from November 2003 through October 2007. Borrowings on the line of credit are limited to the sum of 75% of the loan to cost/value of all equipment of the Company. The note is secured by all equipment of the Company.

The loan of credit agreement contains various restrictive covenants, including a minimum cash-to-liability ratio. The Company was in compliance with these covenants as of June 30, 2003.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

8. Net loss per common share:

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

	Three Months Ended June 30,		Six Months E June 30,	
	2003	2002	2003	

Net loss - (numerator)	$ (307,130)	$ (537,972)	$ (879,037)	$
Basic:				
Weighted average shares outstanding (denominator)	7,010,566	5,066,796	7,048,007	5
Net loss per common share - basic	$ (0.04)	$ (0.11)	$ (0.12)	$
Diluted:				
Weighted average shares outstanding	7,010,566	5,066,796	7,048,007	5
Effect of dilutive securities	--	--	--	
Adjusted weighted average shares (denominator)	7,010,566	5,066,796	7,048,007	5
Net loss per common share - diluted	$ (0.04)	$ (0.11)	$ (0.12)	$

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

9. 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").

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRY
NOTES TO CONDENSED CONSOLIDATED STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2003 AND 2002
(Unaudited)

9. Stock-based compensation (continued):

During the six months ended June 30, 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.

During the six months ended June 30, 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 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.

10. Treasury stock:

During the second quarter of 2003, the Company, as authorized by the Board of Directors, repurchased 100,000 shares of the Company's common stock with a per share price between $2.80 and $3.20 for a total cost of $303,894.

11. 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 formally awarded the Company a 2003 grant of $989,352, a 2002 grant of $814,398 and a 2001 grant of $883,972. 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.

11. National Institutes of Health Grant (continued):

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 $279,000 and $458,000 of costs related to this agreement for the six months ended June 30, 2003 and 2002, respectively.

During the six month period ended June 30, 2003 and 2002, the Company received $444,000 and $189,000, respectively, and recognized revenue of $444,000 and $442,000, respectively, from this grant. 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 fourth quarter of 2003.

12. Related party transactions:

The Company entered into a licensing agreement with a company that is also a shareholder. The agreement included an up-front non-refundable payment of $2 million in license fee revenue, which the Company deferred and is recognizing monthly from January through October 2003 (the period of the related research and development commitment). The agreement also provides for milestone payments. During the six months ended June 30, 2003, the Company recognized $1,200,000 in license fee revenue from this related party.

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

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

For the Six Months Ended June 30, 2003 Compared to the Six Months Ended June 30, 2002

Sponsored Research Revenue. During the six-month period ended June 30, 2003, we reported $510,250 of sponsored research revenues. Of this amount, $444,000 was from a grant from the National Institutes of Health, and $56,250 was from a collaborative research agreement. In the prior year, all revenue aggregating $457,972 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 is recognizing it over the period of the related research and development commitment ($1,200,000 for the six months ended June 30, 2003). The agreement also provides for milestone payments.

Research and Development. Research and development expenses of approximately $1,286,000 and $910,000 were incurred during the six-month periods ended June 30, 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 $1,358,000 and $401,000 were incurred in the six-month periods ended June 30, 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 $260,000 related to BND operating activities that commenced in 2003, $148,000 of which related to offering costs associated with a registration statement.

Interest Income (Expense). Interest income (expense) for the periods ended June 30, 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 six month period ended June 30, 2003, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Other comprehensive loss Other comprehensive loss consists exclusively of unrealized losses on marketable equity securities classified as available 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 June 30, 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 June 30, 2003, we had $4,995,000 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 recognized through June 30, 2003). Additionally, the Company was awarded $989,000 as the final year segment of the three year SBIR award. 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 April 2003, we entered into a $1 million bank line of credit agreement, which will 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, New Jersey lab. The collateral is all equipment owned by us. The initial draw of $650,000 covered our expenditures in the fourth quarter of 2002 of approximately $325,000 and in the first quarter of 2003 of $322,000. The balance was funded in July 2003.

Working capital was $3.9 million and $4.8 million at June 30, 2003 and December 31, 2002, respectively. At June 30, 2002, the working capital was $6.6 million.

From our inception through June 30, 2003, we have incurred approximately $4.8 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. in October 2000, 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 June 30, 2003, we had an accumulated deficit of $9.1 million and total stockholders' equity of $4.6 million. At June 30, 2002, our accumulated deficit was $6.0 million and our stockholders' deficit was approximately $7.2 million.

We anticipate that cash used in operations and our investment in facilities will continue in the future as we research, develop, and, potentially, manufacture our drugs. While we believe further application of our Bioral (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 financing will be sufficient to finance our planned operations and capital expenditures through at least the next 18 to 24 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
- Sale of rights to BND, LLC

There can be no assurance that additional capital will be available on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our drugs, technologies or potential markets, either of which could have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. We believe that the following are some of the more critical judgment areas in the application of our accounting policies that affect our financial condition and results of operations. We have discussed the application of these critical accounting policies with our Board of Directors and its Audit Committee.

Revenue recognition:

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.

Non-refundable license fees are generally 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 revenue 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.

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.

Had compensation cost for the Company's stock option plan been determined on the fair value at the grant dates for stock-based employee compensation arrangements consistent with the method required by SFAS 123, the Company's net loss and net loss per common share would have been the pro forma amounts indicated in Note 2 to the financial statements.

Recent accounting pronouncements:

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. The statement amends and clarifies accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and hedging activities. This statement is designed to improve financial reporting such that contracts with comparable characteristics are accounted for similarly. The statement, which is generally effective for contracts entered into or modified after June 30, 2003, is not anticipated to have a significant effect on the Company's financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the first interim period beginning after June 15, 2003. The Company currently has no such financial instruments outstanding or under consideration and therefore adoption of this standard currently has no financial reporting implications.

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Valuable Interest Entities. This interpretation clarifies rules relating to consolidation where entities are controlled by means other than a majority voting interest and instances in which equity investors do not bear the residual economic risks. This interpretation is effective immediately for variable interest entities created after January 31, 2003 and for interim periods beginning after June 15, 2003 for interests acquired prior to February 1, 2003. The Company currently has no ownership in variable interest entities and therefore adoption of this standard currently has no financial reporting implications.

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ITEM 3. Controls and Procedures

The Company's Chief Executive Officer and Chief Financial Officer (collectively, the "Certifying Officers") are responsible for establishing and maintaining disclosure controls and procedures for the Company. Such officers have concluded (based on their evaluation of these controls and procedures as of the end of the period covered by 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.

Prior to its dismissal on April 18, 2003, the Company's former independent auditor, Grant Thornton LLP ("GT"), 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, as amended July 3, 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 and has authorized GT to respond fully to the inquiries of these accountants concerning this matter.

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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," "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.

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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

On July 3, 2003, the Company filed an amended 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.

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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: August 14, 2003

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

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

Date: August 14, 2003

By: /s/ James A. McNulty

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

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