

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 10QSB

BIODELIVERY SCIENCES INTERNATIONAL INC  
Form 10QSB  
August 15, 2002

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

Form 10-QSB

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

For the quarterly period ended June 30, 2002

OR

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.

(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 I.D. No.)

University of Medicine and Dentistry  
New Jersey Medical School  
Administrative Bldg 4  
185 South Orange Avenue  
Newark, NJ 07103  
(Address of Principal Executive Offices) (Zip Code)

(973) 972-0015  
(Registrant's telephone number)

Indicate by check mark whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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  No

The Issuer had 7,000,863 shares of common stock issued and outstanding as of August 8, 2002.

BioDelivery Sciences International, Inc.  
Form 10-QSB

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PART I. FINANCIAL INFORMATION

Item 1. - Financial Statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
(A Development Stage Company)

Condensed Consolidated Balance Sheets - (Unaudited)

|  | June 30,<br>2002 | December 31,<br>2001 |
|--|------------------|----------------------|
|  | -----            | -----                |
| ASSETS   |                  |                      |
| CURRENT ASSETS:                                      |                  |                      |
| Cash and cash equivalents                            | \$ 7,718,491     | \$ 75,513            |
| Grant receivable, prepaid expenses and other assets  | 501,727          | 111,684              |
|  | -----            | -----                |
| Total current assets                                 | 8,220,218        | 187,197              |
| EQUIPMENT, net                                       | 175,433          | 233,562              |
| INTANGIBLES, net                                     | 561,543          | 547,470              |
| DEFERRED OFFERING COSTS                              | --               | 365,340              |
|  | -----            | -----                |
| Total Assets   | \$ 8,957,194     | \$ 1,333,569         |
|  | =====            | =====                |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)       |                  |                      |
| CURRENT LIABILITIES:                                 |                  |                      |
| Accounts payable and accrued liabilities             | \$ 1,363,081     | \$ 814,279           |
| Due to related parties                               | 123,885          | 74,331               |
| Line of credit                                       | --               | 282,527              |
| Deferred revenue                                     | --               | 37,000               |
| Current portion of capital lease payable             | 11,776           | 14,804               |
| Current portion of notes payable                     | 99,733           | 149,524              |
|  | -----            | -----                |
| Total current liabilities                            | 1,598,475        | 1,372,465            |
| CAPITAL LEASE PAYABLE, less current portion          | 17,196           | 18,369               |
| NOTES PAYABLE, less current portion                  | 101,114          | 151,733              |
| COMMITMENTS AND CONTINGENCIES                        | --               | --                   |
| STOCKHOLDERS' EQUITY (DEFICIT):                      |                  |                      |
| Preferred stock                                      | --               | --                   |
| Common stock   | 7,001            | 5,001                |
| Additional paid-in capital                           | 13,183,961       | 4,903,368            |
| Deficit accumulated during development stage         | (5,950,553)      | (5,117,367)          |
|  | -----            | -----                |
| Total stockholders' equity (deficit)                 | 7,240,409        | (208,998)            |
|  | -----            | -----                |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | \$ 8,957,194     | \$ 1,333,569         |
|  | =====            | =====                |

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
(A Development Stage Company)

Condensed Consolidated Statements of Operations - (Unaudited)

|  | Three Months Ended<br>June 30, |                | Six Months Ended<br>June 30, |                |
|--|--------------------------------|----------------|------------------------------|----------------|
|  | 2002                           | 2001           | 2002                         | 2001           |
| Sponsored research revenues  | \$ 182,972                     | \$ 27,785      | \$ 457,972                   | \$ 27,785      |
| Expenses:  |                                |                |                              |                |
| Research and development   | 459,078                        | 422,690        | 909,553                      | 754,173        |
| General and administrative   | 195,038                        | 621,018        | 400,806                      | 695,412        |
| Total expenses   | 654,116                        | 1,043,708      | 1,310,359                    | 1,449,585      |
| Interest income (expense), net   | (25,949)                       | 2,154          | (35,763)                     | 15,560         |
| Loss before income taxes and<br>minority interest                          | (497,093)                      | (1,013,769)    | (888,150)                    | (1,406,240)    |
| Income tax benefit (expense)   | (40,879)                       | --             | 54,964                       | --             |
| Loss before minority interest  | (537,972)                      | (1,013,769)    | (833,186)                    | (1,406,240)    |
| Minority interest in net loss of<br>subsidiary                             | --                             | --             | --                           | --             |
| Net loss   | \$ (537,972)                   | \$ (1,013,769) | \$ (833,186)                 | \$ (1,406,240) |
| Net loss per common share:   |                                |                |                              |                |
| Basic and diluted  | \$ (0.11)                      | \$ (0.27)      | \$ (0.17)                    | \$ (0.39)      |
| Weighted average common stock<br>shares outstanding - basic<br>and diluted | 5,066,796                      | 3,749,214      | 5,034,011                    | 3,634,335      |

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.  
(A Development Stage Company)

Condensed Consolidated Statement of Stockholders' Equity (Defici

|                                    | Preferred Stock |        | Common Stock |          | Addition<br>Paid-I<br>Capita |
|------------------------------------|-----------------|--------|--------------|----------|------------------------------|
|                                    | Shares          | Amount | Shares       | Amount   |                              |
| BALANCE, DECEMBER 31, 2001         | --              | \$ --  | 5,000,863    | \$ 5,001 | \$ 4,903                     |
| Shares issued for cash (unaudited) | --              | --     | 2,000,000    | 2,000    | 8,280                        |
| Net loss (unaudited)               | --              | --     | --           | --       | --                           |
| BALANCE, JUNE 30, 2002 (unaudited) | --              | \$ --  | 7,000,863    | \$ 7,001 | \$13,183                     |

The accompanying notes are an integral part of this financial statement

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
(A Development Stage Company)

Condensed Consolidated Statements of Cash Flows (Unaudited)

|  | Six Months Ended<br>June 30, |                |    |
|--|------------------------------|----------------|----|
|  | 2002                         | 2001           |    |
| OPERATING ACTIVITIES:  |                              |                |    |
| Net loss   | \$ (833,186)                 | \$ (1,406,240) | \$ |
| Adjustments to reconcile net loss to net cash used in<br>operating activities: |                              |                |    |
| Depreciation and amortization  | 60,137                       | 46,941         |    |
| Loss applicable to minority interest   | --                           | --             |    |

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|  |              |             |
|--|--------------|-------------|
| Deferred revenue                                     | (37,000)     | --          |
| Litigation settlement                                | --           | 300,000     |
| Compensation expense                                 | --           | --          |
| Changes in assets and liabilities:                   |              |             |
| Grants receivable, prepaid expenses and other assets | (405,516)    | (24,319)    |
| Accounts payable and accrued liabilities             | 548,802      | (99,041)    |
| Due to/from related parties                          | 49,554       | 18,796      |
|  | -----        | -----       |
| Net cash used by operating activities                | (617,209)    | (1,163,863) |
| INVESTING ACTIVITIES:                                |              |             |
| Net cash received with business combination          | --           | --          |
| Purchase of equipment                                | (608)        | --          |
| Purchase of minority interest                        | --           | (116,375)   |
|  | -----        | -----       |
| Net cash provided (used) by investing activities     | (608)        | (116,375)   |
| FINANCING ACTIVITIES:                                |              |             |
| Issuance of Preferred Stock                          | --           | --          |
| Issuance of Common Stock, net of issuance costs      | 8,647,933    | 500,000     |
| Net change in line of credit                         | (282,527)    | --          |
| Payment on capital lease payable                     | (4,201)      | (6,506)     |
| Payment on notes payable                             | (100,410)    | (34,698)    |
|  | -----        | -----       |
| Net cash provided by financing activities            | 8,260,795    | 458,796     |
| NET CHANGE IN CASH                                   | 7,642,978    | (821,442)   |
| CASH AT BEGINNING OF PERIOD                          | 75,513       | 950,939     |
|  | -----        | -----       |
| CASH AT END OF PERIOD                                | \$ 7,718,491 | \$ 129,497  |
|  | =====        | =====       |

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
(A Development Stage Company)

Notes to Condensed Consolidated Financial Statements (Unaudited)

June 30, 2002 and the Period From January 6, 1997  
(date of incorporation) to June 30, 2002

NOTE 1 - BASIS OF PRESENTATION

The condensed consolidated balance sheets of BioDelivery Sciences International, Inc. and its subsidiary (collectively "the Company") as of June 30, 2002, and the condensed consolidated statements of operations for the three and six months ended June 30, 2002 and 2001 have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring

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adjustments) necessary to present fairly the financial position, results of operations and cash flows at June 30, 2002 and for all periods presented, have been made. The condensed consolidated balance sheet at December 31, 2001, 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 generally accepted accounting principles 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, 2001, included in the Company's 2001 Annual Report on Form 10-KSB filed with the SEC on April 1, 2002 ("2001 Annual Report").

The results of operations for the three and six months ended June 30, 2002, are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

In March 2002, the Company approved a one for 4.37 reverse stock split. The financial statements have been restated to reflect the reverse stock split.

### NOTE 2 - PLAN OF OPERATIONS

Since inception, the Company has financed its operations principally from the sale of equity securities, grant funding, and a line of credit. Historically, the Company's subsidiary financed its operations principally from funded research arrangements. The Company has not generated revenue from the sale of any product or from any licensing arrangement since inception. The Company intends on financing its research and development efforts and its working capital needs from existing and new sources of financing. For instance, the Company was granted approximately \$2.7 million from the National Institutes of Health to fund specific research efforts to be conducted by the Company through June 2004 of which \$883,972 has been received to date. In June 2002, the Company completed its public offering, which consisted of 2,000,000 Units (\$5.25 per unit), each comprised of one share of common stock and one redeemable Class A Common Stock purchase warrant. While there can be no assurance that such sources will provide adequate funding for the Company's operations, management believes such sources will be available to the Company.

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
(A Development Stage Company)

Notes to Condensed Consolidated Financial Statements (Unaudited)

June 30, 2002 and the Period From January 6, 1997  
(date of incorporation) to June 30, 2002

### NOTE 3 - NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) 141, Business Combinations, and SFAS 142, Goodwill and Intangible Assets. SFAS 141 is effective for all business combinations completed after June 30, 2001. SFAS 142 is effective for the year

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beginning January 1, 2002; however certain provisions of that Statement apply to goodwill and other intangible assets acquired between July 1, 2001, and the effective date of SFAS 142. The Company determined that the adoption of SFAS 142 did not have any impact on the Company's financial statements.

In July 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. This statement addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. This Statement applies to all entities. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or the normal operation of a long-lived asset, except for certain obligations of lessees. This Statement is effective for financial statements issued for fiscal years beginning after June 15, 2002. The Company is evaluating the impact of the adoption of this standard and has not yet determined the effect of adoption on its financial position and results of operations.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes FASB Statement No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be disposed Of. The provisions of the statement are effective for financial statements issued for fiscal years beginning after December 15, 2001. The Company adopted this standard effective January 1, 2002, which did not have a material impact on the Company's financial statements.

#### NOTE 4 - NET LOSS PER COMMON SHARE

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

|  | Three Months Ended<br>June 30, |                | Six Months Ended<br>June 30, |                |
|--|--------------------------------|----------------|------------------------------|----------------|
|  | 2002                           | 2001           | 2002                         | 2001           |
| Net loss - (numerator)                               | \$ (537,972)                   | \$ (1,013,769) | \$ (833,186)                 | \$ (1,406,240) |
| Basic:   |                                |                |                              |                |
| Weighted average shares<br>outstanding (denominator) | 5,066,796                      | 3,749,214      | 5,034,011                    | 3,634,335      |
| Net loss per common share -<br>basic                 | \$ (.11)                       | \$ (.27)       | \$ (.17)                     | \$ (.39)       |



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(date of incorporation) to June 30, 2002

## NOTE 4 - NET LOSS PER COMMON SHARE - Continued

|   | Three Months Ended<br>June 30, |              | Six Months Ended<br>June 30, |              |
|---|--------------------------------|--------------|------------------------------|--------------|
|   | 2002                           | 2001         | 2002                         | 2001         |
| Diluted:  |                                |              |                              |              |
| Weighted average shares<br>outstanding            | \$ 5,066,796                   | \$ 3,749,214 | \$ 5,034,011                 | \$ 3,634,335 |
| Effect of dilutive securities                     | --                             | --           | --                           | --           |
| <hr style="border-top: 1px dashed black;"/>       |                                |              |                              |              |
| Adjusted weighted average<br>shares (denominator) | 5,066,796                      | 3,749,214    | 5,034,011                    | 3,634,335    |
| <hr style="border-top: 1px dashed black;"/>       |                                |              |                              |              |
| Net loss per common share -<br>diluted            | \$ (.11)                       | \$ (.27)     | \$ (.17)                     | \$ (.39)     |
| <hr style="border-top: 1px dashed black;"/>       |                                |              |                              |              |

The effects of all dilutive securities outstanding have been excluded from Common Stock equivalents because their effect would be anti-dilutive.

## NOTE 5 - COMMITMENTS AND CONTINGENCIES

The Company has received notification of a potential claim for a finder's fee and a lawsuit has been filed by Michael Pennessi d/b/a SSP Consultants, who is not affiliated with the Company, arising out of an introduction to a predecessor entity in 2000. Settlement discussions have been conducted. The Company intends to vigorously defend this litigation. It is the Company's belief that the potential claim is neither material nor meritorious.

## NOTE 6 - LINE OF CREDIT

At December 31, 2001, the Company had secured a revolving line of credit from a financial institution, which had an interest rate of prime plus 2.0%. During the six months ended June 30, 2002, the Company continued to draw on the line of credit to fund operations. As of June 30, 2002, the line of credit terminated and was satisfied in full with proceeds from the sale of Common Stock.

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Notes to Condensed Consolidated Financial Statements (Unaudited)

June 30, 2002 and the Period From January 6, 1997  
(date of incorporation) to June 30, 2002

## NOTE 7 - NATIONAL INSTITUTES OF HEALTH GRANT

In 2001, the National Institutes of Health (NIH) awarded the Company a Small Business Innovation Research Grant (SBIR), which will be utilized in research and development efforts. NIH has formally awarded the Company a 2001 grant of \$883,972. Additionally, this award refers to funding levels of \$814,398 and \$989,352 that the Company expects to be awarded in 2002 and 2003, respectively, 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 Company incurred approximately \$458,000 and \$-0- of costs related to this agreement for the six months ended June 30, 2002 and 2001, respectively.

During the six-month period ended June 30, 2002, the Company has received approximately \$189,000 and recognized revenue of approximately \$442,000 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.

As of June 30, 2002, the Company has recognized the full funding level of \$883,972 related to the 2001 award, inclusive of a \$215,940 receivable from NIH.

## NOTE 8 - INCOME TAXES

In March 2002, a new tax law changed the carryback period from two to five years. This allowed the Company to carryback its net operating losses to 1997, which resulted in an additional benefit of \$55,744. The Company initially recognized a tax benefit of \$95,843 during the three month period ended March 31, 2002 based on a preliminary evaluation of the new tax law. The Company subsequently revised its estimate of recoverable income taxes, which resulted in the reduction of income tax receivable by \$40,879.

## 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.

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The Company is a development-stage company and we expect to continue to perform research and development activities in furtherance of our business strategy and product development.

For the Six Months Ended June 30, 2002 Compared to the Six Months Ended June 30, 2001

**Sponsored Research Revenue.** During the six-month periods ended June 30, 2001 and 2002, we reported approximately \$28,000 and \$458,000, respectively, of sponsored research revenues. With the exception of grants by the National Institutes of Health and funding provided to us through various collaborative agreements, we have not derived any revenues from our operations, technologies or products.

**Research and Development.** Research and development expenses of approximately \$754,000 and \$910,000 were incurred during the six-month periods ended June 30, 2001 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 cochleate drug delivery technology.

**General and Administrative Expense.** General and administrative expenses of approximately \$695,000 and \$401,000 were incurred in the six-month periods ended June 30, 2001 and 2002, respectively. These expenses are principally comprised of legal and professional fees and other costs including office supplies, conferences, travel costs, salaries, website update and development, and other business development costs. The amount recognized in the period ended June 2001 includes \$384,000 for litigation settlement costs.

**Interest Income (Expense).** Interest income (expense) for the periods ended June 30, 2001 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, 2002, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved for. 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 1997, resulting in a tax benefit of \$55,744. 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.

### Liquidity and Capital Resources

From inception through June 30, 2002, we raised approximately \$10.1 million, net of issuance costs, through equity financings. At December 31, 2001, we had cash and cash equivalents totaling approximately \$76,000. At June 30, 2002, we had approximately \$7.7 million cash and cash equivalents. The operations of our predecessor, BioDelivery Sciences, Inc., prior to our acquisition of a controlling interest on October 10, 2000 and subsequent merger, were financed

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primarily through funded research agreements. In 2001, the National Institutes of Health awarded to us a Small Business Innovation Research Grant (SBIR), which will continue to be utilized in our research and development efforts.

NIH has formally awarded us a 2001 grant of \$883,972, of which we recognized approximately 50% in 2001 and the remainder was recognized through June 2002. As of June 30, 2002, we have received all but \$215,940, which was recorded as a receivable from NIH. Additionally, this award refers to funding levels of \$814,398 and \$989,352 that we expect to be awarded in 2002 and 2003, respectively, subject to availability and satisfactory progress of the project. Therefore, we expect to receive a total of approximately \$2.7 million related to our initial application for the grant through June 2004. 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 2002 and 2003 amounts noted above may be reduced or eliminated.

Working capital/deficit at December 31, 2001 was \$1,185,268, which reflects our legal claim settlement liability, our line of credit and our liability incurred under our research agreement with the University of Medicine and Dentistry of New Jersey, for which payments were deferred. Working capital at June 30, 2002 was \$6,621,743, which reflects the net proceeds from our June 2002 common stock offering.

We used \$617,209 of cash for operations in the six months ended June 30, 2002, which reflects increased research and development and administrative costs. On a pro forma basis (BioDelivery Sciences, Inc. combined with us) we have used approximately \$2.2 million of cash for operations since inception through June 30, 2002, net of sponsored research proceeds received since inception of approximately \$8.1 million.

Since our inception through June 30, 2002, we have incurred approximately \$2.9 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 June 30, 2002, we had an accumulated deficit of approximately \$6.0 million.

We anticipate that cash used in operations and our investment in facilities will increase significantly in the future as we research and further develop our technology. While we believe further application of our Bioral cochleate technology to other drugs and nutraceuticals will result in license agreements with manufacturers of generic and over-the-counter drugs, as well as the more common nutraceutical applications, 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.

We believe that our existing cash and cash equivalents 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

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sources, including:

- o the public equity market;
- o private equity financing;
- o collaborative arrangements;
- o grants;
- o public or private debt; and
- o 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.

### New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) 141, Business Combinations, and SFAS 142, Goodwill and Intangible Assets. SFAS 141 is effective for all business combinations completed after June 30, 2001. SFAS 142 is effective for the year beginning January 1, 2002; however certain provisions of that Statement apply to goodwill and other intangible assets acquired between July 1, 2001, and the effective date of SFAS 142. The Company determined that the adoption of SFAS 142 did not have any impact on the Company's financial statements.

In July 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. This statement addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. This Statement applies to all entities. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or the normal operation of a long-lived asset, except for certain obligations of lessees. This Statement is effective for financial statements issued for fiscal years beginning after June 15, 2002. The Company is evaluating the impact of the adoption of this standard and has not yet determined the effect of adoption on its financial position and results of operations.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes FASB Statement No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of. The provisions of the statement are effective for financial statements issued for fiscal years beginning after December 15, 2001. The Company adopted this standard effective January 1, 2002, which did not have a material impact on the Company's financial statements.

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## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

We have received notification of a potential claim for a finder's fee and a lawsuit has been filed by Michael Pennessi d/b/a SSP Consultants, who is not affiliated with us, arising out of an introduction to BioDelivery Sciences, Inc. in 2000. Settlement discussions have been conducted. We intend to vigorously defend this litigation. It is our belief that the potential claim is neither material nor meritorious.

### Item 2. Changes In Securities

On June 24, 2002, the Securities and Exchange Commission declared the Company's first Registration Statement on Form SB-2, Registration No. 333-72877, effective. The offering commenced on June 25, 2002.

The offering consisted of 2,000,000 units (the "Units") each Unit consisting of (i) one share of Common Stock, par value \$.001 (the "Common Stock") and (ii) one Class A common stock purchase Warrant (the "Warrants"). Each Warrant entitles the owner to purchase one share of Common Stock at a price of \$6.30 for a period of four years commencing on June 24, 2003.

The offering price for each Unit was \$5.25 and the aggregate offering price was \$10,500,000. The managing underwriter of the offering was Kashner Davidson Securities Corporation. The aggregate underwriting discount was \$897,750 and the non-accountable expense allowance paid to the underwriter was \$315,000. Additional offering expenses paid between the offering date and June 30, 2002 was \$295,000 for printing, \$364,000 for legal fees, \$74,948 for accounting fees and \$103,125 for other expenses of the offering. The total of the offering expenses is estimated at \$2,050,691. None of these expenses were paid to directors, officers or persons owning 10 percent of the securities of the Company.

The net offering proceeds to the Company after deducting the offering expenses described above was \$8,449,309. From June 25, 2002 until June 30, 2002, \$1,050,000 of such proceeds were used to repay the Company's line of credit which terminated June 30, 2002. The remaining proceeds were invested in short term certificates of deposit. There were no payments made to officers, directors, and persons owning more than 10% of the Company's securities.

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

- (a) Exhibits
  - 99.1 Certification by James A. McNulty
  - 99.2 Certification by Francis E. O'Donnell, Jr.
- (b) Reports on Form 8-K
  - NONE

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(A Development Stage Company)

Form 10-QSB

(for the quarterly period ended June 30, 2002)

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: August 13, 2002

/s/ James A. McNulty

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James A. McNulty, Chief Financial Officer  
(Principal Financial Officer)

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EXHIBIT 99.1  
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CERTIFICATIONS  
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I, James A. McNulty, certify that:

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

2. To my knowledge, the information in this report is true in all important respects as of June 30, 2002; and

3. This report contains all information about the company of which I am aware that I believe is important to a reasonable investor, in light of the subjects required to be addressed in this report, as of June 30, 2002.

For purposes of this certification, information is "important to a reasonable investor" if:

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(a) There is a substantial likelihood that a reasonable investor would view the information as significantly altering the total mix of information in the report; and

(b) The report would be misleading to a reasonable investor if the information is omitted from the report.

Date: August 13, 2002

/s/James A. McNulty

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James A. McNulty  
Chief Financial Officer

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EXHIBIT 99.2

CERTIFICATIONS

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

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

2. To my knowledge, the information in this report is true in all important respects as of June 30, 2002; and

3. This report contains all information about the company of which I am aware that I believe is important to a reasonable investor, in light of the subjects required to be addressed in this report, as of June 30, 2002.

For purposes of this certification, information is "important to a reasonable investor" if:

(a) There is a substantial likelihood that a reasonable investor would view the information as significantly altering the total mix of information in the report; and



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(b) The report would be misleading to a reasonable investor if the information is omitted from the report.

Date: August 13, 2002

/s/ Francis E. O'Donnell, Jr.  
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Francis E. O'Donnell, Jr.  
Chief Executive Officer