

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 10QSB

BIODELIVERY SCIENCES INTERNATIONAL INC  
Form 10QSB  
November 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 September 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.)

UMDNJ Medical School  
185 South Orange Avenue, Bldg #4  
Newark, NJ 07103  
-----

(Address of Principal Executive Offices) (Zip Code)

(813) 902-8980  
-----

(Registrant's telephone number)

Securities registered pursuant to Section 12(b) of the Act: None  
Securities registered pursuant to Section 12(g) of the Act:

Title of each Class  
-----

Common Stock. \$.001 Par Value

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

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The Issuer had 7,085,863 shares of common stock issued and outstanding as of November 12, 2002.

## BioDelivery Sciences International, Inc. Form 10-QSB

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#### PART I. FINANCIAL INFORMATION

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## Item 1. - Financial Statements

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

#### Condensed Consolidated Balance Sheets - (Unaudited)

|   | September 30,<br>2002 | December 31,<br>2001 |
|---|-----------------------|----------------------|
|   | -----                 | -----                |
| <b>ASSETS</b>   |                       |                      |
| <b>CURRENT ASSETS:</b>                                |                       |                      |
| Cash and cash equivalents                             | \$ 6,383,359          | \$ 75,513            |
| Grant receivable, prepaid expenses and other assets   | 330,323               | 111,684              |
|   | -----                 | -----                |
| Total current assets                                  | 6,713,682             | 187,197              |
| EQUIPMENT, net  | 173,424               | 233,562              |
| INTANGIBLES, net                                      | 585,254               | 547,470              |
| DEFERRED OFFERING COSTS                               | -                     | 365,340              |
|   | -----                 | -----                |
| Total Assets  | \$ 7,472,360          | \$ 1,333,569         |
|   | =====                 | =====                |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b> |                       |                      |
| <b>CURRENT LIABILITIES:</b>                           |                       |                      |
| Accounts payable and accrued liabilities              | \$ 931,023            | \$ 814,279           |
| Due to related parties                                | 21,718                | 74,331               |
| Line of credit  | -                     | 282,527              |
| Deferred revenue                                      | -                     | 37,000               |
| Current portion of capital lease payable              | 12,265                | 14,804               |
| Current portion of notes payable                      | -                     | 149,524              |
|   | -----                 | -----                |
| Total current liabilities                             | 965,006               | 1,372,465            |
| CAPITAL LEASE PAYABLE, less current portion           | 16,708                | 18,369               |
| NOTES PAYABLE, less current portion                   | -                     | 151,733              |
| COMMITMENTS AND CONTINGENCIES                         | -                     | -                    |
| <b>STOCKHOLDERS' EQUITY (DEFICIT):</b>                |                       |                      |
| preferred stock                                       | -                     | -                    |
| Common stock  | 7,086                 | 5,001                |
| Additional paid-in capital                            | 13,847,484            | 4,903,368            |
| Deficit accumulated during development stage          | (7,363,924)           | (5,117,367)          |
|   | -----                 | -----                |
| Total stockholders' equity (deficit)                  | 6,490,646             | (208,998)            |
|   | -----                 | -----                |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)  | \$ 7,472,360          | \$ 1,333,569         |
|   | =====                 | =====                |

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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>September 30, |              | Nine Months Ended<br>September 30, |                |       |
|--|-------------------------------------|--------------|------------------------------------|----------------|-------|
|  | 2002                                | 2001         | 2002                               | 2001           |       |
| Sponsored research revenues  | \$ 148,000                          | \$ 8,600     | \$ 605,972                         | \$ 36,385      | \$    |
| Expenses:  |                                     |              |                                    |                |       |
| Research and development   | 519,202                             | 389,563      | 1,428,755                          | 1,143,736      |       |
| General and administrative:  |                                     |              |                                    |                |       |
| General and administrative   | 544,210                             | 174,568      | 945,016                            | 869,980        |       |
| Stock compensation   | 526,318                             | -            | 526,318                            | -              |       |
|  | 1,589,730                           | 564,131      | 2,900,089                          | 2,013,716      |       |
| Interest income (expense), net                                       | 28,359                              | (8,033)      | (7,404)                            | 7,527          |       |
|  | (1,413,371)                         | (563,564)    | (2,301,521)                        | (1,969,804)    |       |
| Loss before income taxes and minority interest                       |                                     |              |                                    |                |       |
| Income tax benefit   | -                                   | -            | 54,964                             | -              |       |
|  | (1,413,371)                         | (563,564)    | (2,246,557)                        | (1,969,804)    |       |
| Loss before minority interest  |                                     |              |                                    |                |       |
| Minority interest in net loss of subsidiary                          | -                                   | -            | -                                  | -              |       |
|  | \$ (1,413,371)                      | \$ (563,564) | \$ (2,246,557)                     | \$ (1,969,804) | \$    |
| Net loss   | =====                               | =====        | =====                              | =====          | ===== |
| Net loss per common share:   |                                     |              |                                    |                |       |
| Basic and diluted  | \$ (.20)                            | \$ (.14)     | \$ (.39)                           | \$ (.53)       |       |
|  | =====                               | =====        | =====                              | =====          |       |
| Weighted average common stock shares outstanding - basic and diluted | 7,044,286                           | 3,960,924    | 5,711,467                          | 3,744,394      |       |
|  | =====                               | =====        | =====                              | =====          |       |

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 Statement of Stockholders' Equity (Deficit)

|   | Preferred Stock |        | Common Stock |          | Additi<br>Paid-<br>Capit |
|---|-----------------|--------|--------------|----------|--------------------------|
|   | Shares          | Amount | Shares       | Amount   |                          |
| BALANCE, DECEMBER 31, 2001  | -               | \$ -   | 5,000,863    | \$ 5,001 | \$ 4,903                 |
| Shares issued for cash (unaudited)  | -               | -      | 2,085,000    | 2,085    | 8,623                    |
| Compensation expense related to forgiveness<br>of shareholder notes (unaudited) | -               | -      | -            | -        | 321                      |
| Net loss (unaudited)  | -               | -      | -            | -        |                          |
| BALANCE, SEPTEMBER 30, 2002 (unaudited)   | -               | \$ -   | 7,085,863    | \$ 7,086 | \$13,847                 |

The accompanying notes are an integral part of this financial state

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

Condensed Consolidated Statements of Cash Flows (Unaudited)

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|   | Nine Months Ended<br>September 30, |                |
|---|------------------------------------|----------------|
|   | 2002                               | 2001           |
| OPERATING ACTIVITIES:   |                                    |                |
| Net loss  | \$ (2,246,557)                     | \$ (1,969,804) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                    |                |
| Depreciation and amortization   | 91,413                             | 73,127         |
| Loss applicable to minority interest  | -                                  | -              |
| Deferred revenue  | (37,000)                           | -              |
| Litigation settlement   | -                                  | 300,000        |
| Compensation expense  | 321,054                            | -              |
| Changes in assets and liabilities:  |                                    |                |
| Grants receivable, prepaid expenses and other assets                        | (218,639)                          | (93,159)       |
| Accounts payable and accrued liabilities                                    | 116,744                            | 127,873        |
| Due to/from related parties   | (52,613)                           | 68,554         |
|   | -----                              | -----          |
| Net cash used in operating activities                                       | (2,025,598)                        | (1,493,409)    |
| INVESTING ACTIVITIES:   |                                    |                |
| Net cash received with business combination                                 | -                                  | -              |
| Purchase of equipment   | (29,175)                           | -              |
| Purchase of intangibles   | (39,884)                           | -              |
| Purchase of minority interest   | -                                  | (116,375)      |
|   | -----                              | -----          |
| Net cash provided by (used in) investing activities                         | (69,059)                           | (116,375)      |
| FINANCING ACTIVITIES:   |                                    |                |
| Issuance of Preferred Stock   | -                                  | -              |
| Issuance of Common Stock, net of issuance costs                             | 8,990,487                          | 805,000        |
| Net change in line of credit  | (282,527)                          | 75,000         |
| Payment on capital lease payable  | (4,200)                            | (6,506)        |
| Payment on notes payable  | (301,257)                          | (87,725)       |
|   | -----                              | -----          |
| Net cash provided by financing activities                                   | 8,402,503                          | 785,769        |
| NET CHANGE IN CASH  | 6,307,846                          | (824,015)      |
| CASH AT BEGINNING OF PERIOD   | 75,513                             | 950,939        |
|   | -----                              | -----          |
| CASH AT END OF PERIOD   | \$ 6,383,359                       | \$ 126,924     |
|   | =====                              | =====          |

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

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Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 2002 and the Period From January 6, 1997  
(date of incorporation) to September 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 September 30, 2002, and the condensed consolidated statements of operations for the three and nine months ended September 30, 2002 and 2001 have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows at September 30, 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 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, 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 nine months ended September 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 and through 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 to finance its research and development efforts and its working capital needs from existing and new sources of financing, primarily licensing agreements. For instance, in 2001 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 \$1,031,972 has been received to date. It was also awarded a second NIH grant in August 2002, for \$600,000 over two years. In September 2002, the Company completed its public offering, which consisted of 2,085,000 Units, each comprised of one share of common stock and one redeemable Class A common stock purchase warrant. During the three months ended June 30, 2002, the Company sold 2,000,000 units at \$5.25 per unit. During the three months ended September 30, 2002, the Company sold 85,000 units at \$5.25 per unit. The Company intends to finance its research and development efforts and its working capital needs through licensing and joint venture arrangements with pharmaceutical companies, whose own proprietary pharmaceutical products may benefit from delivery using our nanococheate technology. Moreover,

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

Notes to Condensed Consolidated Financial Statements (Unaudited)

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

NOTE 2 - PLAN OF OPERATIONS - CONTINUED

there is the possibility of licensing income from applications of the Company's technology to over-the-counter drugs, generics, nutraceuticals, processed foods and beverages. To the extent that additional capital needs are required, the Company may raise additional funding from other sources, including debt financing and equity financing. 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.

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

Notes to Condensed Consolidated Financial Statements (Unaudited)

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

## 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>September 30, |              | Nine Months<br>September |
|--|-------------------------------------|--------------|--------------------------|
|  | 2002                                | 2001         | 2002                     |
| Net loss - (numerator)                               | \$ (1,413,371)                      | \$ (563,564) | \$ (2,246,557)           |
| Basic:   |                                     |              |                          |
| Weighted average shares<br>outstanding (denominator) | 7,044,286                           | 3,960,924    | 5,711,467                |
| Net loss per common share -<br>basic                 | \$ (.20)                            | \$ (.14)     | \$ (.39)                 |
| Diluted:   |                                     |              |                          |
| Weighted average shares<br>outstanding               | 7,044,286                           | 3,960,924    | 5,711,467                |
| Effect of dilutive securities                        | -                                   | -            | -                        |
| Adjusted weighted average<br>shares (denominator)    | 7,044,286                           | 3,960,924    | 5,711,467                |
| Net loss per common share -<br>diluted               | \$ (.20)                            | \$ (.14)     | \$ (.39)                 |

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

## NOTE 5 - COMMITMENTS AND CONTINGENCIES

The Company was the defendant in a lawsuit filed by Michael Pennessi d/b/a SSP Consultants, who is not affiliated with the Company, arising out of an introduction to BioDelivery Sciences, Inc. in 2000. A settlement for \$75,000 in cash payable to the plaintiff, was reached prior to September 30, 2002 and is reflected in selling, general and administrative expense.

## NOTE 6 - LINE OF CREDIT

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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 in our public offering.

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

#### Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 2002 and the Period From January 6, 1997  
(date of incorporation) to September 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 has been and will be utilized in research and development efforts. NIH awarded the Company a 2001 grant of \$883,972 and a 2002 grant of \$814,398. 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. In addition, in August 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 2002.

During the nine-month period ended September 30, 2002, the Company recognized revenue of approximately \$606,000 from the initial 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 September 30, 2002, the Company has recognized the full funding level of \$883,972 related to the 2001 award and \$148,000 related to the 2002 award.

#### 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 \$54,964. 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 during the three month period ended September 30, 2002.

#### NOTE 9 - STOCK BASED COMPENSATION

Compensation expense of \$526,318 is associated with the forgiveness of employee stock subscription notes receivable and related income tax payable on behalf of

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the employees. These notes were secured by common stock and were previously included as a reduction of stockholders' equity. This is a non-recurring event and no future costs are expected with regard to this stock based compensation award that was initially granted in 1999.

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

#### Item 2. Management's Discussion and Analysis or Plan of Operations

##### 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.

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 Nine Months Ended September 30, 2002 Compared to the Nine Months Ended September 30, 2001

**Sponsored Research Revenue.** During the nine-month periods ended September 30, 2002 and 2001, we reported approximately \$606,000 and \$36,000, 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 \$1.4 million and \$1.1 million were incurred during the nine-month periods ended September 30, 2002 and 2001, 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 \$1.5 million and \$870,000 were incurred in the nine-month periods ended September 30, 2002 and 2001, 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. In addition, the three months ended September 30, 2002, included compensation expense of approximately \$526,000 associated with the forgiveness of employee stock subscription notes receivable and related income tax payable on behalf of the employees. The nine-month period ended September 30, 2002, also includes executive compensation and directors and officers' liability insurance premiums in excess of amounts incurred in 2001.

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The amount recognized in the period ended September 2001 includes \$384,000 for litigation settlement costs.

Interest Income (Expense). Interest income (expense) for the periods ended September 30, 2002 and 2001 was principally comprised of earnings from invested cash offset by interest expense on the line of credit, notes payable and capital leases payable.

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

#### Item 2. Management's Discussion and Analysis or Plan of Operations

Income Taxes. While net operating losses were generated during the nine month period ended September 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 \$54,964. 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

Since inception, we have financed our operations primarily from the sale of our convertible preferred stock and common stock. From inception through September 30, 2002, we raised approximately \$10.4 million, net of issuance costs, through convertible preferred stock and common stock financings. At December 31, 2001, we had cash and cash equivalents totaling approximately \$76,000. At September 30, 2002, we had approximately \$6.4 million 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 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), and we were awarded a 2002 grant of \$814,398 (of which \$148,000 was recognized in the period ended September 30, 2002, and the balance will be recognized through June 30, 2003). Additionally, this award refers to third-year funding levels of \$989,352 that we expect to be awarded in 2003, 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 2003 amount noted above may be reduced or eliminated. In August 2002, NIH awarded a second grant for \$600,000 over two years, with expected funding in the fourth quarter of 2002.

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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 September 30, 2002 was \$5,748,676, which reflects the net proceeds from our June 2002 common stock offering, as well as payment of the line of credit, and settlement of the legal claim of \$75,000.

We used \$2,025,598 of cash for operations in the nine months ended September 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 \$3.7 million of cash for operations since inception through September 30, 2002, net of sponsored research proceeds received since inception of approximately \$8.3 million.

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

#### Item 2. Management's Discussion and Analysis or Plan of Operations

Since our inception through September 30, 2002, we have incurred approximately \$3.4 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., BioDelivery Sciences, Inc. incurred approximately \$6.8 million of research and development expenses.

We are in the process of securing financing for the acquisition of certain specialized laboratory equipment, with the expectation that we will purchase approximately \$1.5 million of assets between October 2002 and June 30, 2003. We anticipate financing this equipment through a five-year note for \$1,000,000 to \$1,500,000, depending on lender negotiations and initial equipment equity requirements.

We have incurred significant net losses and negative cash flows from operations since our inception. As of September 30, 2002, we had an accumulated deficit of approximately \$7.4 million.

We anticipate that cash used in operations and our investment in facilities will increase significantly in the future as we research and develop our technology. While we believe further application of our Bioral(TM) cochleate technology to other molecules and nutraceuticals may result in license agreements with manufacturers of ethical generic and over-the-counter drugs, as well as nutraceutical applications, our plan of operations in the next 24 months is focused on our further development of the Bioral cochleate technology itself and its use in our lead proprietary product, Bioral Amphotericin B. The Company recently identified the processed food and beverage industry as an additional potential opportunity for licensing our technology.

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 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:

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- o the public equity market;
- o collaborative arrangements;
- o grants;
- o redemption and exercise of warrants
- o license agreements

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.

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

### Item 2. Management's Discussion and Analysis or Plan of Operations

#### 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,

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which did not have a material impact on the Company's financial statements.

### 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 disclosure.

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
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### PART II. OTHER INFORMATION

#### Item 1. Legal Proceedings

A lawsuit was 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. A settlement for \$75,000 in cash was reached prior to September 30, 2002 and recorded in the financial statements. However, the final settlement documents had not been executed prior to September 30, 2002.

#### Item 2. Changes in Securities

During the three month period ended September 30, 2002, an over allotment of 85,000 units (the "Units") associated with the Company's June 2002 offering were issued. Each Unit consists 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. Net proceeds of \$394,708 were received from this issuance of 85,000 Units.

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

(a) Exhibits

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- 10.1 Employment Agreement with Raphael Mannino
- 10.2 Employment Agreement with Susan Gould-Fogerite
- 10.3 Employment Agreement with James A. McNulty
- 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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(for the quarterly period ended September 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: November 13, 2002

/s/ James A. McNulty

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

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(for the quarterly period ended September 30, 2002)

OFFICER CERTIFICATION

I, James A. McNulty certify that:



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1. I have reviewed this quarterly report on Form 10-Q of BioDelivery Sciences International, Inc. (the "Registrant");

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

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, 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 officers and I have disclosed, based on our most recent evaluation, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent functions):

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

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6. The Registrant's other certifying officers and I have indicated in this

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quarterly report whether 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: November 13, 2002

/s/James A. McNulty

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James A. McNulty  
Chief Financial Officer

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(for the quarterly period ended September 30, 2002)

### OFFICER CERTIFICATION

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

1. I have reviewed this quarterly report on Form 10-Q of BioDelivery Sciences International, Inc. (the "Registrant");

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

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, 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

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effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The Registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent functions):

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

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6. The Registrant's other certifying officers and I have indicated in this quarterly report whether 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: November 13, 2002

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

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