

BIODELIVERY SCIENCES INTERNATIONAL INC  
Form 10-Q  
November 03, 2009  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D. C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2009

**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 001-31361

**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

35-2089858  
(I.R.S. Employer  
Identification No.)

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801 Corporate Center Drive, Suite #210

Raleigh, NC  
(Address of principal executive offices)

27607  
(Zip Code)

Registrant's telephone number (including area code): 919-582-9050

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

As of November 2, 2009, there were 21,017,730 shares of company common stock issued and 21,033,221 shares of company common stock outstanding.

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**BioDelivery Sciences International, Inc. and Subsidiaries**

**Form 10-Q**

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|   | September 30, 2009   | December 31, 2008    |
|---|----------------------|----------------------|
| <b>ASSETS</b>   |                      |                      |
| Current assets:   |                      |                      |
| Cash and cash equivalents   | \$ 25,871,683        | \$ 905,720           |
| Accounts receivable   | 1,117,123            | 468,987              |
| Due from related party  | 1,966                |                      |
| Current deferred tax asset  | 176,490              |                      |
| Prepaid expenses and other current assets   | 1,164,501            | 184,007              |
| <b>Total current assets</b>   | <b>28,331,763</b>    | <b>1,558,714</b>     |
| Equipment, net  | 3,806,479            | 126,734              |
| Goodwill  | 2,715,000            | 2,715,000            |
| Other intangible assets:  |                      |                      |
| Licenses  | 1,430,552            | 1,570,020            |
| Acquired product rights   | 5,898,018            | 4,256,888            |
| <b>Total other intangible assets</b>  | <b>7,328,570</b>     | <b>5,826,908</b>     |
| Deposits on equipment   |                      | 2,954,460            |
| Other assets  | 6,132                | 11,571               |
| Restricted cash   | 157,876              | 144,000              |
| <b>Total assets</b>   | <b>\$ 42,345,820</b> | <b>\$ 13,337,387</b> |
| <b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>   |                      |                      |
| Current liabilities:  |                      |                      |
| Notes payable   | \$                   | \$ 76,666            |
| Accounts payable and accrued liabilities, other   | 4,368,939            | 2,684,015            |
| Accounts payable and accrued liabilities, related party   | 163,454              | 260,614              |
| Clinical trial payables and accrued liabilities   | 775,446              | 857,996              |
| Deferred revenue, current (Note 3)  | 70,982,906           | 36,060,500           |
| Derivative liability (Note 4)   | 5,594,251            | 5,350,829            |
| <b>Total current liabilities</b>  | <b>81,884,996</b>    | <b>45,290,620</b>    |
| Deferred revenue, long-term   | 1,628,535            | 1,628,539            |
| <b>Total liabilities</b>  | <b>83,513,530</b>    | <b>46,919,159</b>    |
| Commitments and contingencies (Note 7)  |                      |                      |
| Stockholders' deficit:  |                      |                      |
| Common stock, \$.001 par value; 45,000,000 shares authorized 21,033,221 and 19,179,029 shares issued; 21,017,730 and 19,163,538 shares outstanding in 2009 and 2008, respectively | 21,033               | 19,179               |
| Additional paid-in capital  | 72,964,054           | 58,706,499           |

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|   |               |               |
|---|---------------|---------------|
| Treasury stock, at cost, 15,491 shares, 2009 and 2008 | (47,183)      | (47,183)      |
| Accumulated deficit                                   | (114,105,615) | (92,260,267)  |
| Total stockholders' deficit                           | (41,167,711)  | (33,581,772)  |
| Total liabilities and stockholders' deficit           | \$ 42,345,820 | \$ 13,337,387 |

See notes to condensed consolidated financial statements

**Table of Contents****BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

|  | Three Months Ended<br>September 30, |                | Nine Months Ended<br>September 30, |                |
|--|-------------------------------------|----------------|------------------------------------|----------------|
|  | 2009                                | 2008           | 2009                               | 2008           |
| Royalties, related parties   | \$ 1,986                            | \$ 4,493       | \$ 13,591                          | \$ 39,730      |
| Research fees/consulting   |                                     | 12,500         |                                    | 129,499        |
|  | 1,986                               | 16,993         | 13,591                             | 169,229        |
| Expenses:  |                                     |                |                                    |                |
| Research and development:  |                                     |                |                                    |                |
| Related party  | 47,689                              | 54,000         | 143,065                            | 591,158        |
| Other  | 4,385,503                           | 2,081,022      | 8,061,651                          | 7,930,693      |
| General and administrative:  |                                     |                |                                    |                |
| Related party  | 15,000                              | 16,100         | 45,000                             | 46,400         |
| Other  | 3,370,298                           | 1,810,044      | 6,380,620                          | 5,865,768      |
| Total expenses   | 7,818,490                           | 3,961,166      | 14,630,336                         | 14,434,019     |
| Loss from operations   | (7,816,504)                         | (3,944,173)    | (14,616,745)                       | (14,264,790)   |
| Interest income (expense), net                                     | 8,617                               | 8,062          | 25,620                             | (474,590)      |
| Other expenses   | (16,931)                            |                | (23,891)                           |                |
| Derivative (loss) gain   | 5,048,937                           | (494,715)      | (7,406,822)                        | 1,788,859      |
| Loss before income taxes   | (2,775,881)                         | (4,430,826)    | (22,021,838)                       | (12,950,521)   |
| Deferred income tax benefit  | 176,490                             | 1,760,000      | 176,490                            | 3,760,000      |
| Net loss   | \$ (2,599,391)                      | \$ (2,670,826) | \$ (21,845,348)                    | \$ (9,190,521) |
| Per share amounts, basic and diluted:                              | \$ (0.12)                           | \$ (0.14)      | \$ (1.10)                          | \$ (0.48)      |
| Weighted average common stock shares outstanding basic and diluted | 20,973,354                          | 19,157,183     | 19,933,954                         | 19,144,873     |

See notes to condensed consolidated financial statements

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS DEFICIT**

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009**

**(Unaudited)**

|  | Common Stock |           | Additional<br>Paid-In Capital | Treasury<br>Stock | Accumulated<br>Deficit | Total<br>Stockholders<br>Deficit |
|--|--------------|-----------|-------------------------------|-------------------|------------------------|----------------------------------|
|  | Shares       | Amount    |                               |                   |                        |                                  |
| Balances, January 1, 2009                          | 19,179,029   | \$ 19,179 | \$ 58,706,499                 | \$ (47,183)       | \$ (92,260,267)        | \$ (33,581,772)                  |
| Stock-based compensation                           |              |           | 1,631,625                     |                   |                        | 1,631,625                        |
| Stock option exercises                             | 116,918      | 117       | 300,747                       |                   |                        | 300,864                          |
| Warrant issuance                                   |              |           | 55,452                        |                   |                        | 55,452                           |
| Warrants exercised for cash                        | 1,737,274    | 1,737     | 5,106,332                     |                   |                        | 5,108,069                        |
| Reclassification of derivative liability to equity |              |           | 7,163,399                     |                   |                        | 7,163,399                        |
| Net loss   |              |           |                               |                   | (21,845,348)           | (21,845,348)                     |
| Balances, September 30, 2009                       | 21,033,221   | \$ 21,033 | \$ 72,964,054                 | \$ (47,183)       | \$ (114,105,615)       | \$ (41,167,711)                  |

See notes to condensed consolidated financial statements

**Table of Contents****BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

|  | <b>Nine Months Ended</b>  |                           |
|--|---------------------------|---------------------------|
|  | <b>September 30, 2009</b> | <b>September 30, 2008</b> |
| <b>Operating activities:</b>   |                           |                           |
| Net loss   | \$ (21,845,348)           | \$ (9,190,521)            |
| Adjustments to reconcile net loss to net cash flows from operating activities: |                           |                           |
| Depreciation and amortization  | 569,574                   | 588,871                   |
| Derivative loss (gain)   | 7,406,822                 | (1,788,859)               |
| Unrealized loss on investments   |                           | 13,160                    |
| Accretion of discount on note payable, related party                           |                           | 603,836                   |
| Stock-based compensation   | 1,687,077                 | 1,971,968                 |
| Loss on disposal of fixed assets   | 2,401                     |                           |
| Changes in assets and liabilities:   |                           |                           |
| Accounts receivable  | (658,135)                 | (13,712)                  |
| Prepaid expenses and other current assets                                      | (989,227)                 | 120,436                   |
| Accounts payable and accrued expenses  | 1,341,439                 | (1,663,913)               |
| Income tax payable   |                           | 240,000                   |
| Deferred revenue   | 34,922,405                | 4,318,651                 |
| Deferred income tax asset  | (176,490)                 | (4,000,000)               |
| <b>Net cash flows from operating activities</b>                                | <b>22,260,518</b>         | <b>(8,800,083)</b>        |
| <b>Investing activities:</b>   |                           |                           |
| Purchase of equipment  | (535,923)                 | (28,564)                  |
| Deposits on equipment  |                           | (1,660,700)               |
| Proceeds from certificates of deposit  |                           | 2,800,000                 |
| Purchase of investments  |                           | (375,044)                 |
| Purchase of intangible assets  | (2,000,000)               |                           |
| <b>Net cash flows from investing activities</b>                                | <b>(2,535,923)</b>        | <b>735,692</b>            |
| <b>Financing activities:</b>   |                           |                           |
| Proceeds from exercise of stock options  | 300,864                   | 108,050                   |
| Payment on notes payable, related parties                                      |                           | (1,900,000)               |
| Payment of other notes payable   | (76,665)                  | (148,332)                 |
| Proceeds from exercise of common stock warrants                                | 5,108,069                 | 13                        |
| Repayment of related party borrowings, net                                     | (90,900)                  | (1,830,786)               |
| <b>Net cash flows from financing activities</b>                                | <b>5,241,368</b>          | <b>(3,771,055)</b>        |
| <b>Net change in cash and cash equivalents</b>                                 | <b>24,965,963</b>         | <b>(11,835,446)</b>       |
| <b>Cash and cash equivalents at beginning of period</b>                        | <b>905,720</b>            | <b>13,797,093</b>         |
| <b>Cash and cash equivalents at end of period</b>                              | <b>\$ 25,871,683</b>      | <b>\$ 1,961,647</b>       |

See notes to condensed consolidated financial statements





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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(Unaudited)**

**SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION**

Non-cash investing and financing activities:

The Company reclassified packaging equipment totaling \$3,747,095 from deposits on equipment to Equipment because it was completed and placed in production during the nine months ended September 30, 2009.

The Company financed an insurance policy through the issuance of a note payable in the amount of \$191,664 during the nine months ended September 30, 2008.

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED STATEMENTS**

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

**(Unaudited)**

**1. Basis of presentation:**

***Overview:***

The accompanying unaudited condensed consolidated financial statements of BioDelivery Sciences International, Inc., together with its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. ( Arius One ) and Arius Two, Inc. ( Arius Two ) and its majority-owned, inactive subsidiary, Bioral Nutrient Delivery, LLC ( BND ) (collectively, the Company or we , us or similar terminology) have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at September 30, 2009 and for all periods presented, have been made. All intercompany accounts and transactions have been eliminated.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ( GAAP ) have been condensed or omitted pursuant to the Securities and Exchange Commission ( SEC ) rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2008, included in the Company s 2008 Annual Report on Form 10-K, filed with the SEC on March 20, 2009 (as amended, the 2008 Annual Report ). The accompanying condensed consolidated balance sheet at December 31, 2008 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements.

As used herein, the term Common Stock means the Company s common stock, par value \$.001 per share.

The results of operations for the nine months ended September 30, 2009 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this Quarterly Report are strongly encouraged to review the risk factors relating to the Company which are set forth in the 2008 Annual Report.

BDSI®, BEMA® and Bioral® are registered trademarks, and ONSOLIS™ and BREAKYL™ are trademarks of BioDelivery Sciences International, Inc.

***Fair value of financial assets and liabilities:***

The Company measures the fair value of financial assets and liabilities based on a model that defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Under this methodology the Company maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. The Company considers three levels of inputs when measuring fair value:

- Level 1 quoted prices in active markets for identical assets or liabilities
- Level 2 quoted prices for similar assets and liabilities in active markets or inputs that are observable
- Level 3 inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

**Table of Contents****BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED STATEMENTS****FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008 (Continued)****(Unaudited)****1. Basis of presentation (continued):**

The following table summarizes liabilities measured at fair value on a recurring basis at September 30, 2009:

| <b>Liabilities</b>     | <b>Fair Value Measurements Using</b> |                |                |              |
|------------------------|--------------------------------------|----------------|----------------|--------------|
|                        | <b>Level 1</b>                       | <b>Level 2</b> | <b>Level 3</b> | <b>Total</b> |
| Derivative liabilities | \$                                   | \$ 5,594,251   | \$             | \$ 5,594,251 |

**New accounting pronouncements:**

The Financial Accounting Standards Board ( FASB ) issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* ( SFAS No. 168 ), on June 29, 2009 and, in doing so, authorized the Codification as the sole source for authoritative U.S. GAAP. SFAS No. 168 was effective for financial statements issued for reporting periods that ended after September 15, 2009. Upon effectiveness, it superseded all accounting standards in U.S. GAAP, aside from those issued by the SEC.

In June 2009, the FASB issued Accounting Standards Update No. 2009-01 ( ASU 2009-01 ), which establishes the FASB Accounting Standards Codification as the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. The Company adopted ASU 2009-01 during the three months ended September 30, 2009 and its adoption did not have any impact on the Company's consolidated financial statements.

In August 2009, the FASB issued Accounting Standards Update No. 2009-05 ( ASU 2009-05 ), which clarified how to measure the fair value of liabilities in circumstances when a quoted price in an active market for the identical liability is not available. ASU 2009-05 is effective for the first reporting period beginning after the issuance of this standard. The Company expects to adopt ASU 2009-05 during the three months ended December 31, 2009 and is evaluating the impact that this adoption will have on its consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update No. 2009-13 ( ASU 2009-13 ), which addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified beginning in fiscal years on or after June 15, 2010. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements, if any.

Management, in accordance with guidance regarding subsequent events, has considered subsequent events through November 2, 2009.

**2. Liquidity and management's plans:**

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes and from funded research arrangements and milestone payments. Through September 30, 2009, the Company has not generated revenue from the sale of any product, but has generated revenue and deferred revenues from licensing arrangements, including research and development services in 2008 and 2009. Subsequent to September 30, 2009, the Company has begun to generate initial royalty revenue as a result of initial commercial sales of ONSOLIS (fentanyl buccal soluble film) by the Company's commercial partner for ONSOLIS, Meda AB ( Meda ).



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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED STATEMENTS**

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008 (Continued)**

**(Unaudited)**

**2. Liquidity and management's plans (continued):**

The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock purchase warrants.

On July 16, 2009, the Company and Meda announced approval from the U.S. Food and Drug Administration ( FDA ) to market the Company's product ONSOLIS for the management of breakthrough pain ( BTP ) in patients with cancer, eighteen years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain. ONSOLIS is a formulation of the narcotic fentanyl delivered through the Company's patented transmucosal drug delivery technology, BEMA<sup>®</sup>, a small, erodable polymer film for application to the buccal mucosa (the lining inside the cheek). ONSOLIS will be marketed in Europe under the name BREAKY<sup>™</sup> if regulatory approvals are obtained.

The FDA approval of ONSOLIS, together with the Company's satisfactory preparation of launch supplies of ONSOLIS, triggered the payment by Meda to the Company of approval milestones aggregating \$26.8 million and the termination of a security interest in the ONSOLIS product and related assets which was held by CDC IV, LLC ( CDC ) pursuant to a funding arrangement previously entered into between the Company and CDC. Additionally, the FDA approval triggered a requirement by the Company to pay an approval milestone of \$2.0 million to QLT USA Inc., from which the Company purchased the BEMA<sup>®</sup> delivery technology, which payment was accrued as of the FDA approval date and paid in August 2009.

On October 6, 2009, the Company announced it had received a \$1.3 million grant from the Walter Reed Army Institute of Research to support the clinical study of the Company's Bioral Amphotericin B product candidate in the treatment of Cutaneous Leishmaniasis. Bioral Amphotericin B is an oral formulation of the fungicidal treatment amphotericin B in the Company's patented Bioral drug delivery technology.

Lastly, during the nine months ended September 30, 2009 the Company received cash from the exercise of certain outstanding warrants to purchase Common Stock of approximately \$5.1 million. Stock option exercises during the same time period were approximately \$0.3 million.

As a result, Company management believes that the Company's existing cash and cash equivalents are sufficient to finance planned operations through 2010.

In January 2009, the Company filed a universal shelf registration for up to \$50 million of the Company's securities, which universal shelf registration was declared effective by the SEC. The Company may publicly offer securities via such universal shelf registration over a three year period based on certain terms and conditions to be determined at the time the Company decides if and when it is prudent to utilize the universal shelf registration. The Company also believes that it may have access to other forms of financing as needed, including equipment loans and other debt related arrangements.

As a result of the foregoing, the Company believes that it will be able to secure outside funding at levels sufficient to support planned operations. However, there can be no assurance that additional capital or loans will be available on favorable terms, if at all. If adequate outside funds are not available, the Company would likely be required to significantly reduce or refocus its planned operations or to obtain funds through

**Table of Contents****BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED STATEMENTS****FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008 (Continued)****(Unaudited)****2. Liquidity and management's plans (continued):**

arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company's financial condition and viability.

In addition, the recent worldwide financial and credit crisis has strained investor liquidity and contracted credit and equity markets. If this environment continues or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when the Company requires additional funding. If the Company is unable to attract additional funds, it may materially and adversely affect the Company's ability to achieve its stated or other development and commercialization goals, which could have a material and adverse effect on the Company's business, results of operations, financial condition and stock price. The condensed consolidated financial statements included in this Quarterly Report do not include any adjustment that may arise as a result of these uncertainties.

**3. Meda License, Development and Supply Agreements:**

In August 2006 and September 2007, the Company entered into license, development and supply agreements (collectively referred to as the Meda Agreements) with Meda to develop and commercialize ONSOLIS in the United States, Mexico and Canada (the Meda U.S. Licensing Agreements) and in certain countries in Europe (the Meda EU Licensing Agreements). These arrangements have license terms which commence on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration of all patents covering the product. The Company's rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

| Contractual Rights and Obligations  | Contractual Cash Flow                        |                | Cash Flows Received and Revenue Deferred |                    |                   |
|---|--|----------------|--|--------------------|-------------------|
|   | Nonrefundable Upfront and Milestone Payments |                | As Delivered                             | September 30, 2009 | December 31, 2008 |
|   | U.S. Arrangement                             | EU Arrangement |  |                    |                   |
| License rights to ONSOLIS /BREAKYL (BEMA Fentanyl) patents and trademarks                   | \$ 30,000,000                                | \$ 5,500,000*  |  | \$ 35,500,000*     | \$ 32,500,000     |
| Milestones:   |  |                |  |                    |                   |
| FDA approval  | \$ 15,000,000**                              | n/a            |  | \$ 14,800,000**    |                   |
| Completion of Phase 3 clinical trials   | n/a  | \$ 2,500,000   |  | \$ 2,500,000       | \$ 2,500,000      |
| Governmental Approval in an EU country  | n/a  | \$ 2,500,000   |  |                    |                   |
| Earlier of date of first commercial sale or availability of launch supply product inventory | \$ 15,000,000***                             | n/a            |  | \$ 15,000,000***   |                   |
| Date of first commercial sale in an EU country  | n/a  | \$ 2,500,000   |  |                    |                   |
| Research and Development Services for:  |  |                |  |                    |                   |
| ONSOLIS product through FDA approval  |  |                | None                                     |                    |                   |
| ONSOLIS product through governmental approval in a EU country                               |  |                | Contract Hourly Rates                    | \$ 3,269,871       | \$ 1,553,627      |
| Non-Cancer subsequent indication of product and further development of initial product      |  |                | Contract Hourly Rates                    | \$ 1,541,570       | \$ 1,135,412      |





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|  |                      |                      |  |                                    |
|--|----------------------|----------------------|--|------------------------------------|
| Other services:  |                      |                      |  |                                    |
| Participation on Steering, Development, and Commercialization Committees |                      |                      | None   |                                    |
| Other contractual services   |                      |                      | None   |                                    |
| Product supply   |                      |                      | Company's Fully-burdened Cost                    |                                    |
| Royalties  |                      |                      | Contract percentage of product net sales revenue | \$                                 |
| Commercialization bonuses  |                      |                      | Up to \$30,000,000                               |                                    |
| <b>Total</b>   | <b>\$ 60,000,000</b> | <b>\$ 13,000,000</b> |  | <b>\$ 72,611,441 \$ 37,689,039</b> |

\* The Company received a \$3.0 million non-refundable payment in January 2009 to amend the Meda EU Licensing Agreements with an expansion of territories.

\*\* The Company received a \$3.0 million advance in January 2009 against the \$15.0 million approval milestone. In July 2009 the Company received \$11.8 million, the balance of the approval milestone, less a \$0.2 million fee to Meda.

\*\*\* The Company received the \$15.0 million launch supply milestone in July 2009.

The Company has assessed the arrangement deliverables under applicable accounting guidance to determine which deliverables to these arrangements are considered separate units of accounting at the inception of the arrangement and upon delivery of the items required in the arrangements. The accounting guidance requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and, if so, to determine the fair value to be allocated to each unit of accounting.

The Company determined that upon inception of each arrangement, all deliverables of each arrangement are to be considered one combined unit of accounting since the fair value of the undelivered license was not determinable and the research and development efforts provided do not have standalone value apart from the license. As such, all cash payments from Meda related to these deliverables have been recorded as deferred revenue. All cash payments from Meda for upfront and milestone payments and research and development services provided are nonrefundable. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain research and development services deliverables will have been delivered to Meda based on the residual method.

**Recognition of Certain Deferred Revenue**

Subsequent to September 30, 2009, in October 2009, Meda achieved the first commercial sale of ONSOLIS in the United States. This first commercial sale of ONSOLIS triggered the recognition of approximately \$59.7 million of deferred revenue from U.S. milestones (including research and development services) previously received by the Company from Meda. These earned milestones will be recognized as revenue in October 2009. Remaining amounts in deferred revenue relate to European Union milestones and research and development services that will continue to be deferred until the first commercial sale in Europe as well as a smaller amount for Company obligations related to steering and development committees.



**Table of Contents****BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED STATEMENTS****FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008 (Continued)****(Unaudited)****3. Meda License, Development and Supply Agreements (continued):**

The Company will earn royalties based on a percentage of net sales revenue of the ONSOLIS product. Product royalty revenues will be recognized on at least a quarterly basis when Meda's third-party sales revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. Commercialization bonuses represent additional nonrefundable royalties due if commercial sales exceed certain predefined thresholds. They will be recognized as revenue if and when they are earned.

**4. Derivative Financial Instruments:**

The Company generally does not use derivative instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. However, certain other financial instruments, such as warrants and embedded conversion features that are indexed to the Company's Common Stock, are classified as liabilities when either (a) the holder possesses rights to net-cash settlement or (b) physical or net-share settlement is not within the control of the Company. In such instances, net-cash settlement is assumed for financial accounting and reporting, even when the terms of the underlying contracts do not provide for net-cash settlement. Such financial instruments are initially recorded at fair value estimated on the settlement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate, and then adjusted to fair value at the close of each reporting period.

The following tabular presentation reflects the components of derivative liabilities as of September 30, 2009 and December 31, 2008:

| <b>Derivative liability at fair value:</b> | <b>September 30, 2009</b> | <b>December 31, 2008</b> |
|--|---------------------------|--------------------------|
| Free standing warrants*                    | \$ 5,594,251              | \$ 5,350,829             |

\* These warrants can be settled by issuance of 2,909,991 and 4,622,265 shares of Common Stock at September 30, 2009 and December 31, 2008, respectively.

The following tabular presentation reflects the components of derivative financial instruments for the three and nine months ended September 30, 2009 and 2008:

|  | <b>3 months<br/>ending<br/>September 30,<br/>2009</b> | <b>3 months<br/>ending<br/>September 30,<br/>2008</b> | <b>9 months<br/>ending<br/>September 30,<br/>2009</b> | <b>9 months<br/>ending<br/>September 30,<br/>2008</b> |
|--|---|---|---|---|
| <b>Derivative income (loss) in the accompanying statement of operations is related to the individual derivatives as follows:</b> |   |   |   |   |
| Free standing derivatives (principally warrants)   | 5,048,937   | (494,715)   | (7,406,822)   | 1,788,859   |

**Table of Contents****BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED STATEMENTS****FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008 (Continued)****(Unaudited)****5. Stockholders equity:*****Stock-based compensation:***

During the nine months ended September 30, 2009, 577,658 options (including options that were granted subject to stockholder approval, which was obtained in July 2009) with fair market value of approximately \$2.5 million were granted to certain Company employees and board members at prices equal to the market value of the Common Stock on the dates the options were granted. The options granted have a term of 1-10 years from the grant date and vest either immediately or ratably over a three year period, depending on the terms. The fair value of each option is amortized as compensation expense evenly through the vesting period. The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from historical volatility of the Common Stock, and other factors estimated over the expected term of the options.

The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average for key assumptions used in determining the fair value of options granted during the nine months ended September 30, 2009 follows:

|   |               |
|---|---------------|
| Expected price volatility               | 57.88%-90.24% |
| Risk-free interest rate                 | 0.51%-2.71%   |
| Weighted average expected life in years | 1-6 years     |
| Dividend yield                          |               |

Option activity during the nine months ended September 30, 2009 was as follows:

|                                   | Number<br>of<br>Shares | Weighted Average<br>Exercise Price<br>Per Share | Aggregate<br>Intrinsic<br>Value |
|-----------------------------------|------------------------|---|---------------------------------|
| Outstanding at January 1, 2009    | 3,503,467*             | \$ 3.56   |                                 |
| Granted                           |                        |   |                                 |
| Officers and Directors            | 389,663                | 4.85  |                                 |
| Others                            | 187,995                | 3.41  |                                 |
| Exercised                         | (116,918)              | 2.57  |                                 |
| Forfeitures                       | (46,007)               | 2.55  |                                 |
| Outstanding at September 30, 2009 | 3,918,200              | \$ 3.72   | \$ 5,610,460                    |

\* In July 2009, Company stockholders approved an increase in the size of the Company stock incentive plan from 3,500,000 shares of Common Stock to 6,000,000 shares of Common Stock.



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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED STATEMENTS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008 (Continued)**  
**(Unaudited)**

**5. Stockholders' equity (continued):**

Options outstanding at September 30, 2009 are as follows:

| Range of Exercise Prices | Number<br>Exercisable | Weighted<br>Average<br>Remaining<br>Contractual<br>Life (Years) | Weighted<br>Average<br>Exercise<br>Price | Aggregate<br>Intrinsic<br>Value |
|--------------------------|-----------------------|---|--|---------------------------------|
| \$ 1.00 - 5.00           | 2,976,955             | 7.35  | \$ 2.92                                  |                                 |
| \$ 5.01 - 10.00          | 941,245               | 7.98  | \$ 6.27                                  |                                 |
|                          | 3,918,200             |   |  | \$ 5,610,460                    |

Options exercisable at September 30, 2009 are as follows:

| Range of Exercise Prices | Number<br>Exercisable | Weighted<br>Average<br>Remaining<br>Contractual<br>Life (Years) | Weighted<br>Average<br>Exercise<br>Price | Aggregate<br>Intrinsic<br>Value |
|--------------------------|-----------------------|---|--|---------------------------------|
| \$ 1.00 - 5.00           | 2,119,396             | 6.71  | \$ 2.81                                  |                                 |
| \$ 5.01 - 10.00          | 689,914               | 8.04  | \$ 6.22                                  |                                 |
|                          | 2,809,310             |   |  | \$ 4,207,248                    |

The weighted average grant date fair value of options granted during the nine months ended September 30, 2009 whose exercise price is equal to or above the market price of the stock at the grant date was \$4.45. There were no options granted during the nine months ended September 30, 2009 whose exercise price is lower than the estimated market price of the stock at the grant date.

A summary of the status of the Company's nonvested stock options as of January 1, 2009, and changes during the nine months ended September 30, 2009 is summarized as follows:

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| <b>Nonvested Shares</b>         | <b>Shares</b> | <b>Weighted Average<br/>Grant Date Fair Value</b> | <b>Intrinsic<br/>Value</b> |
|---------------------------------|---------------|---|----------------------------|
| Nonvested at January 1, 2009    | 1,360,212     |   |                            |
| Granted                         | 577,658       |   |                            |
| Vested                          | (782,973)     |   |                            |
| Forfeited                       | (46,007)      |   |                            |
| Nonvested at September 30, 2009 | 1,108,890     | \$ 3.90   | \$ 1,403,212               |

**Table of Contents****BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED STATEMENTS****FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008 (Continued)****(Unaudited)****5. Stockholders' equity (continued):**

As of September 30, 2009, there was approximately \$1.7 million of unrecognized compensation cost related to unvested shares-based compensation awards granted. These costs will be expensed over the next two years.

**Warrants:**

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. Warrants outstanding at September 30, 2009, all of which are exercisable are as follows:

| Range of Exercise Prices | Number Outstanding | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price | Aggregate Intrinsic Value |
|--------------------------|--------------------|---|---------------------------------|---------------------------|
| \$ 0.00 - 5.00           | 2,552,620          | 3.33  | \$ 3.29                         |                           |
| \$ 5.01 - 10.00          | 1,558,871          | 3.35  | \$ 5.22                         |                           |
|                          | 4,111,491          |   |                                 | \$ 3,849,067              |

**Reclassification of derivative liability to equity:**

During the quarter ended September 30, 2009, Laurus Master Fund Ltd. ( Laurus ) exercised warrants to purchase 183,000 shares of Common Stock for \$3.00 to \$3.05 per share. At the time of exercise the warrants were treated as a derivative liability. Upon exercise of the warrants, these amounts were reclassified to equity based on the fair value on the date of exercise.

**6. 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 ended<br>September 30, |                |
|----------|-------------------------------------|----------------|------------------------------------|----------------|
|          | 2009                                | 2008           | 2009                               | 2008           |
| Net loss | \$ (2,599,391)                      | \$ (2,670,826) | \$ (21,845,348)                    | \$ (9,190,521) |



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Basic and diluted:

|   |            |            |            |            |
|---|------------|------------|------------|------------|
| Weighted average shares outstanding (denominator) | 20,973,354 | 19,157,183 | 19,933,954 | 19,144,873 |
| Net loss per common share basic and diluted       | \$ (0.12)  | \$ (0.14)  | \$ (1.10)  | \$ (0.48)  |

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

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED STATEMENTS**

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008 (Continued)**

**(Unaudited)**

**7. Consolidation of Newark laboratory:**

During the quarter ended September 30, 2009, the Company consolidated its laboratory and other operations located in Newark, New Jersey to the Company's headquarters in Raleigh, North Carolina. The Company vacated its Newark facility and eliminated all four positions in Newark.

Expenses associated with closing the Newark facility include: (1) equipment moving and related costs at approximately \$0.06 million and (2) employee severance costs of \$0.04 million.

On October 21, 2009, the Company entered into a Separation Agreement and General Claims Release with Dr. Raphael J. Mannino, the Company's former Executive Vice President and Chief Scientific Officer who was based in the Company's Newark laboratory. As a result of this agreement, the Company will pay a one-time cash severance payment of approximately \$0.3 million to Dr. Mannino. Such amount has been accrued in the September 30, 2009 financial statements. The agreement with Dr. Mannino is filed as an exhibit to this Report.

**8. Potential Contingency Relating to Accentia Biopharmaceuticals**

On March 12, 2004, the Company's Arius One subsidiary (which was then a stand alone entity but was subsequently acquired by the Company in August 2004) granted, pursuant to a Distribution Agreement (the "Distribution Agreement"), exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc. ("TEAMM") with respect to the Company's Emezine product for the treatment of nausea and vomiting. TEAMM is a wholly-owned subsidiary of Accentia Biopharmaceuticals, Inc. ("Accentia"), a related party of the Company through common ownership and management. On November 10, 2008, Accentia and its subsidiaries filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. On December 17, 2008, the Distribution Agreement was terminated in conjunction with the reversion of the Company's rights to Emezine to the owner of such rights, Reckitt Benckiser Healthcare (UK) Limited.

During the quarter ended September 30, 2009, Accentia asserted to the Company that it maintains certain rights under the Distribution Agreement. No legal action has commenced with respect such assertions and, through a special committee of the Company's board of directors consisting of non-conflicted parties, the Company has been in discussions with Accentia regarding this matter during the quarter ended September 30, 2009 and through the date of this Report.

Company management has evaluated Accentia's assertions and believes that they are without merit as Company management believes it has no obligations to Accentia under the terminated Distribution Agreement in accordance with its terms. As the Company's discussions with Accentia may (or may not) eventuate in a negotiated settlement, no estimate of a possible loss to the Company, if any exists, can be made by Company management as of the date of this Report and therefore has not been recorded in the financial statements for the quarter ended September 30, 2009.

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**Table of Contents****Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

The following discussion and analysis should be read in conjunction with the Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Quarterly Report. 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-Q and in the Company's other filings with the Securities and Exchange Commission (the "SEC").

**For the three months ended September 30, 2009 compared to the three months ended September 30, 2008**

**Royalty Revenues.** For the three-month periods ended September 30, 2009 and 2008, the Company recorded \$0.002 million and \$0.004 million, respectively, in royalty revenue from a related company.

**Research fees/consulting.** For the three-month periods ended September 30, 2009 and 2008, the Company recorded zero and \$0.01 million, respectively, in research and development services.

**Research and Development.** Research and development expenses of approximately \$4.4 million and \$2.1 million were incurred during the three-month periods ended September 30, 2009 and 2008, respectively. These aforementioned amounts included zero and \$0.008 million, respectively, paid to a contract research organization, which organization was, until the third quarter of 2008, a stockholder of the Company. The increase in expenses from 2008 to 2009 resulted from costs associated with the Company's clinical development program for its pipeline product candidates, some of which are reimbursed by Meda. The Company's scientific staff continued to work toward increased development and application of our BEMA<sup>®</sup> and Bioral<sup>®</sup> technologies and other drug-related areas. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA<sup>®</sup> and Bioral<sup>®</sup> drug delivery technologies.

**General and Administrative Expenses.** General and administrative expenses of approximately \$3.4 million and \$1.8 million were incurred in the three-month periods ended September 30, 2009 and 2008, respectively. These expenses are principally composed of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries, and other business development costs. The increase from 2008 to 2009 was primarily related to employee bonus payments recorded in 2009 and stock-based compensation. The 2009 bonus payments were based on 2008 achievements that supported the FDA approval of ONSOLIS<sup>®</sup>. Such bonus amounts were, however, not determined and approved until 2009 and, accordingly, were not accrued in 2008. Bonuses for 2009 (to be paid in 2010) that were determined and approved were accrued in 2009. Furthermore, severance payments were recorded and made in connection with the closing of the Newark, New Jersey laboratory.

**Interest Income (expense).** Interest income (expense) for the periods ended September 30, 2009 and 2008 was principally composed of interest expense incurred on notes payable, net of interest earnings on invested cash.

**Derivative Gain (Loss).** Derivative gain (loss) during 2009 and 2008 is related to the adjustment of related derivative liabilities to fair value. These derivatives relate to warrants and certain embedded instruments associated with previous financings (see Note 4 to the condensed consolidated financial statements). The derivative gain in 2009 is due to the Company's stock price decrease during the three months ended September 30, 2009, which triggers non-cash income and an associated decrease in the derivative liability.

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**Income Taxes.** During the three months ended September 30, 2009, the Company recognized a \$0.2 million deferred tax benefit based upon the loss incurred and temporary timing differences through September 30, 2009. During the three months ended September 30, 2008, the Company recognized a \$2.0 million deferred tax benefit based upon the expectation that it was more likely than not that there would be taxable income for the year ended December 31, 2008 because, notwithstanding the Company's financial accounting with regard to this item, approximately \$30.0 million of revenue which was deferred for financial reporting purposes became taxable in 2008. Deferred revenues that will be recognized and taxable in the fourth quarter of 2009 will be substantially offset by the Company's net operating loss carry-forward.

***For the Nine Months Ended September 30, 2009 Compared to the Nine Months Ended September 30, 2008***

**Royalty Revenues.** During the nine-month periods ending September 30, 2009 and 2008, we recorded \$0.01 million and \$0.04 million, respectively, of royalty revenue from a related company.

**Research fees/consulting.** During the nine-month periods ending September 30, 2009 and September 30, 2008, we recorded zero and \$0.1 million, respectively, of research and development services.

**Research and Development.** Research and development expenses of approximately \$8.2 million and \$8.5 million were incurred during the respective nine-month periods ended September 30, 2009 and 2008. These amounts included zero and \$0.4 million, respectively, paid to a contract research organization that was, until the third quarter of 2008, a stockholder of the Company. The increase in expenses from 2008 to 2009 was minimal for the nine-month period, but included costs associated with the Company's clinical development program for its pipeline product candidates, some of which are reimbursed by Meda, while in the prior year most of the research and development was associated with ONSOLIS. Our scientific staff continued to work toward increased development and application of our BEMA<sup>®</sup> and Bioral<sup>®</sup> technologies and other drug-related areas. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA<sup>®</sup> and Bioral<sup>®</sup> drug delivery technologies.

**General and Administrative Expenses including Stock-based Compensation.** General and administrative expenses of approximately \$6.4 million and \$5.9 million were incurred in the nine-month periods ended September 30, 2009 and 2008, respectively. These expenses are principally composed of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries, and other business development costs. The increase from 2008 to 2009 was primarily related to employee bonus payments recorded in 2009 and stock-based compensation. The 2009 bonus payments were based on 2008 achievements that supported the FDA approval of ONSOLIS. Such bonus amounts were, however, not determined and approved until 2009 and, accordingly, were not accrued in 2008. Bonuses for 2009 (to be paid in 2010) that were determined and approved were accrued in 2009. Furthermore, severance payments were recorded and made in connection with the closing of the Newark, New Jersey laboratory.

**Interest Expense Net.** Interest expense for the periods ended September 30, 2009 and 2008 was principally composed of interest expense for amortization of deferred loan costs and notes payable discount amortization, net of interest earnings on invested cash.

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**Derivative Gain (Loss).** Derivative gain (loss) during 2009 and 2008 is related to the adjustment of derivative liabilities to fair value. These derivatives relate to warrants and certain embedded instruments associated with previous financings (see Note 7 to the financial statements). The increase in the derivative loss is due to the increase in the Company's stock price during the nine months ended September 30, 2009, which triggers a non-cash expense and an associated increase in the derivative liability.

**Income Taxes.** During the nine months ended September 30, 2009, the Company recognized a \$0.2 million deferred tax benefit based upon the loss incurred and temporary timing differences through September 30, 2009. During the nine months ended September 30, 2008, the Company recognized a \$2.0 million deferred tax benefit based upon the expectation that it was more likely than not that there would be taxable income for the year ended December 31, 2008 because, notwithstanding the Company's financial accounting with regard to this item, approximately \$30.0 million of revenue which was deferred for financial reporting purposes became taxable in 2008. Deferred revenue that will be recognized and taxable in the fourth quarter of 2009 will be substantially offset by the Company's net operating loss carry-forward.

## ***Liquidity and Capital Resources***

### ***Background***

We have incurred significant net losses and negative cash flows from operations since our inception. As of September 30, 2009, we had stockholders' deficit of \$41.2 million, versus \$33.6 million at December 31, 2008.

Since our inception through October 2009, we have financed our operations primarily from the private sales of our convertible preferred stock, convertible debt, Common Stock and Common Stock warrants, our public offering in 2002 and follow-on public offering in 2005, exercise of options, various strategic and licensing agreements (including a clinical development agreement with CDC and our Meda Agreements), grants, bank financing, and through the sale of a royalty stream asset.

In January 2009, we filed a universal shelf registration for up to \$50 million of our securities which was declared effective by the SEC and under which can publicly offer our securities over a three year period based on certain terms and conditions to be determined at the time we decide if and when it is prudent to utilize the shelf registration.

In July 2009, we received \$26.8 million from Meda, which consisted of \$11.8 million for the approval of ONSOLIS and \$15.0 million for the production of launch supplies.

In August 2006 and September 2007, we received up-front non-refundable payments in connection with our license, development and supply agreements with Meda of \$2.5 million and \$30.0 million, respectively. In March 2008 we received a milestone payment of \$2.5 million in connection with our Meda EU Agreements. In January 2009 we received \$6.0 million from Meda, which consisted of a \$3.0 million advance against the \$15.0 million approval milestone and \$3.0 million for expansion of the Meda EU license.

During the nine months ended September 30, 2009, we received approximately \$5.1 million in proceeds from warrant exercises and \$0.3 million in proceeds from stock option exercises.

At September 30, 2009, we had cash and cash equivalents of approximately \$25.9 million. The adequacy of cash for our operations and continued research is dependent on, among other things,

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licensing and milestone payments, and additional equity or debt financing opportunities that we are able to negotiate in the coming year. We generated \$22.3 million of cash from operations in the nine-months ended September 30, 2009. This principally resulted from: (1) a net loss of \$21.8 million, which included and was offset by net non-cash charges of \$9.7 million (\$7.4 million derivative loss associated with fair value of outstanding warrants; \$1.7 million stock based compensation; \$0.6 million of depreciation and amortization); (2) aforementioned milestone payments from Meda, along with reimbursements for research and development expenses totaling \$35.0 million; and (3) reduction of our accounts payable and accrued liabilities of \$2.2 million. In accordance with our revenue recognition policy, costs associated with non-cancer breakthrough pain and BREAKYL are expensed in the accompanying financial statements, while the associated reimbursement from Meda is treated as deferred revenue until the products are approved and we have the first commercial sale.

We invested \$2.2 million in 2008 in special equipment we will require for packaging ONSOLIS, which together with \$0.7 million expended in 2007 and final payments of \$0.6 million in 2009 has resulted in total cost of the equipment of \$3.5 million, which we may seek to finance in the future.

On October 6, 2009, we announced our award of a \$1.3 million grant from the Walter Reed Army Institute of Research to support the clinical study of the Company's Bioral Amphotericin B product candidate in the treatment of Cutaneous Leishmaniasis. We expect this to be funded over the next year.

### *Discussion of Plans for Sources and Uses of Capital*

We anticipate that cash used in operations and potential investments we may make in personnel and infrastructure will continue beyond our ONSOLIS agreements with Meda as we research, develop, and, potentially, manufacture and commercialize additional pharmaceutical products that utilize our BEMA® (transmucosal delivery) and Bioral® (drug encochleation) delivery technologies. While we believe further application of our BEMA® and Bioral® technologies to other drugs has the potential to result in license agreements with manufacturers of generic and over-the-counter drugs, our plan of operations for the foreseeable future will be focused on further development of our BEMA® and Bioral® technologies for use in a limited number of pharmaceutical applications.

Prior to the FDA approval of ONSOLIS, we were required under our U.S. Meda agreements to pay certain chemistry, manufacturing and control, as well as clinical and regulatory costs associated with the New Drug Application (NDA) for ONSOLIS. We were also required to incur manufacturing and packaging equipment costs for ONSOLIS. However, our agreements with Meda provide that all pre-launch marketing and commercialization costs for ONSOLIS are to be paid by Meda, as well as any required post-FDA approval amendments or changes to risk assessment and mitigation programs and clinical costs associated with ONSOLIS. Meda will pay for costs of Phase 3-b and Phase 4 studies which, although not required as part of our NDA, may be done to support the program with additional market data.

Pursuant to the Meda U.S. Licensing Agreements, in July 2009 we received additional milestone payments of \$26.8 million in connection with FDA approval of, and satisfactory preparation of launch supplies for, ONSOLIS in the U.S. and expect to receive \$5.0 million from Meda in connection with the commercial launch of BREAKYL in Europe. ONSOLIS will be marketed as BREAKYL in Europe.

Our existing cash and cash equivalents are estimated by our management to be sufficient to finance our planned operations (namely, the advancement of our principal product candidates, BEMA® Buprenorphine and Bioral® Amphotericin B) through 2010. This estimation does not take into

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consideration cash that we may receive in the form of milestone or similar payments should we enter into a commercialization agreement for BEMA<sup>®</sup> Buprenorphine during 2010. No assurances can be given, however, that we will be able to enter into such an agreement.

Also, in the third quarter of 2009, we began pre-clinical development of an additional BEMA<sup>®</sup>-based product candidate, BEMA<sup>®</sup> Granisetron, a potential treatment for nausea and vomiting. Our current plan is to commence Phase I clinical trials for this product candidate in the first quarter of 2010, which will require us to expend funds. We also intend to commence clinical development of a fourth potential BEMA<sup>®</sup> product, BEMA<sup>®</sup> Triptan, a potential treatment for migraines, in the second half of 2010.

As such, and notwithstanding our receipt of the July 2009 \$26.8 million milestone payment from Meda, we may require additional capital to fund our general working capital, to support the commercial launch of ONSOLIS and for the pre-clinical and clinical development programs for the aforementioned products in our pipeline, the scale of which will be dependent in part on the performance of ONSOLIS in the marketplace and the resulting royalties to which we will be entitled and on the results from our clinical studies for each of these products, all of which are uncertain. Our need for additional capital to fund our operations going forward will be even greater should we be unable to generate funds in 2010 from a commercialization agreement for BEMA<sup>®</sup> Buprenorphine.

Moreover, we may consume available resources more rapidly than currently anticipated and we may also be faced with unanticipated spending requirements, resulting in the need for additional funding.

Should additional funding be required to advance our business for these or any other reasons, we will explore a variety of sources, including:

public equity markets (including use of our universal shelf registration statement);

private equity financings;

collaborative arrangements;

grants and new license revenues;

bank loans;

equipment financing;

public or private debt; and

exercise of existing warrants.

We may also opportunistically seek funding (even if cash on hand is deemed to be adequate to support planned operations) if factors such as our public share price or the demand for our securities from potential investors make such funding desirable.

However, the recent worldwide financial and credit crisis has strained investor liquidity and contracted credit markets. If this environment continues or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when we require additional financial investment. If we are unable to attract additional funds it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.





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Readers are cautioned that additional capital under any of the aforementioned circumstances may be unavailable 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 technologies and product candidates or potential markets, any of which could have a material adverse effect on us, our financial condition, our results of operations and our stock price in 2010 and beyond. 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 existing stockholders.

### ***Valuation of Goodwill and Intangible Assets***

Our intangible assets include goodwill, product rights, and licenses, all of which are accounted for based on GAAP related to *Goodwill and Other Intangible Assets*. Accordingly, goodwill is not amortized but is tested at least annually for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with limited useful lives are amortized using the straight-line method over their estimated period of benefit, ranging from eleven to thirteen years. Our carrying value of goodwill at September 30, 2009 was \$2.715 million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements or the underlying patents. Our carrying value of other amortizing intangible assets at September 30, 2009 was \$7.3 million, net of accumulated amortization of \$2.1 million. We begin amortizing capitalized intangibles on their date of acquisition.

### ***Impairment Testing***

Our goodwill impairment testing is calculated at the reporting unit level. Our annual impairment test, which is performed in December, has two steps. The first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired and the second step is not necessary. If the carrying value exceeds the fair value, the second step calculates the possible impairment loss by comparing the implied fair value of goodwill with the carrying amount. If the implied fair value of goodwill is less than the carrying amount, a write-down is recorded. No goodwill impairment charges have resulted from this analysis for 2009 or 2008.

In accordance with generally accepted accounting principles related to the impairment of long-lived assets other than goodwill (our other amortizing intangibles), impairment exists if the sum of the future estimated undiscounted cash flows related to the asset is less than the carrying amount of the intangible asset or to its related group of assets. In that circumstance, then an impairment charge is recorded for the excess of the carrying amount of the intangible over the estimated discounted future cash flows related to the asset.

In making this assessment, we predominately use a discounted cash flow model derived from internal budgets in assessing fair values for our impairment testing. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. In addition, selection of a risk-adjusted discount rate on the estimated undiscounted cash flows is susceptible to future changes in market conditions, and when unfavorable, can adversely affect our original estimates of fair values. In the event that our management determines that the value of intangible assets have

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become impaired using this approach, we will record an accounting charge for the amount of the impairment. No impairment charges have been recorded to other amortizing intangibles in either 2009 or 2008.

### ***Stock-Based Compensation and other stock based valuation issues (derivative accounting)***

We account for stock-based awards to employees and non-employees in accordance with generally accepted accounting principles related to share based payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of the Company's Common Stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide the service in exchange for the award. We use the Black-Scholes options-pricing model to determine the fair value of stock option and warrant grants. We also use the Black Scholes option pricing model as the primary basis for valuing our derivative liabilities at each reporting date (both embedded and free-standing derivatives). The underlying assumptions used in this determination are primarily the same as are used in the determination of stock-based compensation discussed in the previous paragraph except contractual lives of the derivative instruments are utilized rather than expected option terms as discussed in the previous paragraph.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

### **Item 4T. Controls and Procedures**

#### ***Evaluation of Disclosure Controls and Procedures***

As of the end of the period covered by this Quarterly Report, the Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer (the Certifying Officers), conducted evaluations of the Company's disclosure controls and procedures. As defined under Sections 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act), the term disclosure controls and procedures means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including the Certifying Officers, to allow timely decisions regarding required disclosures.

Based on this evaluation, the Certifying Officers have concluded that the Company's disclosure controls and procedures were effective to ensure that material information is recorded, processed, summarized and reported by management of the Company on a timely basis in order to comply with the Company's disclosure obligations under the Exchange Act and the rules and regulations promulgated thereunder.

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### ***Changes in Internal Control over Financial Reporting***

Further, there were no changes in the Company's internal control over financial reporting during the Company's third fiscal quarter of 2009 that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### ***Limitations on the Effectiveness of Internal Controls***

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

### **CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS**

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations (and the Liquidity and Capital Resources section thereof) and elsewhere may address or relate to future events and expectations and as such constitute Forward-Looking Statement within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as projects, may, could, would, should, believes, expects, anticipates, estimates, intends, plans or similar expressions. These statements are based on current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results, including, without limitation: (i) actual sales results and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and the Company's need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA's review and/or approval and commercial launch of the Company's formulations and products and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve 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 2008 Annual Report 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 Quarterly Report.

**Table of Contents****PART II. OTHER INFORMATION****Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

On July 10, 2009, the Company issued a common stock purchase warrant to Aveva Drug Delivery Systems, Inc., the primary manufacturer of the Company's ONSOLIS product, which warrant grants the right to purchase 25,000 shares of Common Stock at an exercise price of \$5.87 per share. Such warrant was issued in replacement of a similar warrant previously granted which had expired. Such warrant was issued pursuant to an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended.

**Item 4. Submission of Matters to a Vote of Security Holders**

On July 23, 2009, the Company held its 2009 annual meeting of stockholders (the Annual Meeting). At the Annual Meeting, all proposals presented were approved by the Company's stockholders. The following is a tabulation of the voting on the proposals presented at the Annual Meeting:

Proposal 1: To approve an amendment to the Company's Amended and Restated 2001 Incentive Plan to increase the number of shares of Company common stock reserved for issuance under such plan from 3,500,000 to 6,000,000.

| Shares Voted For | Shares Withheld | Shares Abstaining | Broker Non-Votes |
|------------------|-----------------|-------------------|------------------|
| 8,145,032        | 408,002         | 43,379            | 8,396,704        |

Proposal 2: To elect Francis E. O'Donnell, Jr., M.D. as a Class I director to serve for a three-year term that expires at the 2012 Annual Meeting of Stockholders, or until his successor has been duly elected and qualified.

| Shares Voted For | Shares Withheld | Shares Abstaining | Broker Non-Votes |
|------------------|-----------------|-------------------|------------------|
| 15,675,928       | 480,666         | 836,521           |                  |

Proposal 3: To ratify the appointment by the Audit Committee of the Company's Board of Directors of Cherry, Bekaert & Holland, L.L.P. as the Company's independent auditors for the fiscal year ending December 31, 2009.

| Shares Voted For | Shares Withheld | Shares Abstaining | Broker Non-Votes |
|------------------|-----------------|-------------------|------------------|
| 15,727,630       | 435,349         | 830,137           |                  |

**Item 6. Exhibits.**

| Number | Description  |
|--------|--|
| 10.1   | Separation Agreement and General Claims Release, dated October 21, 2009, by and between Dr. Raphael J. Mannino and the Company |
| 31.1   | Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302  |
| 31.2   | Certification of Chief Financial Officer 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 (*)   |

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\* 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.

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**SIGNATURES**

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: November 2, 2009

By: /s/ MARK A. SIRGO  
**Mark A. Sirgo, President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: November 2, 2009

By: /s/ JAMES A. McNULTY  
**James A. McNulty, Secretary, Treasurer and Chief Financial**  
**Officer**  
**(Principal Financial Officer)**

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