BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
July 30, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 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	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

801 Corporate Center Drive, Suite #210

Raleigh, NC	**27607**
(Address of principal executive offices)	**(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 x 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 x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Date 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 July 30, 2009, there were 21,014,910 shares of company common stock issued and 20,999,419 shares of company common stock outstanding.

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BioDelivery Sciences International, Inc. and Subsidiaries

Form 10-Q

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2009 (Unaudited)	December 31, 2008	Proforma June 30, 2009 (Unaudited) See Note 8
ASSETS			
Current assets:			
Cash	$ 4,939,195	$ 905,720	$ 31,739,195
Accounts receivable	717,698	468,987	717,698
Prepaid expenses and other current assets	70,629	184,007	70,629
Total current assets	5,727,522	1,558,714	32,527,522
Equipment, net	99,050	126,734	126,734
Goodwill	2,715,000	2,715,000	2,715,000
Other intangible assets:			
Licenses	1,477,041	1,570,020	1,477,041
Acquired product rights	4,029,339	4,256,888	6,029,339
Total other intangible assets	5,506,380	5,826,908	7,506,380
Deposits on equipment	3,523,270	2,954,460	3,523,270
Other assets	8,241	11,571	8,241
Restricted cash	156,00	144,000	156,000
Total assets	$ 17,735,464	$ 13,337,387	$ 46,535,464
LIABILITIES AND STOCKHOLDERS DEFICIT			
Current liabilities:			
Notes payable	$	$ 76,666	$
Accounts payable and accrued liabilities, other	1,696,230	2,684,015	3,696,230
Accounts payable and accrued liabilities, related party	209,886	260,614	209,886
Clinical trial payables and accrued liabilities	768,707	857,996	768,707
Deferred revenue, current (Note 3)	43,036,886	36,060,500	69,836,886
Derivative liability (Note 4)	11,385,628	5,350,829	11,385,628
Total current liabilities	57, 097,337	45,290,620	85,897,337
Deferred revenue, long-term	1,628,539	1,628,539	1,628,536
Total liabilities	58,725,873	46,919,159	87,525,873
Commitments and contingencies (Note 7)			
Stockholders deficit:			
Common stock, $.001 par value; 45,000,000 shares authorized; 20,796,859 and 19,179,029 shares issued; 20,781,368 and 19,163,538 shares outstanding in 2009 and 2008, respectively	20,797	19,179	20,797
Additional paid-in capital	70,542,203	58,706,499	70,542,203
Treasury stock, at cost, 15,491 shares, 2009 and 2008	(47,183)	(47,183)	(47,183)
Accumulated deficit	(111,506,226)	(92,260,267)	(111,506,226)

Total stockholders deficit	(40,990,409)	(33,581,772)	(40,990,409)
Total liabilities and stockholders deficit	$ 17,735,464	$ 13,337,387	$ 46,535,464

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Royalties, related parties	$ 5,621	$ 15,488	$ 11,605	$ 35,236
Research fees/consulting		12,500		117,000
	5,621	27,988	11,605	152,236
Expenses:				
Research and development:				
Related party	47,689	70,914	95,376	537,158
Other	1,810,848	2,637,182	3,676,147	5,849,671
General and administrative:				
Related party	15,000	15,000	30,000	30,300
Other	1,559,086	2,645,292	3,010,325	4,055,725
Total expenses	3,432,623	5,368,388	6,811,848	10,472,854
Loss from operations	(3,427,002)	(5,340,400)	(6,800,243)	(10,320,618)
Interest income (expense), net	1,646	34,226	17,003	(482,651)
Currency translation loss	(6,960)		(6,960)	
Derivative (loss) gain	(11,198,433)	47,100	(12,455,759)	2,283,574
Loss before income taxes	(11,203,747)	(5,259,074)	(19,245,959)	(8,519,695)
Deferred income tax benefit		2,000,000		2,000,000
Net loss	$ (14,630,749)	$ (3,259,074)	$ (19,245,959)	$ (6,519,695)
Per share amounts, basic and diluted	$ (0.75)	$ (0.17)	$ (0.99)	$ (0.34)
Weighted average common stock shares outstanding basic and diluted	19,622,243	19,150,546	19,405,640	19,138,650

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 SIX MONTHS ENDED JUNE 30, 2009

(Unaudited)

	Common Stock		Additional	Treasury	Accumulated	Total Stockholders
	Shares	Amount	Paid-In Capital	Stock	Deficit	Deficit
Balances, January 1, 2009	19,179,029	$ 19,179	$ 58,706,499	$ (47,183)	$ (92,260,267)	$ (33,581,772)
Stock-based compensation			727,822			727,822
Stock option exercises	88,556	89	240,883			240,972
Warrants exercised for cash	1,529,274	1,529	4,446,040			4,447,569
Reclassification of derivative liability to equity			6,420,959			6,420,959
Net loss					(19,245,959)	(19,245,959)
Balances, June 30, 2009	20,796,859	$ 20,797	$ 70,542,203	$ (47,183)	$ (111,506,226)	$ (40,990,409)

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended	
	June 30, 2009	June 30, 2008
Operating activities:		
Net loss	$ (19,245,959)	$ (6,519,695)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	348,213	401,531
Derivative loss (gain)	12,455,759	(2,283,574)
Accretion of interest on convertible debentures		603,836
Stock-based compensation	727,822	1,356,030
Changes in assets and liabilities:		
Accounts receivable	(258,710)	(21,206)
Prepaid expenses and other current assets	106,519	59,209
Accounts payable and accrued expenses	(1,232,312)	(1,118,152)
Deferred revenue	6,976,385	3,923,070
Deferred income tax asset		(2,000,000)
Net cash flows from operating activities	(122,283)	(5,598,951)
Investing activities:		
Purchase of equipment		(26,827)
Deposits on equipment	(413,616)	(1,212,528)
Net cash flows from investing activities	(413,616)	(1,239,355)
Financing activities:		
Proceeds from exercise of stock options	240,972	108,051
Payment on notes payable, related parties		(1,900,000)
Payment of other notes payable	(76,666)	(90,835)
Proceeds from exercise of common stock warrants	4,447,569	
(Repayment of) proceeds from related party borrowings, net	(42,501)	(1,754,588)
Net cash flows from financing activities	4,569,374	(3,637,372)
Net change in cash and cash equivalents	4,033,475	(10,475,678)
Cash and cash equivalents at beginning of period	905,720	16,597,093
Cash and cash equivalents at end of period	$ 4,939,195	$ 6,121,415

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 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 June 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 six months ended June 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 report are encouraged to review the risk factors relating to the Company which are set forth in the 2008 Annual Report.

In the pro-forma balance sheet presented, the approval milestones received of $26.8 million is reflected, as well as the intangible asset of $2.0 million for the milestone owed to QLT USA Inc., (QLT) and the corresponding liability. (See footnote 8)

Fair value of financial assets and liabilities:

The Company measures the fair value of financial assets and liabilities based on the guidance of Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (Statement No. 157) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

Statement No. 157 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. Statement No. 157 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Statement No. 157 describes three levels of inputs that may be used to measure fair value:

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

(Unaudited)

1. Basis of presentation (continued):

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)

The following table summarizes liabilities measured at fair value on a recurring basis at June 30, 2009, as required by Statement No. 157:

	Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Derivative liabilities	$	$ 11,385,628	$	$ 11,385,628

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 will be effective for financial statements issued for reporting periods that end after September 15, 2009. Once it s effective, it will supersede all accounting standards in U.S. GAAP, aside from those issued by the SEC. SFAS No. 168 replaces SFAS No. 162 to establish a new hierarchy of GAAP sources for non-governmental entities under the FASB Accounting Standards Codification.

In April 2009, the FASB issued FASB Staff Position (FSP) No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments* (FSP No. 107-1 and APB 28-1), which requires disclosures about fair value of financial instruments for interim reporting periods. This guidance is effective for the Company s interim reporting periods ending after June 15, 2009. The Company has determined that the adoption of this guidance had no financial impact on the consolidated financial statements and disclosures.

In April 2009, the FASB issued FSP FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* (FSP FAS 157-4), FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* (FSP FAS 115-2 and FAS 124-2), and FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments* (FSP FAS 107-1 and APB 28-1) to address fair value valuation concerns in the current market environment. FSP FAS 157-4 affirms that when the market for an asset is not active, the objective of fair value is the price that would be received to sell the asset in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date in the inactive market. The determination of whether a transaction was not orderly should be based on the weight of the evidence. The FSP requires an entity to disclose a change in valuation technique and the related inputs resulting from the application of the FSP and to quantify its effects. Retrospective application is not permitted. The FSP is effective for interim and annual periods ending after June 15, 2009. This adoption has not materially affected the Company s results of operations, statement of position or cash flows.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

(Unaudited)

1. Basis of presentation (continued):

In November 2008, the FASB issued Emerging Issues Task Force 08-1, *Revenue Arrangements with Multiple Deliverables* (EITF 08-1). EITF 08-1 is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after December 31, 2009 and shall be applied on a prospective basis. Earlier application is permitted as of the beginning of a fiscal year. EITF 08-1 addresses some aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. The Company plans to adopt, once there is a consensus and ratification, EITF 08-1 on January 1, 2010, and will evaluate the possible impact on its consolidated financial statements.

Management has adopted the provisions set forth in SFAS No. 165, *Subsequent Events*, and considered subsequent events through July 30, 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. 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. 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.

In addition, the Company expects to generate royalty revenue starting in the fourth quarter of 2009 as a result of the approval of the Company s new drug application (NDA) for its lead product, ONSOLIS (fentanyl buccal soluble film), by the U.S. Food and Drug Administration (FDA) (see Note 8, Subsequent Events, below). ONSOLIS , formerly known as BEMA® Fentanyl, is a treatment 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®, a small, erodable polymer film for application to the buccal mucosa (the lining inside the cheek).

Significant financing or commitments during the six months ended June 30, 2009 consisted of a $6.0 million payment received in January 2009 from the Company s commercialization partner for ONSOLIS , Meda AB (Meda), which consisted of a $3.0 million advance against the $15 million approval milestone for ONSOLIS in the United States and $3.0 million related to amendments to the material agreements between the Company, Arius and Meda (such agreements, collectively, the Meda EU License Agreements) relating to the commercialization of BREAKYL (as ONSOLIS will be known and marketed in Europe) in the European Union, which amendments included the expansion of the territory covered by such agreements to cover the entire world except the U.S., Canada and Mexico (which are covered in separate agreements between the Company, Arius and Meda (such agreements, the Meda U.S. License Agreements)) and Taiwan and South Korea (the rights to which remain with the Company).

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

(Unaudited)

2. Liquidity and management s plans (continued):

During the six months ended June 30, 2009 the Company received cash from the exercise of certain outstanding warrants to purchase Common Stock of approximately $4.4 million. Stock option exercises during the same time period were approximately $0.2 million.

During July 2009, the Company received a $26.8 million milestone payment under the Meda U.S. License Agreements as a result of FDA s approval of the ONSOLIS NDA and the satisfactory preparation of commercial launch supplies of ONSOLIS .

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 or loans 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 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 financial investment. 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 and financial condition.

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 (pursuant to the Meda U.S. Licensing Agreements) and in certain countries in Europe (pursuant to 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

(Unaudited)

3. Meda License, Development and Supply Arrangements (continued):

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 Nonrefundable Upfront and Milestone Payments		As Delivered	Cash Flows Received and Revenue Deferred	
	U.S. Arrangement	EU Arrangement		June 30, 2009	December 31, 2008
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		$ 3,000,000**	
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			
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	$ 2,429,963	$ 1,553,627
Non-Cancer subsequent indication of product and further development of initial product			Contract Hourly Rates	$ 1,235,462	$ 1,135,412
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		
Total				$ 44,665,425	$ 37,689,039

* 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

(Unaudited)

3. Meda License, Development and Supply Arrangements (continued):

The Company has assessed the arrangement deliverables under the guidance of Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21) 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 application of EITF 00-21 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 and based on the residual method an estimated $59.6 million (under the U.S. arrangement) and $15.8 million (under the EU arrangement) of the aggregate upfront and deferred, product development milestone, and research and development services revenue earned will be recognized as revenue.

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

(Unaudited)

4. Derivative Financial Instruments (continued):

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

Derivative liability at fair value:	June 30, 2009 (unaudited)	December 31, 2008
Free standing warrants*	$ 11,385,628	$ 5,350,829

* These warrants can be settled by issuance of 3,092,991 and 4,622,265 shares of Common Stock at June 30, 2009 and December 31, 2008, respectively.

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

Derivative (loss) income in the accompanying statement of operations is related to the individual derivatives as follows:	3 months ending June 30, 2009	3 months ending June 30, 2008	6 months ending June 30, 2009	6 months ending June 30, 2008
Free standing derivatives (principally warrants)	(11,198,433)	47,100	(12,455,759)	2,283,574

5. Stockholders equity:

Stock-based compensation:

During the six months ended June 30, 2009, 391,605 options with fair market value of approximately $0.9 million were granted to certain employees 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 six months ended June 30, 2009 follows:

Expected price volatility	57.88%-84.01%
Risk-free interest rate	0.64%-1.82%
Weighted average expected life in years	1-6 years
Dividend yield	

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

(Unaudited)

5. Stockholders equity (continued):

Option activity during the six months ended June 30, 2009 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2009	3,503,467	$ 3.56	
Granted			
Officers and Directors	221,450	4.66	
Others	170,155	3.06	
Exercised	(88,556)	2.72	
Forfeitures	(8,215)	2.27	
Outstanding at June 30, 2009	3,798,301	$ 3.62	$ 11,622,804

Options outstanding at June 30, 2009 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	3,034,556	7.62	$ 2.90	
$ 5.01 10.00	763,745	7.80	$ 6.47	
	3,798,301			$ 11,622,804

Options exercisable at June 30, 2009 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	1,982,249	6.85	$ 2.86	
$ 5.01 10.00	542,414	7.80	$ 6.44	

	2,524,663	$ 7,705,718

The weighted average grant date fair value of options granted during the six months ended June 30, 2009 whose exercise price is equal to or above the market price of the stock at the grant date was $4.01. There were no options granted during the six months ended June 30, 2009 whose exercise price is lower than the estimated market price of the stock at the grant date.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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(Unaudited)

5. Stockholders equity (continued):

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

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Intrinsic Value
Nonvested at January 1, 2009	1,360,212		
Granted	391,605		
Vested	(469,964)		
Forfeited	(8,215)		
Nonvested at June 30, 2009	1,273,638	$ 3.60	$ 3,917,086

As of June 30, 2009, there was approximately $1.9 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 June 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	3,594,491	3.89	$ 3.68	
$ 5.01 10.00	700,000	2.30	$ 5.45	
	4,294,491			$ 11,636,336

Reclassification of derivative liability to equity:

During the quarter ended June 30, 2009, Laurus Master Fund Ltd. (Laurus) exercised warrants to purchase 1,529,274 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.

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(Unaudited)

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 June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Net loss	$ (14,630,749)	$ (3,259,074)	$ (19,245,959)	$ (6,519,695)
Basic and diluted:				
Weighted average shares outstanding (denominator)	19,622,243	19,150,546	19,405,640	19,138,650
Net loss per common share basic and diluted	$ (0.75)	$ (0.17)	$ (0.99)	$ (0.34)

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

7. Commitments and contingencies:

On August 28, 2007, the Company agreed with Doyen Medipharm Inc. to purchase a BEMA® related pharmaceutical device production machine. The Company has paid approximately $3.5 million (included in deposits on equipment in the accompanying condensed consolidated balance sheet) which is substantially all the total cost.

8. Subsequent events:

On July 16, 2009, the Company and Meda announced approval from the FDA to market ONSOLIS for the management of 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. 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 from which the Company purchased the BEMA® delivery technology, which has been accrued as of the approval date.

On July 22, 2009, the Company announced its receipt of $26.8 in million milestone payments from Meda described above. The Company had received an advance on the approval milestones of $3.0 million in January 2009, as well as an additional $3.0 million for an expansion of the EU license, with an agreement that Meda would reduce the balance of $27.0 million by $0.2 million as a fee. The accompanying financial statements include a pro-forma balance sheet that shows the effect on cash and deferred revenue as a result of our receipt of the milestone payments (see

Note 3 for accounting treatment of deferred revenue). The pro-forma balance sheet also shows the $2.0 million intangible asset and corresponding liability to QLT.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2009 AND 2008

(Unaudited)

8. Subsequent events (continued):

On July 23, 2009, the Company held its 2009 annual meeting of stockholders (the Annual Meeting). At the Annual Meeting, a majority of the Company s shares of Common Stock represented at the Annual Meeting approved, among other matters, a proposal to amend the Company s Amended and Restated 2001 Incentive Plan to increase the number of shares of Common Stock reserved for issuance under such plan from 3,500,000 to 6,000,000. As a result, all stock options grants previously made and reported as having been made subject to the increase in such plan were deemed approved.

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Item 2. Management s Discussion and Analysis or Plan of Operation.

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-Q. 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.

For the three months ended June 30, 2009 compared to the three months ended June 30, 2008

Royalty Revenues. For the three-month period ended June 30, 2009 and 2008, the Company reported $0.01 million and $0.02 million, respectively, in royalty revenue from a related company.

Research fees/consulting. For the three-month period ended June 30, 2009 and 2008, the Company reported $0.0 and $0.01 million, respectively, in research and development services.

Research and Development. Research and development expenses of approximately $1.9 million and $2.7 million were incurred during the three-month periods ended June 30, 2009 and 2008, respectively. These aforementioned amounts included $0.0 and $0.02 million, respectively, paid to a contract research organization, which was a stockholder of the Company. The reduction in expenses from 2008 to 2009 resulted from reduced ONSOLIS product development; as such product was being reviewed for approval by the FDA. The Company s scientific staff continued to work toward increased development and application of our BEMA® and Bioral® technologies and other drug-related areas, however, certain parts of our development program (other than ONSOLIS) were delayed due to cash constraints. 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® and Bioral® drug delivery technologies.

General and Administrative Expenses. General and administrative expenses of approximately $1.6 million and $2.7 million were incurred in the three-month periods ended June 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 decrease from 2008 to 2009 was primarily related to the Company s recording of stock based compensation of $0.4 million and $1.2 million during the three months ended June 30, 2009 and 2008, respectively.

Interest Income (expense). Interest income (expense) for the periods ended June 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 increase in the derivative loss is due to the Company s stock price increase during the three months ended June 30, 2009, which triggers a non-cash expense and an associated increase in the derivative liability.

Income Taxes. While net operating losses were generated during the three months ended June 30, 2009, we did not recognize any benefit associated with these losses, as all related deferred tax assets

have been fully reserved. During the three months ended June 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 revenues which are currently deferred for financial reporting purpose became taxable in 2008.

For the Six Months Ended June 30, 2009 Compared to the Six Months Ended June 30, 2008

Royalty Revenues. During the six-month periods ending June 30, 2009 and 2008, we reported $0.01 million and $0.04 million, respectively, of royalty revenue from a related company.

Research fees/consulting. During the six-month periods ending June 30, 2009 and June 30, 2008, we reported $0.0 and $0.1 million, respectively, of research and development services.

Research and Development. Research and development expenses of approximately $3.8 million and $6.4 million were incurred during the respective six-month periods ended June 30, 2009 and 2008. These aforementioned amounts included $0.0 and $0.5 million, respectively, paid to a contract research organization that was a stockholder of the Company. Our pipeline development is managed based on our available cash resources, which reduced as we approached our initial Prescription Drug User Fee Act (PDUFA) date of August 25, 2008, and then again with our final PDUFA date of June 12, 2009. The reduction in expenses from 2008 to 2009 was a result of the efforts put into ONSOLIS product development being substantially completed as we progressed toward final approval, which we received on July 16, 2009. Our scientific staff continued to work toward increased development and application of our BEMA® and Bioral® technologies and other drug-related areas, but certain parts of our development program (other than ONSOLIS) were delayed due to cash constraints. 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® and Bioral® drug delivery technologies.

General and Administrative Expenses including Stock-based Compensation. General and administrative expenses of approximately $3.0 million and $4.1 million were incurred in the six-month periods ended June 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 decrease from 2008 to 2009 was primarily related to reduced legal fees and the Company s recording of stock based compensation of $0.7 million and $1.4 million during the six months ended June 30, 2009 and 2008, respectively.

Interest Expense Net. Interest expense for the periods ended June 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.

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 Company s stock price during the six months ended June 30, 2009, which triggers a non-cash expense and an associated increase in the derivative liability.

Income Taxes. While net operating losses were generated during the six months ended June 30, 2009, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. During the six months ended June 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 approximately $30.0 million of revenues which are currently deferred for financial reporting purpose became taxable in 2008, notwithstanding the Company s financial accounting with regard to this item.

Liquidity and Capital Resources

Since our inception through July 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), NIH 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 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 six months ended June 30, 2009, we received approximately $4.4 million in proceeds from warrant exercises and $0.2 million in proceeds from stock option exercises.

At June 30, 2009, we had cash and cash equivalents of approximately $4.9 million. The adequacy of cash for our operations and continued research is dependent on, among other things, licensing and milestone payments, and additional equity or debt financing opportunities that we are able to negotiate in the coming year. We used $0.1 million of cash from operations in the six-months ended June 30, 2009. This principally resulted from: (1) a net loss of $19.2 million, which included and was offset by net non-cash charges of $13.5 million ($12.5 million derivative loss associated with fair value of outstanding warrants; $0.7 million stock based compensation; $0.3 million of depreciation and amortization); (2) an aforementioned payment from Meda of $6.0 million; (3) reimbursement by Meda of $1.0 million for research and development work on non-cancer breakthrough pain and BREAKYL approval in Europe; and (4) reduction of our accounts payable and accrued liabilities of $1.2 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 upon acceptance and validation of the equipment.

We have incurred significant net losses and negative cash flows from operations since our inception. As of June 30, 2009, we had stockholders deficit of $41.0 million, versus $33.6 million at December 31, 2008.

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We anticipate that cash used in operations and our investment in facilities will continue beyond our ONSOLIS agreements with Meda, as we research, develop, and, potentially, manufacture and commercialize additional drug formulations with our BEMA® (transmucosal delivery) and Bioral® (drug encochleation) technologies. While we believe further application of our BEMA® and Bioral® technologies to other drugs have 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 applications. Such focus will not be on the marketing or sale of FDA approved products.

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 NDA. 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 change 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.

Under our existing Meda agreements, in July 2009 we have 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 in connection with the commercial launch of BREAKYL in Europe.

Our existing cash and cash equivalents are believed by our management to be sufficient to finance planned operations (including the advancement of our product candidates, including principally BEMA® Buprenorphine and Bioral® Amphotericin) through 2010.

However, and notwithstanding our receipt of the $26.8 million milestone payment from Meda, additional capital will be required in order to proceed with our support of the commercial launch of ONSOLIS , clinical development programs for other products in our pipeline, such as BEMA® Buprenorphine and Bioral® Amphotericin B (the scale of which is dependent in part on the success of ONSOLIS and on the results from our clinical studies for each of these products), and for general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

- public equity markets;
- private equity financings;
- collaborative arrangements;
- grants and new license revenues;
- bank loans;
- equipment financing;

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- public or private debt; and
- exercise of existing warrants.

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.

Readers are cautioned that additional capital 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 drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations 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 Financial Accounting Standard Statement No. 142 Goodwill and Other Intangible Assets (FAS 142). As described below, 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 June 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 June 30, 2009 was $5.5 million, net of accumulated amortization of $1.9 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 Statements of Financial Accounting Standards (SFAS) 144, which relates to 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.

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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 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 using the accounting provisions of SFAS 123R *Accounting for 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 Commission 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, included the Certifying Officers, to allow timely decisions regarding required disclosures.

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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.

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 second 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

The information set forth in this Quarterly Report on Form 10-Q under the Sections Management s Discussion and Analysis or Plan of Operation , Management s plans regarding liquidity and capital resources and elsewhere relate to future events and expectations and as such constitute Forward-Looking Statement within the meaning of the Private Securities Litigation Act of 1995. 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 , anticipates , estimates , intends , plans or similar expressions. These statements are based upon the 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.

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PART II. OTHER INFORMATION

Item 6. Exhibits.

Number	Description
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 (*)

* 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: July 30, 2009

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

Date: July 30, 2009

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