BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 15, 2009
Table of Contents

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 March 31, 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 has submitted electronically and posted on its corporate Web site, 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 ¨

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 May 15, 2009, there were 19,248,303 shares of company common stock issued and 19,232,812 shares of company common stock outstanding.

Table of Contents

BioDelivery Sciences International, Inc. and Subsidiaries

Form 10-Q

TABLE OF CONTENTS

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2009 (Unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash	$ 2,682,888	$ 905,720
Accounts receivable	487,181	468,987
Prepaid expenses and other current assets	153,741	184,007
Total current assets	3,323,810	1,558,714
Equipment, net	111,588	126,734
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,523,531	1,570,020
Acquired product rights	4,143,113	4,256,888
Total other intangible assets	5,666,644	5,826,908
Deposits on equipment	3,180,237	2,954,460
Other assets	10,010	11,571
Restricted cash	154,190	144,000
Total assets	$ 15,161,479	$ 13,337,387
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Notes payable	$ 19,166	$ 76,666
Accounts payable and accrued liabilities, other	1,105,103	2,684,015
Accounts payable and accrued liabilities, related party	316,547	260,614
Clinical trial payables and accrued liabilities	760,956	857,996
Deferred revenue, current	42,570,628	36,060,500
Derivative liability (Note 4)	6,414,948	5,350,829
Total current liabilities	51,187,348	45,290,620
Deferred revenue, long-term	1,628,536	1,628,539
Total liabilities	52,815,884	46,919,159
Commitments and contingencies (Note 7)		
Stockholders deficit:		
Common stock, $.001 par value; 45,000,000 shares authorized 19,248,303 and 19,179,029 shares issued; 19,232,812 and 19,163,538 shares outstanding in 2009 and 2008, respectively	19,248	19,179
Additional paid-in capital	59,249,007	58,706,499
Treasury stock, at cost, 15,491 shares, 2009 and 2008	(47,183)	(47,183)
Accumulated deficit	(96,875,477)	(92,260,267)
Total stockholders deficit	(37,654,405)	(33,581,772)

Total liabilities and stockholders deficit	$ 15,161,479	$ 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	
	March 31, 2009	March 31, 2008
Revenues:		
Royalty revenue, related party	$ 5,984	$ 19,748
Research fees		104,500
Total revenues	5,984	124,248
Expenses:		
Research and development:		
Related party	47,687	466,244
Other	1,865,299	3,212,488
General and administrative:		
Related party	15,000	15,300
Other	1,451,240	1,407,085
Total expenses	3,379,226	5,101,117
Loss from operations	(3,373,242)	(4,976,869)
Interest income (expense), net	15,357	(520,226)
Derivative (loss) gain	(1,257,325)	2,236,474
	(1,241,968)	1,716,248
Net loss	(4,615,210)	(3,260,621)
Loss attributable to common stockholders	$ (4,615,210)	$ (3,260,621)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (0.24)	$ (0.17)
Weighted average common stock shares outstanding basic and diluted	19,186,629	19,126,755

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS DEFICIT

FOR THE THREE MONTHS ENDED MARCH 31, 2009

(Unaudited)

	Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders
	Shares	Amount	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			349,303			349,303
Warrants exercised for cash	69,274	69				69
Reclassification of derivative liability to equity			193,205			193,205
Net loss					(4,615,210)	(4,615,210)
Balances, March 31, 2009	19,248,303	$ 19,248	$ 59,249,007	$ (47,183)	$ (96,875,477)	$ (37,654,405)

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended	
	March 31, 2009	March 31, 2008
Operating activities:		
Net loss	$ (4,615,210)	$ (3,260,621)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	175,409	201,081
Derivative loss (gain)	1,257,325	(2,236,474)
Accretion of interest on notes payable, related party		603,836
Stock-based compensation	349,303	140,538
Changes in assets and liabilities:		
Accounts receivable	(28,193)	72,598
Prepaid expenses and other current assets	21,638	(27,990)
Accounts payable and accrued expenses	(1,815,157)	(1,290,631)
Deferred revenue	6,510,128	3,124,080
Net cash flows from operating activities	1,855,243	(2,673,583)
Investing activities:		
Redemption of certificate of deposit		2,800,000
Purchase of equipment		(25,444)
Deposits on equipment	(86,578)	(630,305)
Net cash flows from investing activities	(86,578)	2,144,251
Financing activities:		
Proceeds from issuance of common stock		108,051
Warrants exercised for cash	69	
Change in amounts due to related parties	65,933	(1,437,288)
Payment on notes payable	(57,499)	(1,968,124)
Net cash flows from financing activities	8,503	(3,297,361)
Net change in cash	1,777,168	(3,826,693)
Cash at beginning of period	905,720	13,797,093
Cash at end of period	$ 2,682,888	$ 9,970,400

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 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 March 31, 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 three months ended March 31, 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.

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 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:

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 THREE MONTHS ENDED MARCH 31, 2009 AND 2008

(Unaudited)

1. Basis of presentation (continued):

The following table summarizes liabilities measured at fair value on a recurring basis at March 31, 2009, as required by Statement No. 157:

	Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Derivative liabilities	$	$ 6,414,948	$	$ 6,414,948

New accounting pronouncements

In April 2009, the Financial Accounting Standards Board (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 and will apply to disclosures beginning with the second fiscal quarter of 2009. The Company has determined that the adoption of this guidance will have no financial impact on the consolidated financial statements and disclosures.

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 ratified, EITF 08-1 on January 1, 2010, and will evaluate the possible impact on its consolidated financial statements.

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 is not expected to materially affect the Company s results of operations, statement of position or cash flows.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2009 AND 2008

(Unaudited)

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. 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.

Significant financing or commitments during the three months ended March 31, 2009 consisted of a $6.0 million payment received in January 2009, which consisted of a $3.0 million advance against the $15 million approval milestone for the Company s lead product in development in the United States, ONSOLIS , and $3.0 million related to amendments to the material agreements relating to the commercialization of BREAKYL (as ONSOLIS will be known and marketed in Europe) in the European Union (the Meda EU License Agreements) between the Company, Arius and the Company s commercial partner for ONSOLIS , Meda AB (Meda), 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 and Meda (such agreements, the Meda U.S. License Agreements) and Taiwan and South Korea (the rights to which remain with the Company).

Company management believes that the Company s existing cash and cash equivalents are sufficient to finance planned basic operations (minimal research and development activities beyond those covered under the Company s agreements with Meda) through the second quarter of 2009.

While the Company expects that significant additional payments (aggregating an additional $35.0 million) will be received in 2009 under the Meda U.S. and EU License Agreements, the receipt of such payments is conditional upon, among other things, approval of the Company s new drug application (NDA) for ONSOLIS by the U.S. Food and Drug Administration (FDA) and its subsequent 2009 approval of BREAKYL in Europe. As such, payments may not be received in 2009 or at all. Accordingly, and especially if such payments are not received, additional outside capital will be required in order to support the Company s 2009 operations, as well as future development activities around the Company s current pipeline of products in development or other initiatives that the Company may elect to pursue.

As an additional potential source of cash, the Company is also currently negotiating an equipment loan financing for specialized equipment manufactured for the Company by Doyen Medipharm Inc. and which will be used by our third-party manufacturer of the ONSOLIS product. No assurances can be given that such financing shall be entered into.

In addition, 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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2009 AND 2008

(Unaudited)

2. Liquidity and management s plans (continued):

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 , a drug treatment for breakthrough cancer pain delivered through a patented transmucosal drug delivery technology, BEMA (applied to the inner cheek mucosa) 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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 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		March 31, 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	$ 1,972,164	$ 1,553,627
Non-Cancer subsequent indication of product and further development of initial product			Contract Hourly Rates	$ 1,227,000	$ 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				$ 44,199,164	$ 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.

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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2009 AND 2008

(Unaudited)

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

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 $16.3 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 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 March 31, 2009 and December 31, 2008:

Derivative liability at fair value:	March 31, 2009 (unaudited)	December 31, 2008
Free standing warrants*	$ 6,414,948	$ 5,350,829

* These warrants can be settled by issuance of 4,552,991 and 4,622,265 Common Shares at March 31, 2009 and December 31, 2008, respectively.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2009 AND 2008

(Unaudited)

4. Derivative Financial Instruments (continued):

The following tabular presentation reflects the components of derivative financial instruments for the three months ended March 31, 2009 and 2008:

Derivative (expense) income in the accompanying statements of operations is related to the individual derivatives as follows:	**March 31, 2009**	**March 31, 2008**
Free standing derivatives (principally warrants)	$ (1,257,325)	$ 2,236,474

5. Stockholders equity:

Stock-based compensation:

During the three months ended March 31, 2009, 190,389 options with fair market value of about $0.6 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 three months ended March 31, 2009 follows:

Expected price volatility	57.88%-74.55%
Risk-free interest rate	0.64%-1.61%
Weighted average expected life in years	1-6 years
Dividend yield	

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2009 AND 2008

(Unaudited)

5. Stockholders equity (continued):

Option activity during the three months ended March 31, 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	42,163	3.05	
Others	148,226	2.99	
Exercised			
Forfeitures	(6,999)	2.23	
Outstanding at March 31, 2009	3,686,857*	$ 3.53	$ 2,215,512

Options outstanding at March 31, 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	2,923,112	7.72	$ 2.76	
$ 5.01 10.00	763,745	8.04	$ 6.48	
	3,686,857*			$ 2,515,512

Options exercisable at March 31, 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	2,068,039	7.13	$ 2.85	
$ 5.01 10.00	287,916	8.06	$ 6.33	
	2,355,955			$ 1,454,417

The weighted average grant date fair value of options granted during the three months ended March 31, 2009 whose exercise price is equal to the market price of the stock at the grant date was $3.00. There were no options granted during the three months ended March 31, 2009 whose exercise price is greater or lower than the estimated market price of the stock at the grant date.

(*) As of the date of this Quarterly Report, the Company has issued stock options under its Amended and Restated 2001 Incentive Plan in excess of the 3,500,000 shares of Common Stock currently authorized under such plan. Any such excess issuances are subject to approval by the Company s stockholders. Readers are advised that the Company plans on proposing an increase in the number of shares of Common Stock available for issuance under the Company s Amended and Restated 2001 Incentive Plan, which proposal is expected to be voted upon at the Company s upcoming 2009 Annual Meeting of Stockholders.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2009 AND 2008

(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 three months ended March 31, 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	190,389		
Vested	(212,700)		
Forfeited	(6,999)		
Nonvested at March 31, 2009	1,330,902	$ 3.99	$ 761,095

As of March 31, 2009, there was approximately $1.0 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 March 31, 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	5,079,491	4.35	$ 3.50	
$ 5.01 10.00	700,000	2.54	$ 5.45	
	5,779,491			$ 1,307,651

Reclassification of derivative liability to equity:

During the quarter ended March 31, 2009, Laurus Master Fund Ltd. (Laurus) exercised warrants to purchase 69,274 shares of the Company s common stock for $0.001 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 March 31,	
	2009	**2008**
Net loss attributable to common stockholder (numerator)	$ (4,615,210)	$ (3,260,621)
Basic and diluted:		
Weighted average shares outstanding (denominator)	19,186,629	19,126,755
Net loss per common share basic and diluted	$ (0.24)	(0.17)

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2009 AND 2008

(Unaudited)

6. Net loss per common share (continued):

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:

Equipment purchase commitment

On August 28, 2007, the Company agreed with Doyen Medipharm Inc. to purchase a BEMA related pharmaceutical device production machine. The Company has made payments or has accrued approximately $3.2 million (included in deposits on equipment in the accompanying condensed consolidated balance sheet) toward the total cost, which will be approximately $3.5 million. Payments are being made in separate increments during the production of the equipment.

Vendor contract

In February and March 2009, the Company entered into a Master Clinical Development Agreement and related proposal with Premier Research International LLC for research and development services related to the Company s BEMA Buprenorphine product. The services to be provided are approximately $1.2 million which will be performed over nine months. The Company has a termination clause which upon 30 days written notice allows them to terminate the contract.

Employee bonuses

In April 2009, the Compensation Committee of the Board of Directors, approved payment of employee bonuses of approximately $0.8 million contingent upon approval of ONSOLIS and receipt of approval and launch milestones.

Table of Contents

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.

For the Three Months Ended March 31, 2009 Compared to the Three Months Ended March 31, 2008

Research Fee Revenues. During the three-month period ending March 31, 2008 we reported research revenues of $0.1 million. There were no such research revenues during the three-month period ending March 31, 2009.

Royalty Revenues. During the three-month periods ending March 31, 2009 and March 31, 2008, we reported $0.006 million and $0.02 million, respectively, of royalty revenue from a related company.

Research and Development. Research and development expenses of approximately $1.9 million and $3.7 million were incurred during the respective three-month periods ended March 31, 2009 and 2008. These aforementioned amounts included $0.5 million in the three-month period ended March 31, 2008, paid to a contract research organization that was a stockholder of the Company. Our scientific staff continued to work toward increased development and application of our BEMA and Bioral 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 and Bioral drug delivery technologies.

General and Administrative Expenses including Stock-based Compensation. General and administrative expenses of approximately $1.5 million and $1.4 million were incurred in the three-month periods ended March 31, 2009 and 2008, respectively. Such amounts included $0.3 million and $0.1 million in stock based compensation expense during the three months ended March 31, 2009 and 2008, respectively. General and administrative 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.

Interest Expense Net. Interest expense for the periods ended March 31, 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 (Loss) gain. Derivative (loss) gain during 2009 and 2008 is related to the adjustment of derivative liabilities to fair value. These derivatives relate to prior financings with CDC IV, LLC (CDC), Laurus and Hopkins Capital Group II, LLC (HCG). The change in derivative (loss) gain is attributed to the increase in the stock price of the Company and the interest rate from the period ended March 31, 2009 from December 31, 2009.

Income Taxes. While net operating losses were generated during the three months ended March 31, 2009 and 2008, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved.

Table of Contents

Liquidity and Capital Resources

Since our inception through May 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.

At March 31, 2009, we had cash and cash equivalents of approximately $2.7 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 $1.9 million of cash from operations in the three-months ended March 31, 2009. This principally resulted from: (1) a net loss of $4.6 million, which included net non-cash charges of $1.8 million; (2) an aforementioned payment from Meda of $6.0 million; (3) reimbursement from Meda of $0.5 million for research and development work on non-cancer breakthrough pain and BREAKYL approval in Europe, which accordingly increased our deferred revenue; and (4) reduction of our accounts payable and accrued liabilities were reduced by $1.8 million.

We invested an additional $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 will result 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 March 31, 2009, we had stockholders deficit of $37.7 million, versus $33.6 million at December 31, 2008.

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, production or sale of FDA approved products.

Until FDA approval of ONSOLIS , we are 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.

Table of Contents

We are 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 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, we expect to receive additional milestone payments of $31.9 million upon approval and commercial launch of ONSOLIS in the U.S. ($26.9 million) and BREAKYL in Europe ($5 million). We expect a decision from FDA regarding ONSOLIS in the first half of 2009.

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.

Our existing cash and cash equivalents are believed by our management to be sufficient to finance planned basic operations (only minimal research and development activities beyond those covered under our Meda and other related agreements), debt repayment obligations and capital expenditures through the second quarter of 2009.

However, we may never receive FDA approval or the timing of such approval, if received, may take substantially longer than anticipated, which would delay the expected milestone payments from Meda. Moreover, 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;
- public or private debt; and

Table of Contents

exercise of existing warrants.

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 2009 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 March 31, 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 March 31, 2009 was $5.7 million, net of accumulated amortization of $1.3 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.

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

Table of Contents

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.

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.

Table of Contents

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 first 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.

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.

Table of Contents

PART II. OTHER INFORMATION

Item 5. Other Information.

In February and March 2009, the Company entered into a Master Clinical Development Agreement and related proposal with Premier Research International LLC for research and development services related to the Company s BEMA Buprenorphine product. The services to be provided are approximately $1.2 million which will be performed over nine months. The Company has a termination clause which upon 30 days written notice allows them to terminate the contract. The Master Clinical Development Agreement and related proposal are filed as exhibits to this Quarterly Report.

Item 6. Exhibits.

Number	Description
10.1	Master Clinical Development Agreement, dated February 12, 2009, between the Company and Premier Research International LLC +
10.2	Proposal for Clinical Research Services, dated March 13, 2009, between the Company and Premier Research International LLC +
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 (*)

+ Confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.

* 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.

Table of Contents

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: May 15, 2009

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

Date: May 15, 2009

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

S-1