BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 10, 2010
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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 March 31, 2010

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

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

As of May 7, 2010, there were 24,038,445 shares of company common stock issued and 24,022,954 shares of company common stock outstanding.

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BioDelivery Sciences International, Inc. and Subsidiaries

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF MARCH 31, 2010 AND DECEMBER 31, 2009

AND PROFORMA CONDENSED CONSOLIDATED BALANCE SHEETS AS OF MARCH 31, 2010

(Unaudited)

	March 31, 2010	December 31, 2009	Proforma March 31, 2010 (Note 8)
ASSETS			
Current assets:			
Cash and cash equivalents	$ 17,110,838	$ 23,873,403	$ 27,110,838
Accounts receivable, other	466,401	1,268,712	466,401
Prepaid expenses and other current assets	214,847	287,978	214,847
Total current assets	17,792,086	25,430,093	27,792,086
Equipment, net	3,729,905	3,743,011	3,729,905
Goodwill	2,715,000	2,715,000	2,715,000
Other intangible assets:			
Licenses	1,337,572	1,384,063	1,337,572
Acquired product rights	5,592,271	5,745,144	5,592,271
Total other intangible assets	6,929,843	7,129,207	6,929,843
Derivative asset (warrant), related party	3,124,400		3,124,400
Due from related party, warrant receivable		638,600	
Other assets	21,976	21,976	21,976
Total assets	$ 34,313,210	$ 39,677,887	$ 44,313,210
LIABILITIES AND STOCKHOLDERS EQUITY			
Current liabilities:			
Accounts payable and accrued liabilities, other	$ 919,053	$ 3,172,406	$ 1,181,553
Accounts payable and accrued liabilities, related party	221,581	2,723,844	221,581
Clinical trial payables and accrued liabilities, other	584,058	674,343	584,058
Income taxes payable		312,128	
Deferred revenue, current	11,970,840	11,758,732	11,970,840
Derivative liabilities (note 5)	4,211,284	4,978,256	7,072,161
Total current liabilities	17,906,816	23,619,709	21,030,193
Deferred revenue, long-term	1,607,911	1,599,879	1,607,911
Total liabilities	19,514,727	25,219,588	22,638,104
Commitments and contingencies			
Stockholders equity:			
	21,214	21,182	24,039

Common Stock, $.001 par value; 45,000,000 shares authorized, 21,213,587 and 21,181,854 shares issued; 21,198,096 and 21,166,363 shares outstanding in 2009 and 2008, respectively			
Additional paid-in capital	74,229,192	73,697,818	81,102,990
Treasury stock, at cost, 15,491 shares, 2010 and 2009	(47,183)	(47,183)	(47,183)
Accumulated deficit	(59,404,740)	(59,213,518)	(59,404,740)
Total stockholders equity	14,798,483	14,458,299	21,675,106
Total liabilities and stockholders equity	$ 34,313,210	$ 39,677,887	$ 44,313,210

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

	March 31, 2010	March 31, 2009
Revenues:		
Royalty revenue, related party	$	$ 5,984
Royalty revenue, other	12,532	
Research fees	177,143	
Contract revenue	37,707	
Total revenues	227,382	5,984
Cost of royalty revenue, other	12,429	
Expenses:		
Research and development	1,449,465	1,865,299
Related party research and development		47,687
General and administrative	2,204,761	1,451,240
Related party general and administrative, net	(360,500)	15,000
Total expenses	3,293,726	3,379,226
Loss from operations	(3,078,773)	(3,373,242)
Interest income	3,291	15,357
Derivative gain (loss)	2,869,972	(1,257,325)
Other income	14,288	
	2,887,551	(1,241,968)
Net loss	$ (191,222)	$ (4,615,210)
Net loss attributable to common stockholders	$ (191,222)	$ (4,615,210)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (0.01)	$ (0.24)
Weighted average common stock shares outstanding- basic and diluted	21,177,116	19,186,629

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

FOR THE THREE MONTHS ENDED MARCH 31, 2010

(Unaudited)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity
Balances, January 1, 2010	21,181,854	$ 21,182	$ 73,697,818	$ (47,183)	$ (59,213,518)	$ 14,458,299
Stock-based compensation			433,524			433,524
Stock option exercises	31,733	32	97,850			97,882
Net loss					(191,222)	(191,222)
Balances, March 31, 2010	21,213,587	$ 21,214	$ 74,229,192	$ (47,183)	$ (59,404,740)	$ 14,798,483

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

	March 31, 2010	March 31 2009
Operating activities:		
Net loss	$ (191,222)	$ (4,615,210)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	303,949	175,409
Derivative (gain) loss	(2,869,972)	1,257,325
Stock-based compensation expense	433,524	349,303
Gain on settlement	(382,000)	
Changes in assets and liabilities:		
Accounts receivable	802,312	(28,193)
Prepaid expenses and other assets	73,131	21,638
Accounts payable and accrued liabilities	(2,305,765)	(1,815,157)
Income taxes payable	(350,000)	
Deferred revenue	220,140	6,510,128
Net cash flows from operating activities	(4,265,903)	1,855,243
Investing activities:		
Purchase of equipment	(91,480)	
Deposits on equipment		(86,578)
Net cash flows from investing activities	(91,480)	(86,578)
Financing activities:		
Proceeds from exercise of stock options	97,881	69
Payment on notes payable		(57,499)
(Repayment of) proceeds from related party advances, net	(2,503,063)	65,933
Net cash flows from financing activities	2,405,182	8,503
Net change in cash and cash equivalents	(6,762,565)	1,777,168
Cash and cash equivalents at beginning of period	23,873,403	905,720
Cash and cash equivalents at end of period	$ 17,110,838	$ 2,682,888

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(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, 2010 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, 2009, included in the Company s 2009 Annual Report on Form 10-K, filed with the SEC on March 19, 2010. The accompanying condensed consolidated balance sheet at December 31, 2009 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, 2010 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this Quarterly Report are strongly encouraged to review the risk factors relating to the Company which are set forth in the 2009 Annual Report.

BDSI® , BEMA® and Bioral® are registered trademarks of BioDelivery Sciences International, Inc. ONSOLIS® is a registered trademark of Meda Pharmaceuticals, Inc.

Fair value of financial assets and liabilities:

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

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

1. Basis of presentation (continued):

The following table summarizes liabilities measured at fair value on a recurring basis for the periods presented:

	March 31, 2010				December 31, 2009			
Fair Value Measurements Using:	**Level 1**	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets								
Derivative asset (warrant)	$	$ 3,124,400	$	$ 3,124,400	$	$ 638,600*	$	$ 638,600*
Liabilities								
Derivative liabilities	$	$ 4,211,284	$	$ 4,211,284	$	$ 4,978,256	$	$ 4,978,256

* Included in Due from related party, warrant receivable in the accompanying condensed consolidated balance sheets.

New accounting pronouncements:

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

In February 2010, the FASB issued authoritative guidance that amends the disclosure requirements related to subsequent events. This guidance includes the definition of a Securities and Exchange Commission filer, removes the definition of a public entity, redefines the reissuance disclosure requirements and allows companies to omit the disclosure of the date through which subsequent events have been evaluated. This guidance is effective for financial statements issued for interim and annual periods ending after February 2010. This guidance did not materially impact the Company s results of operations or financial position, but did require changes to the Company s disclosures in its financial statements.

In April 2010, the FASB issued Accounting Standards Update No. 2010-17 (ASU 2010-17) which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. ASU 2010-17 is effective prospectively for milestones achieved in fiscal years and interim periods within those years, beginning in fiscal years on or after June 15, 2010. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements, if any.

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, funded research arrangements and revenue generated as a result of its agreements with Meda AB (Meda) regarding the Company s one approved product, ONSOLIS® (see Note 3). The Company intends to finance its research and development and

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

2. Liquidity and management s plans (continued):

commercialization efforts and its working capital needs from existing cash, royalty revenue, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

Significant financing and revenue in 2010 consisted of:

- $9.7 million in net proceeds from registered direct offering in April 2010 (see Note 8).
- Approximately $0.2 million in research revenues from various contractor agreements; and
- Approximately $0.1 million from the exercise of Common Stock options.

Significant financing and revenue in 2009 consisted of:

- $26.8 million payment received in July 2009 for the approval milestone for ONSOLIS®, related to agreements between the Company, Arius One and Meda.
- $6.0 million payment received in January 2009 which included a $3.0 million advance against the $15 million approval milestone for ONSOLIS® and $3.0 million related to amendments to the material agreements between the Company, Arius One and Meda for the expansion of the territory covered by the Company s European agreement with Meda.
- Approximately $5.1 million from the exercise of warrants and approximately $0.7 million from the exercise of Common Stock options.
- Approximately $2.8 million received in royalty revenues during 2009 related to ONSOLIS® sales in the U.S; and
- $1.3 million grant received in October 2009 from the Walter Reed Army Institute of Research.

Company management believes that the Company s existing cash and cash equivalents, when combined with the proceeds from the Company s April 2010 registered direct offering (see Note 8), are sufficient to finance planned operations (clinical and commercial development of product candidates beyond those covered under the Company s Meda and related agreements and potential capital expenditures) into the second half of 2011.

When required, the Company currently 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, products, product candidates and/or potential markets, any of which could have a material adverse effect on the Company s financial condition and viability.

The recent worldwide financial and credit crisis has strained investor liquidity and contracted credit markets. If this environment continues, fluctuates 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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

2. Liquidity and management s plans (continued):

requires additional financial investment. If the Company is 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 the Company s business, results of operations, financial condition and stock price.

3. Meda License, Development and Supply Agreements:

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

Contractual Rights and Obligations	Milestone Payments	Notes	Cash flows received and revenue deferred March 31, 2010	Cash flows received and revenue deferred December 31, 2009
North America				
License rights to ONSOLIS® (BEMA® Fentanyl) patents and trademarks	$ 30,000,000		$ 30,000,000	$ 30,000,000
Milestones:				
FDA approval	$ 15,000,000	Less a $200,000 discount	$ 14,800,000	$ 14,800,000
Earlier of date of first commercial sale or availability of launch supply product	$ 15,000,000		$ 15,000,000	$ 15,000,000
Research and Development Services for:				
Non-Cancer subsequent indication of product and further development of initial product		Contract Hourly Rates	$ 1,541,570	$ 1,541,570
Total North America Agreement Milestones	$ 60,000,000		$ 61,341,571	$ 61,341,570
Europe and Rest of World				
License rights to BREAKYL (BEMA® Fentanyl) patents and trademarks	$ 5,500,000		$ 5,500,000	$ 5,500,000
Milestones:				

Completion of Phase 3 clinical trials	$ 2,500,000		$ 2,500,000	$ 2,500,000
Governmental Approval in an EU country	$ 2,500,000			
Date of first sale in an EU country	$ 2,500,000			
Research and Development Services for:				
BREAKYL product through governmental approval in a EU country		Contract Hourly Rates	$ 4,002,529	$ 3,744,674
Total Europe and Rest of World Milestones	$ 13,000,000		$ 12,002,529	$ 11,744,674
Total All Milestones	**$ 73,000,000**		**$ 73,344,099**	**$ 73,086,244**
Release of Milestones subsequent to first sale			$ (59,765,348)	$ (59,727,633)
Remaining Deferred Revenue		Contract Hourly Rates	$ 13,578,751	$ 13,358,611

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

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

The Company has, in accordance with GAAP, assessed these arrangements and their deliverables to determine if such deliverables are considered separate units of accounting at the inception or upon delivery of the items required in the arrangements. The assessment requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable and, if so, to determine the fair value to be allocated to each unit of accounting.

The Company determined that upon inception of both the Meda U.S. and Meda EU arrangements all deliverables 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 that were related to these deliverables were 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 deliverables associated with research and development services will be deliverable to Meda. The first commercial sale in the U.S. occurred in October 2009. As a result, as of the three months ended March 31, 2010, $59.8 million of the aggregate milestones and services revenue were recognized. Upon first commercial sale in a European country, an estimated $17.4 million will be recognized, which includes an additional $5.0 million in milestones and approximately $0.7 million in research and development services.

In connection with delivery of the license to Meda, the Company has determined that each of the undelivered obligations have stand-alone value to Meda as these post-commercialization services encompass additional clinical trials on different patient groups but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. Further, the Company obtained third-party evidence of fair value for the non-cancer and other research and development services and other service obligations, based on hourly rates billed by unrelated third-party providers for similar services contracted by the Company. The Company also obtained third-party evidence of fair value of the product supply deliverable based on the outsourced contract manufacturing cost charged the Company from the third-party supplier of the product. The arrangements do not contain any general rights of return. Therefore, the remaining deliverables to the arrangements will be accounted for as three separate units of accounting to include (1) product supply, (2) research and development services for the non-cancer indication and further research and development of the first indication of the ONSOLIS® product and (3) the combined requirements related to the remaining other service-related obligations due Meda to include participation in committees and certain other specified services. The estimated portion of the upfront payments of approximately $1.6 million (under the Meda U.S. Agreements) and $0.2 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided through expiration of the license terms.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

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

In accordance with GAAP, the Company has determined that it is acting as a principal under the Meda Agreements and, as such, will record product supply revenue, research and development services revenue and other services revenue amounts on a gross basis in the Company s consolidated financial statements.

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. The Company has earned royalty revenue of approximately $0.01 million for the three months ended March 31, 2010. The Company has incurred cost of royalty revenue, other of approximately $0.01 million related to this royalty revenue.

4. Related Party Transactions:

On December 30, 2009, the Company entered into an Emezine Settlement Agreement (the Settlement Agreement) with Accentia Biopharmaceuticals, Inc., a related party (Accentia), Arius One and Accentia Pharmaceuticals, Inc. f/k/a TEAMM Pharmaceuticals Inc., a subsidiary of Accentia (TEAMM). Pursuant to the Settlement Agreement, the Company has received a warrant to purchase 2 million shares of common stock of Accentia s majority-owned subsidiary, Biovest International, Inc. (Biovest), from Accentia. Such warrant has an exercise price equal to 120% of the closing bid price of Biovest s common stock as of the date the bankruptcy court overseeing Accentia s Chapter 11 reorganization enters a final order authorizing Accentia to carry out the Settlement Agreement. The warrant was recorded at December 31, 2009 with a Black-Scholes value of $0.6 million. However, the warrant was not received by the Company until February 17, 2010, the date of which the bankruptcy court issued the final order authorizing the Settlement Agreement. At that date, the warrant was valued using the Black-Scholes model, which resulted in a gain on settlement of $0.4 million.

This amount is included in related party, general and administrative, in the accompanying consolidated statements of operations.

5. 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 THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

5. Derivative Financial Instruments (continued):

The following tabular presentation reflects the components of derivative assets and liabilities as of March 31, 2010 and December 31, 2009:

	March 31, 2010	December 31, 2009	Proforma March 31, 2010
Derivative assets at fair value:			
Free standing warrants, related party*	$ 3,124,400	$ 638,600	$ 3,124,400

	March 31, 2010	December 31, 2009	Proforma March 31, 2010
Derivative liability at fair value:			
Free standing warrants**	$ 4,211,284	$ 4,978,256	$ 7,072,161

* Included in Due from related party, warrant receivable in the accompanying condensed balance sheets.

** These warrants can be settled by issuance of 2,909,991 shares of Common Stock at March 31, 2010 and December 31, 2009 and 4,322,420 shares in the pro forma March 31, 2010 balance, respectively.

The following tabular presentation reflects the components of derivative financial instruments for the three months ended March 31, 2010 and 2009:

	3 months ending March 31, 2010	3 months ending March 31, 2009
Derivative income (loss) in the accompanying statement of operations is related to the individual derivatives as follows:		
Free standing warrants assets, related party	$ 2,103,000	$
Free standing warrants liabilities	766,972	(1,257,325)
	$ 2,869,972	$ (1,257,325)

6. Stockholders equity:

Stock-based compensation:

During the three months ended March 31, 2010, 281,956 options with fair market value of approximately $1.1 million were granted to certain Company 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 10 years from the grant date and vest ratably over a three year period. 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, 2010 follows:

Expected price volatility	78.41%-79.02%
Risk-free interest rate	2.34%-2.36%
Weighted average expected life in years	6 years
Dividend yield	

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

6. Stockholders equity (continued):

Option activity during the three months ended March 31, 2010 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2010	3,662,133	$ 3.78	
Granted			
Officers and Directors	87,179	3.90	
Others	194,777	3.90	
Exercised	(31,733)	3.08	
Forfeitures	(62,701)	3.20	
Outstanding at March 31, 2010	3,849,655	$ 3.80	$ 2,689,335

Options outstanding at March 31, 2010 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	2,908,410	7.17	$ 3.01	
$ 5.01 10.00	941,245	7.48	$ 6.27	
	3,849,655			$ 2,689,335

Options exercisable at March 31, 2010 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	2,038,213	6.42	$ 2.81	
$ 5.01 10.00	689,914	7.54	$ 6.22	

	2,728,127	$ 2,158,166

The weighted average grant date fair value of options granted during the three months ended March 31, 2010 whose exercise price is equal to or above the market price of the stock at the grant date was $3.90. There were no options granted during the three months ended March 31, 2010 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

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

6. Stockholders equity (continued):

A summary of the status of the Company s non-vested stock options as of January 1, 2010, and changes during the three months ended March 31, 2010 is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Nonvested at January 1, 2010	1,055,745		
Granted	281,956		
Vested	(155,041)		
Forfeited	(61,132)		
Nonvested at March 31, 2010	1,121,528	$ 4.13	$ 531,169

As of March 31, 2010, there was approximately $1.6 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, 2010, all of which are exercisable are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.00 5.00	2,552,620	2.83	$ 3.29	
$ 5.01 10.00	1,333,871	3.39	$ 5.21	
	3,886,491			$ 1,373,025

7. 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,	
	2010	2009
Net loss	$ (191,222)	$ (4,615,210)
Basic and diluted:		
Weighted average shares outstanding (denominator)	21,177,116	19,126,755
Net loss per common share - basic and diluted	$ (0.01)	$ (0.24)

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2010 AND 2009

(Unaudited)

8. Subsequent events:

April 2010 Registered Direct offering

On April 23, 2010, the Company completed a registered direct offering with certain institutional investors, which offering consisted of 2,824,858 shares of Common Stock at $3.54 per share, for aggregate proceeds of $10 million, and warrants to purchase up to an aggregate of 1,412,429 shares of Common Stock with an exercise price of $4.67 per share, which warrants expire April 23, 2015. Net proceeds from the offering were approximately $9.7 million. No placement agent was utilized in connection with the offering.

The warrants qualified for liability accounting as they contain a reset provision. The Black-Scholes fair market value at the time of issuance was $2.9 million and has been recorded as an offset to additional paid-in capital in the accompanying pro forma balance sheet. The Offering was consummated pursuant to a Securities Purchase Agreement. Expenses directly related to this offering amounted to approximately $0.3 million and have been included in additional paid-in capital in the accompanying pro forma balance sheet.

Proceeds from the offering are expected be used by the Company for the continued clinical development of the Company s product candidate pipeline, including BEMA® Buprenorphine, for general corporate and working capital purposes and to generally maintain a positive cash position during commercial partnering discussions throughout 2010.

Due to the significant nature, the above transaction is reflected in these financial statements on a pro forma basis as if the transaction had occurred on March 31, 2010. Amounts associated with these transactions that are reflected in the pro forma balance sheet follow:

Assets:	
Cash	$ 10,000,000
Total assets	$ 10,000,000
Liabilities:	
Accounts payable	$ 262,500
Derivative liability	2,860,877
Total liabilities	3,123,377
Stockholders equity:	
Common stock	2,825
Additional paid-in capital	6,873,798
Total stockholders equity	6,876,623
Total liabilities and stockholders equity	$ 10,000,000

Approval of ONSOLIS® in Canada

On May 10, 2010, the Company announced the approval of a New Drug Submission by Health Canada, the regulatory authority in Canada, for the Company s ONSOLIS® product in the management of breakthrough pain in opioid tolerant, adult patients with cancer. ONSOLIS® is the first product approved in Canada for this indication. ONSOLIS® will be marketed in Canada by Meda Valeant Pharma Canada Inc., a joint venture between Meda and Valeant Canada Limited. The Company expects that ONSOLIS® will be launched in the third quarter of this year. Under the terms of its commercialization agreement with Meda regarding ONSOLIS®, the Company will receive a double-digit royalty on net sales.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Quarterly Report. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company s actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Form 10-Q and in the Company s other filings with the Securities and Exchange Commission (the SEC).

For the three months ended March 31, 2010 compared to the three months ended March 31, 2009

***Royalties, Related Party*.** We recognized $0.06 million in royalty revenue during the three months ended March 31, 2009, under our license agreement with Accentia relating to chronic rhinosinusitis. There was no royalty revenue from related parties received during the three months ended March 31, 2010.

Royalty Revenues, Other. We recognized $0.01 million in royalty revenue, other during the three months ended March 31, 2010 under our license agreement with Meda. There was no royalty revenue, other during the three months ended March 31, 2009.

***Research Revenues*.** We recognized $0.2 million of revenue related to various contractor agreements during the three months ended March 31, 2010. There was no research revenue during the three months ended March 31, 2009.

Contract Revenues. We recognized $0.04 million during the three months ended March 31, 2010 in previously deferred contract revenue under our license agreement with Meda. There was no contract revenue recognized during the three months ended March 31, 2009.

Cost of Royalty Revenues, Other. We recognized $0.01 million in cost of royalty revenue during the three months ended March 31, 2010 related to direct costs attributable to the production of our product ONSOLIS®. There was no cost of royalty revenues, other, recognized during the three months ended March 31, 2009.

Research and Development Expenses. During the three months ended March 31, 2010 and 2009, research and development expenses totaled $1.5 million and $1.9 million, respectively. Our scientific staff continued to work toward development and application of our BEMA® and Bioral® delivery technologies, but particularly with respect to ONSOLIS®. Funding of this research in 2010 and 2009 was obtained through deferred license revenue, sponsored research revenue, exercise of options by employees and directors and sales of securities. Research and development expenses generally include compensation for 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, net. During the three months ended March 31, 2010 and 2009, general and administrative expenses totaled $2.2 million and $1.5 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. During the three months ended March 31, 2010, we recorded a gain on settlement for a warrant from a related party which totaled approximately $0.4 million (See Note 8 to the accompanying financial statements). This is included in general and administrative, related party.

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Interest Income. During the three months ended March 31, 2010 and 2009 we had interest income of $0.004 million and $0.02 million, respectively.

***Derivative (loss) gain*.** Derivative (loss) gain for the three months ended March 31, 2010 and 2009 is related to the adjustment to fair value of derivative assets and liabilities to fair value. Changes in derivative (loss) gain can be attributed to the decrease in stock price of the Company and an increase in Biovest stock price which underlies our derivative asset.

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, the sale of a royalty stream asset, sponsored research, funded research arrangements and from various strategic and licensing agreements, including a clinical development agreement with CDC IV, LLC and commercialization agreements with Meda, all relating to ONSOLIS®. We intend to finance our research and development and commercialization efforts and our working capital needs from existing cash, royalty revenue, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

On April 23, 2010, we completed a registered direct offering with certain institutional investors of 2,824,858 shares of our common stock and warrants to purchase up to an aggregate of 1,412,429 shares of our common stock, which resulted in gross proceeds of $10 million and net proceeds of approximately $9.86 million. The offering was consummated pursuant to a Securities Purchase Agreement. No placement agent was utilized in connection with the offering. Proceeds from the offering are expected be used for the continued clinical development of our product candidate pipeline, including BEMA® Buprenorphine, for general corporate and working capital purposes and to generally maintain a positive cash position during commercial partnering discussions throughout 2010.

At March 31, 2010, we had cash and cash equivalents of approximately $17.1 million. We used $4.3 million of cash from operations during the three months ended March 31, 2010. After giving effect to the above referenced offering, we had cash and cash equivalents of approximately $27.1 million.

As of March 31, 2010, we had stockholders equity of $14.8 million, versus $14.5 million at December 31, 2009. After giving effect to the above referenced offering, our stockholders equity was approximately $21.7 million.

We anticipate that cash used in operations and our investment in our facilities will continue beyond our ONSOLIS® agreements with Meda as we research, develop, and potentially, manufacture and commercialize additional drug formulations with our BEMA® and Bioral® technologies. While we believe further application of our BEMA® and Bioral® delivery technologies to other drugs will result in license agreements with additional pharmaceutical manufacturers, our plan of operations for the foreseeable future will be to develop additional products with our BEMA® technology and further develop our Bioral® technology for use in a limited number of applications. Our near term focus will not be on the marketing, production or sale of FDA approved products, although we may seek to develop these capabilities in the future as part of our longer term strategic plan.

Our existing cash and cash equivalents as supplemented by the proceeds of our direct stock sale in April are believed by our management to be sufficient to finance planned operations (clinical and commercial development of product candidates beyond those covered under our Meda and other related agreements and potential capital expenditures) into the second half of 2011.

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However, additional capital will likely 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

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 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.

In addition, the recent worldwide financial and credit crisis has strained investor liquidity and contracted credit markets. If this environment continues, fluctuates 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.

Critical Accounting Policies

Valuation of Goodwill and Intangible Assets

Our intangible assets include goodwill, product rights, and licenses, all of which are accounted for based on GAAP related to Goodwill and Other Intangible Assets. Accordingly, goodwill is not amortized but is tested at least annually for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with limited useful lives are amortized using the straight-line method over their estimated benefit, ranging from eleven to thirteen years. Our carrying value of goodwill at March 31, 2010 was $2.715 million.

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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, 2010 was $6.9 million, net of accumulated amortization of $2.4 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 2010 or 2009.

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

In making this assessment, we predominately use a discounted cash flow model derived from internal budgets in assessing fair values for our impairment testing. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. In addition, selection of a risk-adjusted discount rate on the estimated undiscounted cash flows is susceptible to future changes in market conditions, and when unfavorable, can adversely affect our original estimates of fair values. In the event that our management determines that the value of intangible assets have 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 2010 or 2009.

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

We account for stock-based awards to employees and non-employees in accordance with generally accepted accounting principles related to share based payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our 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.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

Our cash and cash equivalents consist entirely of highly liquid investments with an original maturity of three months or less. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents with financial institutions in the United States. In October and November 2008 the Federal Deposit Insurance Corporation (FDIC) temporarily increased coverage to $250,000 for substantially all depository accounts and temporarily provides unlimited coverage (through June 30, 2010) for certain qualifying and participating non-interest bearing transaction accounts. The increased coverage for depository accounts is scheduled to expire on December 31, 2013, at which time it is anticipated that amounts insured by the FDIC will return to $100,000. As of March 31, 2010 the Company had approximately $16 million that exceeds current FDIC insured limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro or other applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

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Changes in Internal Control over Financial Reporting

Further, there were no changes in the Company s internal control over financial reporting during the Company s first fiscal quarter of 2010 that materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Limitations on the Effectiveness of Internal Controls

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

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations (and the Liquidity and Capital Resources section thereof) and elsewhere may address or relate to future events and expectations and as such constitute Forward-Looking Statement within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company s plans, objectives, projections, expectations and intentions and other statements identified by words such as projects , may , could , would , should , believes , expects , anticipates , estimates , intends , plans or similar expressions. These statements ar 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: May 10, 2010

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

Date: May 10, 2010

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

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