BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
August 09, 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 June 30, 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 August 6, 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 JUNE 30, 2010 AND DECEMBER 31, 2009

(Unaudited)

	June 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,119,938	$ 23,873,403
Accounts receivable, other	1,019,350	1,268,712
Prepaid expenses and other current assets	302,826	287,978
Total current assets	26,442,114	25,430,093
Equipment, net	3,628,395	3,743,011
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,047,436	1,384,063
Acquired product rights	6,439,398	5,745,144
Total other intangible assets	7,486,834	7,129,207
Due from related party, warrant receivable		638,600
Derivative asset, warrant	2,259,600	
Other assets	21,976	21,976
Total assets	$ 42,553,919	$ 39,677,887
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	$ 2,102,816	$ 3,172,406
Accounts payable and accrued liabilities, related party	157,325	2,723,844
Clinical trial payables and accrued liabilities, other	833,636	674,343
Income taxes payable		312,128
Deferred revenue, current	12,202,404	11,758,732
Derivative liabilities (note 6)	2,900,891	4,978,256
Total current liabilities	18,197,072	23,619,709
Deferred revenue, long-term	1,668,810	1,599,879
Total liabilities	19,865,882	25,219,588
Commitments and contingencies		
Stockholders equity:		
Common Stock, $.001 par value; 45,000,000 shares authorized, 24,038,445 and 21,181,854 shares issued; 24,022,954 and 21,166,363 shares outstanding in 2010 and 2009, respectively	24,039	21,182
Additional paid-in capital	81,340,060	73,697,818
Treasury stock, at cost, 15,491 shares, 2010 and 2009	(47,183)	(47,183)
Accumulated deficit	(58,628,879)	(59,213,518)
Total stockholders equity	22,688,037	14,458,299

Total liabilities and stockholders equity	$ 42,553,919	$ 39,677,887

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 AND SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Revenues:				
Royalties, related parties	$	$ 5,621	$	$ 11,605
Royalties, other	1,745,896		1,796,135	
Research fees	220,194		397,337	
Contract revenue	250,476		250,476	
Total Revenue:	2,216,566	5,621	2,443,948	11,605
Cost of royalties, other	796,525		808,954	
Expenses:				
Research and development	1,521,531	1,810,848	2,970,996	3,676,147
Related party research and development:		47,689		95,376
General and administrative	2,196,886	1,559,086	4,401,647	3,010,325
Related party general and administrative, net:	21,500	15,000	(339,000)	30,000
Impairment of intangible license	243,648		243,648	
Total Expenses:	3,983,565	3,432,623	7,277,291	6,811,848
Loss from operations	(2,563,524)	(3,427,002)	(5,642,297)	(6,800,243)
Interest income	4,280	1,646	7,571	17,003
Derivative gain (loss)	3,306,470	(11,198,433)	6,176,442	(12,455,759)
Other income (expense), net	28,635	(6,960)	42,923	(6,960)
Net Income (loss)	775,861	(14,630,749)	584,639	(19,245,959)
Net Income (loss) attributable to common stockholders	$ 775,861	$ (14,630,749)	$ 584,639	$ (19,245,959)
Basic earnings per share:	$ 0.03	$ (0.75)	$ 0.03	$ (0.99)
Diluted earnings per share:	$ 0.01	$ (0.75)	$	$ (0.99)

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 SIX MONTHS ENDED JUNE 30, 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			660,594			660,594
Stock option exercises	31,733	32	97,850			97,882
Registered direct stock offering, net	2,824,858	2,825	9,744,675			9,747,500
Warrants related to equity financing			(2,860,877)			(2,860,877)
Net income					584,639	584,639
Balances, June 30, 2010	24,038,445	$ 24,039	$ 81,340,060	$ (47,183)	$ (58,628,879)	$ 22,688,037

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 SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

	June 30, 2010	June 30 2009
Operating activities:		
Net income (loss)	$ 584,639	$ (19,245,959)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	610,171	348,213
Derivative (gain) loss	(6,176,442)	12,455,759
Stock-based compensation expense	660,594	727,822
Intangible license impairment	243,648	
Gain on settlement	(382,800)	
Changes in assets and liabilities:		
Accounts receivable	249,362	(258,710)
Prepaid expenses and other assets	(14,848)	106,519
Accounts payable and accrued liabilities	(872,424)	(1,232,312)
Income taxes payable	(350,000)	
Deferred revenue	512,603	6,976,385
Net cash flows from operating activities	(4,935,497)	(122,283)
Investing activities:		
Purchase of equipment	(96,831)	
Deposits on equipment		(413,616)
Purchase of intangible assets	(1,000,000)	
Net cash flows from investing activities	(1,096,831)	(413,616)
Financing activities:		
Proceeds from issuance of common stock	9,747,500	
Proceeds from exercise of stock options	97,882	240,972
Change in amounts due to related parties	(2,566,519)	(42,502)
Payment on notes payable		(76,665)
Proceeds from exercise of common stock warrants		4,447,569
Net cash flows from financing activities	7,278,862	4,569,374
Net change in cash and cash equivalents	1,246,535	4,033,475
Cash and cash equivalents at beginning of period	23,873,403	905,720
Cash and cash equivalents at end of period	$ 25,119,938	$ 4,939,195

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 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 June 30, 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 2009 Annual Report). 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 and six months ended June 30, 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)

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

	June 30, 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)	$	$ 2,259,600	$	$ 2,259,600	$	$ 638,600*	$	$ 638,600*
Liabilities								
Derivative liabilities	$	$ 2,900,891	$	$ 2,900,891	$	$ 4,978,256	$	$ 4,978,256

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

During the period, we impaired a license, adjusting its carrying value to zero (see Note 9). This was based on our estimate of the fair value of such license which was a level 3 measurement.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

1. Basis of presentation (continued):

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. The adoption of this standard had no material impact on the company s consolidated 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. The Company has adopted this standard and adjusted its revenue recognition policy to apply the milestone method of revenue recognition for research and development contracts.

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 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 through June 30, 2010 consisted of:

- $9.7 million in net proceeds from registered direct offering of Common Stock and warrants in April 2010;
- Approximately $1 million in net royalties;
- Approximately $0.4 million in research revenues from various contractor agreements;
- Approximately $0.3 million in contract revenue from licensing and supply agreement (see note 4); 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 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 equity, debt or other financing 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 financing is not available, the Company would likely be required

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

2. Liquidity and management s plans (continued):

to significantly reduce or refocus its planned operations or to obtain financing 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 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 June 30, 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		$ 61,341,570	$ 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	$ 4,231,853	$ 3,744,674
Total Europe and Rest of World Milestones	$ 13,000,000		$ 12,231,853	$ 11,744,674
Total All Milestones	**$ 73,000,000**		**$ 73,573,423**	**$ 73,086,244**
Release of Milestones subsequent to first sale			$ (59,702,208)	$ (59,727,633)
Remaining Deferred Revenue			$ 13,871,214	$ 13,358,611

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 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 and as a result, $59.7 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.

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 $1.7 million for the six months ended June 30, 2010. The Company has incurred cost of royalty revenue, other of approximately $0.8 million related to this royalty revenue.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

4. License Agreements and Acquired Product Rights:

KunWha License Agreement

In May 2010, the Company entered into a License and Supply Agreement, (the KunWha License Agreement), with KunWha Pharmaceutical Co., Ltd., a corporation organized under the laws of the Republic of Korea (KunWha), to develop, manufacture, sell and distribute the Company s BEMA® Fentanyl product (the Licensed Product) in the Republic of Korea (the Territory). BEMA® Fentanyl is marketed as ONSOLIS® in the United States.

Under the terms of the KunWha License Agreement, KunWha will receive exclusive licensing rights for the Licensed Product in the Territory, while the Company will retain all other licensing rights to the Licensed Product not previously granted to third parties. KunWha paid to the Company an upfront payment of $300,000 (net of taxes approximately $250,000) and will be responsible to pay certain milestone payments which could aggregate up to $1,275,000. In addition, KunWha will pay royalties to the Company based on Net Sales (as defined in the KunWha License Agreement) and will purchase all supplies of the Licensed Product from the Company.

KunWha will be responsible for payment of all costs associated with the Licensed Product in the Territory. KunWha and the Company will own any Improvements (as defined in the KunWha License Agreement) made exclusively by such party with respect to the Licensed Product and will jointly own any Improvements that are the product of collaboration.

The upfront payment from KunWha (net of taxes, approximately $250,000) received in June 2010 is recorded as contract revenue in the accompanying consolidated statements of operations. The Company early adopted the provisions of ASU 2010-17 in analyzing the up-front milestone in the license agreement.

Agreement with QLT to Purchase Non-US BEMA® Rights

The Company s August 2006 agreement with QLT USA, Inc. (QLT) to purchase the non-US rights to the BEMA® delivery technology required a payment by the Company of $1,000,000 upon the approval in the first non-US country, which was included in acquired product rights in the accompanying condensed consolidated balance sheet. This payment was triggered by the Company s announcement on May 10, 2010 of a New Drug Submission by Health Canada, the regulatory authority in Canada, for ONSOLIS®. The Company made a payment to QLT of $750,000 in June 2010 with the remaining $250,000 expected to be paid in 2011.

5. 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, which was $0.89 per share. 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 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 for the six months ended June 30, 2010.

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

6. Derivative Financial Instruments:

The Company generally does not use derivative instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. However, certain other financial instruments, such as warrants and embedded conversion features that are indexed to the Company s Common Stock, are classified as liabilities when either:

(a) the holder possesses rights to net-cash settlement or (b) physical or net-share settlement is not within the control of the Company. In such instances, net-cash settlement is assumed for financial accounting and reporting, even when the terms of the underlying contracts do not provide for net-cash settlement. Such financial instruments are initially recorded at fair value estimated on the settlement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate, and then adjusted to fair value at the close of each reporting period.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

6. Derivative Financial Instruments (continued):

The following tabular presentation reflects the components of derivative assets and liabilities as of June 30, 2010 and December 31, 2009:

	June 30, 2010	December 31, 2009
Derivative assets at fair value:		
Free standing warrants, related party	$ 2,259,600	$ 638,600*

	June 30, 2010	December 31, 2009
Derivative liability at fair value:		
Free standing warrants**	$ 2,900,891	$ 4,978,256

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

** These warrants can be settled by issuance of 5,298,921 and 2,909,991 shares of Common Stock at June 30, 2010 and December 31, 2009, respectively.

The following tabular presentation reflects the components of derivative financial instruments for the six months ended June 30, 2010 and 2009:

	3 months ending June 30, 2010	3 months ending June 30, 2009	6 months ending June 30, 2010	6 months ending June 30, 2009
Derivative gain (loss) in the accompanying statement of operations is related to the individual derivatives as follows:				
Free standing warrants assets, related party	$ (864,800)	$	$ 1,238,200	$
Free standing warrants liabilities	4,171,270	(11,198,433)	4,938,242	(12,455,759)
	$ 3,306,470	$ (11,198,433)	$ 6,176,442	$ (12,455,759)

7. Stockholders Equity:

Stock-based compensation:

During the six months ended June 30, 2010, 308,923 options with fair market value of approximately $1.2 million were granted to Company employees and directors at exercise prices equal to the market value of the Common Stock on the dates the options were granted. The employee options granted have a term of 10 years from the grant date and vest ratably over a three year period. Director options vest immediately. The fair value of each option is amortized as compensation expense evenly through the vesting period. The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from historical volatility of the Common Stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average for key assumptions used in determining the fair value of options granted during the six months ended June 30, 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 SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

7. Stockholders Equity (continued):

Option activity during the six months ended June 30, 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	221,744	3.80	
Exercised	(31,733)	3.08	
Forfeitures	(76,034)	3.34	
Outstanding at June 30, 2010	3,863,289	$ 3.80	$ 218,595

Options outstanding at June 30, 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	2,922,044	6.95	$ 3.00	
$ 5.01 10.00	941,245	7.23	$ 6.27	
	3,863,289			$ 218,595

Options exercisable at June 30, 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	2,094,313	6.25	$ 2.87	
$ 5.01 10.00	911,245	7.17	$ 6.30	

	3,005,558	$ 161,609

The weighted average grant date fair value of options granted during the six months ended June 30, 2010 whose exercise price is equal to or above the market price of the stock at the grant date was $3.83. There were no options granted during the six months ended June 30, 2010 whose exercise price was lower than the estimated market price of the stock at the grant date. A summary of the status of the Company s non-vested stock options as of January 1, 2010, and changes during the six months ended June 30, 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	308,923		
Vested	(432,472)		
Forfeited	(74,465)		
Nonvested at June 30, 2010	857,731	$ 3.42	$ 56,985

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

7. Stockholders Equity (continued):

As of June 30, 2010, there was approximately $1.4 million of unrecognized compensation cost related to unvested shares-based compensation awards granted. These costs will be expensed over the next two years.

Warrants:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. Warrants outstanding at June 30, 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	4,798,921	2.87	$ 3.99	
$ 5.01 10.00	500,000	0.99	$ 5.57	
	5,298,921			$

April 2010 Registered Direct offering:

On April 23, 2010, the Company completed a registered direct offering with certain institutional investors, which 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 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 changes in fair value from inception to June 30, 2010 were recorded in derivative gain in the accompanying statement of operations. 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 as offset against the proceeds in additional paid-in capital in the accompanying condensed consolidated balance sheet.

8. Net Loss per Common Share:

The following table reconciles the numerators and denominators of the basic and diluted loss per share computations.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Basic:				

Net income (loss) attributable to common stockholders	$ 775,861	($ 14,630,749)	$ 584,639	($ 19,245,959)
Weighted average common shares outstanding	23,340,021	19,622,243	22,264,543	19,405,640
Basic earnings per common share	**$ 0.03**	**($ 0.75)**	**$ 0.03**	**($ 0.99)**
Diluted:				
Effect of dilutive securities:				
Net income (loss) attributable to common stockholders	$ 775,861	($ 14,630,749)	$ 584,639	($ 19,245,959)
Adjustments to Income for Dilutive options and warrants	(558,981)	0	(683,297)	0
	216,880	(14,630,749)	(98,658)	(19,245,959)
Weighted average common shares outstanding	23,340,021	19,622,243	22,264,543	19,405,640
Effect of Dilutive options and warrants	536,829	0	796,946	0
Diluted weighted average common shares outstanding	23,876,850	19,622,243	23,061,489	19,405,640
Diluted earnings per common share	**$ 0.01**	**($ 0.75)**	**$**	**($ 0.99)**

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2010 AND 2009

(Unaudited)

8. Net Loss per Common Share (continued)

Basic earnings per common share is calculated using the weighted average common shares outstanding during the period. Common equivalent shares from stock options and warrants using the treasury stock method, are also included in the diluted per share calculations unless their effect of inclusion would be antidilutive. During the six months ended June 30, 2010 and 2009, 5,575,248 and 8,092,792 outstanding stock options and warrants, respectively, were not included in the computation of diluted earnings per common share. To do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods.

9. Impairment of License:

The Company holds patents and patent applications for the Bioral® (cochleate) drug delivery technology, and is the worldwide, exclusive licensee of the technology pursuant to licensing agreements with the University of Medicine and Dentistry of New Jersey and Albany Medical College (the Bioral® License Agreements). Since 2004, the Company s development and commercialization activities have focused increasingly (and from 2008 through 2010, almost exclusively) on its BEMA® delivery technology and related products and product candidates. The most advanced development of the Bioral® technology was a Phase 1 study performed with Bioral® Amphotericin B, on which preliminary results were reported in February 2009. Regarding the most recent developments with the Bioral® platform, on January 20, 2009, the Company entered into a Research Collaboration and License Agreement with the Drugs for Neglected Diseases initiative (DNDi), a not-for-profit foundation, for the development and distribution of Bioral® Amphotericin B for Visceral Leishmaniasis, and on October 6, 2009, the Company announced it was awarded a $1.3 million grant from the Walter Reed Army Institute of Research (WRAIR) to support the clinical study of Bioral® Amphotericin B in the treatment of Cutaneous Leishmaniasis. Both infections are typically found in third world countries. To date, $50,000 of WRAIR grant has been funded to the Company.

During the period ended June 30, 2010, an animal study undertaken by DNDi was found to be marginally positive, but treatment of the infection did not warrant further consideration with Bioral® Amphotericin B. Also during the period ended June 30, 2010, the Company elected not to pursue the application of Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis, and as such to not continue the WRAIR agreement, which was terminated. As such, the initial $50,000 funded by WRAIR was refunded in July 2010. In addition, as previously reported, in September 2009 the Company vacated its Newark, New Jersey research facility (where research on the Bioral® technology was being undertaken) and terminated its relationship with Dr. Raphael Mannino, the Company s then Chief Scientific Officer and the inventor of many of the patents directed to the cochleate technology. The Company dedicated very limited resources to the Bioral® platform during the first half of 2010. The Bioral® platform and its associated intellectual property are presently being reviewed for potential strategic, commercial, licensing and divestiture opportunities.

As a result of these developments, at June 30, 2010, the Company performed an impairment test on the carrying value of the Bioral® License Agreements and determined an impairment charge for the full unamortized carrying value of approximately $0.2 million was warranted. The amount is shown in the accompanying income statement as impairment of intangible license.

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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 June 30, 2010 compared to the three months ended June 30, 2009

Royalties, Related Party. We recognized $0.01 million in royalty revenue during the three months ended June 30, 2009, under our license agreement with Accentia relating to chronic rhinosinusitis. There was no corresponding royalty revenue received during the three months ended June 30, 2010.

Royalty Revenues, Other. We recognized $1.7 million in royalty revenue, other during the three months ended June 30, 2010 under our license agreement with Meda. There was no royalty revenue, other during the three months ended June 30, 2009.

Research Revenues. We recognized $0.2 million of revenue related to various contractor agreements during the three months ended June 30, 2010. There was no research revenue during the three months ended June 30, 2009.

Contract Revenues. We recognized $0.3 million during the three months ended June 30, 2010 in contract revenue under our license agreement with KunWha. There was no contract revenue recognized during the three months ended June 30, 2009.

Cost of Royalty Revenues, Other. We recognized $0.8 million in cost of royalty revenue during the three months ended June 30, 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 June 30, 2009.

Research and Development Expenses. During the three months ended June 30, 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® delivery technology, but particularly with respect to ONSOLIS®. Funding of this research in 2010 and 2009 was obtained through deferred license revenue, registered direct stock offering, 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® drug delivery technologies.

General and Administrative Expenses, net. During the three months ended June 30, 2010 and 2009, general and administrative expenses totaled $2.2 million and $1.6 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs.

Impairment of intangible license. During the three months ended June 30, 2010 we had an impairment of intangible license of $0.2 million representing 100% of the remaining unamortized carrying value, related to the Bioral® drug delivery technology. There were no impairment charges during the three months ended June 30, 2009.

Interest Income. During the three months ended June 30, 2010 and 2009 we had interest income of $0.004 million and $0.001 million, respectively.

Derivative gain (loss). Derivative gain (loss) for the three months ended June 30, 2010 and 2009 is related to the adjustment to fair value of derivative assets and liabilities to fair value. Changes in derivative gain (loss) can be attributed to the decrease in stock price of the Company and an increase in Biovest stock price which underlies our derivative asset.

For the six months ended June 30, 2010 compared to the six months ended June 30, 2009

***Royalties, Related Party*.** We recognized $0.01 million in royalty revenue during the six months ended June 30, 2009, under our license agreement with Accentia relating to chronic rhinosinusitis. There was no corresponding royalty revenue received during the six months ended June 30, 2010.

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Royalty Revenues, Other. We recognized $1.8 million in royalty revenue, other during the six months ended June 30, 2010 under our license agreement with Meda. There was no royalty revenue, other during the six months ended June 30, 2009.

Research Revenues. We recognized $0.4 million of revenue related to various contractor agreements during the six months ended June 30, 2010. There was no research revenue during the six months ended June 30, 2009.

Contract Revenues. We recognized $0.3 million during the six months ended June 30, 2010 in contract revenue under our license agreement with KunWha. There was no contract revenue recognized during the six months ended June 30, 2009.

Cost of Royalty Revenues, Other. We recognized $0.8 million in cost of royalty revenue during the six months ended June 30, 2010 related to direct costs attributable to the production of our product ONSOLIS®. There was no cost of royalty revenues, other, recognized during the six months ended June 30, 2009.

Research and Development Expenses. During the six months ended June 30, 2010 and 2009, research and development expenses totaled $2.9 million and $3.8 million, respectively. Our scientific staff continued to work toward development and application of our BEMA® delivery technologies, but particularly with respect to ONSOLIS®. Funding of this research in 2010 and 2009 was obtained through deferred license revenue, registered direct stock offering, 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® drug delivery technologies.

General and Administrative Expenses, net. During the six months ended June 30, 2010 and 2009, general and administrative expenses totaled $4.1 million and $3.0 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 six months ended June 30, 2010, we recorded a gain on settlement for a warrant from a related party which totaled approximately $0.4 million (See Note 5 to the accompanying financial statements). This is included in general and administrative, related party.

Impairment of intangible license. During the six months ended June 30, 2010 we had an impairment of intangible license of $0.2 million, representing 100% of the remaining unamortized carrying value, related to the Bioral® drug delivery technology. There was no impairment charges during the six months ended June 30, 2009.

Interest Income. During the six months ended June 30, 2010 and 2009 we had interest income of $0.007 million and $0.02 million, respectively.

Derivative gain (loss). Derivative gain (loss) for the six months ended June 30, 2010 and 2009 is related to the adjustment to fair value of derivative assets and liabilities to fair value. Changes in derivative gain (loss) 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 relating to ONSOLIS®. We intend to finance our research and development programs, 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 $9.7 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.

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On May 10, 2010, we announced the approval of a New Drug Submission by Health Canada, the regulatory authority in Canada, for our ONSOLIS® product for 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. We expect that ONSOLIS® will be launched in the third quarter of this year. Under the terms of its commercialization agreement with Meda regarding ONSOLIS®, we will receive a double-digit royalty on net sales. The first non-US approval triggered a payment due to QLT of $1,000,000. The Company made a payment to QLT of $750,000 in June 2010 with the remaining $250,000 expected to be paid in 2011.

At June 30, 2010, we had cash and cash equivalents of approximately $25.1 million. We used $4.6 million of cash from operations during the six months ended June 30, 2010. As of June 30, 2010, we had stockholders equity of $22.9 million, versus $14.5 million at December 31, 2009.

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® technology. While we believe further application of our BEMA® delivery technology 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. 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 plans.

Our existing cash and cash equivalents 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.

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 (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.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of June 30, 2010 are as follows:

	Payments Due by Period			
	Less than 1 year	**1-3 years**	**3-5 years**	**More than 5 years**
Operating Lease Obligations	$ 102,761	$ 223,699		
Employment agreements	$ 348,573			
Minimum royalty expenses*	$ 375,000	3,000,000	3,000,000	6,750,000
Total contractual cash obligations	$ 826,334	$ 3,223,699	$ 3,000,000	$ 6,750,000

* Minimum royalty expenses represent a contractual floor that we are obligated to pay CDC regardless of actual sales.

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Bioral® Technology Update

We hold patents and patent applications for the Bioral® (cochleate) drug delivery technology, and are the worldwide, exclusive licensee of the technology pursuant to licensing agreements with the University of Medicine and Dentistry of New Jersey and Albany Medical College (the Bioral® License Agreements). Since 2004, our development and commercialization activities have focused increasingly (and from 2008 through 2010, almost exclusively) on our BEMA® delivery technology and related products and product candidates. The most advanced development of the Bioral® technology was a Phase 1 study performed with Bioral® Amphotericin B, on which preliminary results were reported in February 2009. Regarding the most recent developments with the Bioral® platform, on January 20, 2009, we entered into a Research Collaboration and License Agreement with the Drugs for Neglected Diseases initiative (DNDi), a not-for-profit foundation, for the development and distribution of Bioral® Amphotericin B for Visceral Leishmaniasis, and on October 6, 2009, we announced we were awarded a $1.3 million grant from the Walter Reed Army Institute of Research (WRAIR) to support the clinical study of Bioral® Amphotericin B in the treatment of Cutaneous Leishmaniasis. Both infections are typically found in third world countries. To date, $50,000 of WRAIR grant has been funded to us.

During the period ended June 30, 2010, an animal study undertaken by DNDi was found to be marginally positive, but treatment of the infection did not warrant further consideration with Bioral® Amphotericin B. Also during the period ended June 30, 2010, we elected not to pursue the application of Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis, and as such to not continue the WRAIR agreement, which was terminated. As such, the initial $50,000 funded by WRAIR was refunded in July 2010. In addition, as previously reported, in September 2009 we vacated our Newark, New Jersey research facility (where research on the Bioral® technology was being undertaken) and terminated our relationship with Dr. Raphael Mannino, our then Chief Scientific Officer and the inventor of many of the patents directed to the cochleate technology. We dedicated very limited resources to the Bioral® platform during the first half of 2010. The Bioral® platform and its associated intellectual property are presently being reviewed for potential strategic, commercial, licensing and divestiture opportunities.

As a result of these developments, at June 30, 2010, we performed an impairment test on the carrying value of the Bioral® License Agreements and determined an impairment charge for the full unamortized carrying value of approximately $0.2 million was warranted. The amount is shown in the accompanying income statement as impairment of intangible license.

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 annually in December 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 June 30, 2010 was $2.715 million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements or the underlying patents. Our carrying value of other amortizing intangible assets at June 30, 2010 was $7.7 million, net of accumulated amortization of $2.6 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.

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.

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

There were no impairment charges during 2009. We recorded a $0.2 million impairment charge during the six months ended June 30, 2010. The impairment charge removed the remaining intangible asset related to Bioral®. The Company determined not to pursue Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis (see note 9).

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.

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 six 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. As of June 30, 2010 the Company had approximately $24.3 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.

Market indexed security risk

We have a warrant to purchase 2 million shares of common stock of Biovest International. This warrant investment is re-measured to its fair value at each reporting period with changes in its fair value recorded as derivative gain (loss) in the condensed consolidated statement of operations. We use the Black-Scholes model for valuation of the warrants.

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.

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

Changes in Internal Control over Financial Reporting

Further, there were no changes in the Company s internal control over financial reporting during the Company s second fiscal quarter of 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 constitutes forward-looking statements 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 our plans, objectives, projections, expectations and intentions and other statements identified by words such as projects , may , could , would , should , believes , expects , anticipates , estimates , intends , plans or similar expressions. These statements are based upon the c and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our 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 our 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 our products and product candidates 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 our actual results, performance or achievements 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 2009 Annual Report and other factors detailed from time to time in our 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. We undertake no obligation to publically update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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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: August 9, 2010

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

(Principal Executive Officer)

Date: August 9, 2010

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

(Principal Financial Officer)

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