BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
November 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 September 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 November 9, 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

Quarterly Report on Form 10-Q

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF SEPTEMBER 30, 2010 AND DECEMBER 31, 2009

(Unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,155,703	$ 23,873,403
Accounts receivable, other	578,943	1,268,712
Prepaid expenses and other current assets	241,321	287,978
Total current assets	22,975,967	25,430,093
Equipment, net	3,528,891	3,743,011
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,010,897	1,384,063
Acquired product rights	6,253,191	5,745,144
Total other intangible assets	7,264,088	7,129,207
Due from related party, warrant receivable		638,600
Derivative asset, warrant	1,844,200	
Other assets	21,976	21,976
Total assets	$ 38,350,122	$ 39,677,887
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	$ 3,629,572	$ 3,846,749
Accounts payable and accrued liabilities, related party	101,533	2,723,844
Income taxes payable		312,128
Deferred revenue, current	12,404,511	11,758,732
Derivative liabilities (note 6)	3,596,024	4,978,256
Total current liabilities	19,731,640	23,619,709
Deferred revenue, long-term	1,644,353	1,599,879
Total liabilities	21,375,993	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	81,794,536	73,697,818
Treasury stock, at cost, 15,491 shares, 2010 and 2009	(47,183)	(47,183)
Accumulated deficit	(64,797,263)	(59,213,518)

Total stockholders equity	16,974,129	14,458,299
Total liabilities and stockholders equity	$ 38,350,122	$ 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 NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Product royalties	$ 56,263	$	$ 1,852,398	$
Product royalties, related parties		1,986		13,591
Research fees	160,940		558,277	
Contract revenue			250,476	
Total Revenue:	217,203	1,986	2,661,151	13,591
Cost of product royalties	19,490		828,444	
Expenses:				
Research and development	3,215,749	4,385,503	6,186,745	8,061,651
Related party research and development		47,689		143,065
General and administrative	2,092,988	3,370,298	6,494,635	6,380,620
Related party general and administrative, net	20,779	15,000	(318,221)	45,000
Impairment of intangible license			243,648	
Total Expenses:	5,329,516	7,818,490	12,606,807	14,630,336
Loss from operations	(5,131,803)	(7,816,504)	(10,774,100)	(14,616,745)
Interest income	63,804	8,617	71,375	25,620
Derivative (loss) gain	(1,110,533)	5,048,937	5,065,909	(7,406,822)
Other (expense) income, net	10,148	(16,931)	53,071	(23,891)
Net Loss	(6,168,384)	(2,775,881)	(5,583,745)	(22,021,838)
Deferred income tax benefit		176,490		176,490
Net Loss attributable to common stockholders	$ (6,168,384)	$ (2,599,391)	$ (5,583,745)	$ (21,845,348)
Per share amounts, basic and diluted:	(0.26)	(0.12)	(0.24)	(1.10)
Weighted average common stock shares outstanding-basic and diluted:	24,022,954	20,973,354	22,857,121	19,933,954

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 NINE MONTHS ENDED SEPTEMBER 30, 2010

(Unaudited)

	Common Stock					Total
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	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			1,115,069			1,115,069
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			(2,860,876)			(2,860,876)
Net income (loss)					(5,583,745)	(5,583,745)
Balances, September 30, 2010	24,038,445	$ 24,039	$ 81,794,536	$ (47,183)	$ (64,797,263)	$ 16,974,129

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 NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009

(Unaudited)

	Sep 30, 2010	Sep 30, 2009
Operating activities:		
Net loss	$ (5,583,745)	(21,845,348)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	938,634	569,574
Derivative (gain) loss	(5,065,909)	7,406,822
Stock-based compensation expense	1,115,069	1,687,077
Loss on disposal of fixed assets		2,401
Intangible license impairment	243,648	
Warrants received in settlement	(382,800)	
Changes in assets and liabilities:		
Accounts receivable	689,770	(658,135)
Prepaid expenses and other assets	46,657	(989,227)
Accounts payable and accrued expenses	(217,176)	1,341,439
Deferred revenue	690,253	34,922,405
Income tax payable	(312,128)	
Deferred income tax asset		(176,490)
Net cash flows used in operating activities	(7,837,727)	22,260,518
Investing activities:		
Purchase of equipment	(103,044)	(535,923)
Purchase of intangible assets	(1,000,000)	(2,000,000)
Net cash flows from investing activities	(1,103,044)	(2,535,923)
Financing activities:		
Proceeds from issuance of common stock	9,747,500	
Proceeds from exercise of stock options	97,882	300,864
Change in amounts due to related parties	(2,622,311)	(90,900)
Payment on notes payable		(76,665)
Proceeds from exercise of common stock warrants		5,108,069
Net cash flows from financing activities	7,223,071	5,241,368
Net change in cash and cash equivalents	(1,717,700)	24,965,963
Cash and cash equivalents at beginning of year	23,873,403	905,720

Cash and cash equivalents at end of year	$ 22,155,703	$ 25,871,683

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 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 September 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 nine month periods ended September 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:

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1. Basis of presentation (continued):

	September 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)	$	$ 1,844,200	$	$ 1,844,200	$	$ 638,600*	$	$ 638,600*
Liabilities								
Derivative liabilities	$	$ 3,596,024	$	$ 3,596,024	$	$ 4,978,256	$	$ 4,978,256

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

During the nine months ended September 30, 2010, 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.

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 September 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 $0.6 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.

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2. Liquidity and management s plans (continued):

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; and
- Approximately $2.8 million received in royalty revenues during 2009 related to ONSOLIS® sales in the U.S.

Subsequent to September 30, 2010, in November 2010, the Company received notification from the U.S. Internal Revenue Service that it was approved to receive a grant in the amount of $0.245 million for qualified investments under the U.S. Government s Qualifying Therapeutic Discovery Project. The grant is for investments related to therapies utilizing the Company s proprietary BioErodible MucoAdhesive (BEMA) technology. See Note 10.

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 funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) will be available on favorable terms, if at all. If adequate outside financing is not available, the Company would likely be required 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.

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 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. Meda may terminate the North American license agreement at any time after a specified notice to us. The Company s rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

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

Contractual Rights and Obligations	Milestone Payments	Notes	Cash flows received and revenue deferred September 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	$ 4,419,263	$ 3,744,674
Total Europe and Rest of World Milestones	$ 13,000,000		$ 12,419,263	$ 11,744,674
Total All Milestones	**$ 73,000,000**		**$ 73,760,833**	**$ 73,086,244**
Release of Milestones upon first sale			(59,711,969)	$ (59,727,633)
Remaining Deferred Revenue			$ 14,048,864	$ 13,358,611

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.

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

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, $61.3 million of the aggregate milestones and services revenue were recognized. Upon first commercial sale in a European country, an estimated $17.9 million will be recognized, which includes an additional $5.0 million in milestones and approximately $0.5 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 $0.1 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 product royalty revenue of approximately $1.9 million for the nine months ended September 30, 2010. The Company has incurred cost of product royalty revenue of approximately $0.8 million related to this royalty revenue.

4. Other 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. The Kunwha License Agreement is for a term beginning on May 26, 2010 until the date of expiration of the patents, or July 23, 2027, whichever is later.

Under the terms of the Kunwha License Agreement, Kunwha was granted 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 $0.3 million (net of taxes approximating $0.25 million) and will be responsible to make certain milestone payments which could aggregate up to $1.3 million (net of taxes approximating $1.1 million). 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.

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4. License Agreements and Acquired Product Rights (continued):

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 $0.3 million (net of taxes, approximating $0.25 million) 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 $1.0 million 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 $0.75 million in June 2010 with the remaining $0.25 million 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 $0.84 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 nine months ended September 30, 2010. The gain is included in related party general and administrative in the accompanying condensed consolidated statement of operations.

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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6. Derivative Financial Instruments (continued):

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

Derivative assets at fair value:	Sep 30, 2010	Dec 31, 2009
Free standing warrants related party	1,844,200	$ 638,600*

Derivative liability at fair value:	Sep 30, 2010	Dec 31, 2009
Free standing warrants**	3,596,024	$ 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 5,273,921 and 2,909,991 shares of Common Stock at September 30, 2010 and December 31, 2009, respectively.

The following tabular presentation reflects the components of derivative financial instruments for the three and nine month periods ended September 30, 2010 and 2009:

Derivative income (expense) in the accompanying statement of operations is related to the individual derivatives as follows:	3 months ending Sep 30, 2010	3 months ending Sep 30, 2009	9 months ending Sep 30, 2010	9 months ending Sep 30, 2009
Free standing derivatives (principally warrants)	(1,110,533)	5,048,937	5,065,909	(7,406,822)

7. Stockholders Equity:

Stock-based compensation:

During the nine months ended September 30, 2010, 787,281 options with fair market value of approximately $2.3 million were granted to Company employees and directors. 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. During the nine months ended, 8,279 of employee bonus options were granted which vested 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 nine months ended September 30, 2010 follows:

Expected price volatility	73.41%-79.02%

Risk-free interest rate	1.17%-2.36%
Weighted average expected life in years	6 years
Dividend yield	

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7. Stockholders Equity (continued):

Option activity during the nine months ended September 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	399,661	2.68	
Others	382,476	3.22	
Exercised	(31,733)	3.08	
Forfeitures	(100,998)	3.10	
Outstanding at September 30, 2010	4,311,539	$ 3.68	$ 1,102,720

Options outstanding at September 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	3,370,294	7.13	$ 2.92	
$ 5.01 10.00	941,245	6.98	$ 6.27	
	4,311,539			$ 1,102,720

Options exercisable at September 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	2,336,171	6.32	$ 2.80	
$ 5.01 10.00	921,245	6.94	$ 6.29	
	3,257,416			$ 858,099

The weighted average grant date fair value of options granted during the nine months ended September 30, 2010 was $2.94. There were no options granted during the nine months ended September 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 nine months ended September 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	782,137		
Vested	(682,761)		

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7. Stockholders Equity (continued):

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Forfeited	(100,998)		
Nonvested at September 30, 2010	1,054,123	$ 2.84	$ 244,621

As of September 30, 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 September 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	2.62	$ 3.99	
$ 5.01 10.00	475,000	0.79	$ 5.55	
	5,273,921			$

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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss	($ 6,168,384)	($ 2,599,391)	($ 5,583,745)	($ 21,845,348)
Basic and Diluted:				
Weighted average shares outstanding (denominator)	24,022,954	20,973,354	22,857,121	19,933,954
Net loss per common share basic and diluted	$ (0.26)	$ (0.12)	$ (0.24)	$ (1.10)

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

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

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9. Impairment of License (continued):

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. Accordingly, the aforementioned initial $50,000 funded by WRAIR was refunded in July 2010 and is included in General and Administrative expenses in the Condensed consolidated statements of income. 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.

10. Subsequent Events:

On October 7, 2010, the Company announced a license and supply agreement with TTY Biopharm Co., Ltd. (TTY) for the exclusive rights to develop and commercialize BEMA® Fentanyl (marketed as ONSOLIS® in the U.S.) in the Republic of China, Taiwan. The agreement results in potential milestone payments to the Company of up to $1.3 million, which includes an upfront payment of $0.3 million. In addition, the Company will receive an ongoing royalty based on net sales. TTY will be responsible for the regulatory filing of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. BEMA® Fentanyl is approved in the U.S. and Canada, under the trade name ONSOLIS®, for the treatment of breakthrough pain in opioid-tolerant adult patients with cancer. BEMA® Fentanyl is licensed to Meda for all territories with the exception of Taiwan and South Korea. In South Korea, BEMA® Fentanyl is licensed to Kunwha Pharmaceutical Co. The term of the agreement with TTY is for the period from October 4, 2010 until the date fifteen (15) years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

On October 20, 2010, the Company and Meda announced approval of BEMA® Fentanyl in Europe via the Decentralized Procedure, with Germany acting as Reference Member State. BEMA® Fentanyl is indicated for the management of breakthrough pain in opioid tolerant, adult patients with cancer. National marketing authorization approvals, enabling commercial sales in each of the 25 individual EU countries, are now expected over the next several months. BEMA® Fentanyl, which is approved in the U.S. and Canada as ONSOLIS® (fentanyl buccal soluble film), will be marketed as BREAKYL (fentanyl buccal film) in Europe. Under the terms of its licensing agreement with Meda, the Company will receive a milestone payment of $2.5 million triggered by the first national marketing authorization of BREAKYL and another $2.5 million at the time of the first commercial sale that is anticipated sometime prior to the end of 2011. Additionally, the Company will receive a double-digit royalty on net sales.

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10. Subsequent Events (continued):

In November 2010, the Company received notification from the U.S. Internal Revenue Service that it was approved to receive a grant in the amount of $0.245 million for qualified investments under the U.S. Government s Qualifying Therapeutic Discovery Project. The grant is for investments related to therapies utilizing the Company s proprietary BioErodible MucoAdhesive (BEMA) technology. The Company expects to receive such grant funds in the fourth quarter of 2010.

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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, risk and other factors set forth in the following discussion and elsewhere in this Quarterly Report and in the Company s other filings with the Securities and Exchange Commission (the SEC). See Cautionary Note Regarding Forward Looking Statements below.

For the three months ended September 30, 2010 compared to the three months ended September 30, 2009

Product Royalty Revenues. We recognized $0.06 million in product royalty revenue during the three months ended September 30, 2010 under our license agreement with Meda. There was no product royalty revenue during the three months ended September 30, 2009.

Product Royalties, Related Party. We recognized $0.002 million in product royalty revenue, related party during the three months ended September 30, 2009, under our license agreement with Accentia relating to chronic rhinosinusitis. There was no corresponding product royalty revenue, related party received during the three months ended September 30, 2010.

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

Contract Revenues. There was no contract revenue recognized during the three months ended September 30, 2010 or 2009.

Cost of Product Royalties. We recognized $0.02 million in cost of product royalty revenue during the three months ended September 30, 2010 related to direct costs attributable to the production of our product ONSOLIS®. There was no cost of product royalty revenues recognized during the three months ended September 30, 2009.

Research and Development Expenses. During the three months ended September 30, 2010 and 2009, research and development expenses totaled $3.2 million and $4.4 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. During the three months ended September 30, 2009, the company paid bonuses related to 2008 performance and also accrued bonuses for 2009, of which $0.5 million was paid to Company employees engaged in research and development activities. In addition, there was $0.8 million of research and development expenses related to ONSOLIS® incurred during the three months ended September 30, 2009 that is no longer applicable since the product is approved and being commercialized.

General and Administrative Expenses, net. During the three months ended September 30, 2010 and 2009, general and administrative expenses totaled $2.1 million and $3.4 million, respectively. General and administrative

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costs include legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. During the three months ended September 30, 2009, the company paid bonuses related to 2008 performance and also accrued bonuses for 2009, which accounted for $0.8 million in general and administrative expenses. Furthermore, stock based compensation for the three months ended September 30, 2009 was $0.5 million more than the three months ended September 30, 2010 due to the relatively higher value attributed to the options via Black Scholes calculations.

Impairment of intangible license. There were no impairment charges during the three months ended September 30, 2010 or 2009.

Interest Income. During the three months ended September 30, 2010 and 2009 we had interest income of $0.06 million and $0.009 million, respectively.

***Derivative (loss) gain*.** Derivative gain (loss) is related to the adjustment to fair value of derivative assets and liabilities. The derivative loss for the three months ended September 30, 2010 can be attributed to an increase in our public stock price, which increases the liability related to free-standing warrants, combined with a decrease in Biovest s stock price, which underlies our derivative asset. For the nine months ended September 30, 2010, the opposite occurred. Our public stock price decreased and the Biovest derivative asset increased, causing a derivative gain.

For the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009

Product Royalty Revenues. We recognized $1.9 million in product royalty revenue during the nine months ended September 30, 2010 under our license agreement with Meda. There was no product royalty revenue during the nine months ended September 30, 2009.

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

Research Revenues. We recognized $0.6 million of revenue related to various contractor agreements during the nine months ended September 30, 2010. There was no research revenue during the nine months ended September 30, 2009.

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

Cost of Product Royalties. We recognized $0.8 million in cost of product royalty revenue during the nine months ended September 30, 2010 related to direct costs attributable to the production of our product ONSOLIS®. There was no cost of product royalty revenues recognized during the nine months ended September 30, 2009.

Research and Development Expenses. During the nine months ended September 30, 2010 and 2009, research and development expenses totaled $6.2 million and $8.1 million, respectively. Our scientific staff continued to work toward development and application of our BEMA® delivery technologies, but particularly with respect to ONSOLIS® which was approved in July 2009, and our pipeline of BEMA® products under development including Buprenorphine and Granisetron. 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. The decrease in research and development expenses during the nine months ended September 30, 2010 as related to the same time period in 2009 can be contributed to the closure of the Newark laboratory in September, 2009, and elimination of associated expenses.

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General and Administrative Expenses, net. During the nine months ended September 30, 2010 and 2009, general and administrative expenses, including related party totaled $6.2 million and $6.4 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 nine months ended September 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 nine months ended September 30, 2010 we had an impairment of intangible license and associated charge of $0.2 million. This represented 100% of the remaining unamortized carrying value, related to the Bioral® drug delivery technology. There was no impairment charge during the nine months ended September 30, 2009.

Interest Income. During the nine months ended September 30, 2010 and 2009 we had interest income of $0.07 million and $0.02 million, respectively.

Derivative gain (loss). Derivative gain (loss) is related to the adjustment to fair value of derivative assets and liabilities. The derivative loss for the three months ended September 30, 2010 can be attributed to an increase in our public stock price, which increases the liability related to free-standing warrants, combined with a decrease in Biovest s stock price, which underlies our derivative asset. For the nine months ended September 30, 2010, the opposite occurred. Our public stock price decreased and the Biovest derivative asset increased, causing a derivative gain.

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, product 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 have been and are expected to 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 and into 2011.

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 first quarter of 2011. 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 $1.0 million. We made a payment to QLT of $0.75 million in June 2010 with the remaining $0.25 million expected to be paid in 2011.

In May 2010, we 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 our BEMA® Fentanyl product (the Licensed Product) in the Republic of

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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 we will retain all other licensing rights to the Licensed Product not previously granted to third parties. Kunwha made an upfront payment of $0.3 million (net of taxes approximating $0.25 million) and will be responsible to pay certain milestone payments which could aggregate up to $1.3 million (net of taxes approximating $1.1 million). In addition, Kunwha will pay royalties to us based on Net Sales (as defined in the Kunwha License Agreement) and will purchase all supplies of the Licensed Product from us. The Kunwha License Agreement is for a term beginning on May 26, 2010 until the date of expiration of the patents, or July 23, 2027, whichever is later.

On October 7, 2010, we announced a license and supply agreement with TTY Biopharm Co., Ltd., for the exclusive rights to develop and commercialize BEMA® Fentanyl (marketed as ONSOLIS® in the U.S.) in the Republic of China, Taiwan. The agreement results in potential milestone payments to us of up to $1.3 million, which includes an upfront payment of $0.3 million (which was received in October 2010). In addition, we will receive an ongoing royalty based on net sales. TTY will be responsible for the regulatory filing of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. The term of the agreement with TTY is for the period from October 4, 2010 until the date fifteen (15) years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

On October 20, 2010, we, along with Meda announced approval of BEMA® Fentanyl in Europe via the Decentralized Procedure, with Germany acting as Reference Member State. BEMA® Fentanyl is indicated for the management of breakthrough pain in opioid tolerant, adult patients with cancer. National marketing authorization approvals, enabling commercial sales in each of the 25 individual EU countries, are now expected over the next several months. BEMA® Fentanyl, which is approved in the U.S. and Canada as ONSOLIS® (fentanyl buccal soluble film), will be marketed as BREAKYL (fentanyl buccal film) in Europe. Under the terms of its licensing agreement with Meda, we will receive a milestone payment of $2.5 million triggered by the first national marketing authorization of BREAKYL and another $2.5 million at the time of the first commercial sale that is anticipated sometime prior to the end of 2011. Additionally, we will receive a double-digit royalty on net sales.

In November 2010, we received notification from the U.S. Internal Revenue Service that we were approved to receive a grant in the amount of $0.245 million for qualified investments under the U.S. Government s Qualifying Therapeutic Discovery Project. The grant is for investments related to therapies utilizing our proprietary BioErodible MucoAdhesive (BEMA) technology. We expect to receive such grant funds in the fourth quarter of 2010.

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.

At September 30, 2010, we had cash and cash equivalents of approximately $22.2 million. We used $7.8 million of cash from operations during the nine months ended September 30, 2010. As of September 30, 2010, we had stockholders equity of $17 million, versus $14.5 million at December 31, 2009. 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

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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 funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) 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 2011 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.

Update on Timing for Canadian Launch of ONSOLIS®

In May 2010, we announced the approval by Health Canada, the regulatory authority in Canada, for ONSOLIS® for the management of breakthrough pain in opioid-tolerant adult patients with cancer. At the same time, we estimated that the commercial launch of ONSOLIS® in Canada would occur in the third quarter of 2010. Subsequently, certain equipment and regulatory issues at our primary U.S. manufacturer for ONSOLIS® have led to the temporary stoppage of manufacturing of all products at that site, including ONSOLIS®. This temporary stoppage is anticipated to delay the Canadian launch of ONSOLIS® to the first quarter of 2011. This is currently not expected to have an impact on the U.S. supply of ONSOLIS® given current inventory levels held by our commercial partner Meda Pharmaceuticals. Full production of ONSOLIS® is expected to resume in November 2010 and, assuming this occurs, we anticipate that launch stocks of ONSOLIS® would be available for market release in Canada in February or March of 2011. Royalties that we may have earned on sales of ONSOLIS® in Canada during the aforementioned delay period would not, in our management s estimation, have been material to our results of operations.

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Contractual Obligations and Commercial Commitments

Our contractual obligations as of September 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	$ 120,126	$ 166,004		
Employment agreements	$ 1,110,386			
Minimum royalty expenses*	$	3,000,000	3,000,000	4,875,000
Total contractual cash obligations	$ 1,230,512	$ 3,166,004	$ 3,000,000	$ 4,875,000

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

Off - Balance Sheet Arrangements

As of September 30, 2010, we had no off-balance sheet arrangements.

Effects of Inflation

We do not believe that inflation has had a material effect on our financial position or results of operations. However, there can be no assurance that our business will not be affected by inflation in the future.

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 September 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 September 30, 2010 was $7.3 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 nine months ended September 30, 2010. The impairment charge removed the remaining intangible asset related to Bioral®. We determined not to pursue Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis (see Note 9 to the accompanying financial statements).

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 nine 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. The Federal Deposit Insurance Corporation (FDIC) covers $0.25 million for substantially all depository accounts and temporarily provides unlimited coverage through December 31, 2012 for certain qualifying and participating non-interest bearing transaction accounts. As of September 30, 2010, we had approximately $21.4 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

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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.

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 third 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

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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, the risk factors 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 1. Legal Proceedings.
During the quarter ending September 30, 2010 we were not a party to any material pending legal proceeding. We are not aware of any pending legal proceeding to which any of our officers, directors, or any beneficial holders of 5% or more of our voting securities are adverse to us or have a material interest adverse to us.

Item 1A: Risk Factors.
There were no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.
None.

Item 3. Defaults upon Senior Securities.
None.

Item 4. (Removed and Reserved).

Item 5. Other Information.
On November 5, 2010, we received notice of a possible legal action against us for alleged patent infringement involving a third-party patent. As of the date of this Report, no action has been served upon our company. Allegations of patent infringement are standard for business such as ours. Should any action be filed against us we intend to oppose any allegations vigorously.

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: November 9, 2010

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

(Principal Executive Officer)

Date: November 9, 2010

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

(Principal Financial Officer)

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