BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
November 14, 2011
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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, 2011

¨ **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 x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of November 10, 2011, there were 29,577,146 shares of company common stock issued and 29,561,655 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, 2011 AND DECEMBER 31, 2010

	September 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,119,420	$ 18,208,659
Accounts receivable, other	1,654,626	633,216
Prepaid expenses and other current assets	249,269	236,112
Total current assets	17,023,315	19,077,987
Equipment, net	3,370,355	3,424,869
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,900,000	1,900,000
Acquired product rights	8,000,000	8,000,000
Accumulated amortization	(3,526,893)	(2,858,657)
Total other intangible assets	6,373,107	7,041,343
Derivative asset, warrant (note 6)	466,140	1,299,031
Other assets	21,976	21,976
Total assets	$ 29,969,893	$ 33,580,206
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	$ 7,034,738	$ 4,656,295
Deferred revenue, current	12,501,711	12,491,907
Derivative liabilities (note 6)	788,249	4,989,993
Total current liabilities	20,324,698	22,138,195
Deferred revenue, long-term	1,661,009	1,655,681
Total liabilities	21,985,707	23,793,876
Commitments and contingencies		
Stockholders equity:		
Common Stock, $.001 par value; 75,000,000 and 45,000,000 shares authorized; 29,577,146 and 24,038,445 shares issued; 29,561,655 and 24,022,954 shares outstanding in 2011 and 2010, respectively	29,578	24,039
Additional paid-in capital	99,489,464	82,055,934
Treasury stock, at cost, 15,491 shares, 2011 and 2010	(47,183)	(47,183)
Accumulated deficit	(91,487,673)	(72,246,460)
Total stockholders equity	7,984,186	9,786,330
Total liabilities and stockholders equity	$ 29,969,893	$ 33,580,206

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, 2011 AND 2010

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Product royalties	$ 2,659,728	$ 56,263	$ 2,693,954	$ 1,852,398
Research revenues		160,940	226,843	558,277
Contract revenues	4,000		10,800	250,476
Total Revenues:	2,663,728	217,203	2,931,597	2,661,151
Cost of product royalties	1,507,125	19,490	1,378,615	828,444
Expenses:				
Research and development	6,215,106	3,215,749	17,625,989	6,186,745
General and administrative	2,593,913	2,092,988	6,289,277	6,494,635
Related party general and administrative, net:	20,250	20,779	57,750	(318,221)
Impairment of intangible license				243,648
Total Expenses:	8,829,269	5,329,516	23,973,016	12,606,807
Loss from operations	(7,672,666)	(5,131,803)	(22,420,034)	(10,774,100)
Interest income	61,409	63,804	147,604	71,375
Derivative gain (loss)	2,472,550	(1,110,533)	3,032,106	5,065,909
Other income (expense), net	15,156	10,148	(889)	53,071
Net loss	(5,123,551)	(6,168,384)	(19,241,213)	(5,583,745)
Net loss attributable to common stockholders	$ (5,123,551)	$ (6,168,384)	$ (19,241,213)	$ (5,583,745)
Weighted average common stock shares outstanding-basic and diluted:	$ (0.17)	$ (0.26)	$ (0.69)	$ (0.24)

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, 2011

(Unaudited)

	Common Stock					Total Stockholders
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Equity
Balances, January 1, 2011	24,038,445	$ 24,039	$ 82,055,934	$ (47,183)	$ (72,246,460)	$ 9,786,330
Stock-based compensation			1,006,614			1,006,614
Stock option exercises	129,888	130	349,546			349,676
Reclassification of derivative liability to equity			336,747			336,747
Exercise of warrants	601,120	601	1,748,658			1,749,259
Private placement offering, net	4,807,693	4,808	13,991,965			13,996,773
Net loss					(19,241,213)	(19,241,213)
Balances, September 30, 2011	29,577,146	$ 29,578	$ 99,489,464	$ (47,183)	$ (91,487,673)	$ 7,984,186

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, 2011 AND 2010

(Unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
Operating activities:		
Net loss	$ (19,241,213)	$ (5,583,745)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	989,613	938,634
Derivative gain	(3,032,106)	(5,065,909)
Stock-based compensation expense	1,006,614	1,115,069
Intangible license impairment		243,648
Gain on settlement		(382,800)
Changes in assets and liabilities:		
Accounts receivable	(1,021,409)	689,770
Prepaid expenses and other assets	(13,157)	46,657
Accounts payable and accrued expenses	2,372,321	(217,176)
Deferred revenue	15,133	690,253
Income tax payable		(312,128)
Net cash flows used in operating activities	(18,924,204)	(7,837,727)
Investing activities:		
Purchase of equipment	(214,616)	(103,044)
Purchase of intangible assets		(1,000,000)
Net cash flows from investing activities	(214,616)	(1,103,044)
Financing activities:		
Proceeds from issuance of common stock	13,996,773	9,747,500
Proceeds from exercise of stock options	349,676	97,882
Proceeds from exercise of warrants	1,749,259	
Change in amounts due to related parties	(46,127)	(2,622,311)
Net cash flows from financing activities	16,049,581	7,223,071
Net change in cash and cash equivalents	(3,089,239)	(1,717,700)
Cash and cash equivalents at beginning of period	18,208,659	23,873,403
Cash and cash equivalents at end of period	$ 15,119,420	$ 22,155,703

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, 2011 AND 2010

(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, 2011 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, 2010, included in the Company s 2010 Annual Report on Form 10-K, filed with the SEC on March 11, 2011 (the 2010 Annual Report) The accompanying condensed consolidated balance sheet at December 31, 2010 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, 2011 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 2010 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 in accordance with GAAP which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

GAAP 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. GAAP also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. GAAP describes three levels of inputs that may be used to measure fair value:

Level 1 quoted prices in active markets for identical assets or liabilities

Level 2 quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

The following table summarizes assets and liabilities measured at fair value on a recurring basis at September 30, 2011 and December 31, 2010, respectively:

	September 30, 2011				December 31, 2010			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Fair Value Measurements Using:								
Assets								
Derivative asset (warrant)	$	$ 466,140	$	$ 466,140	$	$ 1,299,031	$	$ 1,299,031
Liabilities								
Derivative liabilities	$	$ 788,249	$	$ 788,249	$	$ 4,989,993	$	$ 4,989,993

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

(Unaudited)

1. Basis of presentation (continued):

The table below provides a reconciliation of the beginning and ending balances for the assets and liabilities measured at fair value using significant observable inputs (Level 2). The table reflects net gains and losses for all financial assets and liabilities categorized as Level 2 as of September 30, 2011 and December 31, 2010.

	$	Number of Warrants
Assets:		
Warrant asset as of January 1, 2011	$ 1,299,031	2,000,000
Decrease in fair value of warrants	(832,891)	
Warrant asset as of September 30, 2011	$ 466,140	2,000,000
Liabilities:		
Warrant liability as of January 1, 2011	$ 4,989,993	4,322,421
Increase in fair value of warrants issued in April 2010 financing due to anti-dilution adjustment of exercise price to $3.12 from $4.67 as a result of March 2011 private placement offering	460,452	
Decrease due to exercise of warrants by CDC	(336,747)	(601,120)
Decrease in fair value of warrants	(4,325,449)	
Decrease due to expiration of Hopkins Capital Group II warrants		(475,000)
Warrant liability as of September 30, 2011	$ 788,249	3,246,301

New accounting pronouncements:

In April 2010, the FASB issued Accounting Standards Update 2010-12 (ASU 2010-12), Income Taxes (Topic 740): Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts. On March 30, 2010, the President of the United States signed the Health Care and Education Reconciliation Act of 2010, which is a reconciliation bill that amends the Patient Protection and Affordable Care Act that was signed on March 23, 2010 (collectively, the Acts). ASU No. 2010-12 allows entities to consider the two Acts together for accounting purposes. Upon adoption, the elimination of the future tax deduction for prescription drug costs associated with the Company s post-retirement medical and dental plans was not material to the Company s financial position, results of operations or cash flows. The Company does not believe this amendment will have a material impact on the Company s financial statements.

In December 2010, the FASB released Accounting Standards Update 2010-28 (ASU 2010-28), Intangibles-Goodwill and Other (Topic 350): When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts. The update requires a company to perform Step 2 of the goodwill impairment test if the carrying value of the reporting unit is zero or negative and adverse qualitative factors indicate that it is more likely than not that a goodwill impairment exists. The qualitative factors to consider are consistent with the existing guidance and examples in Topic 350, which requires that goodwill of a reporting unit be tested for impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying amount. The requirements in ASU 2010-28 are effective for public companies in the first annual period beginning after December 15, 2010. ASU

2010-28 has not had, and is not expected to have, a material impact on the Company s consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs (ASU 2011-04). ASU 2011-04 is intended to result in convergence between U.S. GAAP and International Financial Reporting Standards (IFRS) requirements for measurement of and disclosures about fair value. The amendments are not expected to have a significant impact on companies applying U.S. GAAP. Key provisions of the amendment include: a prohibition on grouping financial instruments

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

(Unaudited)

1. Basis of presentation (continued):

for purposes of determining fair value, except when an entity manages market and credit risks on the basis of the entity s net exposure to the group; an extension of the prohibition against the use of a blockage factor to all fair value measurements (that prohibition currently applies only to financial instruments with quoted prices in active markets); and a requirement that for recurring Level 3 fair value measurements, entities disclose quantitative information about unobservable inputs, a description of the valuation process used and qualitative details about the sensitivity of the measurements. In addition, for items not carried at fair value but for which fair value is disclosed, entities will be required to disclose the level within the fair value hierarchy that applies to the fair value measurement disclosed. ASU 2011-04 is effective for interim and annual periods beginning after December 15, 2011. The Company will adopt these standards on January 1, 2012 and does not expect the adoption to have a material impact on its condensed consolidated financial statements.

In September 2011, the FASB issued ASU 2011-08, Intangibles Goodwill and Other (Topic 350), Testing Goodwill for Impairment (ASU 2011-08), to allow entities to use a qualitative approach to test goodwill for impairment. ASU 2011-08 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, it is necessary to perform the currently prescribed two-step goodwill impairment test. Otherwise, the two-step goodwill impairment test is not required. ASU 2011-08 is effective for the Company in fiscal 2013 and earlier adoption is permitted. The Company is currently evaluating the impact of the pending adoption of ASU 2011-08 on the consolidated financial statements.

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 one or more (or combinations) of the following: existing cash, royalty revenue, debt and/or equity financings, 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 for the nine months ended September 30, 2011 consisted of:

- $14 million in net proceeds from a private placement offering of Common Stock in March 2011;
- Approximately $1.3 million in net royalties;
- Approximately $1.7 million from the exercise of Common Stock warrants;
- Approximately $0.2 million in research revenues from various contractor agreements; and

Approximately $0.3 million from the exercise of Common Stock options.

Significant financing and revenue for the fiscal year ended December 31, 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 $0.7 million in research revenues from various contractor agreements;

Approximately $0.5 million in contract revenue from licensing and supply agreements;

Approximately $0.2 million in sponsored research revenue from the U.S. Government s Qualifying Therapeutic Discovery Project; and

Approximately $0.1 million from the exercise of Common Stock options.

Company management believes that the Company s existing cash and cash equivalents are sufficient to finance planned operations into the second quarter of 2012, including budgeted development costs of BEMA® Buprenorphine/Naloxone. However, current cash will not support the required new clinical trials for BEMA® Buprenorphine for chronic pain, for which additional funding will need to be obtained.

The Company believes that it will be able to secure outside funding or loans at levels sufficient to support planned operations. However, there can be no assurance that additional capital or loans (including, without limitation, via new commercial partnerships) will be available on favorable terms, if at all. If adequate outside funds are not available, the Company would likely be required to significantly reduce or refocus its planned operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, any or all of which could have a material adverse effect on the Company s financial condition and viability.

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FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

(Unaudited)

2. Liquidity and management s plans:

In addition, if the Company is faced with disruptions or crises in the worldwide financial markets as occurred since 2008, the Company s future ability to raise funds (and the cost of raising such funds) through the debt or equity markets could be materially more expensive or could make such markets unavailable at a time when the Company desires or requires additional financial investment. If the Company is unable to attract additional funds, it may adversely affect the Company s ability to achieve its 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 September 2007 and August 2006, the Company entered into license, development and supply agreements (collectively referred to as the Meda Agreements) with Meda to develop and commercialize ONSOLIS®, respectively, 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 the patents, which begin to expire in January 2019. Meda may terminate the Meda U.S. Licensing Agreements at any time after a specified notice to the Company and may terminate the Meda EU Licensing Agreements only upon breach of a material provision of the contract. The Company s rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

Contractual Rights and Obligations	Cash flows received and revenue deferred	
	September 30, 2011	December 31, 2010
North America		
License rights to ONSOLIS® (BEMA® Fentanyl) and milestone payments	$ 59,800,000	$ 59,800,000
Research and Development Services for:		
Non-cancer subsequent indication of product and further development of initial product	$ 1,541,570	$ 1,541,570
Total North America Agreement Milestones	$ 61,341,570	$ 61,341,570
Europe and Rest of World		
License rights to BREAKYL (BEMA® Fentanyl) and milestone payments	$ 8,000,000	$ 8,000,000
Research and Development Services for:		
BREAKYL product through governmental approval in a E.U. country	$ 4,548,720	$ 4,522,788
Total Europe and Rest of World Milestones	$ 12,548,720	$ 12,522,788
Total All Milestones	**$ 73,890,290**	**$ 73,864,358**

Release of Milestones upon and subsequent to first sale	$ (59,727,570)	$ (59,716,770)
Remaining Deferred Revenue	$ 14,162,720	$ 14,147,588

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

(Unaudited)

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

The Company determined that, upon inception of both the Meda Agreements, 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 were deliverable to Meda. The first commercial sale in the U.S. occurred in October 2009. As a result, $59.7 million of the aggregate milestones and services revenue were recognized. To be received upon first commercial sale in a European country, an estimated $18.0 million will be recognized, which includes an additional $5.0 million in milestones and approximately $0.5 million in research and development services. At September 30, 2011, there was remaining deferred revenue of $14.2 million, of which $12.6 million is related to the EU Meda arrangement milestones and EU Meda research and development services. The Company has estimated the amount of time and associated dollars (based on comparable services provided by outside third parties), as further noted below. As time progresses, the Company will continue to estimate the time required for ongoing obligations, and adjust the remaining deferral accordingly on a quarterly basis.

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. A portion of the upfront payments attributed to other service-related obligations will be recognized as revenue as services are provided through expiration of the license. This represents approximately $1.6 million (under the Meda U.S. Agreements) and $0.1 million (under the Meda EU Agreements).

In accordance with GAAP, the Company has determined that it is acting as a principal under the Meda Agreements and, as such, has recorded 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.

ONSOLIS® was approved by the Canadian regulatory authorities in May 2010, and is the first product approved in Canada for the management of breakthrough cancer pain. ONSOLIS® is marketed in Canada by Meda Valeant Pharma Canada Inc., a joint venture between Meda and Valeant Canada Limited. In the third quarter 2011, ONSOLIS® product was released by the Company s third party manufacturer for distribution in both Canada and the United States. This release of product provided the launching stocks for the commercial launch of ONSOLIS® in Canada, as well as provided for supply of ONSOLIS® in the United States.

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 E.U. countries, are now

expected over the next several months. BEMA® Fentanyl 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 2012. Additionally, the Company will receive a double-digit royalty on net sales.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

(Unaudited)

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., (Kunwha) a corporation organized under the laws of the Republic of Korea, to develop, manufacture, sell and distribute the Company s BEMA® Fentanyl product in the Republic of Korea. The Kunwha License Agreement is for a term beginning on May 26, 2010 until the later of the date of expiration of PCT/US07/16634 (WO 2008/011194) filed in South Korea as 10-2009-7003532 or July 23, 2027. Either the Company or Kunwha may terminate the Kunwha License Agreement prior to the expiration of the term: (i) upon or after the cessation of operations of the other party or the bankruptcy, insolvency, dissolution or winding up of the other party (other than dissolution or winding up for the purposes or reconstruction or amalgamation); or (ii) upon or after the breach of any material provision of Kunwha License Agreement by the other party if the breaching party has not cured such breach within a period of time after written notice thereof by the non-breaching party. In addition, both the Company and Kunwha have the right to terminate the Kunwha License Agreement on advanced written notice upon the occurrence of certain specified events such as failure to pay required royalties or the loss, revocation, suspension, termination or expiration of approvals to engage in the activities covered by the Kunwha License Agreement.

Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for BEMA® Fentanyl in the Republic of Korea, while the Company will retain all other licensing rights to BEMA® Fentanyl not previously granted to third parties. Kunwha paid to the Company an upfront payment of $0.3 million in May 2010 (net of taxes the company received approximately $0.25 million) and will be responsible to make certain milestone payments which could aggregate up to $1.3 million (net of taxes the company receives approximately $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 BEMA® Fentanyl from the Company.

Kunwha will be responsible for payment of all costs associated with BEMA® Fentanyl in the Republic of Korea. 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, approximately $0.25 million) received in June 2010 was recorded as contract revenue upon receipt.

TTY License and Supply Agreement

On October 7, 2010, the Company announced a license and supply agreement (the TTY Agreement) with TTY Biopharm 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 TTY Agreement results in potential milestone payments to the Company of up to $1.3 million, which includes an already received upfront payment of $0.3 million that was recorded as contract revenue upon receipt. 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. The term of the TTY Agreement 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. Either the Company or TTY may terminate the TTY Agreement prior to the expiration of the term: (i) upon or after the cessation of operations of the other party or the bankruptcy, insolvency, dissolution or winding up of the other party (other than dissolution or winding up for the purposes or reconstruction or amalgamation); or (ii) upon or after the breach of any material provision of TTY Agreement by the other party if the breaching party has not cured such breach within a period of time after written notice thereof by the non-breaching party. In addition, TTY may terminate the TTY Agreement on advanced written notice to the Company, and both the Company and TTY have the right to terminate the TTY Agreement on advanced written notice upon the occurrence of certain specified events such as failure to pay required royalties or the loss, revocation, suspension, termination or expiration of approvals to engage in the activities covered by the TTY 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 to QLT upon the approval in the first BEMA-related product in a non-US country. This payment, included in acquired product rights in the accompanying condensed consolidated balance sheet, was triggered by the Company s announcement on May 10, 2010 of the approval 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 upon the complete transfer of all required patent documentation.

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FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

(Unaudited)

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

License Amendment with CDC

On May 12, 2011, the Company entered into an Amendment to Clinical Development and License Agreement (the CDLA Amendment) by and among CDC V, LLC (CDC), NB Athyrium LLC (Athyrium). The Company is a party to a Clinical Development and License Agreement, dated as of July 14, 2005 (as amended, the CDLA), with a predecessor to CDC pursuant to which CDC provided funding for the development of the Company s ONSOLIS® product. Athyrium holds certain rights, acquired from CDC, to receive royalties on sales of ONSOLIS®.

Under the terms of the CDLA Amendment, among other matters, the parties agreed to increase the royalty rate to be received by CDC/Athyrium retroactively to the initial launch date of ONSOLIS® and, accordingly, the Company has recorded $0.3 million as additional cost of product royalties for the nine months ended September 30, 2011. In addition, certain terms of the CLDA were amended and restated to clarify that royalty payments by the Company under the CDLA will be calculated based on Meda s sales of ONSOLIS®, whereas previous Company royalty payments to CDC were calculated based on Company sales of ONSOLIS® to Meda.

The difference between these two calculations resulted in a $1.1 million overpayment by the Company which was recorded as a prepayment. As a result, the Company did not pay any of the 2011 quarterly royalty payments due to CDC/Athyrium and will not be required to pay another royalty payment until the December 31, 2011 royalty calculation, which is due during the first quarter of 2012.

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. 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 entered 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 Settlement Date), the date which the bankruptcy court issued the final order authorizing the Settlement Agreement. At the settlement 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, and is included in related party general and administrative in the accompanying condensed consolidated statement of operations. Subsequent to the Settlement Date and prior to the end of the nine months ended September 30, 2010, the stock price of Biovest s common stock increased, resulting in a derivative gain of $0.8 million and is included in derivative (loss) gain in the accompanying condensed consolidated statement of operations. During the nine months ended September 30, 2011, the stock price of Biovest s common stock declined, resulting in a derivative loss of $0.8 million. This derivative loss partially offsets the overall derivative gain that is in the accompanying condensed consolidated statement 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.

The following tabular presentation reflects the components of derivative assets and liabilities as of September 30, 2011 and December 31, 2010:

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6. Derivative Financial Instruments (continued):

	September 30, 2011	December 31, 2010
Derivative asset at fair value:		
Free standing warrants related party	$ 466,140	$ 1,299,031

	September 30, 2011	December 31, 2010
Shares into which derivative asset can be settled:		
Free standing warrants related party	2,000,000	2,000,000

	September 30, 2011	December 31, 2010
Derivative liability at fair value:		
Free standing warrants*	$ 788,249	$ 4,989,993

* These warrants can be settled by issuance of 3,246,301 and 4,322,421 shares of Common stock at September 30, 2011 and December 31, 2010, respectively.

The following tabular presentation reflects the components of the gain (loss) of derivative financial instruments for the three and nine month periods ended September 30, 2011 and 2010:

	3 months ending September30, 2011	3 months ending September30, 2010	9 months ending September30, 2011	9 months ending September30, 2010
Derivative gain (loss) in the accompanying statement of operations is related to the individual derivatives as follows:				
Free standing warrants assets, related party	$ (124,400)	$ (415,400)	$ (832,891)	$ 822,800
Free standing warrants liabilities	2,596,950	(695,133)	3,864,997	4,243,109
	$ 2,472,550	$ (1,110,533)	$ 3,032,106	$ 5,065,909

7. Stockholders Equity:

Incentive Plans:

On July 20, 2011, the Company s Amended and Restated 2001 Incentive Plan, (2001 Plan) expired and accordingly, the Company adopted a new 2011 Equity Incentive Plan (2011 Plan) which was approved by the Company s stockholders. On August 24, 2011, the Company filed a Registration Statement on Form S-8 to register:

an additional 1,821,179 shares of the Common Stock underlying options previously granted under the 2001 Plan, which shares are in addition to 3,500,000 shares underlying options granted under the 2001 Plan, such 3,500,000 shares having been previously registered on a Registration Statement on Form S-8 (No. 333-142590) as filed with the Securities and Exchange Commission on June 8, 2007 and supplemented on June 5, 2009; and

4,200,000 shares of Common Stock issuable pursuant to the 2011 Plan, of which 147,500 shares underlying options were granted to certain of the Company s officers and directors under 2011 Plan in July 2011.

Stock-based compensation:

During the nine months ended September 30, 2011, a total of 296,174 options with an aggregate fair market value of approximately $1 million were granted under the 2001 Plan prior to its expiration to Company employees and directors and 147,500 options with an aggregate fair market value of approximately $0.5 million were granted under the 2011 Plan to Company 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. The fair value of each option is amortized as compensation expense evenly

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7. Stockholders Equity (continued):

Stock-based compensation (continued):

through the vesting period. The fair value of each option award is estimated on the grant date 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, 2011 follows:

Expected price volatility	69.05%-73.21%
Risk-free interest rate	1.58%-1.99%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the nine months ended September 30, 2011 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2011	4,311,539	$ 3.65	
Granted			
Officers and Directors	204,756		
Others	238,918		
Exercised	(129,888)		
Forfeitures	(76,937)		
Outstanding at September 30, 2011	4,548,388	$ 3.67	$

Options outstanding at September 30, 2011 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining	Weighted Average Exercise	Aggregate Intrinsic Value

			Contractual Life (Years)	Price	
$ 1.00	5.00	3,607,143	6.51	$ 2.99	
$ 5.01	10.00	941,245	5.98	$ 6.27	
		4,548,388			$

Options exercisable at September 30, 2011 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	2,824,288	5.89	$ 2.82	
$ 5.01	10.00	931,245	5.96	$ 6.28	
		3,755,533			$

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7. Stockholders Equity (continued):

The weighted average grant date fair value of options granted during the nine months ended September 30, 2011 was $3.45. There were no options granted during the nine months ended September 30, 2011 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, 2011, and changes during the nine months ended September 30, 2011 is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Nonvested at January 1, 2011	1,036,960		
Granted	296,174		
Vested	(463,342)		
Forfeited	(76,937)		
Nonvested at September 30, 2011	792,855	$ 3.38	$

As of September 30, 2011, there was approximately $1.2 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed ratably 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, 2011, 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	4,197,801	1.89	$ 3.63	
	4,197,801			$

Reclassification of derivative liability to equity:

During the nine months ended September 30, 2011, CDC exercised warrants to purchase 601,120 shares of Common Stock for $2.91 per share. At the time of exercise the warrants were treated as a derivative liability. Upon exercise of the warrants, these amounts were reclassified to equity based on the fair value on the date of exercise.

8. Earnings 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,	
	2011	2010	2011	2010
Net loss	$ (5,123,551)	$ (6,168,384)	$ (19,241,213)	$ (5,583,745)
Basic and Diluted:				
Weighted average shares outstanding (denominator)	29,561,655	24,022,954	27,904,879	22,857,121
Net loss per common share basic and diluted	$ (0.17)	$ (0.26)	$ (0.69)	$ (0.24)

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

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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. $50,000 of the WRAIR grant was funded to the Company but later refunded as described below.

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 was included in general and administrative expenses in the Company s 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 directly related to the cochleate technology. The Company dedicated very limited resources to the Bioral® platform during the first half of 2010 and subsequently. 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. There were no impairments during the nine months ending September 30, 2011.

10. Subsequent Event:

On November 7, 2011, the Company announced that TTY submitted a New Drug Application for marketing authorization of BEMA® Fentanyl to the Taiwan Food and Drug Administration. TTY is responsible for the regulatory filing of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. The Company expects to receive a milestone payment of $0.3 million in the fourth quarter of 2011 related to this submission.

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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 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, 2011 compared to the three months ended September 30, 2010

Product Royalty Revenues. We recognized $2.7 million and $0.06 million in product royalty revenue during the three months ended September 30, 2011 and 2010, respectively, under our license agreement with Meda. The increase in product royalty revenues can be attributed to the commercial launch of ONSOLIS® in Canada and a re-supply order for ONSOLIS® in the U.S., whereas there were no ONSOLIS® orders in the corresponding period in 2010.

Research Revenues. We recognized $0.2 million of revenue related to a research and development agreement with Meda during the three months ended September 30, 2010. There was no corresponding research revenue recognized during the three months ended September 30, 2011.

Contract Revenues. We recognized $0.004 million in contract revenue related to previously deferred revenue under our license agreement with Meda during the three months ended September 30, 2011. There was no corresponding contract revenue recognized during the three months ended September 30, 2010.

Cost of Product Royalties. We recognized a $1.5 million and $0.002 million during the three months ended September 30, 2011 and 2010, respectively, in cost of product royalties. This includes not only manufacturing costs, but also royalty costs owed to CDC V, LLC (CDC) and NB Athyrium LLC (Athyrium). We are required to pay royalties to CDC and Athyrium under a Clinical Development and License Agreement entered into in 2005, and which was amended most recently in May 2011. The $1.5 million expense during the three months ended September 30, 2011 directly relates to shipments of ONSOLIS® made to the U.S. and Canadian markets.

Research and Development Expenses. During the three months ended September 30, 2011 and 2010, research and development expenses totaled $6.2 million and $3.2 million, respectively. The increase in research and development expenses can be attributed to the BEMA® Buprenorphine clinical trials in 2011. Our scientific staff continued to work toward development and application of our BEMA® delivery technology, but particularly with respect to ONSOLIS® and Buprenorphine. Funding of this research in 2011 and 2010 was obtained through deferred license revenue, a private placement stock offering in March 2011, a registered direct offering in April 2010 and exercise of options by employees and directors. 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 September 30, 2011 and 2010, general and administrative expenses totaled $2.6 million and $2.1 million, respectively. General and administrative costs include legal, accounting and management wages, legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. The increase in general and administrative expenses, net can be attributed to an increase in legal expenses.

Interest Income. We had interest income of $0.06 million during each of the three months ended September 30, 2011 and 2010.

***Derivative gain (loss)*.** The $2.5 million derivative gain for the three months ended September 30, 2011 was related to an adjustment to fair value of both derivative assets and liabilities. Our derivative liability consists of free standing warrants. Due to a decline in the value of our common stock, the related warrant liability declined by $2.6 million, causing a derivative gain. This gain was partially offset by a $0.1 million loss in the fair value of our derivative asset, which consists of 2 million Biovest warrants. Both calculations utilize the Black Scholes method to determine fair value. During the three months ended September 30, 2010, we had a $1.1 million derivative loss. Due to an increase in the value of our Common Stock, the fair value of the warrant liability declined by $0.7 million, resulting in a derivative loss. In addition, the fair value of our Biovest derivative asset declined by $0.4 million.

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For the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010

Product Royalty Revenues. We recognized $2.7 million and $1.9 million in product royalty revenue during the nine months ended September 30, 2011 and 2010, respectively, under our license agreement with Meda. The increase in product royalty revenues can be attributed to the commercial launch of ONSOLIS® in Canada.

Research Revenues. We recognized $0.2 million and $0.6 million of revenue related to a research and development agreement with Meda during the nine months ended September 30, 2011 and 2010, respectively.

Contract Revenues. We recognized $0.01 million and $0.3 million during the nine months ended September 30, 2011 and 2010, respectively, in contract revenue related to previously deferred revenue under our license agreement with Meda.

Cost of Product Royalties. We recognized $1.4 million and $0.8 million during the nine months ended September 30, 2011 and 2010, respectively, in cost of product royalties. This includes both manufacturing costs and royalty costs owed to CDC and Athyrium. We are required to pay royalties to CDC and Athyrium under a Clinical Development and License Agreement entered into in 2005, and most recently amended in May 2011. Product royalty expense of $1.5 million was incurred during the three months ended September 30, 2011, and directly relates to shipments made to the U.S. and Canadian markets. There was a small offsetting credit of $0.1million incurred during the three months ended June 30, 2011 that related to the net effect of an amendment to the CDC and Athyrium royalty agreement.

Research and Development Expenses. During the nine months ended September 30, 2011 and 2010, research and development expenses totaled $17.6 million and $6.2 million, respectively. The increase in research and development expenses can be attributed to the BEMA® Buprenorphine clinical trials in 2011. Our scientific staff continued to work toward development and application of our BEMA® delivery technology, but particularly with respect to ONSOLIS® and Buprenorphine. Funding of this research in 2011 and 2010 was obtained through deferred license revenue, a private placement stock offering in March 2011, a registered direct offering in April 2010 and exercise of options by employees and directors. 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 nine months ended September 30, 2011 and 2010, general and administrative expenses totaled $6.3 million and $6.2 million, respectively. General and administrative costs include legal, accounting and management wages, 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 condensed consolidated financial statements). This is included in related party general and administrative, net.

Impairment of intangible license. During the nine months ended September 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. (See note 9 to the accompanying condensed consolidated financial statements.) There were no impairment charges during the nine months ended September 30, 2011.

Interest Income. During the nine months ended September 30, 2011 and 2010 we had interest income of $0.1 million and $0.07 million, respectively.

Derivative gain (loss). The $3.0 million derivative gain for the nine months ended September 30, 2011 was related to an adjustment to fair value of both derivative assets and liabilities. Our derivative liability consists of free standing warrants. Due to a decline in the value of our common stock in 2011, the fair value of the related warrant liability declined by $3.8 million, resulting in a derivative gain. This gain was partially offset by a $0.8 million loss in the fair value of our derivative asset, which consists of 2 million Biovest warrants. Both calculations utilize the Black Scholes method to determine fair value. The $5.1 million derivative gain for the nine months ended September 30, 2010 was due to the decline in value of our common stock. As a result, the fair value of the warrant liability declined by approximately $4.3 million, resulting in a derivative gain. In addition, due to increases in the value of the Biovest stock, the fair value of our Biovest derivative asset increased by $0.8 million, resulting in 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 and commercialization agreements with Meda relating to ONSOLIS®. We

intend to finance our research and development

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

On March 11, 2011, we consummated a private placement offering to institutional investors of an aggregate of 4,807,693 shares of our Common Stock at a price equal to $3.12 per share, representing a 10% discount to an agreed upon volume weighted average price of our stock. Gross proceeds we received from the offering were $15 million (net proceeds approximated $14 million). No warrants were issued to investors in the private placement offering. Proceeds from this offering were used principally for the clinical development of our pipeline of products, particularly BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone. We also believe that the proceeds also strengthen our balance sheet as we participate in commercial partnering discussions for BEMA® Buprenorphine.

In the third quarter of 2011, ONSOLIS® product was released for distribution in both Canada and the United States. This release of product provided the launching stocks for the commercial launch of ONSOLIS® in Canada, as well as provided for supply of ONSOLIS® in the United States. ONSOLIS® is approved in the U.S., Canada, and the E.U. (where it will be marketed as BREAKYL) for the management of breakthrough pain in opioid tolerant, adult patients with cancer. ONSOLIS® is marketed in Canada by Meda Valeant Pharma Canada Inc., a joint venture between our commercial partner for ONSOLIS®, Meda, and Valeant Canada Limited.

Our cash to be used in operations will continue beyond our ONSOLIS® agreements with Meda as we research, develop, and potentially, manufacture and commercialize additional drug formulations with our BEMA® technology (most notably BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone). We believe further application of our BEMA® delivery technology to other drugs will result in license agreements (and potential upfront, milestone and/or royalty payments to us) with other commercial partners such as Meda, and so 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, 2011, we had cash and cash equivalents of approximately $15.1 million. We used $18.9 million of cash from operations during the nine months ended September 30, 2011. As of September 30, 2011, we had stockholders equity of $8 million, compared to $9.8 million at December 31, 2010. Our existing cash and cash equivalents are believed by our management to be sufficient to finance planned operations into the second quarter of 2012, including budgeted development costs of BEMA® Buprenorphine/Naloxone. However, our current cash will not support the required new clinical trials for BEMA® Buprenorphine for chronic pain, for which additional funding will need to be obtained.

Additional capital will be required in order to proceed with our support of the manufacturing of ONSOLIS®, and for the development of 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. In particular, in September 2011, we announced that our Phase 3 clinical trial for BEMA Buprenorphine did not meet its primary endpoint; as a result, we will be required to conduct new trials. The capital requirements for this activity alone will be significant.

In addition, 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 will be required to raise additional capital, which may be available to us through a variety of sources, including:

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;

sale of product royalty;

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 potential commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not

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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, any 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, if we are faced with worldwide financial and credit crises as occurred since 2008, it may make the future cost of raising funds through the debt or equity markets more expensive or make financial markets unavailable to us at times when we require additional financing.

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 September 30, 2011 are as follows:

	Payments Due by Period				
		Less than			More than
	Total	1 year	1-3 years	3-5 years	5 years
Operating lease obligations	$ 171,735	$ 128,028	$ 43,707	$	$
Employment agreements	954,168	954,168			
Minimum royalty expenses*	12,038,000	1,163,000	3,000,000	3,000,000	4,875,000
Total contractual cash obligations	$ 13,163,903	$ 2,245,196	$ 3,043,707	$ 3,000,000	$ 4,875,000

* Minimum royalty expenses represent a contractual floor that we are obligated to pay CDC regardless of actual sales. Minimum royalties began in the second quarter of 2011.

Off-Balance Sheet Arrangements

As of September 30, 2011, 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, 2011 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, 2011 was $6.4 million, net of accumulated amortization of $3.5 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.

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

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

There were no impairment charges during the nine months ended September 30, 2011. We recorded a $0.2 million impairment charge in 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 and assets 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 previously discussed.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents include Ultra Short Term Government Funds. 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 on deposit with financial institutions in the United States. On November 9, 2010, the Federal Deposit Insurance Corporation (FDIC) issued a Final Rule implementing Section 343 of the Dodd-Frank Wall Street Reform and Consumer Protection Act that provides for unlimited insurance coverage of noninterest-bearing transaction accounts. Beginning December 31, 2010, through December 31, 2012, all non-interest bearing transaction accounts are fully insured, regardless of the balance of the account, at all FDIC-insured institutions. The unlimited insurance coverage is available to all depositors, including consumers, businesses, and government entities. This unlimited coverage is separate from, and in addition to, the $250,000 insurance coverage provided to a depositor s other deposit accounts held at an FDIC-insured institution. As of September 30, 2011, we had approximately $14.7 million which exceed these 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.

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Market indexed security risk

We have a warrant to purchase 2 million shares of common stock of Biovest International and have issued warrants to various holders underlying shares of our common stock. These warrant investments are re-measured to their fair value at each reporting period with changes in their fair value recorded as derivative (loss) gain 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 our 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 our disclosure controls and procedures were effective to ensure that material information is recorded, processed, summarized and reported by our management on a timely basis in order to comply with our 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 our internal control over financial reporting during our third fiscal quarter of 2011 that materially affected, or are reasonably likely to materially affect, our 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 our 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, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

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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 SEC. 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 1A of our 2010 Annual Report and other factors detailed from time to time in our other filings with the SEC. 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.

On November 2, 2010, MonoSol Rx, LLC (MonoSol) filed an action against us and our ONSOLIS® commercial partners in the Federal District Court of New Jersey (DNJ) for alleged patent infringement. We were formally served in this matter on January 19, 2011. MonoSol claims that our manufacturing process for ONSOLIS®, which has never been disclosed publicly and which we and our partners maintain as a trade secret, infringes its patent (United States Patent No. 7,824,588). MonoSol also has made a claim of false marking as part of its complaint. Of note, the BEMA® technology itself is not at issue in the case, but rather only the manner in which ONSOLIS®, which incorporates the BEMA® technology, is manufactured. Pursuant to its compliant, MonoSol is seeking an unspecified amount of damages, attorney s fees and an injunction preventing future infringement of MonoSol s patents.

We strongly refute as without merit MonoSol s assertion of patent infringement, which relates to our confidential, proprietary manufacturing process for ONSOLIS®. On February 23, 2011, we filed our initial answer in this case. In our answer, we stated our position that our products, methods and/or components do not infringe MonoSol s patent because they do not meet the limitations of any valid claim of MonoSol s patent. Moreover, in our answer, we stated our position that MonoSol s patent, which is the subject of the case, is actually invalid and unenforceable for failure to comply with one or more of the requirements of applicable U.S. patent law. For these and other reasons, we intend to defend this case vigorously, and we anticipate that MonoSol s claims will be rejected.

We have engaged in voluntary and court mandated settlement discussions with MonoSol, but to date have been unable to reach any settlement with them. These discussions are part of the normal course of such an action but does not alter our view of non-infringement and invalidity of the subject patents.

During the third quarter ending September 30, 2011, a case management conference was held on July 13, 2011 and a mandatory settlement conference before the magistrate judge was held on September 8, 2011.

On September 12, 2011, we filed a request for *inter partes* re examination in the United States Patent and Trademark Office (USPTO) of MonoSol s US patent No 7,824,588 demonstrating that all claims of the patent were anticipated by or obvious in the light of prior art references, including several prior art references not previously considered by the USPTO. On September 16, 2011, we filed in court a motion for stay pending the outcome of the re examination proceedings.

On September 26, 2011, MonoSol filed a second amended complaint, which added two additional patents not previously asserted and on October 4, 2011 MonoSol filed an opposition to the motion for stay. We filed an answer to the second amended complaint denying infringement and asserting challenges to the validity of the two newly-asserted patents. The court conducted a status conference on October 25, 2011, at which it denied the motion to stay without prejudice, set November 18, 2011 as the date for MonoSol to file supplemental initial disclosures and its infringement contentions pursuant to the DNJ Local Patent Rules, and the first week in January as the date for defendants to serve their non infringement and invalidity contentions. The court stated that it would conduct a status conference immediately thereafter and invited defendants to renew their motion to stay based on developments in the USPTO and otherwise.

It is our position that court proceedings in this matter should be stayed pending the outcome of the re-examination proceedings because such proceedings may result in the rejection or narrowing of MonoSol s patent claims, obviating the need for further court proceedings on those claims. We expect to renew our motion for stay in January 2012.

Item 1A. Risk Factors.

On September 28, 2011, we announced that our Phase 3 clinical study of BEMA® Buprenorphine for the treatment of moderate to severe chronic pain did not meet its primary endpoint. Given the impact of this event on our Company, we are updating the following previously reported risk factors:

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Risks Relating to Our Business

Until we have a larger royalty revenue stream from ONSOLIS ® and milestone payments from a partnership around BEMA® Buprenorphine for chronic pain, and perhaps even thereafter, we will likely need to raise additional capital to continue our operations from time to time, and our failure to do so would significantly impair our ability to fund our operations, develop our technologies and product candidates, attract commercial partners, retain key personnel or promote our products.

Our operations have been funded almost entirely by external financing. Such financing has historically come primarily from license and royalty fees, the sale of common and preferred stock and convertible debt to third parties, related party loans and, to a lesser degree, from grants and bank loans. At September 30, 2011, we had cash of approximately $15.1 million. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development) that our current working capital will be sufficient to satisfy our contemplated cash requirements into the second quarter of 2012, although this excludes the additional capital that will be required for additional clinical trials of BEMA® Buprenorphine for chronic pain and further assumes that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements.

Depending on the timing of our certain potential commercial partnerships or financings, and given our anticipated cash usage and lack of significant revenues, we will likely need to raise additional capital in the future to fund our anticipated operating expenses and progress our business plans. This is particularly the case with respect to additional Phase 3 clinical trials for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain, which will be required because, as announced in late September 2011, our initial Phase 3 trial for this product failed to meet its primary endpoint. As a result, the further development of BEMA® Buprenorphine will require significant additional capital to complete. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on our operations may make raising additional capital more difficult or impossible and may also result in a lower price for our shares.

Risks Related to Our Products in Development and Regulation

Conducting and completing the clinical trials necessary for FDA approval is costly and subject to intense regulatory scrutiny as well as the risk of failing to meet the primary endpoint of such trials. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a formulation or product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators did not follow the FDA s requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are permanently halted by the FDA, we would not be able to achieve any revenue from such product as it is illegal to sell any drug or medical device for human consumption or use without FDA approval.

Moreover, it is our stated intention to seek to avail ourselves of the FDA s 505(b)(2) approval procedure where it is appropriate to do so. If this approval pathway is not available to us with respect to a particular formulation or product, or at all, the time and cost associated with developing and commercializing such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

Moreover, there is a risk that our clinical trials will fail to meet their primary endpoints, which would make them unacceptable in having the subject product approved by the FDA. In September 2011, we announced that our Phase 3 clinical trial for BEMA® Buprenorphine did not meet its primary endpoint and therefore we will be required to conduct a new trial. Conducting a new clinical trial in accordance with the FDA requirements will require significant additional capital, and we will not be able to commercialize and sell our BEMA® Burprenorphine product until we are able to meet our primary endpoint and subsequent FDA approval.

Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

Data already obtained, or in the future obtained, from non-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later non-clinical studies and clinical trials. Moreover, non-clinical and clinical data are susceptible to multiple and varying interpretations, which could delay, limit or prevent regulatory approval. A number of

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companies in the pharmaceutical industry, including those involved in competing drug delivery technologies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the product candidate, resulting in delays to commercialization, and could materially harm our business. In additional, our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

Finally, if any of our clinical trials do not meet their primary endpoints, we would need to redo such clinical trials in order to progress development of the subject product. These additional trials would be costly and divert resources from other projects.

The foregoing risks were evidenced by the failure of our Phase 3 trial for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain to meet its primary endpoint, which we announced September 2011.

Risks Related to Our Common Stock

If we cannot meet the NASDAQ Capital Market s continuing listing requirements and NASDAQ rules, NASDAQ may delist our securities, which could negatively affect our company, the price of our securities and your ability to sell our securities.

As of the date of this quarterly report, our shares are listed on the NASDAQ Capital Market. In the future, however, we may not be able to meet the continued listing requirements of the NASDAQ Capital Market and NASDAQ rules, which require, among other things, maintaining a minimum bid price per share of $1.00, minimum stockholders equity of $2.5 million or a minimum market capitalization of $35 million and a majority of independent directors on our board of directors. We have been subject to delisting proceedings and comments by NASDAQ in the past, and recently our stock price has declined to levels that put us at risk of not being able to maintain the required minimum bid price or market capitalization levels or both. If we are unable to satisfy the NASDAQ criteria for continued listing, especially at our current stock price levels, our securities could again be subject to delisting. Trading, if any, of our securities would thereafter be conducted in the over-the-counter market, in the so-called pink sheets or on the OTC Bulletin Board. As a consequence of any such delisting, our stockholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the prices of our securities.

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.
None.

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 (*)
101.ins**	XBRL Instance Document
101.xsd**	XBRL Taxonomy Extension Schema Document
101.cal**	XBRL Taxonomy Calculation Linkbase Document
101.def**	XBRL Taxonomy Definition Linkbase Document
101.lab**	XBRL Taxonomy Label Linkbase Document
101.pre**	XBRL Taxonomy Presentation Linkbase Document

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* 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.

** Furnished. Not filed. Not incorporated by reference. Not subject to liability.

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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 14, 2011

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

(Principal Executive Officer)

Date: November 14, 2011

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

(Principal Financial Officer)

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