BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 10, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2012

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

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

As of May 4, 2012, there were 29,644,321 shares of company common stock issued and 29,628,830 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 MARCH 31, 2012 AND DECEMBER 31, 2011

	March 31, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,114,967	$ 10,750,205
Accounts receivable, other	197,718	101,132
Prepaid expenses and other current assets	574,905	229,886
Total current assets	32,887,590	11,081,223
Equipment, net	3,174,567	3,288,108
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,900,000	1,900,000
Acquired product rights	9,050,000	8,000,000
Accumulated amortization	(4,004,857)	(3,749,637)
Total other intangible assets	6,945,143	6,150,363
Derivative asset, warrant (note 7)	661,900	388,540
Other assets	21,976	21,976
Total assets	$ 46,406,176	$ 23,645,210
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	$ 5,002,940	$ 5,090,795
Deferred revenue, current	12,543,961	12,507,471
Derivative liabilities (note 7)	2,419,908	279,302
Total current liabilities	19,966,809	17,877,568
Deferred revenue, long-term	1,561,159	1,647,249
Total liabilities	21,527,968	19,524,817
Commitments and contingencies		
Stockholders equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized in 2012 and 2011; 0 shares outstanding in 2012 and 2011		
Common Stock, $.001 par value; 75,000,000 shares authorized; 29,577,146 shares issued; 29,561,655 shares outstanding in 2012 and 2011, respectively	29,578	29,578
Additional paid-in capital	100,171,338	99,709,574
Treasury stock, at cost, 15,491 shares, 2012 and 2011	(47,183)	(47,183)
Accumulated deficit	(75,275,525)	(95,571,576)
Total stockholders equity	24,878,208	4,120,393
Total liabilities and stockholders equity	$ 46,406,176	$ 23,645,210

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS ENDED MARCH 31, 2012 AND 2011

(Unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Revenues:		
Product royalty revenues	$	$ 34,225
Research fees	14,200	193,238
Contract revenue	30,049,600	2,000
Total Revenue:	30,063,800	229,463
Cost of product royalties	375,000	297,419
Expenses:		
Research and development	4,711,610	6,690,674
General and administrative	2,840,795	1,764,489
Related party general and administrative, net	26,250	18,750
Total Expenses:	7,578,655	8,473,913
Income (loss) from operations	22,110,145	(8,541,869)
Interest income	56,616	37,784
Derivative loss	(1,867,246)	(487,313)
Other expense, net	(3,464)	(27,913)
Net income (loss)	$ 20,296,051	$ (9,019,311)
Basic:		
Weighted average common stock shares outstanding	29,561,655	25,105,563
Basic earnings per share	$ 0.69	($ 0.36)
Diluted:		
Diluted weighted average common stock shares outstanding	29,586,036	25,105,563
Diluted earnings per share	$ 0.69	($ 0.36)

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

FOR THE THREE MONTHS ENDED MARCH 31, 2012

(Unaudited)

	Common Stock					Total
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Stockholders Equity
Balances, January 1, 2012	29,577,146	$ 29,578	$ 99,709,574	$ (47,183)	$ (95,571,576)	$ 4,120,393
Stock-based compensation			461,764			461,764
Net income					20,296,051	20,296,051
Balances, March 31, 2012	29,577,146	$ 29,578	$ 100,171,338	$ (47,183)	$ (75,275,525)	$ 24,878,208

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2012 AND 2011

(Unaudited)

	Three months Ended March 31,	
	2012	**2011**
Operating activities:		
Net income (loss)	$ 20,296,051	$ (9,019,311)
Adjustments to reconcile net income (loss) to net cash flows from operating activities:		
Depreciation and amortization	372,760	326,923
Derivative loss	1,867,246	487,313
Stock-based compensation expense	461,764	246,056
Changes in assets and liabilities:		
Accounts receivable	(96,586)	(108,126)
Prepaid expenses and other assets	(345,019)	(144,721)
Accounts payable and accrued expenses	(6,257)	1,964,333
Deferred revenue	(49,600)	108,035
Net cash flows from operating activities	22,500,359	(6,139,498)
Investing activities:		
Purchase of equipment	(24,792)	(1,398)
Purchase of intangible assets	(1,050,000)	
Net cash flows from investing activities	(1,074,792)	(1,398)
Financing activities:		
Proceeds from issuance of common stock		13,996,773
Proceeds from exercise of stock options		207,454
Change in amounts due to related parties	(60,805)	(50,873)
Net cash flows from financing activities	(60,805)	14,153,354
Net change in cash and cash equivalents	21,364,762	8,012,458
Cash and cash equivalents at beginning of period	10,750,205	18,208,659
Cash and cash equivalents at end of period	$ 32,114,967	$ 26,221,117

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2012 AND 2011

(Unaudited)

1. Basis of presentation:

Overview:

The accompanying unaudited condensed consolidated financial statements of BioDelivery Sciences International, Inc., a Delaware corporation, together with its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc., a Delaware corporation (Arius One) and Arius Two, Inc., a Delaware corporation (Arius Two) and its majority-owned, inactive subsidiary, Bioral Nutrient Delivery, LLC, a Delaware limited liability company (BND) (collectively, the Company or we , us or similar terminology) have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at March 31, 2012 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, 2011, included in the Company s 2011 Annual Report on Form 10-K, filed with the SEC on March 19, 2012 (the 2011 Annual Report). The accompanying condensed consolidated balance sheet at December 31, 2011 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 month period ended March 31, 2012 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 2011 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 March 31, 2012 and December 31, 2011, respectively:

	March 31, 2012				December 31, 2011			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Fair Value Measurements Using:								
Assets								
Derivative asset (warrant)	$	$ 661,900	$	$ 661,900	$	$ 388,540	$	$ 388,540
Liabilities								
Derivative liabilities	$	$ 2,419,908	$	$ 2,419,908	$	$ 279,302	$	$ 279,302

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2012 AND 2011

(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 March 31, 2012 and December 31, 2011.

	$	Number of Warrants
Assets:		
Warrant asset as of January 1, 2012	$ 388,540	2,000,000
Increase in fair value of warrants	273,360	
Warrant asset as of March 31, 2012	$ 661,900	2,000,000
Liabilities:		
Warrant liability as of January 1, 2012	$ 279,302	3,246,301
Expiration of CDC warrants	0	(1,000,000)
Increase in fair value of warrants	2,140,606	
Warrant liability as of March 31, 2012	$ 2,419,908	2,246,301

New accounting pronouncements:

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 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 adopted these standards on January 1, 2012. The adoption of this standard had no material impact on the Company s condensed 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, revenue generated as a result of its worldwide license and development agreement with Meda AB (Meda) regarding ONSOLIS® and revenue generated as a result of its January 2012 license and development agreement with Endo

Pharmaceuticals Inc. (Endo) regarding the Company s BEMA buprenorphine product candidate. The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, royalty revenue, new sources of financing, existing and new 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 three months ended March 31, 2012 consisted of:

- $30 million in contract revenue from license agreement (see note 4); and
- approximately $0.05 million in previously deferred contract revenue.

Significant financing and revenue through December 31, 2011 consisted of:

- approximately $14 million in net proceeds from a private placement offering of Common Stock in March 2011;
- approximately $1 million in net royalties;
- approximately $1.7 million from the exercise of Common Stock warrants;

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2012 AND 2011

(Unaudited)

2. Liquidity and management s plans (continued):

approximately $0.3 million in contract revenue from licensing and supply agreement (see note 6);

approximately $0.2 million in research revenues from various contractor agreements; and

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

In February 2012, the Company s universal shelf registration statement, pursuant to which it could issue up to $50 million of its securities from time to time and subject to certain conditions, expired. In January 2012, the Company filed a renewal of its shelf registration statement which registered up to $40 million of the Company s securities for potential future issuance, and such registration statement was declared effective on February 24, 2012 and will expire in February 2015 unless it is renewed prior to such expiration.

At March 31, 2012, the Company had cash and cash equivalents of approximately $32.1 million. The Company generated $22.5 million of cash from operations during the three months ended March 31, 2012. As of March 31, 2012, the Company had stockholders equity of $24.9 million, versus $4.1 million at December 31, 2011.

In January 2012, the Company received a $30 million, upfront non-refundable milestone payment related to the Company s definitive license and development agreement with Endo to license, develop, manufacture, market and sell its BEMA® Buprenorphine product on a worldwide basis. In addition, in May 2012, the Company received an additional $15 million milestone payment from Endo due to its achievement of a certain intellectual project related milestone. However, and unless alternative financing is utilized, this aggregate $45 million in cash is anticipated to be used in its entirety to fund the Company s clinical research with respect to this product.

The Company s existing cash, even with the aforementioned $45 million milestone payments, together with other expected cash inflows from other milestones and royalties, are anticipated by management to be sufficient to fully fund at the planned level the Company s operations through the first quarter of 2013. Included in this estimation are costs of between $0.6 million and $1.2 million that the Company expects will be incurred in connection with the reformulation project (described further in Note 3 below) associated with the Company s FDA-approved product ONSOLIS®. Also included are savings in legal expense that the Company expects due to the March 2012 stay of its litigation with MonoSol Rx, LLC (MonoSol). Certain planned expenditures are discretionary and could be deferred if the Company is required to do so to fund critical operations.

Accordingly, additional capital will likely be required to support commercialization efforts for ONSOLIS® (including commercial launch in Europe which is expected in 2012), clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of the Company s agreement with Endo), planned development of BEMA® Buprenorphine/Naloxone and general working capital. Based on product development timelines and agreements with the Company s 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.

In addition, the worldwide financial and credit crisis that began in 2008 and has fluctuated to the present time has strained investor liquidity and contracted credit markets. During the three months ending March 31, 2012, the financial and credit crisis did not directly nor materially impact the Company. However, if this environment continues, fluctuates or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when the Company requires additional financial investment. If the Company is unable to attract additional funds it may adversely affect its ability to achieve development and commercialization goals, which

could have a material and adverse effect on the business, results of operations and financial condition.

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NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2012 AND 2011

(Unaudited)

3. Meda License, Development and Supply Agreements:

In August 2006 and September 2007, the Company entered into license, development and supply agreements (collectively referred to as the Meda Agreements) with Meda to develop and commercialize ONSOLIS® (the Company s sole FDA-approved product) in, 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 2020. 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:

	Cash flows received and revenue deferred	
Contractual Rights and Obligations	**March 31, 2012**	**December 31, 2011**
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	$ 4,548,720
Total Europe and Rest of World Milestones	$ 12,548,720	$ 12,548,720
Total All Milestones	**$ 73,890,290**	**$ 73,890,290**
Release of Milestones upon and subsequent to first sale	$ (59,785,170)	$ (59,735,570)
Remaining Deferred Revenue	$ 14,105,120	$ 14,154,720

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

arrangements are separable and, if so, to determine the fair value to be allocated to each unit of accounting.

The Company determined that, upon inception of both the U.S. and EU Meda arrangements, all deliverables were 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, $59.8 million of the aggregate milestones and services revenue have been recognized. Upon first commercial sale in a European country, an estimated $17.6 million will be recognized, which includes an additional $5.0 million in milestones to be received at that date and approximately $0.5 million in research and development services. At March 31, 2012, there was remaining deferred revenue of $14.1 million, of which $12.5 million is related to the EU Meda arrangement milestones and EU Meda research and development services. The Company has estimated the amount of time (based on expected man-days) 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.

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NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2012 AND 2011

(Unaudited)

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

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 to Meda to include participation in committees and certain other specified services. The estimated portion of the upfront payments of approximately $1.6 million (under the Meda U.S. Agreements) and $0.1 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided through expiration of the license terms.

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

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. The Company has earned product royalty revenues of approximately $0 and $0.03 million for the three months ended March 31, 2012 and 2011, respectively. The Company has incurred cost of product royalties of approximately $0.4 million and $0.3 million for the three months ended March 31, 2012 and 2011, respectively, related to this royalty revenue, which is related to minimum quarterly payments owed to CDC, regardless of ONSOLIS® royalty levels (see note 5).

On March 12, 2012, the Company announced the postponement of the U.S. relaunch of ONSOLIS® until the product formulation can be modified to address two appearance issues raised by the FDA following an inspection of the ONSOLIS® manufacturing facility. Specifically, the FDA identified the formation of microscopic crystals and a slight fading of the color during the 24-month shelf life of the product. Management estimates that the total cost of the ONSOLIS® reformulation project will be between $0.6 million and $1.2 million, although such estimate is subject to change as the FDA s requirements become clearer.

4. Endo License and Development Agreement:

On January 5, 2012, the Company, Arius and Arius Two, entered into a definitive License and Development Agreement with Endo (the Endo Agreement), pursuant to which the Company, Arius and Arius Two agreed to grant Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company s BEMA® Buprenorphine product and to complete U.S. development of such products for purposes of seeking FDA approval.

Pursuant to the Endo Agreement, the Company is responsible for the completion of all clinical trials regarding BEMA® Buprenorphine necessary to submit an NDA to the FDA in order to obtain approval of BEMA® Buprenorphine in the U.S., pursuant to a development plan set forth in the Endo Agreement (as it may be amended pursuant to the Endo Agreement). The Company is responsible for all development activities through the filing of the NDA in the U.S., while Endo is responsible for the development following the NDA submission as well as the

manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis. In addition, Endo is responsible for all filings required in order to obtain regulatory approval of BEMA® Buprenorphine.

Pursuant to the Endo Agreement, the Company will receive the following payments (some portion(s) of which will be utilized by the Company to support its development obligations under the Endo Agreement with respect to the product):

- $30 million non-refundable payment by January 19, 2012 (received January 17, 2012);
- up to an aggregate of $95 million in potential milestone payments based on pre-defined intellectual property, clinical development and regulatory events, including $15 million upon issuance of a certain patent covering the product; and
- up to an aggregate of $55 million based on the achievement of certain potential sales milestones.

Such milestone payments are further subject to certain other conditions, adjustments and qualifications set forth in the Endo Agreement.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2012 AND 2011

(Unaudited)

4. Endo License and Development Agreement (continued):

In addition to the milestone payments set forth above, the Company is also entitled to receive a tiered, mid- to upper-teen royalty on net sales of BEMA® Buprenorphine in the United States and a mid- to high-single digit royalty on net sales of BEMA® Buprenorphine outside the United States, which royalty payments are subject to certain restrictions and adjustment features.

The term of the Endo Agreement shall last, on a country-by-country basis, until the later of: (i) 10 years from the date of the first commercial sale of BEMA® Buprenorphine in a particular country or (ii) the date on which the last valid claim of the Company s patents covering BEMA® Buprenorphine in a particular country has expired or been invalidated. The Endo Agreement shall be subject to termination: (i) by Endo, at any time, upon a specific amount of prior written notice to the Company, (ii) by Endo and the Company upon their mutual written agreement, (iii) by either party upon a material default or breach of the Endo Agreement and such default or breach is not cured within a specified timeframe, (iv) the voluntary or involuntary bankruptcy of either party or (v) by the Company if Endo does not meet certain diligence obligations outside of the United States.

On February 16, 2012, the Company announced that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance regarding the Company s patent application (No. 13/184306), which patent will extend the exclusivity of the BEMA® drug delivery technology for its BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone products from 2020 to 2027. In April 17, 2012, the Company announced that this patent was granted. As a result, pursuant to the Endo Agreement, the Company received a milestone payment from Endo in the amount of $15 million in May 2012. An additional milestone payment of $20 million will be due at the time of FDA approval of BEMA® Buprenorphine for the treatment of chronic pain.

5. 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 Pharmaceuticals Co. Ltd. (Kunwha) to develop, manufacture, sell and distribute the Company s BEMA® Fentanyl product in the Republic of Korea (the Kunwha Territory). BEMA® Fentanyl is marketed as ONSOLIS® in North America. The Kunwha License Agreement is for a term beginning on May 26, 2010 until the date of expiration of the patents, or July 23, 2027, whichever is later. Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for BEMA® Fentanyl in the Kunwha Territory, while the Company retained all other licensing rights to the Licensed Product not previously granted to third parties. Kunwha paid to the Company an upfront payment of $0.3 million (net of taxes approximating $0.25 million) and will be responsible to make certain milestone payments which could aggregate up to $1.3 million (net of taxes approximating $1.1 million). In addition, Kunwha will pay royalties to the Company based on Net Sales (as defined in the Kunwha License Agreement) and will purchase all supplies of BEMA® Fentanyl from the Company.

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

The upfront payment from Kunwha of $0.3 million (net of taxes, approximating $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 with TTY for the exclusive rights to develop and commercialize BEMA® Fentanyl in the Republic of China, Taiwan. The agreement results in potential milestone payments to the Company of up to $1.3 million, which includes an upfront payment of $0.3 million, which 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 agreement with TTY is for the period from October 4, 2010 until the date fifteen (15) years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

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

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. This triggered a milestone payment to the Company of approximately $0.3 million, which was received November 2011.

Agreement with Tolmar to Purchase BEMA® Rights

In August 2006, the Company purchased from QLT USA, Inc. (renamed TOLMAR Therapeutics, Inc. and referred to herein as Tolmar) all of the non-U.S. rights to the BEMA® drug delivery technology, including all patent rights and related intellectual property and other assets. This is included in acquired product rights in the accompanying condensed consolidated balance sheet. The Company had previously licensed such rights from Tolmar. The aggregate purchase price for the non-U.S. portion of the BEMA® technology was $3 million, consisting of $1 million in cash paid at closing and a promissory note of $2 million to be paid over time as follows: (i) $1 million by the end of first quarter 2007 (which was paid March 30, 2007) and (ii) $1 million to be paid within 30 days of regulatory approval of the first non-U.S. BEMA® product. On June 18, 2010, in conjunction with BEMA® approval in Canada, the Company paid $0.75 million of the $1 million to Tolmar and the remaining $0.25 million was paid in December 2011. As part of the transaction, and solely with respect to the non-U.S. portion of the former license with Tolmar, no further milestone payments or ongoing royalties will be due to Tolmar for the non-U.S. BEMA® rights.

In September 2007, the Company purchased all North American (U.S., Canada and Mexico) assets related to the BEMA® drug delivery technology from Tolmar for $7 million, consisting of $3 million in cash and a promissory note of $4 million, $2 million of which was paid in July 2009 following approval of ONSOLIS® in the U.S., and $2 million of which is due within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA®-based products reach $30 million. This is included in acquired product rights in the accompanying condensed consolidated balance sheet. The Company had previously licensed such rights from Tolmar. As part of the transaction, no further milestone payments or ongoing royalties will be due to Tolmar for the North American territory. To secure the Company s obligation to pay the remaining $2 million amount when due, Tolmar was granted a security interest in the North American BEMA® assets, subject to a license of those assets from Tolmar to us for North America that would be granted to us on the original license terms upon any exercise of rights under such security interest.

On January 5, 2012, the Company and Arius Two executed a letter agreement with Tolmar and its parent company, Tolmar Holding, Inc., whereby the parties agreed that, if Arius Two paid Tolmar $1.05 million by February 28, 2012, Tolmar would accept such payment as satisfaction in full of the remaining $2 million outstanding under the Tolmar note (pursuant to which the Company acquired the North American rights to the BEMA® technology) and, upon receipt of such payment (i) the related security agreements, security interests, liens, guaranties and payment obligations with respect to such note and the assets securing its repayment would terminate, (ii) Tolmar would execute a corresponding release and (iii) neither the Company nor Arius Two will have any further payment obligations to Tolmar under the note or BEMA® acquisition documents, except with respect to certain indemnification obligations of Arius Two. Arius Two paid the $1.05 million contemplated by the letter agreement on January 6, 2012, fully satisfying the outstanding balance of the note, and Tolmar subsequently executed its final release of the related security interests contemplated by the letter agreement. As a result, the Company now owns all rights to the BEMA® technology on a worldwide basis.

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 year ended December 31, 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 in 2011. As a result, the Company did not pay any of the 2011 quarterly royalty payments due to CDC/Athyrium and was not required to pay another royalty payment until the December 31, 2011 royalty calculation, which was due during the first quarter of 2012.

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6. 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. During the three months ended March 31, 2011, the stock price of Biovest s common stock decreased, resulting in a derivative loss of $0.6 million which is included within the derivative loss in the accompanying condensed consolidated statement of operations. During the three months ended March 31, 2012, the stock price of Biovest s common stock increased, resulting in a derivative gain of $0.3 million. This derivative gain partially offsets the overall derivative loss that is in the accompanying condensed consolidated statement of operations.

7. 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 March 31, 2012 and December 31, 2011:

	March 31, 2012	December 31, 2011
Derivative asset at fair value:		
Free standing warrants related party	$ 661,900	$ 388,540

	March 31, 2012	December 31, 2011
Shares into which derivative asset can be settled:		
Free standing warrants related party	2,000,000	2,000,000

	March 31, 2012	December 31, 2011
Derivative liability at fair value:		

Free standing warrants	$ 2,419,908	$ 279,302

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7. Derivative Financial Instruments (continued):

The following tabular presentation reflects the components of the gain (loss) of derivative financial instruments for the three months ended March 31, 2012 and 2011:

	March 31, 2012	March 31, 2011
Shares into which derivative liability can be settled:		
Free standing warrants	$ 2,246,301	$ 4,322,421

	March 31, 2012	March 31, 2011
Derivative (expense) income in the accompanying statement of operations related to the derivatives as follows:		
Free standing warrants assets, related party	$ 273,360	($ 594,891)
Free standing warrants liability	(2,140,606)	107,578
	($ 1,867,246)	$ 487,313

8. Stockholders Equity:

Stock-based compensation:

During the three months ended March 31, 2012, a total of 482,361 options with an aggregate fair market value of approximately $0.7 million were granted to Company employees and directors. The options granted have a term of 10 years from the grant date. Of the options granted, 164,008 options vested immediately and the remainder vest ratably over a three year period. The fair value of each option is amortized as compensation expense evenly through the vesting period. The fair value of each option award is estimated on the 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 three months ended March 31, 2012 follows:

Expected price volatility	83.67%-83.69%
Risk-free interest rate	0.84%

Weighted average expected life in years	6 years
Dividend yield	

Option activity during the three months ended March 31, 2012 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2012	4,553,251	$ 3.66	
Granted in 2012:			
Officers and Directors	223,674	1.85	
Others	258,687	1.83	
Exercised			
Forfeitures	(250,741)	3.26	
Outstanding at March 31, 2012	4,784,871	$ 3.50	$ 595,436

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8. Stockholders Equity (continued):

Options outstanding at March 31, 2012 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	3,873,626	6.44	$ 2.84	
$ 5.01 10.00	911,245	5.41	$ 6.30	
	4,784,871			$ 595,436

Options exercisable at March 31, 2012 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	3,052,965	5.78	$ 2.88	
$ 5.01 10.00	911,245	5.41	$ 6.30	
	3,964,210			$ 388,858

The weighted average grant date fair value of options granted during the three months ended March 31, 2012 was $1.50. There were no options granted during the three months ended March 31, 2012 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, 2012, and changes during the three months ended March 31, 2012 is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Nonvested at January 1, 2012	786,188		
Granted	318,353		
Vested	(214,296)		
Forfeited	(69,584)		

Nonvested at March 31, 2012	820,661	$ 2.72	$ 206,578

As of March 31, 2012, 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 three years.

Warrants:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. Warrants outstanding at March 31, 2012, 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
$ 0.01 5.00	2,291,301	2.70	$ 3.80	$

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9. Earnings per Common Share

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

	March 31, 2012	March 31, 2011
Basic:		
Net income (loss) attributable to common stockholders	$ 20,296,051	$ (9,019,311)
Weighted average common shares outstanding	29,561,655	25,105,563
Basic earnings per common share	$ 0.69	$ (0.36)
Diluted:		
Effect of dilutive securities:		
Net income (loss)	$ 20,296,051	$ (9,019,311)
Adjustments to Income for Dilutive options and warrants		
	20,296,051	(9,019,311)
Weighted average common shares outstanding	29,561,655	25,105,563
Effect of Dilutive options and warrants	24,381	
Diluted weighted average common shares outstanding	29,586,036	25,105,563
Diluted earnings per common share	$ 0.69	$ (0.36)

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. In addition to the weighted average shares of Common Stock outstanding, common equivalent shares from stock options and warrants using the treasury stock method, are included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the three months ended March 31, 2012 and 2011, outstanding stock options and warrants of 6,419,130 and 9,798,512, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods.

The following is the total outstanding options and warrants for the three months ended March 31, 2012 and 2011, respectively.

	March 31, 2012	March 31, 2011
Options and warrants to purchase Common Stock	7,076,172	9,798,512

10. Commitments and contingencies:

In March, 2012, the Company announced that the New Jersey Federal Court has granted a stay of further litigation in the patent infringement lawsuit previously filed by MonoSol against the Company and its ONSOLIS® commercial partners. The court ordered that the case would be stayed pending resolution by USPTO of reexamination proceedings and follows the recent rejection by the USPTO of all claims in all three patents asserted by MonoSol against the Company and its commercial partners for ONSOLIS®.

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10. Commitments and contingencies (continued):

Should the USPTO uphold its initial decisions, the MonoSol patents will be rendered invalid, supporting the Company s assertion that MonoSol s claims from the beginning had no merit. (See Part II, Item 1, Legal Proceedings). Due to the stay of further litigation, the Company expects savings in legal expense during 2012.

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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 March 31, 2012 compared to the three months ended March 31, 2011

Product Royalty Revenues. We recognized $0.03 million in product royalty revenue during the three months ended March 31, 2011 under our license agreement with Meda. For the period noted, we did not ship product to Meda and therefore, the revenue recognized was for minor pricing reconciliations. There was no product royalty revenue during the three months ended March 31, 2012.

Research Revenues. We recognized $0.01 million and $0.2 million of revenue related to a research and development agreement with Meda during the three months ended March 31, 2012 and 2011, respectively.

Contract Revenues. We recognized $30 million during the 3 months ended March 31, 2012 in contract revenue related to our license agreement with Endo. We also recognized $0.05 million and $0.002 million during the three months ended March 31, 2012 and 2011, respectively, in contract revenue related to previously deferred revenue under our license agreement with Meda.

Cost of Product Royalties. We recognized $0.4 million and $0.3 million during the three months ended March 31, 2012 and 2011, respectively, in cost of product royalties which is related to minimum quarterly payments owed to CDC.

Research and Development Expenses. During the three months ended March 31, 2012 and 2011, research and development expenses totaled $4.7 million and $6.7 million, respectively. The decrease in research and development expenses can be attributed to the ramp-up of the Buprenorphine clinical trials that occurred in 2011. Our scientific staff continues to work toward development and application of our BEMA® delivery technology, particularly with respect to ONSOLIS® and BEMA® Buprenorphine. Funding of this research in 2012 and 2011 was obtained through contract revenue, deferred license revenue, a private placement stock offering, exercise of options by employees and directors and sales of securities. Research and development expenses generally include compensation for scientific personnel, research supplies, facility rent, manufacturing 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 March 31, 2012 and 2011, general and administrative expenses totaled $2.8 million and $1.8 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 administration expenses can be attributed to additional legal costs associated with our MonoSol litigation and Endo licensing agreement.

Interest Income. During the three months ended March 31, 2012 and 2011 we had interest income of $0.06 million and $0.04 million, respectively.

***Derivative loss*.** Our derivative liability consists of free standing warrants measured at their fair market value, using the Black-Scholes method. During the three months ended March 31, 2012, our stock price increased, which is the largest component of the Black Scholes calculation. As a result, our warrant liability also increased, resulting in a $2.1 million loss. This loss was offset by a $0.3 gain from 2 million shares of Biovest related party options that we own. During the three months ended March 31, 2011, our share price had only a very small decrease. Therefore, our derivative liability declined by $0.1 million along with a corresponding gain. This gain was offset by a $0.6 million loss on the value of our Biovest options.

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, funded research arrangements, revenue generated as a result of our worldwide license and development agreement with Meda regarding ONSOLIS® and revenue generated as a result of our January 2012 agreement with Endo regarding our BEMA® Buprenorphine product candidate. We intend to finance our research and development, commercialization efforts and our working capital needs from existing cash, royalty revenue, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

In February 2012, our universal shelf registration statement pursuant to which we could issue up to $50 million of our securities from time to time and subject to certain conditions was scheduled to expire. In January 2012, we filed a renewal of our shelf registration statement which registered up to $40 million of our securities for potential future issuance, and such registration statement was declared effective on February 24, 2012 and will expire in February 2015 unless it is renewed prior to such expiration.

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At March 31, 2012, we had cash and cash equivalents of approximately $32.1 million. We generated $22.5 million of cash from operations during the three months ended March 31, 2012. As of March 31, 2012, we had stockholders equity of $24.9 million versus $4.1 million at December 31, 2011. In January 2012, we received a $30 million, upfront non-refundable milestone payment related to our definitive license and development agreement with Endo to license, develop, manufacture, market and sell our BEMA® Buprenorphine product candidate. In addition, in May 2012, we received an additional $15 million milestone payment from Endo due to our achievement of a certain intellectual project related milestone. However, this $45 million in cash is anticipated to be used in its entirety to fund our clinical research with respect to this product. As such, our existing cash, even with the aforementioned $45 million milestone payments, together with other expected cash inflows from other milestones and royalties, are anticipated by management to be sufficient to fully fund our planned level of operations through the first quarter of 2013. Included in this estimation are costs of between $0.6 million and $1.2 million that we expect will be incurred in connection with the reformulation of ONSOLIS®. Also included are savings in legal expense that we expect will result from the March 2012 stay in litigation with MonoSol (see Part II, Item 1. Legal Proceedings). Certain planned expenditures are discretionary and could be deferred if we are required to do so to fund critical operations.

Capital will be required to support commercialization efforts for ONSOLIS® (including commercial launch in Europe which is expected in the second half of 2012), clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of our agreement with Endo), planned development of BEMA® Buprenorphine/Naloxone and general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

Additionally, the worldwide financial and credit crisis that began in 2008 and has fluctuated to the present time has strained investor liquidity and contracted credit markets. During the three months ending March 31, 2012, the financial and credit crisis did not directly nor materially impact us. However, if this environment continues, fluctuates or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when we require additional financial investment. If we are unable to attract additional funds it may adversely affect our ability to achieve development and commercialization goals, which could have a material and adverse effect on the business, results of operations and financial condition.

Also, 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 and options.

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 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 2012 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

If we are unable to attract additional funds on commercially acceptable terms, 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.

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Contractual Obligations and Commercial Commitments

Our contractual obligations as of March 31, 2012 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	$ 107,871	$ 107,871	$	$	$
Employment agreements	875,646	875,646			
Minimum royalty expenses*	11,625,000	1,500,000	3,000,000	3,000,000	4,125,000
Total contractual cash obligations**	$ 12,608,517	$ 2,483,517	$ 3,000,000	$ 3,000,000	$ 4,125,000

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

** Endo will have worldwide rights to market our BEMA® Buprenorphine product. In return for milestone payments and royalties, we are required to conduct and pay for certain clinical trials as outlined in a mutually agreed development plan. These costs will depend on the size and scope of the required trials. The Endo agreement does not specify minimums in terms of the cost of the trials.

Off-Balance Sheet Arrangements

As of March 31, 2012, 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 period of benefit, ranging from eleven to thirteen years. Our carrying value of goodwill at March 31, 2012 was $2.715 million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements or the underlying patents. Our carrying value of other amortizing intangible assets at March 31, 2012 was $6.9 million, net of accumulated amortization of $4 million. We begin amortizing capitalized intangibles on their date of acquisition.

Impairment Testing

The FASB issued ASU 2011-08, Testing Goodwill for Impairment . The update allows us to qualitatively assess whether the fair value of a reporting unit is less than its carrying amount, and is effective for fiscal years beginning after December 15, 2011. We perform this analysis in conjunction with our annual impairment test described below.

Our goodwill impairment testing is calculated at the reporting unit level. Our annual impairment test, which is performed in December, has two steps. The first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired and the second step is not necessary. If the carrying value exceeds the fair value, the second step

calculates the possible impairment loss by comparing the implied fair value of goodwill with the carrying amount. If the implied fair value of goodwill is less than the carrying amount, a write-down is recorded.

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

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 three months ended March 31, 2012 or 2011.

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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 previously discussed 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 March 31, 2012, we had approximately $31.1 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.

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.

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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 first fiscal quarter of 2012 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 control 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.

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 2011 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) (the 588 Patent). 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 complaint, 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 the 588 Patent because they do not meet the limitations of any valid claim of such patent. Moreover, in our answer, we stated our position that the 588 Patent is actually invalid and unenforceable for failure to comply with one or more of the requirements of applicable U.S. patent law.

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* reexamination in the United States Patent and Trademark Office (USPTO) of the 588 Patent demonstrating that all claims of such 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 reexamination 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 2012 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.

On November 28, 2011, we announced that we were informed by the USPTO that it had rejected all 191 claims of the 588 Patent.

On January 3, 2012, we served our non infringement and invalidity contentions in the case. On January 5, 2012, the Court conducted a status conference and invited the re-filing of our motion for stay pending the outcome of reexamination proceedings in the USPTO. On January 20, 2012, we filed requests for reexamination before the USPTO of MonoSol s US patent No 7,357,891 (the 891 Patent), and No 7,425,292 (the 292 Patent), the two additional patents asserted by MonoSol, demonstrating that all claims of those two patents were anticipated by or obvious in the light of prior art references, including prior art references not previously considered by the USPTO. We then filed with the Court our renewed motion for stay pending the outcome of the reexamination proceedings on January 23, 2012.

In February and March 2012, respectively, the USPTO granted the requests for reexamination we filed with respect to the 292 Patent and the 891 Patent. In its initial office action in each, the USPTO rejected every claim in each patent. The USPTO has now rejected every claim regarding the three patents asserted by MonoSol against us. The court conducted a status conference on March 7, 2012, at which it granted our motion to stay the case pending outcome of the reexamination proceedings in the USPTO.

Empirical evidence from previous reexamination proceedings would suggest that amended claims will likely be filed by MonoSol during the proceedings that significantly narrow the scope of their patents. The USPTO could allow such revised patents; however, we believe that our assertion that our products and technologies do not infringe on MonoSol s original patents would only be strengthened based on any narrowing of the claims in such patents.

We will continue to defend this case vigorously, and we anticipate that MonoSol s claims against us will ultimately be rejected.

Item 1A. Risk Factors.
No update.

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

Item 3. Defaults upon Senior Securities.
None.

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Item 4. Mine Safety Disclosures.
None.

Item 5. Other Information.
Subsequent to our announcement on March 12, 2012 regarding the postponement of the U.S. relaunch of our FDA-approved product ONSOLIS®, we have been working on various formulation adjustments to resolve certain color fading and crystal formation issues observed with this product. Significant and positive progress has been made that has led to an initial follow-up discussion with FDA. With this FDA feedback, reformulation work is expected to be complete prior to the end of the second quarter of 2012, at which time we expect to immediately request a meeting with FDA to discuss final results and conclusions. We believe this meeting will determine what FDA would expect in the information package that we will be required to submit to FDA for their review of this matter, as well as the type of submission classification and associated review time. Once known, this would allow us to then predict with greater certainty the timing of the relaunch of ONSOLIS®.

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

* 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: May 10, 2012

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

(Principal Executive Officer)

Date: May 10, 2012

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

(Principal Financial Officer)