BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q/A
March 18, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

(Amendment No. 1)

(Mark One)

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

For the quarterly period ended June 30, 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 August 7, 2012, there were 30,064,098 shares of company common stock issued and 30,048,607 shares of company common stock outstanding.

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EXPLANATORY NOTE

As disclosed in our Current Report on Form 8-K filed with the Securities and Exchange Commission (the Commission) on February 28, 2013, the purpose of this Amendment No. 1 (Amendment No. 1) to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012 (the Original 10-Q), which we filed with the Commission on August 9, 2012, is to restate our company s unaudited financial statements and related disclosures (including, without limitation, those contained under Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations) contained in the Original 10-Q with respect to our accounting for a $30 million non-refundable license fee (the Upfront Fee) we received in January 2012 under our license and development agreement for BEMA® Buprenorphine for chronic pain with Endo Pharmaceuticals, Inc. (now known as Endo Health Solutions, Inc.) (the Endo Agreement). On February 25, 2013, the Audit Committee of our Board of Directors and our executive management jointly determined that an aggregate of approximately $14.4 million of the Upfront Fee should not have been recognized as revenue upon receipt, but should have instead been deferred and recognized as clinical development services were provided by us under the Endo Agreement. We are therefore filing this Amendment No. 1 to reflect the deferral and recognition of revenue for clinical development services performed during the period covered by the Original 10-Q, as well as changes in our footnote disclosure on this topic and related disclosure of our revenue recognition policies with respect to the Endo Agreement.

As several parts of the Original 10-Q are amended and/or restated by this Amendment No. 1, for convenience, we have repeated the entire text of the Original 10-Q, as amended and/or restated by this Amendment No. 1. Readers should therefore read and rely on this Amendment No. 1 in lieu of the Original 10-Q.

This Amendment No. 1 also contains currently dated officer certifications as Exhibits 31.1, 31.2, 32.1 and 32.2.

Except as amended and/or restated by this Amendment No. 1, no other changes have been made to the Original 10-Q. This Amendment No. 1 speaks as of the original filing date of the Original 10-Q and does not reflect events that may have occurred subsequent to such original filing date.

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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 JUNE 30, 2012 AND DECEMBER 31, 2011

	Restated June 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 43,030,542	$ 10,750,205
Accounts receivable, other	23,092	101,132
Prepaid expenses and other current assets	129,127	229,886
Total current assets	43,182,761	11,081,223
Equipment, net	3,057,150	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	(4,260,077)	(3,749,637)
Total other intangible assets	6,689,923	6,150,363
Derivative asset, warrant (note 7)	401,200	388,540
Other assets	21,976	21,976
Total assets	$ 56,068,010	$ 23,645,210
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	$ 5,813,366	$ 5,090,795
Deferred revenue, current	22,314,498	12,507,471
Derivative liabilities (note 7)	5,638,001	279,302
Total current liabilities	33,765,865	17,877,568
Deferred revenue, long-term	6,538,085	1,647,249
Total liabilities	40,303,950	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; 29,756,324 and 29,577,146 shares issued; 29,740,833 and 29,561,655 shares outstanding in 2012 and 2011, respectively	29,757	29,578
Additional paid-in capital	100,819,805	99,709,574
Treasury stock, at cost, 15,491 shares, 2012 and 2011	(47,183)	(47,183)
Accumulated deficit	(85,038,319)	(95,571,576)
Total stockholders equity	15,764,060	4,120,393

Total liabilities and stockholders equity	$ 56,068,010	$ 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 AND SIX MONTHS ENDED JUNE 30, 2012 AND 2011

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	Restated 2012	2011	Restated 2012	2011
Revenues:				
Product royalties	$	$	$	$ 34,225
Research revenues		33,606	14,200	226,843
Contract revenues	16,297,972	4,800	32,802,137	6,800
Total Revenues:	16,297,972	38,406	32,816,337	267,868
Cost of product royalties	375,000	(425,930)	750,000	(128,510)
Expenses:				
Research and development	6,546,579	4,720,208	11,258,189	11,410,882
General and administrative	2,209,284	1,930,875	5,050,079	3,695,364
Related party general and administrative, net	19,500	18,750	45,750	37,500
Total Expenses:	8,775,363	6,669,833	16,354,018	15,143,746
Income (loss) from operations	7,147,609	(6,205,497)	15,712,319	(14,747,368)
Interest income	63,501	48,411	120,117	86,194
Derivative (loss) gain	(3,478,793)	1,046,869	(5,346,039)	559,556
Other income (expense), net	50,324	11,866	46,860	(16,044)
Net income (loss)	3,782,641	(5,098,351)	10,533,257	(14,117,662)
Net income (loss) attributable to common stockholders	3,782,641	$ (5,098,351)	10,533,257	$ (14,117,662)
Basic earnings per share:	$ 0.13	$ (0.18)	$ 0.36	$ (0.52)
Diluted earnings per share:	$ 0.12	$ (0.18)	$ 0.35	$ (0.52)

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

FOR THE SIX MONTHS ENDED JUNE 30, 2012

(Unaudited)

Restated

	Common Stock		Additional	Treasury	Accumulated	Total Stockholders
	Shares	Amount	Paid-In Capital	Stock	Deficit	Equity
Balances, January 1, 2012	29,577,146	$ 29,578	$ 99,709,574	$ (47,183)	$ (95,571,576)	$ 4,120,393
Stock-based compensation			700,008			700,008
Exercise of stock options	179,178	179	410,223			410,402
Net income					10,533,257	10,533,257
Balances, June 30, 2012	29,756,324	$ 29,757	$ 100,819,805	$ (47,183)	$ (85,038,319)	$ 15,764,060

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2012 AND 2011

(Unaudited)

	Six months Ended June 30,	
	Restated 2012	2011
Operating activities:		
Net income (loss)	$ 10,533,257	$ (14,117,662)
Adjustments to reconcile net income (loss) to net cash flows from operating activities:		
Depreciation and amortization	745,396	653,764
Derivative loss (gain)	5,346,039	(559,556)
Stock-based compensation expense	700,008	448,693
Changes in assets and liabilities:		
Accounts receivable	78,040	410,589
Prepaid expenses and other assets	100,759	(606,626)
Accounts payable and accrued expenses	751,170	791,001
Deferred revenue	14,697,863	35,913
Net cash flows from operating activities	32,952,532	(12,943,884)
Investing activities:		
Purchase of equipment	(24,792)	(127,760)
Purchase of intangible assets	(1,050,000)	
Net cash flows from investing activities	(1,074,792)	(127,760)
Financing activities:		
Proceeds from issuance of common stock		13,996,773
Proceeds from exercise of stock options	410,402	349,676
Proceeds from exercise of warrants		1,749,259
Change in amounts due to related parties	(7,805)	(44,623)
Net cash flows from financing activities	402,597	16,051,085
Net change in cash and cash equivalents	32,280,337	2,979,441
Cash and cash equivalents at beginning of period	10,750,205	18,208,659
Cash and cash equivalents at end of period	$ 43,030,542	$ 21,188,100

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 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 June 30, 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 rules and regulations of the U.S. Securities and Exchange Commission (SEC). These unaudited condensed consolidated financial statements should be read in conjunction with the Company s 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 six month period ended June 30, 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, as the same may have been subsequently amended in the Company s SEC filings.

BDSI® and BEMA® are registered trademarks of the Company. 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; and

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 June 30, 2012 and December 31, 2011, respectively:

	June 30, 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) (note 7)	$	$ 401,200	$	$ 401,200	$	$ 388,540	$	$ 388,540
Liabilities								
Derivative liabilities (note 7)	$	$ 5,638,001	$	$ 5,638,001	$	$ 279,302	$	$ 279,302

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 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 June 30, 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	12,660	
Warrant asset as of June 30, 2012	$ 401,200	2,000,000
Liabilities:		
Warrant liability as of January 1, 2012	$ 279,302	3,246,301
Expiration of CDC* warrants		(1,000,000)
Increase in fair value of warrants	5,358,699	
Warrant liability as of June 30, 2012	$ 5,638,001	2,246,301

* Clinical Development Capital, LLC and its successors and/or affiliates (CDC), who previously provided financing for the development of the Company s ONSOLIS® product. See Note 5.

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 and cash flow generated as a result of its worldwide license and development agreements with Meda AB (Meda) regarding the Company s ONSOLIS® product and revenue and cash flow generated as a result of its January 2012 license and development agreement (the Endo Agreement) with Endo Health Solutions, 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 sources during the six months ended June 30, 2012 consisted of:

approximately $45 million in an upfront license fee and milestone payment from Endo pursuant to the Endo Agreement (see note 4);

$2.5 million in deferred contract revenue under the Meda agreements (see note 3);

approximately $0.4 million from the exercise of stock options; and

approximately $0.1 million in previously deferred contract revenue.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2012 AND 2011

(Unaudited)

2. Liquidity and management s plans (continued):

Significant financing sources during the year ended 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 under the Meda agreements;
- approximately $1.7 million from the exercise of Common Stock warrants;
- 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 January 2012, the Company received a $30 million, upfront non-refundable license fee under the Endo Agreement. Pursuant to the Endo Agreement, the Company has granted Endo a license to develop, manufacture, market and sell the Company s 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 property-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 candidate.

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. 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 June 30, 2012, the Company had cash and cash equivalents of approximately $43 million. The Company generated $33 million of cash from operations during the six months ended June 30, 2012. As of June 30, 2012, the Company had stockholders equity of $15.8 million, versus $4.1 million at December 31, 2011.

The Company s existing cash, even with the aforementioned $45 million upfront and milestone payment, together with other expected cash inflows from other milestones and royalties, is anticipated by management to be sufficient to fully fund the Company s planned operations through the first quarter of 2013. Included in this estimation are costs of between $0.6 million and $0.8 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 Food and Drug Administration (FDA)-approved product ONSOLIS® Also included are reduced expenditures from previous levels 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 the fourth quarter of 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 the Company s BEMA® Buprenorphine/Naloxone (known as BNX) product candidate and other potential products or technologies, as well as general working capital. Based on product development timelines and agreements with the Company s existing development and commercialization 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 six months ending June 30, 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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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 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	**June 30, 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	$ 10,500,000	$ 8,000,000
Research and Development Services for:		
BREAKYL product through governmental approval in an E.U. country	$ 4,548,720	$ 4,548,720
Total Europe and Rest of World Milestones	$ 15,048,720	$ 12,548,720
Total All Milestones	**$ 76,390,290**	**$ 73,890,290**
Release of Milestones upon and subsequent to first sale	$ (59,834,770)	$ (59,735,570)
Remaining Deferred Revenue	$ 16,555,520	$ 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 stand-alone 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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2012 AND 2011

(Unaudited)

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

includes an additional $2.5 million milestones to be received upon launch in Europe, which is expected to be late 2012. At June 30, 2012, there was remaining deferred revenue of $16.6 million, of which $15.0 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 work 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 to Meda to include participation in committees and certain other specified services. The estimated portion of the upfront payments of approximately $1.5 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 six months ended June 30, 2012 and 2011, respectively. The Company has incurred cost of product royalties of approximately $0.8 million and ($0.1) million for the six months ended June 30, 2012 and 2011, respectively, related to this royalty revenue. The cost of product royalties for the six months ended June 30, 2012 is related to minimum quarterly payments owed to CDC, regardless of ONSOLIS® royalty levels (see note 5). The cost of product royalties for the six months ended June 30, 2011 of ($0.4) million is due to an Amendment, dated May 12, 2011 (the CDLA Amendment) to the original Clinical Development and License Agreement with CDC, dated July 14, 2005 (as amended, the CDLA) pursuant to which the parties clarified the Company s royalty obligations under the CDLA. Among other items, certain terms of the CDLA were amended and restated retroactively to clarify that the Company s royalty payments are required to be calculated based on Meda s sales of ONSOLIS®, whereas the Company s previous royalty payments to CDC were calculated based on their sales to Meda. As a result, the Company did not pay $0.75 million in minimum royalty payments that would have been payable as of June 30, 2011. The remaining $0.4 million was accounted for as a credit to cost of product royalties.

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 $0.8 million, although such estimate is

subject to change as the FDA s requirements become clearer.

On May 21, 2012, the Company announced receipt of a pre-launch milestone payment of $2.5 million from Meda in conjunction with the first country registration and pricing approval for BREAKYL (tradename for ONSOLIS® in the EU). This $2.5 million milestone payment has been recorded as deferred revenue and will be recorded as contract revenue at the time of commercial launch in EU. A last milestone payment related to the EU of $2.5 million is payable at the time of commercial launch, which is anticipated in late 2012. BREAKYL will be commercialized in the EU by Meda.

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4. Endo License and Development Agreement:

In January 2012, the Company entered into the Endo Agreement with Endo pursuant to which the Company granted to 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 product candidate for purposes of seeking FDA approval.

Pursuant to the Endo Agreement, Endo has obtained all rights necessary to complete the clinical and commercial development of BEMA® Buprenorphine and to sell the product worldwide. Although Endo has obtained all such necessary rights, the Company has agreed under the Endo Agreement to be responsible for the completion of certain clinical trials regarding BEMA® Buprenorphine (and providing clinical trial materials for such trials) necessary to submit a NDA to the FDA in order to obtain approval of BEMA® Buprenorphine in the U.S., in each case 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 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 has received (or is expected to receive upon satisfaction of applicable conditions) 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 BEMA® Buprenorphine):

- $30 million non-refundable upfront license fee (received January 17, 2012);
- up to an aggregate of $95 million in six separate potential milestone payments based on the following pre-defined events: (i) enhancement of intellectual property rights (two milestones aggregating $35 million in potential milestone payments, including $15 million upon issuance of a certain patent covering the product which was received May 2012), (ii) clinical development (two milestones aggregating $20 million in potential milestone payments) and (iii) regulatory events (two milestones aggregating $40 million in potential milestone payments);
- up to an aggregate of $55 million based on the achievement of four separate post-approval sales thresholds; and
- sales-based royalties in a particular percentage range on U.S. sales of BEMA® Buprenorphine, and royalties in a lesser range on sales outside the United States, subject to certain restrictions and adjustments.

The Company has assessed its arrangement with Endo and the Company s deliverables thereunder at inception to determine: (i) the separate units of accounting for revenue recognition purposes, (ii) which payments should be allocated to which of those units of accounting and (iii) the appropriate revenue recognition pattern or trigger for each of those payments. The assessment requires subjective analysis and requires management to make judgments, estimates and assumptions about whether deliverables within multiple-element arrangements are separable and, if so, to determine the amount of arrangement consideration to be allocated to each unit of accounting.

At the inception of the Endo arrangement and in accordance with the revenue recognition criteria under ASC Topic 605, the Company determined that: the Endo Agreement is a multi-deliverable arrangement under ASC Topic 605 with three deliverables: (1) the license rights related to BEMA® Buprenorphine, (2) services related to obtaining enhanced intellectual property rights through the issuance of a particular

patent, and (3) clinical development services. The Company concluded that the license delivered to Endo at the inception of the Endo Agreement has stand-alone value under ASC 605-25 because Endo obtained, at the inception of the Endo Agreement, all of the rights and knowledge necessary to fully exploit its license without the Company s further involvement. It was also determined that there was a fourth deliverable, the provision of clinical trial material (CTM). The amounts involved are, however, immaterial and delivered in essentially the same time frame as the clinical development services. Accordingly, the Company has not separately accounted for the CTM deliverable, but considers it part of the clinical development services deliverable.

The initial non-refundable $30 million license fee was required to be allocated to each of the three deliverables based upon their relative selling prices using best estimates. The analysis of the best estimate of the selling price of the deliverables was based on the income approach, the Company s negotiations with Endo and other factors, and was further based on management s estimates and assumptions which included consideration of how a market participant would use the license, estimated market opportunity and market share, Company s estimates of what contract research organizations would charge for clinical development services, the costs of clinical trial materials and other factors. Also considered were entity specific assumptions regarding the results of clinical trials, the likelihood of FDA approval of the subject product and the likelihood of commercialization based in part on the Company s prior agreements with the BEMA® technology.

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4. Endo License and Development Agreement (continued):

Based on this analysis, $15.6 million of the up-front license fee was allocated to the license (which was estimated to have a value significantly in excess of $30 million), and $14.4 million to clinical development services (which is inclusive of the cost of CTM). Although the intellectual property component was considered a separate deliverable, no distinct amount of the up-front payment was assigned to this deliverable because the Company determined the deliverable to be perfunctory. In April 2012, the patent being sought by the Company was granted as described further below, and in May 2012, the applicable intellectual property milestone payment of $15 million was received and recognized as revenue. The amount allocated to the license was recognized as revenue in January 2012.

The portion of the upfront license fee allocated to the clinical development services deliverable ($14.4 million) is being recognized as those services are performed. The Company estimates that such performance will extend into early 2014. Based on the estimated proportion of those services performed during the six months ended June 30, 2012, $2.1 million of that amount was recognized and, as a result, $12.3 million remains deferred at June 30, 2012.

The Company analyzed the milestone payments noted above in accordance with ASC 605-28 to determine if such milestones are substantive. This determination included an analysis of the Company s performance to achieve each milestone, the enhancement of value of the delivered items, the timing of performance related to the milestone, and the reasonability of the milestone relative to all the deliverables and payment terms. The Company concluded that each of the milestones are substantive under the guidance in ASC 605-28.

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 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 issued a Notice of Allowance regarding its patent application (No. 13/184306), which patent will extend the exclusivity of the BEMA® drug delivery technology for the Company s BEMA® Buprenorphine and BNX product candidates from 2020 to 2027. On 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. As discussed above, this milestone had been evaluated to be a substantive milestone under ASC 605-28, and therefore was recognized as revenue when the milestone was received.

The remaining milestone payments are expected to be recognized as revenue as and if they are achieved, except that one milestone is contingently refundable for a period of time. Revenue related to that milestone is expected to be recognized as refund provisions as defined in the agreement expire. Sale threshold payments and sales-based royalties will be recognized as they accrue under the terms of the Endo Agreement.

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.

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

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.

On November 7, 2011, the Company announced that TTY submitted an NDA 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 September 2007, the Company purchased all North American (U.S., Canada and Mexico) assets related to the BEMA® drug delivery technology from QLT USA, Inc. (renamed TOLMAR Therapeutics, Inc. and referred to herein as 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 the CDLA Amendment with CDC and NB Athyrium LLC (Athyrium). Pursuant to the CDLA, CDC previously 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

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

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 repayment 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.

6. Related Party Transactions:

In 2009, as part of a settlement arrangement, the Company received a warrant from Accentia Biopharmaceuticals, Inc., a related party (Accentia), to purchase 2 million shares of common stock of Biovest International, Inc. (Biovest) held by Accentia. Biovest is a majority-owned subsidiary of Accentia. Such warrant has an exercise price of $0.89 per share. During the six months ended June 30, 2012, the stock price of Biovest s common stock slightly increased, resulting in a derivative gain of $0.01 million in the accompanying condenses consolidated statement of operations. During the six months ended June 30, 2011, the stock price of Biovest s common stock decreased, resulting in a derivative loss of $0.7 million which is included within the derivative loss 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 June 30, 2012 and December 31, 2011:

	June 30, 2012	December 31, 2011
Derivative asset at fair value:		
Free standing warrants related party	$ 401,200	$ 388,540

	June 30, 2012	December 31, 2011
Shares into which derivative asset can be settled:		

Free standing warrants related party	2,000,000	2,000,000

	June 30, 2012	December 31, 2011
Derivative liability at fair value:		
Free standing warrants	$ 5,638,001	$ 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 six months ended June 30, 2012 and 2011:

	June 30, 2012	June 30, 2011
Shares into which derivative liability can be settled:		
Free standing warrants	2,246,301	3,721,301

	June 30, 2012	June 30, 2011
Derivative income (expense) in the accompanying statement of operations related to the derivatives as follows:		
Free standing warrants assets, related party	$ 12,660	($ 708,231)
Free standing warrants liability	(5,358,699)	1,267,787
	($ 5,346,039)	$ 559,556

8. Stockholders Equity:

Stock-based compensation:

During the six months ended June 30, 2012, a total of 584,214 options to purchase Common Stock with an aggregate fair market value of approximately $0.9 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, 194,008 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 six months ended June 30, 2012 follows:

Expected price volatility	82.71%-82.97%
Risk-free interest rate	0.76%-1.02%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the six months ended June 30, 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	360,540	2.14	
Exercised	(179,178)	2.29	
Forfeitures	(250,741)	3.26	
Outstanding at June 30, 2012	4,707,546	$ 3.50	$ 6,171,895

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8. Stockholders Equity (continued):

Options outstanding at June 30, 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	3,796,301	6.28	$ 2.87	
$ 5.01 10.00	911,245	5.17	$ 6.30	
	4,707,546			$ 6,171,895

Options exercisable at June 30, 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	2,979,443	5.56	$ 2.95	
$ 5.01 10.00	911,245	5.17	$ 6.30	
	3,890,688			$ 4,619,278

The weighted average grant date fair value of options granted during the six months ended June 30, 2012 was $1.62. There were no options granted during the six months ended June 30, 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 six months ended June 30, 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	390,206		
Vested	(289,952)		

Forfeited	(69,584)		
Nonvested at June 30, 2012	816,858	$ 2.72	$ 1,552,617

As of June 30, 2012, there was approximately $1.1 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 June 30, 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	2.45	$ 3.80	$ 1,987,505

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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.

	Three Months Ended June 30,		Six Months Ended June 30,	
	Restated 2012	2011	Restated 2012	2011
Basic:				
Net income (loss) attributable to common stockholders	$ 3,782,641	$ (5,098,351)	$ 10,533,257	$ (14,117,662)
Weighted average common shares outstanding	29,669,058	28,998,451	29,615,357	27,062,761
Basic earnings per common share	**$ 0.13**	**$ (0.18)**	**$ 0.36**	**$ (0.52)**
Diluted:				
Effect of dilutive securities:				
Net income (loss) attributable to common stockholders	$ 3,782,641	$ (5,098,351)	$ 10,533,257	$ (14,117,662)
Adjustments to Income for Dilutive options and warrants				
	3,782,641	(5,098,351)	10,533,257	(14,117,662)
Weighted average common shares outstanding	29,669,058	28,998,451	29,615,357	27,062,761
Effect of Dilutive options and warrants	1,476,918	0	532,729	0
Diluted weighted average common shares outstanding	31,145,976	28,998,451	30,148,086	27,062,761
Diluted earnings per common share	**$ 0.12**	**$ (0.18)**	**$ 0.35**	**$ (0.52)**

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 six months ended June 30, 2012 and 2011, outstanding stock options and warrants of 3,047,964 and 9,073,689, 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 at June 30, 2012 and June 30, 2011, respectively.

	June 30, 2012	June 30, 2011
Options and warrants to purchase Common Stock	6,998,847	9,073,689

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®.

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 reduced expenditures from previous levels during 2012.

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11. Termination of BDSI License and Sublicenses with UMDNJ:

In June 2012, the Company entered into an agreement to terminate its license agreement with the University of Medicine and Dentistry of New Jersey (UMDNJ) and certain sublicenses related to the Bioral® drug delivery technology previously developed by the Company under such license. Under this agreement, the Company agreed to assign to UMDNJ its know-how to the Bioral® technology. Once all previously executed sublicenses related to the Bioral® technology have been formally terminated, the Company will assign to UMDNJ its know-how and patent rights the Bioral® technology in consideration of 10% of future potential revenues collected by UMDNJ for commercialization of Bioral® formulated Amphotericin B products and 3.5% for non- Bioral® formulated Amphotericin B products which utilize such patent rights and know-how. In conjunction with the termination agreement, the Company also donated to New Jersey Health Foundation, a not-for-profit organization, the University of Medicine and Dentistry of New Jersey-New Jersey Medical School and the H. Lee Moffitt Cancer Center and Research Foundation, Inc. in Tampa, Florida, various items of unused and fully depreciated lab equipment. These donations had no impact on the Company s condensed consolidated financial statements.

12. Restatements:

In September 2012, the Company began a review of its revenue recognition accounting with respect to certain non-refundable cash payments received by the Company during the three months ended March 31, 2012 under the Endo Agreement (including the $30 million non-refundable upfront license fee received by the Company under the Endo Agreement in January 2012 (the Upfront Fee)).

Based on the Company s process and related internal deliberations, and with input from outside consultants and representatives of Cherry Bekaert LLP, the Company s independent registered public accounting firm, the Audit Committee of the Board of Directors and the executive management of the Company jointly determined that the Company should have allocated approximately $14.4 million of the Upfront Fee to the clinical development services unit of accounting under the Endo arrangement, and accordingly the Company should have deferred such $14.4 million amount. As such, and since the Upfront Fee was originally recognized in full during the quarter ended March 31, 2012, a determination was made that the Company s unaudited financial statements for the three months ended March 31, 2012 required restatement to correct the error with respect to such recognition of revenue under the Endo Agreement. The following represents a summary of the restatement adjustments by financial statement line item:

	As of June 30, 2012
Balance Sheet data:	
Deferred revenue, current	7,234,697
Deferred revenue, long term	5,062,366
Total liabilities	12,297,063
Accumulated deficit	(12,297,063)
Total stockholders equity	(12,297,063)

	Three months ended June 30, 2012	Six months ended June 30, 2012
Statement of Operations data:		
Contract revenue	1,248,372	(12,297,063)

Income (loss) from operations	1,248,372	(12,297,063)
Income (loss) before income taxes	1,248,372	(12,297,063)
Net income (loss)	1,248,372	(12,297,063)

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12. Restatements (continued):

	June 30, 2012	
	As Reported	As Restated
Balance Sheet data:		
Deferred revenue, current	15,079,801	22,314,498
Deferred revenue, long term	1,475,719	6,538,085
Total liabilities	28,006,887	40,303,950
Accumulated deficit	(72,741,256)	(85,038,319)
Total stockholders equity	28,061,123	15,764,060

	Three months ended June 30, 2012		Six months ended June 30, 2012	
	As Reported	As Restated	As Reported	As Restated
Statement of Operations data:				
Contract revenue	15,049,600	16,297,972	45,099,200	32,802,137
Income from operations	5,899,237	7,147,609	28,009,382	15,712,319
Income before income taxes	2,534,269	3,782,641	22,830,320	10,533,257
Net income	2,534,269	3,782,641	22,830,320	10,533,257
Basic earnings per share	0.09	0.13	0.77	0.36
Diluted earnings per share	0.08	0.12	0.76	0.35

13. Subsequent Events:

On August 2, 2012, the Company and Endo announced the initiation of the Phase 3 clinical program for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain. The Phase 3 program will consist of two efficacy studies, one in opioid naïve and one in opioid experienced subjects. Both studies are anticipated to be completed by late 2013 or early 2014.

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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 June 30, 2012 compared to the three months ended June 30, 2011

Research Revenues. We recognized $0.03 million of revenue related to a research and development agreement with Meda during the three months ended June 30, 2011. There was no research revenues during the three months ended June 30, 2012.

Contract Revenues. We recognized $16.3 million during the three months ended June 30, 2012 in contract revenue related to our license agreement with Endo. This amount includes $15 million received from Endo in May 2012 for a milestone associated with the granting of a certain patent and $1.2 million in previously deferred contract revenue that is to be recognized as revenue as clinical development services are provided to Endo. The remaining deferred contract revenue will likewise be recognized over the period that clinical development services are provided to Endo. Such services are currently anticipated to be provided from 2012 through early 2014. We also recognized $0.05 million and $0.005 million during the three months ended June 30, 2012 and 2011, respectively, in contract revenue related to previously deferred amounts under our license agreement with Meda.

Cost of Product Royalties. We recognized a charge of $0.4 million and a credit of $0.4 million during the three months ended June 30, 2012 and 2011, 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 under a Clinical Development and License Agreement entered into in 2005 (as amended, the CDLA) pursuant to which a predecessor to CDC provided funds for the development of ONSOLIS®. Athyrium subsequently acquired certain rights to such royalties from CDC.

On May 12, 2011, we entered into an Amendment to the CDLA (the CDLA Amendment) with CDC and Athyrium pursuant to which the parties clarified our royalty obligations under the CDLA. Among other items, certain terms of the CDLA were amended and restated retroactively to clarify that our royalty payments are required to be calculated based on Meda s sales of ONSOLIS®, whereas our previous royalty payments to CDC were calculated based on our sales to Meda. This difference between these two calculations will be rectified by adjusting future royalty payments. As a result, we did not pay $0.75 million in minimum royalty payments that would have been payable as of June 30, 2011. The remaining $0.4 million was accounted for as a credit to cost of product royalties for the three months ended June 30, 2011.

Research and Development Expenses. During the three months ended June 30, 2012 and 2011, research and development expenses totaled $6.5 million and $4.7 million, respectively. The increase in 2012 research and development expenses can be attributed primarily to an increase in expenditures associated with the preparation for our BEMA® Buprenorphine clinical trials as required under our agreement with Endo. As part of this effort, during the second quarter of 2012, we entered into a contract research organization agreement associated with such clinical trials, which agreement accounted for a material portion of the increased expenditures. Our scientific staff continues to work toward development and application of our BEMA® delivery technology, particularly with respect to ONSOLIS®, BEMA® Buprenorphine and BNX. 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, manufacturing equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of our BEMA® drug delivery technology.

General and Administrative Expenses. During the three months ended June 30, 2012 and 2011, general and administrative expenses totaled $2.2 million and $1.9 million, respectively. General and administrative costs include accounting and management wages and other employee compensation costs, 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 June 30, 2012 and 2011 we had interest income of $0.06 million and $0.05 million, respectively.

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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 June 30, 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 $3.2 million loss. Also included in the loss was a $0.3 million loss from a warrant we hold to purchase 2 million shares of Biovest International, Inc., a related party (Biovest). During the three months ended June 30, 2011, our share price decreased. Therefore, our derivative liability declined by $1.2 million, which resulted in a corresponding derivative gain. This gain was offset by a $0.1 million loss on the value of our Biovest warrant.

For the six months ended June 30, 2012 compared to the six months ended June 30, 2011

Product Royalty Revenues. We recognized $0.03 million in product royalty revenue during the six months ended June 30, 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 six months ended June 30, 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 six months ended June 30, 2012 and 2011, respectively.

Contract Revenues. We recognized $32.8 million during the six months ended June 30, 2012 in contract revenue related to our license agreement with Endo. This amount includes $15.6 million in January 2012 of the $30 million up-front license fee from Endo ($14.4 million was recorded as deferred contract revenue), $15 million received from Endo in May 2012 for a milestone associated with the granting of a certain patent and $2.1 million in previously deferred contract revenue. The remaining deferred contract revenue will be recognized over the period that clinical development services are supplied to Endo. It is currently anticipated that such services will be provided from 2012 through early 2014. We also recognized $0.1 million and $0.007 million during the six months ended June 30, 2012 and 2011, respectively, in contract revenue related to previously deferred amounts under our license agreement with Meda.

Cost of Product Royalties. We recognized a charge of $0.8 million and a credit of $0.1 million during the six months ended June 30, 2012 and 2011, respectively, in cost of product royalties. This includes both manufacturing costs and product royalty costs owed to CDC and Athyrium. On May 12, 2011, we entered into the CDLA Amendment, pursuant to which the parties agreed to increase the royalty rate retroactively to the initial launch date of ONSOLIS® and, accordingly, we recorded $0.3 million as additional cost of product royalties. This expense was recognized during three months ended March 31, 2011.

In addition, the CDLA Amendment amended and restated certain provisions of the CDLA to retroactively clarify that our royalty payments are required to be calculated based on Meda s sales of ONSOLIS®, whereas our previous royalty payments to CDC were calculated based on our sales to Meda. This difference between these two calculations will be rectified by adjusting future royalty payments. As a result, we did not pay $0.75 million in minimum royalty payments that would have been payable as of June 30, 2011. The remaining $0.4 million was posted as a credit to cost of product royalties for the six months ended June 30, 2011. When this credit is combined with the $0.3 million CDLA amendment noted in the previous paragraph, the result is the $0.1 million credit shown in cost of product royalties.

Research and Development Expenses. During the six months ended June 30, 2012 and 2011, research and development expenses totaled $11.3 million and $11.4 million, respectively. Our scientific staff continues to work toward development and application of our BEMA® delivery technology, particularly with respect to ONSOLIS®, BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone. 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, manufacturing equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of our BEMA® drug delivery technology.

General and Administrative Expenses. During the six months ended June 30, 2012 and 2011, general and administrative expenses totaled $5.1 million and $3.7 million, respectively. General and administrative costs include accounting and management wages and other employee compensation costs, legal and professional fees, office supplies, travel 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 six months ended June 30, 2012 and 2011 we had interest income of $0.1 million and $0.09 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 six months ended June 30, 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 $5.4 million loss. This loss was offset by a $0.01 million gain from a warrant we

hold to purchase 2 million shares of Biovest. During the six months ended June 30, 2011, our stock price decreased and the fair value of the related warrant liability declined by $1.3 million, resulting in a derivative gain. This gain was partially offset by a $0.7 million loss in the fair value of our Biovest warrant.

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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 and cash flow generated as a result of our worldwide license and development agreements with Meda regarding our ONSOLIS® product and revenue and cash flow 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. Such registration statement was declared effective on February 24, 2012 and will expire in February 2015 unless it is renewed prior to such expiration.

On May 21, 2012, we announced receipt of a pre-launch milestone payment of $2.5 million from Meda in conjunction with the first country registration and pricing approval for BREAKYL (tradename for ONSOLIS® in the EU). This $2.5 million milestone payment has been recorded as deferred revenue and will be recorded as contract revenue at the time of commercial launch in EU. A last milestone payment related to the EU of $2.5 million is payable at the time of commercial launch, which is anticipated in late 2012. BREAKYL will be commercialized in the EU by Meda.

At June 30, 2012, we had cash and cash equivalents of approximately $43 million. We generated $33 million of cash from operations during the six months ended June 30, 2012. As of June 30, 2012, we had stockholders equity of $15.8 million versus $4.1 million at December 31, 2011. In January 2012, we received a $30 million, upfront non-refundable 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 property-related milestone. 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 upfront and milestone payments, together with other expected cash inflows from other milestones and royalties, is 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 $0.8 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.

Additional capital will likely be required to support commercialization efforts for ONSOLIS® (including commercial launch in Europe which is expected in the fourth quarter 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 product candidate and other potential products or technologies, as well as general working capital. Based on product development timelines and agreements with our existing development and commercialization 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 six months ending June 30, 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;

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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.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of June 30, 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	$ 75,789	$ 75,789	$	$	$
Employment agreements	485,340	485,340			
Minimum royalty expenses*	11,250,000	1,500,000	3,000,000	3,000,000	3,750,000
Total contractual cash obligations**	$ 11,811,129	$ 2,061,129	$ 3,000,000	$ 3,000,000	$ 3,750,000

* 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 June 30, 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 June 30, 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 June 30, 2012 was $6.7 million, net of accumulated amortization of $4.3 million. We begin amortizing capitalized intangibles on their date of acquisition.

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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 six months ended June 30, 2012 or 2011.

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.

Revenue recognition

We periodically enter into license and development agreements to develop and commercialize our products. The arrangements typically are multi-deliverable arrangements that are funded through up-front payments and milestones and covered under generally accepted accounting standards promulgated through ASC Topic 605. We have two major agreements (Meda and Endo) that are described fully in Footnotes 3 and 4. We adopted the milestone method of revenue recognition in 2010.

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 June 30, 2012, we had approximately $38.3 million, which exceed these insured limits.

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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 rules and forms of the Securities and Exchange Commission (SEC). 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 not appropriately 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. The ineffective nature of such controls relates solely to our failure to properly consider and evaluate accounting guidance related to the recognition of the revenue related to the $30 million non-refundable upfront license fee that we received from Endo in January 2012 (the Upfront Fee), which failure was discovered by the Company following comments regarding our accounting for such fee from the staff of the SEC.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our second fiscal quarter of 2012 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, subsequent to March 31, 2012, the Audit Committee of our board of directors, together with our management, conducted a review of our policies and procedures related to revenue recognition in light of the SEC s comments regarding our accounting for the Upfront Fee. The Audit Committee and Company management reached the joint decision to restate our financial statements for the six months ended June 30, 2012, specifically and only in regard to the treatment of the Upfront Fee. In order to mitigate similar issues in the future and to assure complete and accurate interpretation of salient revenue recognition guidance, the Company has implemented a policy (beginning in late 2012) to utilize a revenue recognition consultant to help analyze at inception of the transaction, any significant license agreement prior to implementation of the accounting treatment.

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

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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 expre statements are based upon the current beliefs 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.

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.

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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.

As expected, in the 891 Patent and 292 Patent Ex Parte Reexamination proceedings, MonoSol amended the claims several times and made multiple declarations and arguments in an attempt to overcome the rejections made by the US Patent Office. These amendments, declarations and other statements regarding the claim language significantly narrowed the scope of their patents. In the case of the 891 Patent, not one of the original claims survived reexamination and five separate amendments were filed. Additionally, arguments and admissions made by MonoSol prevent it from seeking a broader construction during any subsequent litigation by employing arguments or taking positions that contradict those made during prosecution. Our original assertion that our products and technologies do not infringe on MonoSol s original patents are only strengthened by the significant narrowing of the claims in both patents. An intent to reissue the 891 Patent in its amended form was mailed July 6, 2012. A Reexamination Certificate for the 292 Patent in its amended form was issued on July 3, 2012. In the 588 Patent, the USPTO on July 20, 2012 issued a second Office action closing prosecution. The Action rejects all claims as anticipated or obvious for a second time. It also rejects the amended claims proposed by MonoSol as unclear and lacking support.

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.

The Company hereby updates and amends its risk factor relating to healthcare reform and insurance reimbursement.

Government and other efforts to reform the healthcare industry could have adverse effects on our company, including the inability of users of our current and future approved products to obtain adequate reimbursement from third-party payers, which could lead to diminished market acceptance of, and revenues from, such products.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (the PPACA). The Healthcare and Education Reconciliation Act of 2010 (the Reconciliation Act), which contains a number of amendments to the PPACA, was signed into law on March 30, 2010. Two primary goals of the PPACA, combined with the Reconciliation Act (collectively referred to as the Health Reform Legislation), are to provide for increased access to coverage for healthcare and to reduce healthcare-related expenses. On June 28, 2012, the United States Supreme Court upheld the constitutionality of the requirement in PPACA that individuals maintain health insurance or pay a penalty.

The Healthcare Reform Legislation contains a number of provisions that are expected to impact our business and operations or those of our commercial partners, including provisions governing enrollment in federal healthcare programs, reimbursement and discount programs and fraud and abuse prevention and control. The impact of these programs on our business is presently uncertain and may have unexpected consequences for our company. For example, expansion of health insurance coverage under the Health Reform Legislation may result in a reduction in uninsured patients and increase in the number of patients with access to healthcare that have either private or public program coverage, and subsequently prescription drug coverage, including coverage for those products currently marketed or in development by us or our partners. However, this outcome, along with any other potential benefits of the Health Reform Legislation which could prove a benefit for us or our commercial partners, is uncertain and may not occur.

In addition to the Health Reform Legislation, we expect that there will continue to be proposals by legislators or new laws, rules and regulations at both the federal and state levels, as well as actions by healthcare and insurance regulators, insurance companies, health maintenance organizations and other payers of healthcare costs aimed at keeping healthcare costs down while expanding individual healthcare benefits. Certain of these changes (including, without limitation, those enacted in connection with the federal or state implementation of the Health Reform Legislation) could impose limitations on the prices we or our commercial partners will be able to charge for any of our approved products or the amounts of reimbursement available for these products from governmental agencies or third-party payors, or may increase the tax obligations on life sciences companies such as ours. Any or all of these changes (which are presently unclear and subject to potential modification on an ongoing basis) could impact the ability of users of our approved products to obtain insurance reimbursement for the use of such products or the ability of healthcare professionals to prescribe such products, any of which could have a material adverse effect on our revenues (royalty or otherwise), potential profitability and results of operations.

Furthermore, the ability of Meda to sell ONSOLIS® and our ability to commercialize our product candidates with partners such as Endo or otherwise will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products

and related treatments are obtained by governmental authorities, private health insurers, managed care, and other organizations and may all result in lower prices for or rejection of our products, which could further have a material adverse effect on our revenues (royalty or otherwise) and results of operations.

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

Item 3. Defaults upon Senior Securities.
None.

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. Reformulation work at both lab scale and commercial scale has been completed. Final test results from the commercial scale batches are being compiled for an expected August submission of our formal meeting request to FDA. This is a few weeks behind our original anticipated timing. We believe this meeting will determine what FDA would expect in the formal 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 U.S. 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: March 18, 2013

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

Date: March 18, 2013

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