BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
November 09, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 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 November 6, 2012, there were 30,705,816 shares of company common stock issued and 30,690,325 shares of company common stock outstanding.

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BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF SEPTEMBER 30, 2012 AND DECEMBER 31, 2011

	September 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,319,153	$ 10,750,205
Accounts receivable	24,303	101,132
Prepaid expenses and other current assets	227,488	229,886
Total current assets	31,570,944	11,081,223
Equipment, net	2,944,514	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	(4,515,296)	(3,749,637)
Total other intangible assets	6,434,704	6,150,363
Derivative asset, warrant (note 7)	187,600	388,540
Other assets	21,976	21,976
Total assets	$ 43,874,738	$ 23,645,210
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 7,389,459	$ 5,090,795
Deferred revenue, current	15,149,561	12,507,471
Derivative liabilities (note 7)	8,949,412	279,302
Total current liabilities	31,488,432	17,877,568
Deferred revenue, long-term	1,356,359	1,647,249
Total liabilities	32,844,791	19,524,817
Commitments and contingencies (note 10)		
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; 30,408,518 and 29,577,146 shares issued; 30,393,027 and 29,561,655 shares outstanding in 2012 and 2011, respectively	30,410	29,578
Additional paid-in capital	103,091,109	99,709,574
Treasury stock, at cost, 15,491 shares, 2012 and 2011	(47,183)	(47,183)
Accumulated deficit	(92,044,389)	(95,571,576)
Total stockholders equity	11,029,947	4,120,393
Total liabilities and stockholders equity	$ 43,874,738	$ 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 NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Product royalties	$	$ 2,659,728	$	$ 2,693,954
Research revenues			13,375	226,843
Contract revenues	49,600	4,000	45,148,800	10,800
Total Revenues:	49,600	2,663,728	45,162,175	2,931,597
Cost of product royalties	375,000	1,507,125	1,125,000	1,378,615
Expenses:				
Research and development	12,546,912	6,215,106	23,804,276	17,625,989
General and administrative	2,992,354	2,593,913	8,042,433	6,289,277
Related party general and administrative, net	20,000	20,250	65,750	57,750
Total Expenses:	15,559,266	8,829,269	31,912,459	23,973,016
Loss (income) from operations	(15,884,666)	(7,672,666)	12,124,716	(22,420,034)
Interest income	90,167	61,409	210,284	147,604
Derivative (loss) gain	(3,525,011)	2,472,550	(8,871,050)	3,032,106
Other income (expense), net	16,377	15,156	63,237	(889)
Net (loss) income	(19,303,133)	(5,123,551)	3,527,187	(19,241,213)
Net (loss) income attributable to common stockholders	$ (19,303,133)	$ (5,123,551)	$ 3,527,187	$ (19,241,213)
Basic earnings per share:	$ (0.64)	$ (0.17)	$ 0.12	$ (0.69)
Diluted earnings per share:	$ (0.64)	$ (0.17)	$ 0.12	$ (0.69)

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012

(Unaudited)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity
Balances, January 1, 2012	29,577,146	$ 29,578	$ 99,709,574	$ (47,183)	$ (95,571,576)	$ 4,120,393
Stock-based compensation			1,373,970			1,373,970
Exercise of stock options	728,872	729	1,872,668			1,873,397
Warrant exercises	45,000	45	134,955			135,000
Shares issued upon vesting of equity awards	57,500	58	(58)			
Net income					3,527,187	3,527,187
Balances, September 30, 2012	30,408,518	$ 30,410	$ 103,091,109	$ (47,183)	$ (92,044,389)	$ 11,029,947

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

(Unaudited)

	Nine months Ended September 30,	
	2012	2011
Operating activities:		
Net income (loss)	$ 3,527,187	$ (19,241,213)
Adjustments to reconcile net income (loss) to net cash flows from operating activities:		
Depreciation and amortization	1,120,741	989,613
Derivative loss (gain)	8,871,050	(3,032,106)
Stock-based compensation expense	1,373,970	1,006,614
Changes in assets and liabilities:		
Accounts receivable	76,829	(1,021,409)
Prepaid expenses and other assets	2,398	(13,157)
Accounts payable and accrued expenses	2,327,264	2,372,321
Deferred revenue	2,351,200	15,133
Net cash flows from operating activities	19,650,639	(18,924,204)
Investing activities:		
Purchase of equipment	(32,283)	(214,616)
Purchase of intangible assets	(1,050,000)	
Net cash flows from investing activities	(1,082,283)	(214,616)
Financing activities:		
Proceeds from issuance of common stock		13,996,773
Proceeds from exercise of stock options	1,873,397	349,676
Proceeds from exercise of warrants	135,000	1,749,259
Change in amounts due to related parties	(7,805)	(46,127)
Net cash flows from financing activities	2,000,592	16,049,581
Net change in cash and cash equivalents	20,568,948	(3,089,239)
Cash and cash equivalents at beginning of period	10,750,205	18,208,659
Cash and cash equivalents at end of period	$ 31,319,153	$ 15,119,420

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 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 September 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 nine month period ended September 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 September 30, 2012 and December 31, 2011, respectively:

	September 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)	$	$ 187,600	$	$ 187,600	$	$ 388,540	$	$ 388,540
Liabilities								
Derivative liabilities (note 7)	$	$ 8,949,412	$	$ 8,949,412	$	$ 279,302	$	$ 279,302

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 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 September 30, 2012 and December 31, 2011.

	$	Number of Warrants
Assets:		
Warrant asset as of January 1, 2012	$ 388,540	2,000,000
Decrease in fair value of warrants	(200,940)	
Warrant asset as of September 30, 2012	$ 187,600	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	8,670,110	
Warrant liability as of September 30, 2012	$ 8,949,412	2,246,301

* Related to 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.

In July 2012, the FASB issued ASU 2012-02 Testing Indefinite-Lived Intangible Assets for Impairment (ASU 2012-02) in order to reduce the cost and complexity of performing an impairment test for indefinite-lived intangible assets by simplifying how an entity tests those assets for impairment and to improve consistency in impairment testing guidance. The new guidance allows an entity the option to make a qualitative assessment about the likelihood that an indefinite-lived intangible asset is impaired to determine whether it should perform a quantitative impairment test. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 and early adoption is permitted. The Company is currently evaluating ASU 2012-02, but does not expect the adoption of this standard to have a 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 with Endo Pharmaceuticals Inc. (Endo) regarding the Company s BEMA® Buprenorphine product candidate. The Company intends to finance its research and development and

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

(Unaudited)

2. Liquidity and management s plans (continued):

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

Significant financing and revenue for the nine months ended September 30, 2012 consisted of:

- $45 million in contract revenue from the Endo license agreement (see note 4);
- $2.5 million in deferred contract revenue under the Meda agreements (see note 3);
- approximately $2.0 million from the exercise of stock options; and
- approximately $0.1 million in previously deferred contract revenue.

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

- approximately $14 million in net proceeds from a private placement offering of Common Stock in March 2011;
- approximately $1 million in net royalties 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, non-refundable payment related to the Company s definitive license and development agreement with Endo to license, develop, manufacture, market and sell its BEMA® Buprenorphine product candidate 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, 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 September 30, 2012, the Company had cash and cash equivalents of approximately $31.3 million. The Company generated $19.7 million of cash from operations during the nine months ended September 30, 2012. As of September 30, 2012, the Company had stockholders equity of $11.0 million, versus $4.1 million at December 31, 2011.

The Company s existing cash, even with the aforementioned $30 million up-front license payment and the $15 million 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 into the second 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 ONSOLIS®. 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 occurred October 2012), clinical development programs for BEMA® Buprenorphine (the scale of which is being governed by the requirements of the Company s agreement with Endo), planned development of the Company s 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 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 nine months ending September 30, 2012, the financial and credit crisis did not

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FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

(Unaudited)

2. Liquidity and management s plans (continued):

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.

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:

Contractual Rights and Obligations	Cash flows received and revenue deferred September 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 North American sale	$ (59,884,370)	$ (59,735,570)
Remaining Deferred Revenue	$ 16,505,920	$ 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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

(Unaudited)

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

efforts provided do not have standalone value apart from the license. As such, all cash payments from Meda that were related to these deliverables were recorded as deferred revenue. All cash payments from Meda for upfront and milestone payments and research and development services provided are nonrefundable. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain deliverables associated with research and development services were deliverable to Meda. The first commercial sale in the U.S. occurred in October 2009. As a result, $59.8 million of the aggregate milestones and services revenue have been recognized. Upon first commercial sale in a European country, an estimated $17.6 million will be recognized, which includes an additional $2.5 million milestone received upon launch in Europe, which occurred October 2012. At September 30, 2012, there was remaining deferred revenue of $16.5 million, of which $15.0 million is related to the EU Meda arrangement milestones and EU Meda research and development services.

In connection with delivery of the license to Meda, the Company has determined that each of the undelivered obligations have stand-alone value to Meda as these post-commercialization services encompass additional clinical trials on different patient groups but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. Further, the Company obtained third-party evidence of fair value for the non-cancer and other research and development services and other service obligations, based on hourly rates billed by unrelated third-party providers for similar services contracted by the Company. The Company also obtained third-party evidence of fair value of the product supply deliverable based on the outsourced contract manufacturing cost charged the Company from the third-party supplier of the product. The arrangements do not contain any general rights of return. Therefore, the remaining deliverables to the arrangements will be accounted for as three separate units of accounting to include: (1) product supply, (2) research and development services for the non-cancer indication and further research and development of the first indication ONSOLIS® 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 ONSOLIS®. 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 $2.7 million for the nine months ended September 30, 2012 and 2011, respectively. The Company has incurred cost of product royalties of approximately $1.1 million and $1.4 million for the nine months ended September 30, 2012 and 2011, respectively, related to this royalty revenue. The cost of product royalties for the nine months ended September 30, 2012 is related to minimum quarterly payments owed to CDC, regardless of ONSOLIS® royalty levels (see note 5).

Subsequent to the Company s announcement on March 12, 2012 regarding the postponement of the U.S. relaunch of the Company s FDA-approved ONSOLIS®, the Company has been working on various formulation adjustments to resolve (i) certain color fading and (ii) crystal formation issues observed with this product, although neither had any impact on product performance. The positive reformulation efforts led to the results being submitted to FDA in October 2012 with a request for a Type A meeting to review the Company s findings and what the Company believes to be a pathway forward. This meeting, scheduled for mid-December, will provide the Company with an opportunity: (1) for FDA to review with the Company the data the Company generated from the reformulation work to hopefully resolve the concerns FDA had regarding the two issues noted above; (2) to determine the content of the formal submission package that FDA will require for their formal review; and (3) to establish the formal submission classification and its associated review time. This Type A meeting and its

outcome will enable the Company to better predict with greater certainty the potential timing of the U.S. relaunch of ONSOLIS®.

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 the EU. A final milestone payment related to the EU of $2.5 million was paid at the time of commercial launch, which launch occurred in October 2012. BREAKYL will be commercialized in the EU by Meda.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

(Unaudited)

4. Endo License and Development Agreement:

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

Pursuant to the Endo Agreement, 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 clinical trials regarding BEMA® Buprenorphine necessary to submit a New Drug Application (NDA) to the FDA in order to obtain approval of BEMA® Buprenorphine in the U.S., pursuant to a development plan set forth in the Endo Agreement (as it may be amended pursuant to the Endo Agreement). The Company is responsible for 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 will receive the following payments (some portion(s) of which will be utilized by the Company to support its development obligations under the Endo Agreement with respect to the product):

- $30 million non-refundable upfront payment by January 19, 2012 (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 potential sales milestones; 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 fair value 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 (and specifically ASC 605-25-25), the Company determined that: (i) the Endo Agreement is a multi-deliverable arrangement under ASC Topic 605 and (ii) one of the multi-deliverable features is a license with stand-alone value under ASC 605-25-25-5a. In such analysis, it was determined that the license to

Endo had stand-alone value under ASC 605-25-25-5a as a result of the transfer of the license, ownership of the subject Investigational New Drug Application, certain know-how and certain patents rights to Endo. As noted above, the result was that Endo obtained, at the inception of the Endo Agreement, all of the rights and knowledge necessary to fully exploit its license without the further involvement of the Company. Additionally, the Company concluded that the value of the license delivered to Endo at contract inception exceeded the up-front payment received, and that the milestone payments were adequate consideration for the other deliverables in the arrangement. Accordingly, the upfront payment of $30 million was recognized upon receipt.

The analysis of the fair value 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, and assumed royalty rates that would be paid for sales of products relying on the license. 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.

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

On February 16, 2012, the Company announced that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance regarding the Company s patent application (No. 13/184306), which patent will extend the exclusivity of the BEMA® drug delivery technology for its BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone products from 2020 to 2027. In April 17, 2012, the Company announced that this patent was granted. As a result, pursuant to the Endo Agreement, the Company received a milestone payment from Endo in the amount of $15 million in May 2012. This milestone had been evaluated to be a substantive milestone under ASC 605-28, and therefore was recognized as revenue when the patent was granted.

The remaining milestone payments will also be recognized as revenue when they are achieved, except that one milestone is contingently refundable for a period of time. Revenue related to that milestone will be recognized as refund provisions expire. Sales-based royalties will be recognized as they accrue under the terms of the Endo Agreement.

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5. Other License Agreements and Acquired Product Rights:

Kunwha License Agreement

In May 2010, the Company entered into a License and Supply Agreement (the Kunwha License Agreement) with Kunwha Pharmaceuticals Co. Ltd. (Kunwha) to develop, manufacture, sell and distribute the Company s BEMA® Fentanyl product in the Republic of Korea (the Kunwha Territory). BEMA® Fentanyl is marketed as ONSOLIS® in North America. The Kunwha License Agreement is for a term beginning on May 26, 2010 until the date of expiration of the patents, or July 23, 2027, whichever is later.

Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for BEMA® Fentanyl in the Kunwha Territory, while the Company retained all other licensing rights to the Licensed Product not previously granted to third parties. Kunwha paid to the Company an upfront payment of $0.3 million (net of taxes approximating $0.25 million) and will be responsible to make certain milestone payments which could aggregate up to $1.3 million (net of taxes approximating $1.1 million). In addition, Kunwha will pay royalties to the Company based on Net Sales (as defined in the Kunwha License Agreement) and will purchase all supplies of BEMA® Fentanyl from the Company.

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

The upfront payment from Kunwha of $0.3 million (net of taxes, approximating $0.25 million) received in June 2010 was recorded as contract revenue upon receipt.

TTY License and Supply Agreement

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

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 the Company for North America that would be granted to the Company 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

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

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 additional cost of product royalties for year ended December 31, 2011. In addition, certain terms of the CLDA were amended and restated to clarify that royalty payments by the Company under the CDLA will be calculated based on Meda s sales of ONSOLIS®, whereas previous Company royalty payments to CDC were calculated based on Company sales of ONSOLIS® to Meda. The difference between these two calculations resulted in a $1.1 million overpayment by the Company which was recorded as a prepayment in 2011. As a result, the Company did not pay any of the 2011 quarterly royalty payments due to CDC/Athyrium and was not required to pay another royalty payment until the December 31, 2011 royalty calculation, which was due during the first quarter of 2012.

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 nine months ended September 30, 2012, the stock price of Biovest s common stock decreased, resulting in a derivative loss of $0.3 million in the accompanying condensed consolidated statement of operations. During the nine months ended September 30, 2011, the stock price of Biovest s common stock decreased, resulting in a derivative loss of $0.8 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.

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7. Derivative Financial Instruments (continued):

The following tabular presentation reflects the components of derivative assets and liabilities as of September 30, 2012 and December 31, 2011:

	September 30, 2012	December 31, 2011
Derivative asset at fair value:		
Free standing warrants related party	$ 187,600	$ 388,540

	September 30, 2012	December 31, 2011
Shares into which derivative asset can be settled:		
Free standing warrants related party	2,000,000	2,000,000

	September 30, 2012	December 31, 2011
Derivative liability at fair value:		
Free standing warrants	$ 8,949,412	$ 279,302

	September 30, 2012	December 31, 2011
Shares into which derivative liability can be settled:		
Free standing warrants	2,246,301	3,246,301

The following tabular presentation reflects the components of the (loss) gain of derivative financial instruments for the nine months ended September 30, 2012 and 2011:

	3 months ending	3 months ending	9 months ending	9 months ending

	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2012
Derivative (loss) gain in the accompanying statement of operations is related to the individual derivatives as follows:				
Free standing warrants assets, related party	$ (213,600)	$ (124,400)	$ (200,940)	$ (832,891)
Free standing warrants liabilities	(3,311,411)	2,596,950	(8,670,110)	3,864,997
	$ (3,525,011)	$ 2,472,550	$ (8,871,050)	$ 3,032,106

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8. Stockholders Equity:

Stock-based compensation:

During the nine months ended September 30, 2012, a total of 666,714 options to purchase Common Stock with an aggregate fair market value of approximately $1.2 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, 251,508 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 nine months ended September 30, 2012 follows:

Expected price volatility	82.37%-83.69%
Risk-free interest rate	0.62%-1.02%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the nine months ended September 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	281,174	2.36	
Others	385,540	2.30	
Exercised	(728,872)	2.57	
Forfeitures	(250,741)	3.26	
Outstanding at September 30, 2012	4,240,352	$ 3.67	$ 11,443,601

Options outstanding at September 30, 2012 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Aggregate Intrinsic Value

			Life (Years)		
$ 1.00	5.00	3,329,107	6.31	$	2.94
$ 5.01	10.00	911,245	4.91	$	6.30
		4,240,352			$ 11,443,601

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8. Stockholders Equity (continued):

Options exercisable at September 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	2,574,467	5.58	$ 3.03	
$ 5.01 10.00	911,245	4.91	$ 6.30	
	3,485,712			$ 8,688,721

The weighted average grant date fair value of options granted during the nine months ended September 30, 2012 was $1.83. There were no options granted during the nine months ended September 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 nine months ended September 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	415,206		
Vested	(377,170)		
Forfeited	(69,584)		
Nonvested at September 30, 2012	754,640	$ 2.67	$ 2,754,880

As of September 30, 2012, there was approximately $1.0 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 September 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	2,246,301	2.15	$ 3.82	$ 5,620,485

Restricted stock units:

During the nine months ended September 30, 2012, a total of 57,500 restricted stock units with a fair market value of approximately $0.3 million were granted to independent directors of the Company pursuant to the Company s director remuneration policy. The fair value of restricted units is determined using quoted market prices of the common stock and the number of shares expected to vest. These units were originally issued in July 2012 as restricted stock units under our 2011 Equity Incentive Plan. Such restricted stock units vested in their entirety, and the shares were issued accordingly, in September 2012.

Warrant exercises:

During the nine months ended September 30, 2012, one of the Company s affiliates exercised warrants to purchase 45,000 shares of Common Stock for $3.00 per share.

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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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Basic:				
Net (loss) income attributable to common stockholders	($ 19,303,133)	($ 5,123,551)	$ 3,527,187	($ 19,241,213)
Weighted average common shares outstanding	30,071,813	29,561,655	29,768,620	27,904,879
Basic earnings per common share	**($ 0.64)**	**($ 0.17)**	**$ 0.12**	**($ 0.69)**
Diluted:				
Effect of dilutive securities:				
Net income (loss) attributable to common stockholders	($ 19,303,133)	($ 5,123,551)	$ 3,527,187	($ 19,241,213)
Adjustments to Income for Dilutive options and warrants				
	(19,303,133)	(5,123,551)	3,527,187	(19,241,213)
Weighted average common shares outstanding	30,071,813	29,561,655	29,768,620	27,904,879
Effect of Dilutive options and warrants			65,958	
Diluted weighted average common shares outstanding	30,071,813	29,561,655	29,834,578	27,904,879
Diluted earnings per common share	**($ 0.64)**	**($ 0.17)**	**$ 0.12**	**($ 0.69)**

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 nine months ended September 30, 2012 and 2011, there were 6,419,005 and 0, respectively, outstanding stock options or warrants 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 September 30, 2012 and September 30, 2011, respectively.

	September 30, 2012	September 30, 2011
Options and warrants to purchase Common Stock	6,484,963	8,746,189

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10. Commitments and contingencies:

In March 2012, the Company announced that the New Jersey Federal Court granted a stay of further litigation in the patent infringement lawsuit previously filed by MonoSol Rx, LLC (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®.

In July 2012, a Reexamination Certificate for MonoSol s 292 Patent in its amended form was issued by the USPTO. The USPTO also issued a second Office Action closing prosecution on MonoSol s 588 Patent. 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. In August 2012, a Reexamination Certificate for MonoSol s 891 Patent in its amended form was issued (See Part II, Item 1, Legal Proceedings).

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 to 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 UMDNJ 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. Subsequent Events:

On October 15, 2012, the Company announced the commercial launch of BREAKYL in the EU. Under the terms of its EU agreement with Meda, the Company will now receive a final milestone payment of $2.5 million, which payment was received October 26, 2012. The Company will also receive a royalty on net sales of BREAKYL in the EU. BREAKYL is being launched in the EU by Meda and will be available for sale in a selected number of countries in 2012, including Germany. BREAKYL will thereafter be launched in most EU countries throughout 2013. Upon first commercial sale, deferred revenue in the accompanying condensed consolidated statements of operations of $16.5 will be recognized as contract revenues.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Quarterly Report. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company s actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Quarterly Report and in the Company s other filings with the Securities and Exchange Commission (the SEC). See Cautionary Note Regarding Forward Looking Statements below.

For the three months ended September 30, 2012 compared to the three months ended September 30, 2011

Product Royalty Revenues. We recognized $2.7 million in product royalty revenue during the three months ended September 30, 2011 under our license agreement with Meda. There was no product royalty revenue during the three months ended September 30, 2012.

Contract Revenues. We recognized $0.05 million and $0.004 million during the three months ended September 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 $0.4 million and $1.5 million during the three months ended September 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.

Research and Development Expenses. During the three months ended September 30, 2012 and 2011, research and development expenses totaled $12.5 million and $6.2 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 well as costs associated with our BEMA® Buprenorphine/Naloxone product candidate. As part of the efforts related to the Endo agreement during the second quarter of 2012, we entered into a terminable 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 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 three months ended September 30, 2012 and 2011, general and administrative expenses totaled $3.0 million and $2.6 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 primarily attributed to stock compensation expense, which was $0.7 million and $0.6 million for the three months ended September 30, 2012 and 2011, respectively.

Interest Income. During the three months ended September 30, 2012 and 2011 we had interest income of $0.09 million and $0.06 million, respectively.

***Derivative loss*.** Our derivative liability consists of free standing warrants measured at their fair market value, using the Black-Scholes method. During the three months ended September 30, 2012, our stock price increased, which is one of the largest components of the Black Scholes calculation. As a result, our warrant liability also increased, resulting in a $3.3 million non-cash charge to income. Also included was a $0.3 million non-cash charge from a warrant we hold to purchase 2 million shares of Biovest International, Inc., a related party (Biovest). During the three months ended September 30, 2011 our share price declined, resulting in a derivative liability decrease of $2.6 million. This 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 nine months ended September 30, 2012 compared to the nine months ended September 30, 2011

Product Royalty Revenues. We recognized $2.7 million in product royalty revenue during the nine months ended September 30, 2011 under our license agreement with Meda. There was no product royalty revenue during the nine months ended September 30, 2012.

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Research Revenues. We recognized $0.01 million and $0.2 million of revenue related to a research and development agreement with Meda during the nine months ended September 30, 2012 and 2011, respectively.

Contract Revenues. We recognized $45 million from Endo during the nine months ended September 30, 2012 in contract revenue related to our license agreement with Endo , consisting of a non-refundable up-front license payment of $30.0 million and a milestone payment of $15.0 million related to a patent extension which granted an additional seven years of exclusivity. We also recognized $0.1 million and $0.01 million during the nine months ended September 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 $1.1 million and $1.4 million during the nine months ended September 30, 2012 and 2011, respectively, in cost of product royalties. This includes both manufacturing costs and product royalty costs owed to CDC and Athyrium.

Research and Development Expenses. During the nine months ended September 30, 2012 and 2011, research and development expenses totaled $23.8 million and $17.6 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 well as costs associated with our BEMA® Buprenorphine/Naloxone product candidate. 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 nine months ended September 30, 2012 and 2011, general and administrative expenses totaled $8.0 million and $6.3 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 stock compensation expense, legal fees, compensation increases and increases in various other professional services in conjunction with the large new clinical trials underway this year.

Interest Income. During the nine months ended September 30, 2012 and 2011 we had interest income of $0.2 million and $0.1 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 nine months ended September 30, 2012, our stock price increased, which is one of the largest component of the Black Scholes calculation. As a result, our warrant liability also increased, resulting in an $8.7 million non-cash charge. In addition, there was a $0.2million decrease in the fair market value of a warrant we hold to purchase 2 million shares of Biovest. During the nine months ended September 30, 2011 our stock price decreased and the fair value of the related warrant liability declined by $3.8 million, resulting in a corresponding derivative gain. This gain was partially offset by a $0.8 million loss in the fair value of our Biovest warrant.

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 ONSOLIS® 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

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final milestone payment related to the EU of $2.5 million was paid at the time of commercial launch, which was October 2012. BREAKYL will be commercialized in the EU by Meda. As such, a total of $16.5 million of previously deferred revenue will be recorded as contract revenues in the fourth quarter of 2012 related to the EU agreement with Meda.

At September 30, 2012, we had cash and cash equivalents of approximately $31.3 million. We generated $19.7 million of cash from operations during the nine months ended September 30, 2012. As of September 30, 2012, we had stockholders equity of $11.0 million versus $4.1 million at December 31, 2011. In January 2012, we received and recognized as contract revenues 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 and recognized as contract revenues 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 payments, together with other expected cash inflows from other milestones and royalties, are anticipated by management to be sufficient to fully fund our planned level of operations into the second 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®. 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 occurred in October 2012), clinical development programs for BEMA® Buprenorphine (the scale of which is being governed 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 nine months ending September 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 agreements with our development partners and, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

Accordingly, we anticipate that we will be required to raise additional capital, which may be available to us through a variety of sources, including:

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;
- sale of product royalty;
- grants and new license revenues;

bank loans;

equipment financing;

public or private debt; and

exercise of existing warrants and options.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from potential commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, any of which could have a material adverse effect on us, our financial condition and our results of operations in 2012 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

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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 September 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	$ 288,739	$ 111,300	$ 177,439	$	$
Employment agreements	817,141	817,141			
Minimum royalty expenses*	11,250,000	1,500,000	3,000,000	3,000,000	3,750,000
Total contractual cash obligations**	$ 12,355,880	$ 2,428,441	$ 3,177,439	$ 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 has worldwide rights to market, upon FDA approval, our BEMA® Buprenorphine product. Under our agreement with Endo, among other deliverables, we are required to conduct and pay for certain specific clinical trials and, in connection with such specific trials, provide clinical trial materials, as outlined in a mutually agreed development plan. The costs for such trials and materials will depend on the size and scope of the specified trials. The Endo agreement does not specify minimums in terms of the cost of the trials, but does provide for a cost sharing arrangement under which we will be responsible for a material amount of such costs, up to a certain threshold, whereupon Endo will be responsible for a significantly less amount of such costs (if any are incurred), up to second threshold amount, and thereafter, costs (if any are incurred) will be shared equally by us and Endo.

Off-Balance Sheet Arrangements

As of September 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 September 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 September 30, 2012 was $6.4 million, net of accumulated amortization of $4.5 million. We begin amortizing capitalized intangibles on their date of acquisition.

Impairment Testing

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

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

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

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

There were no impairment charges during the nine months ended September 30, 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents include Ultra Short Term Government Funds. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents on deposit with financial institutions in the United States. On November 9, 2010, the Federal Deposit Insurance Corporation (FDIC) issued a Final Rule implementing Section 343 of the Dodd-Frank Wall Street Reform and Consumer Protection Act that provides for unlimited insurance coverage of noninterest-bearing transaction accounts. Beginning December 31, 2010, through December 31, 2012, all non-interest bearing transaction accounts are fully insured, regardless of the balance of the account, at all FDIC-insured institutions. The unlimited insurance coverage is available to all depositors, including consumers, businesses, and government entities. This unlimited coverage is separate from, and in addition to, the $250,000 insurance coverage provided to a depositor s other deposit accounts held at an FDIC-insured institution. As of September 30, 2012, we had approximately $28.7 million, which exceed these insured limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro or other applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

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.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, the Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer (the Certifying Officers), conducted evaluations of our disclosure controls and procedures. As defined under Sections 13a 15(e) and 15d 15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act), the term disclosure controls and procedures means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer s management, including the Certifying Officers, to allow timely decisions regarding required disclosures.

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

Changes in Internal Control over Financial Reporting

Further, there were no changes in our internal control over financial reporting during our third fiscal quarter of 2012 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Internal Controls

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our control have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations (and the Liquidity and Capital Resources section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes forward-looking statements within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as projects , may , could , would , should , believes , expects , anticipates , estimates , intends , plans or similar expressions. These statements are based upon the c and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) actual sales results and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s review and/or approval and commercial launch of our products and product candidates and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1A of our 2011 Annual Report and other factors detailed from time to time in our other filings with the SEC. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Quarterly Report. We undertake no obligation to publically update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Readers are advised that the following disclosure regarding our ongoing litigation with MonoSol Rx, LLC (MonoSol) is intended to provide some background and an update on the matter as required by the rules of the SEC. Additional details regarding the past procedural history of the matter can be found in our previously filed periodic filings with the SEC.

On November 2, 2010, MonoSol Rx, LLC (MonoSol) filed an action against us and our commercial partners for ONSOLIS® in the Federal District Court of New Jersey (DNJ) for alleged patent infringement and false marking. 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). Of note, the BEMA® technology itself is not at issue in the case, nor is BEMA Buprenorphine or BEMA Buprenorphine/Naloxone (BNX), 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 MonoSol s 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 MonoSol s 588 Patent is actually invalid and unenforceable for failure to comply with one or more of the requirements of applicable U.S. patent law.

On September 12, 2011, we filed a request for inter partes reexamination in the United States Patent and Trademark Office (USPTO) of MonoSol s 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, and thus invalid. On September 16, 2011, we filed in court a motion for stay pending the outcome of the reexamination proceedings, which subsequently was granted due to the results of the USPTO proceedings as described below.

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

In February and March 2012, respectively, the USPTO granted the requests for reexamination we filed with respect to MonoSol s 292 and 891 Patents. In its initial office action in each, the USPTO rejected every claim in each patent. Based on the action of the USPTO on these three patent reexaminations, the court in our case with MonoSol conducted a status conference on March 7, 2012, at which it granted our motion to stay the case pending final 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 claims in these two patents. In the case of the 891 Patent, not one of the original claims survived reexamination and five separate amendments were filed confirming our position that the patent was invalid. Additionally, we believe that 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.

A Reexamination Certificate for MonoSol s 891 Patent in its amended form was issued August 21, 2012. A Reexamination Certificate for MonoSol s 292 Patent in its amended form was issued on July 3, 2012. These actions by the USPTO confirm the invalidity of the original patents and through the narrowing of the claims in the reissued patents strengthens our original assertion that our products and technologies do not infringe on MonoSol s original patents.

Importantly, in the case of the third MonoSol patent 588 Patent , the USPTO on July 20, 2012 issued a second Office Action closing prosecution. The second Action rejects for a second time all claims as anticipated or obvious. It also rejects the amended claims proposed by MonoSol as unclear and lacking support. This action confirms that all claims of this patent are also invalid, but unlike 292 and 891, the USPTO has not found that any amended or narrower claims should be granted. We anticipate that the USPTO will issue a Right of Appeal notice in the next several months with its final position that no claims of the 588 patent will survive reexamination. We anticipate that the USPTO will issue a Right of

Appeal notice in the next several months.

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Based on our original assertion that our proprietary manufacturing process for ONSOLIS® does not infringe on patents held by MonoSol, and the denial and subsequent narrowing of the claims on the two reissued patents MonoSol has asserted against BDSI while the third has twice had all claims rejected by the USPTO, we remain very confident in our original stated position regarding this matter. Thus far we have proven that the original 292 and 891 patents were indeed invalid and the third and final patent, 588, appears will have a similar fate. Importantly, we will continue to defend this case vigorously, and we anticipate that MonoSol s claims against us will ultimately be rejected.

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Item 1A. Risk Factors.
No update.

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

Item 3. Defaults upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
None.

Item 5. Other Information.
Update on Relaunch Activities in the U.S. for ONSOLIS®

Subsequent to our announcement on March 12, 2012 regarding the postponement of the U.S. relaunch of our FDA-approved ONSOLIS®, we have been working on various formulation adjustments to resolve (i) certain color fading and (ii) crystal formation issues observed with this product, although neither had any impact on product performance. The positive reformulation efforts led to the results being submitted to FDA in October 2012 with a request for a Type A meeting to review our findings and what we believe to be a pathway forward. This meeting, scheduled for mid-December, will provide us with an opportunity: (1) for FDA to review with us the data we generated from the reformulation work to hopefully resolve the concerns FDA had regarding the two issues noted above (2) to determine the content of the formal submission package that FDA will require for their formal review; and (3) to establish the formal submission classification and its associated review time. This Type A meeting and its outcome will enable us to better predict with greater certainty the potential timing of the U.S. relaunch of ONSOLIS®.

Open SEC Comments Regarding Endo Revenue Recognition

On September 5, 2012, we received a comment letter from the staff (the Staff) of the Securities and Exchange Commission (the SEC) relating to our revenue recognition accounting under our licensing agreement for BEMA Buprenorphine with Endo. Since that date, we have been in discussions with the Staff regarding the terms of the Endo agreement and our accounting treatments related thereto and we are continuing to work with the Staff to answer any remaining questions or comments they may have in order to resolve this matter satisfactorily.

We believe that our revenue recognition relating to the Endo agreement has been undertaken in accordance with generally accepted accounting principles and related current accounting literature. In addition, we believe that the types of questions being asked by the Staff are not unusual for these types of clinical development and license agreements.

Importantly, and particularly in light of the earned and non-refundable nature of the $45 million in payments we have received in 2012 from Endo, we believe that our cash position and operations will not be impacted by the outcome of our discussions with the Staff, regardless of the ultimate revenue recognition treatment afforded such $45 million of payments or any future payments we may receive under our agreement with Endo.

As of the date of this Report, we cannot determine with certainty what impact the Staff comments will have on our previous or future disclosures and related policies regarding the revenue recognition treatment of our payments from Endo, including the financial information contained in this Form 10-Q. Based on the ultimate outcome of our discussions with the Staff, we may reach a determination to supplement our future financial disclosure, or restate prior financial disclosures, which could have a material impact on our aforementioned revenue recognition and policies related thereto, but not, as stated above, on our cash position or ability to continue and progress ongoing operations.

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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: November 9, 2012

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

Date: November 9, 2012

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