BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
August 09, 2013
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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 June 30, 2013

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

For the transition period from _____ to _____

Commission file number 001-31361

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

801 Corporate Center Drive, Suite #210

Raleigh, NC	**27607**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number (including area code): 919-582-9050

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

As of August 7, 2013, there were 38,025,027 shares of company Common Stock issued and 38,040,518 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 JUNE 30, 2013 AND DECEMBER 21, 2012

	June 30, 2013 (Unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,430,878	$ 63,189,307
Accounts receivable, other	509,016	520,812
Prepaid expenses and other current assets	269,712	226,064
Total current assets	38,209,606	63,936,183
Equipment, net	2,649,404	2,835,707
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,900,000	1,900,000
Acquired product rights	9,050,000	9,050,000
Accumulated amortization	(5,268,324)	(4,770,516)
Total other intangible assets	5,681,676	6,179,484
Derivative asset, warrant (note 1)		50,300
Other assets		21,976
Total assets	$ 49,255,686	$ 75,738,650
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 11,961,869	$ 10,755,049
Deferred revenue, current	5,613,843	7,990,231
Derivative liabilities (note 1)	3,030,140	4,497,977
Total current liabilities	20,605,852	23,243,257
Deferred revenue, long-term	1,563,642	2,718,180
Total liabilities	22,169,494	25,961,437
Commitments and contingencies		
Stockholders equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,709,300 shares of Series A Non-Voting Convertible Preferred Stock outstanding in 2013 and 2012.	2,709	2,709
Common Stock, $.001 par value; 75,000,000 shares authorized; 38,015,518 and 37,497,703 shares issued; 38,000,027 and 37,482,212 shares outstanding in 2013 and 2012, respectively	38,016	37,499
Additional paid-in capital	147,149,696	143,703,583
Treasury stock, at cost, 15,491 shares, 2013 and 2012	(47,183)	(47,183)
Accumulated deficit	(120,057,046)	(93,919,395)
Total stockholders equity	27,086,192	49,777,213
Total liabilities and stockholders equity	$ 49,255,686	$ 75,738,650

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues:				
Product royalties	$ 855,101	$	$ 855,101	$
Research revenues				14,200
Contract revenues	1,908,949	16,297,972	3,530,926	32,802,137
Total Revenues:	2,764,050	16,297,972	4,386,027	32,816,337
Cost of product royalties	690,207	375,000	1,065,207	750,000
Expenses:				
Research and development	12,758,215	6,546,579	24,790,383	11,258,189
General and administrative	3,110,754	2,209,284	6,021,010	5,050,079
Related party general and administrative, net	13,000	19,500	29,500	45,750
Total Expenses:	15,881,969	8,775,363	30,840,893	16,354,018
(Loss) Income from operations	(13,808,126)	7,147,609	(27,520,073)	15,712,319
Interest income	96,006	63,501	168,516	120,117
Derivative gain (loss)	392,586	(3,478,793)	1,417,537	(5,346,039)
Other (expense) income, net	(95,477)	50,324	(118,631)	46,860
Net (loss) income before taxes	(13,415,011)	3,782,641	(26,052,651)	10,533,257
Income tax expense			(85,000)	
Net (loss) income attributable to common stockholders	(13,415,011)	$ 3,782,641	(26,137,651)	$ 10,533,257
Basic earnings per share:	$ (0.35)	$ 0.13	$ (0.69)	$ 0.36
Diluted earnings per share:	$ (0.35)	$ 0.12	$ (0.69)	$ 0.35

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

FOR THE SIX MONTHS ENDED JUNE 30, 2013

(Unaudited)

	Preferred Stock Series A		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Equity
Balances, January 1, 2013	2,709,300	$ 2,709	37,497,703	$ 37,499	$ 143,703,583	$ (47,183)	$ (93,919,395)	$ 49,777,213
Stock-based compensation					1,365,259			1,365,259
Restricted stock awards			12,111	12	(12)			
Shares issued to Arcion in acquisition of research and development license			500,516	500	2,071,636			2,072,136
Exercise of stock options			5,188	5	9,230			9,235
Net loss							(26,137,651)	(26,137,651)
Balances, June 30, 2013	2,709,300	$ 2,709	38,015,518	$ 38,016	$ 147,149,696	$ (47,183)	$ (120,057,046)	$ 27,086,192

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2013 AND 2012

(Unaudited)

	Six months Ended June 30, 2013	2012
Operating activities:		
Net (loss) income	$ (26,137,651)	$ 10,533,257
Adjustments to reconcile net (loss) income to net cash flows from operating activities:		
Depreciation and amortization	685,759	745,396
Derivative (gain) loss	(1,417,537)	5,346,039
Purchase of Arcion license with common stock	2,072,136	
Stock-based compensation expense	1,365,259	700,008
Changes in assets and liabilities:		
Accounts receivable	11,796	78,040
Prepaid expenses and other assets	(21,672)	100,759
Accounts payable and accrued expenses	1,121,820	751,170
Income tax payable	85,000	
Deferred revenue	(3,530,926)	14,697,863
Net cash flows from operating activities	(25,766,016)	32,952,532
Investing activities:		
Purchase of equipment	(1,648)	(24,792)
Purchase of intangible assets		(1,050,000)
Net cash flows from investing activities	(1,648)	(1,074,792)
Financing activities:		
Proceeds from exercise of stock options	9,235	410,402
Change in amounts due to related parties		(7,805)
Net cash flows from financing activities	9,235	402,597
Net change in cash and cash equivalents	(25,758,429)	32,280,337
Cash and cash equivalents at beginning of period	63,189,307	10,750,205
Cash and cash equivalents at end of period	$ 37,430,878	$ 43,030,542

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENT

FOR THE SIX MONTHS ENDED JUNE 30, 2013 AND 2012

(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 , together with Arius One and Arius Two, collectively, the Company or we , us or similar terminology) have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows at June 30, 2013, and for all periods presented, have been made. All intercompany accounts and transactions have been eliminated.

Certain information and note disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2012, which are included in the Company s 2012 Annual Report on Form 10-K, filed with the SEC on March 18, 2013 (the 2012 Annual Report). The accompanying condensed consolidated balance sheet at December 31, 2012 has been derived from the audited financial statements at that date, but does not include all information and notes required by GAAP for complete financial statements.

The Company is a specialty pharmaceutical company that is leveraging its novel and proprietary patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics. The Company is focusing on developing products to meet unmet patient needs in the areas of pain management and addiction.

The Company s pain franchise currently consists of three products, two of which utilize the patented BioErodible MucoAdhesive (BEMA) drug delivery technology, a thin film applied to the inner lining of the cheek. ONSOLIS (fentanyl buccal soluble film) is approved in the U.S., Canada, E.U. (where it is marketed as BREAKYL) and Taiwan (where it is marketed as PAINKYL), for the management of breakthrough pain in opioid tolerant, adult patients with cancer. The commercial rights to ONSOLIS are licensed to Meda AB (Meda) for all territories worldwide except for Taiwan (licensed to and TTY Biopharm Co. Ltd. (TTY)) and South Korea (licensed to Kunwha Pharmaceutical Co., Ltd. (Kunwha)). The Company s second pain product using the BEMA technology, BEMA Buprenorphine, is in Phase 3 clinical trials for the treatment of moderate to severe chronic pain and is licensed on a worldwide basis to Endo Health Solutions, Inc. (Endo). The Company s third pain product in development is Clonidine Topical Gel for the treatment of painful diabetic neuropathy, which was licensed from Arcion Therapeutics, Inc. (Arcion) in March 2013. Additionally, in July 2013, the Company filed a New Drug Application for BUNAVAIL (buprenorphine naloxone buccal film), a high dose formulation of buprenorphine in combination with naloxone for the maintenance treatment of opioid dependence.

The results of operations for the six month period ended June 30, 2013 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 2012 Annual Report.

BDSI® and BEMA® are registered trademarks of the Company. The BioDelivery Sciences logo and BUNAVAIL™ are trademarks owned by the Company. ONSOLIS® is a registered trademark of Meda Pharmaceuticals, Inc. ONSOLIS® is a registered trademark of Meda Pharmaceuticals, Inc. BREAKYL is a trademark owned by Meda Pharma GmbH & Co. KG. PAINKYL is a trademark owned by TTY Biopharm. All other trademarks and tradenames are owned by their respective owners.

As used herein, the term Common Stock means the Company s common stock, par value $.001 per share.

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENT

FOR THE SIX MONTHS ENDED JUNE 30, 2013 AND 2012

(Unaudited)

1. Basis of presentation (continued):

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

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

The following table summarizes assets and liabilities measured at fair value on a recurring basis at June 30, 2013 and December 31, 2012, respectively:

	June 30, 2013				December 31, 2012			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Fair Value Measurements Using:								
Assets								
Derivative asset (warrant)	$	$	$	$	$	$ 50,300	$	$ 50,300
Liabilities								
Derivative liabilities	$	$ 3,030,140	$	$ 3,030,140	$	$ 4,497,977	$	$ 4,497,977

The table below provides a reconciliation of the beginning and ending balances for the assets and liabilities measured at fair value using observable inputs (Level 2). The table reflects net gains and losses for all financial assets and liabilities categorized as Level 2 as of June 30, 2013 and December 31, 2012.

	$	Number of Warrants
Assets:		
Warrant asset as of December 31, 2012	$ 50,300	2,000,000
Decrease in fair value of warrants (Note 7)	(50,300)	(2,000,000)
Warrant asset as of June 30, 2013	$	
Liabilities:		
Warrant liability as of December 31, 2012	$ 4,497,977	2,009,436
Decrease in fair value of warrants	(1,467,837)	
Warrant liability as of June 30, 2013	$ 3,030,140	2,009,436

2. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, funded research arrangements and revenue generated as a result of its agreements with Meda regarding ONSOLIS® and Endo regarding BEMA® Buprenorphine. The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, royalty revenue, new sources of financing, existing and new licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

Significant new operating sources during the six months ended June 30, 2013 consisted of:

- approximately $0.9 million in net royalties under the Meda agreements.

Significant new operating sources during the year ended December 31, 2012 consisted of:

- approximately $45 million in upfront and milestone payments from the Endo license agreement (see note 4);
- approximately $38.4 million in net proceeds from a registered direct offering of Common Stock and newly designated Series A Non-Voting Convertible Preferred Stock, par value $.001 per share (the Series A Preferred) in November 2012;
- approximately $2.1 million from the exercise of stock options; and
- approximately $0.9 million from the exercise of Common Stock warrants.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENT

FOR THE SIX MONTHS ENDED JUNE 30, 2013 AND 2012

(Unaudited)

2. Liquidity and management s plans (continued):

On July 5, 2013, the Company, together with Arius One and Arius Two, entered into a $20 million secured loan facility pursuant to a Credit and Security Agreement (the Credit Agreement) with MidCap Financial SBIC, LP, as agent and lender (MidCap). The Company received net proceeds in the aggregate amount of $19.9 million and will use the loan proceeds for general corporate purposes or other activities permitted under the Credit Agreement. See Note 12.

At June 30, 2013, the Company had cash and cash equivalents of approximately $37.4 million. The Company used $25.8 million of cash from operations during the six months ended June 30, 2013. As of June 30, 2013, the Company had stockholders equity of $27.1 million, versus $49.8 million at December 31, 2012. The Company s existing cash (after giving effect to the proceeds of the loan from MidCap), supplemented with other expected cash inflows from milestones, royalties and the aforementioned loan, is anticipated by management to be sufficient to fully fund the Company s operations through the fourth quarter of 2014 at the planned level of expenditures. 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 be required to support commercialization activities for BUNAVAIL , clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of the Company s agreement with Endo), the reformulation project for and anticipated commercial relaunch of ONSOLIS®, planned development of the Company s Clonidine Topical Gel product for painful diabetic neuropathy and general working capital. Based on product development timelines and agreements with the Company s development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

3. Meda License, Development and Supply Agreements:

In August 2006 and September 2007, the Company entered into certain agreements with Meda to develop and commercialize the ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered through the BEMA® technology. The aforementioned agreements relate to the United States, Mexico and Canada (such agreements, the Meda U.S. Agreements) and to certain countries in Europe (such agreements, the Meda EU Agreements , together with Meda U.S. Agreements, the Meda Agreements). They carry license terms that 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 2017.

The Company has 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 are to be considered one combined unit of accounting since the fair value of the undelivered license was not determinable and the research and development efforts provided do not have stand-alone value apart from the license. As such, all cash payments from Meda that were related to these deliverables were recorded as deferred revenue. All cash payments from Meda for upfront and milestone payments and research and development services provided are nonrefundable. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain deliverables associated with research and development services were deliverable to Meda. The first commercial sale in the U.S. occurred in October 2009. As a result, $59.7 million of the aggregate milestones and services revenue was recognized as revenue. The first commercial sale in a European country occurred in October 2012. As a result, $17.5 million was recognized as revenue, which included $5.0 million in milestones received

during the year ended December 31, 2012. At June 30, 2013, there was remaining deferred revenue of $1.4 million which is related to the Meda research and development services. The Company has estimated the amount of time (based on expected man-days) and associated dollars (based on comparable services provided by outside third parties), as further noted below. As time progresses, the Company will continue to estimate the time required for ongoing obligations, and adjust the remaining deferred revenue accordingly on a quarterly basis.

In connection with delivery of the license to Meda, the Company has determined that each of the undelivered obligations have stand-alone value to Meda as these post-commercialization services encompass additional clinical trials on different patient groups but do not require further product development by the Company. These services and product supply obligations, if needed, 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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENT

FOR THE SIX MONTHS ENDED JUNE 30, 2013 AND 2012

(Unaudited)

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

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 to the Company from the third-party supplier of the product.

The arrangements do not contain any general rights of return. Therefore, the remaining deliverables to the arrangements will be accounted for as three separate units of accounting to include: (1) product supply, (2) research and development services for the non-cancer indication and further research and development of the first indication of the ONSOLIS® product and (3) the combined requirements related to the remaining other service-related obligations due to Meda to include participation in committees and certain other specified services. The remaining portion of the upfront payments of approximately $1.31 million (under the Meda U.S. Agreements) and $0.06 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.

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

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. The Company earned $0.9 million and $0 in product royalty revenue for the six months ended June 30, 2013 and 2012, respectively. The Company has incurred cost of product royalties of approximately $1.1 million and $0.8 million for the six months ended June 30, 2013 and 2012, respectively, which included minimum royalty expenses that the Company is obligated to pay CDC IV, LLC (CDC) and NB Athyrium LLC (Athyrium) regardless of actual sales.

On March 12, 2012, the Company announced the postponement of the U.S. re-launch of ONSOLIS® until the product formulation could be modified to address two appearance issues raised by the U.S. Food and Drug Administration (FDA) following an inspection of the Aveva manufacturing facility where ONSOLIS® is produced. The FDA requested that the Company identify, characterize and address the formation of microscopic crystals and a slight fading of the color during the 24-month shelf life of the product. While these changes do not affect the product s underlying integrity or safety, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and product specifications before additional product can be manufactured and distributed. Therefore, the U.S. re-launch and additional manufacturing of ONSOLIS® has been postponed until such product appearance issues have been resolved.

The crystal and fading issues for ONSOLIS® were presented to the FDA at a favorable meeting in December 2012. A data generation plan to support the approval of a new formulation that resolved both issues was submitted to FDA in March 2013 and followed by initiation of manufacturing in second quarter. Submission of initial stability results for the new formulation is expected early in 2014 with approval by mid-year and re-launch of ONSOLIS® in the second half of 2014.

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

On September 13, 2012, the Company executed a Manufacturing, Supply, and License Agreement, effective April 26, 2012, with LTS Lohmann Therapie-Systeme AG (LTS), under which LTS will manufacture and supply the Company its BREAKYL product for distribution outside of the U.S. and Canada. The Company is required to supply BREAKYL product to Meda, Kunwha and TTY pursuant to its obligations under certain

license and supply agreements under which Meda, Kunwha, and TTY develop and commercialize the BREAKYL product. In conjunction with the agreement, LTS has waived all royalties on products that they produce. This does not preclude royalties that the Company owes to LTS if the Company produces BREAKYL with another company.

4. Endo License and Development Agreement:

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENT

FOR THE SIX MONTHS ENDED JUNE 30, 2013 AND 2012

(Unaudited)

4. Endo License and Development Agreement (continued):

Pursuant to the Endo Agreement, Endo has obtained all rights necessary to complete the clinical and commercial development of BEMA® Buprenorphine and to sell the product worldwide. Although Endo has obtained all such necessary rights, the Company has agreed under the Endo Agreement to be responsible for the completion of certain clinical trials regarding BEMA® Buprenorphine (and providing clinical trial materials for such trials) necessary to submit a New Drug Application (NDA) to the FDA in order to obtain approval of BEMA® Buprenorphine in the U.S., in each case pursuant to a development plan set forth in the Endo Agreement (as it may be amended pursuant to the Endo Agreement). The Company is responsible for development activities through the filing of the NDA in the U.S., while Endo is responsible for the development following the NDA submission as well as the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis. In addition, Endo is responsible for all filings required in order to obtain regulatory approval of BEMA® Buprenorphine.

Pursuant to the Endo Agreement, the Company has received (or is expected to receive upon satisfaction of applicable conditions) the following payments (some portion(s) of which will be utilized by the Company to support its development obligations under the Endo Agreement with respect to BEMA® Buprenorphine):

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

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

At the inception of the Endo arrangement and in accordance with the revenue recognition criteria under ASC Topic 605, the Company determined that the Endo Agreement is a multi-deliverable arrangement under ASC Topic 605 with three deliverables: (1) the license rights related to BEMA® Buprenorphine, (2) services related to obtaining enhanced intellectual property rights through the issuance of a particular patent and (3) clinical development services. The Company concluded that the license delivered to Endo at the inception of the Endo Agreement has stand-alone value under ASC 605-25 because Endo obtained, at the inception of the Endo Agreement, all of the rights and knowledge necessary to fully exploit its license without the Company s further involvement. It was also determined that there was a fourth deliverable, the

provision of clinical trial material (CTM). The amounts involved are, however, immaterial and delivered in essentially the same time frame as the clinical development services. Accordingly, the Company has not separately accounted for the CTM deliverable, but considers it part of the clinical development services deliverable.

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

Based on this analysis, $15.6 million of the up-front license fee was allocated to the license (which was estimated to have a value significantly in excess of $30 million), and $14.4 million to clinical development services (which is inclusive of the cost of CTM). Although the intellectual property component was considered a separate deliverable, no distinct amount of the up-front

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4. Endo License and Development Agreement (continued):

payment was assigned to this deliverable because the Company determined the deliverable to be perfunctory. In April 2012, the patent being sought by the Company was granted as described further below, and in May 2012, the applicable intellectual property milestone payment of $15 million was received and recognized as revenue. The amount allocated to the license was recognized as revenue in January 2012.

The portion of the upfront license fee allocated to the clinical development services deliverable ($14.4 million) is being recognized as those services are performed. The Company estimates that such clinical development services will extend into early 2014. Based on the estimated proportion of those services performed through June 30, 2013, $5.2 million was recognized as revenue in fiscal year 2012 and $3.4 million was recognized as revenue during the first six months of 2013. As a result, $5.9 million remains deferred at June 30, 2013.

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

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

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

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

5. Arcion License Agreement:

On March 26, 2013, the Company entered into a definitive Exclusive License Agreement (the Arcion Agreement) with Arcion pursuant to which Arcion agreed to grant to the Company an exclusive commercial world-wide license, with rights of sublicense, under certain patent and other intellectual property rights related to in-process research and development to develop, manufacture, market, and sell gel products containing clonidine (or a derivative thereof), alone or in combination with other active ingredients, for topical administration for the treatment of painful diabetic neuropathy and other indications (the Arcion Products).

Pursuant to the Arcion Agreement, the Company is responsible for using commercially reasonable efforts to develop and commercialize Arcion Products, including the use of such efforts to conduct certain clinical trials within certain time frames.

Upon execution of the Arcion Agreement, the Company issued to Arcion 500,516 unregistered shares of Common Stock (having a fair market value of $2.1 million), which shares are subject to a nine month lock-up and certain limitations on sale thereafter. The issuance of such shares (delivered April 2013) was exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(2) thereof. In addition, the Company is required to make the following payments to Arcion:

$2.5 million upon filing and acceptance by the FDA of an NDA with respect to an Arcion Product, payable at the Company s option, in cash or unregistered shares of Common Stock (with such shares also being subject to a nine month lock-up and certain limitations on sale thereafter); and

up to a potential $60 million in cash payments upon achieving certain pre-determined sales thresholds in the U.S., none of which occur prior to achieving at least $200 million in U.S. net sales.

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5. Arcion License Agreement (continued):

In addition, the Company shall pay Arcion $35 million in cash on initial FDA approval of an Arcion Product, unless; (i) the Company does not receive at least $70 million in FDA approval-related milestone payments from its US sublicensees (if any sublicenses are involved) with respect to the Arcion Product, in which case the Company shall pay Arcion a prorated amount between $17.5 million and $35 million based on the total amount of such milestone payments received by the Company and its affiliates from its sublicenses (if any sublicenses are involved); or (ii) the FDA requires or recommends the performance of a capsaicin challenge test as a precondition or precursor to the prescribing of the Arcion Product (as a condition of approval, a labeling requirement, or otherwise), in which case such milestone shall be reduced to $17.5 million, but the first and second sales threshold payments described above shall each be increased by $8 million.

All milestone payments due Arcion under the Arcion Agreement are payable only once each.

In addition to the milestones set forth above, the Company will pay Arcion:

- a low single digit royalty on the Company s and its affiliates net sales of Arcion Products in the U.S.;
- a low double digit percentage of all sales-based payments received by the Company and its affiliates with respect to sublicensees sales of Arcion Products in the U.S.;
- a low single digit royalty on all net sales of Arcion Products outside the U.S.; and
- a low double digit percentage of all milestone payments received by the Company and its affiliates from their sublicensees that are triggered by the receipt of regulatory approval of the Arcion Product in certain jurisdictions outside of the U.S.

The aforementioned sales royalties are subject to certain reductions, on a country-by-country and product-by-product basis, under certain agreed upon circumstances. In addition, in the event the amount due upon FDA approval of the Arcion Product in the U.S. is less than $35 million for any reason other than an FDA requirement or recommendation of a capsaicin challenge test, as described above, the Company shall pay Arcion a portion of any milestone payments received by the Company and its affiliates from their sublicensees on the basis of any events occurring in the U.S. following FDA approval but prior to (and including) first commercial sale of an Arcion Product in the U.S., and certain of the payments to Arcion referred to above shall also be subject to upward adjustment (with such upward adjustments payable in the form of cash or unregistered shares of the Company s Common Stock, as elected solely by the Company), until such time as the sum of all such additional payments and upward adjustments (including the value of any issuances of stock, if elected by the Company) and the initial amount paid on the initial FDA approval totals $35 million.

The term of the Arcion Agreement continues, on a country-by-country and product-by-product basis, until the earlier of (i) the expiration of the royalty term for a particular Arcion Product in a particular country or (ii) the effective date of termination by either party pursuant to customary termination provisions. The royalty term for any given country is the later of (i) the first date there are no valid claims against any Arcion patent, (ii) expiration of patent exclusivity or (iii) tenth anniversary of the first commercial sale. Further, the Company may, in its sole discretion, terminate the Arcion Agreement upon certain notice to Arcion. Upon expiration of the Agreement pursuant to clause (i) above with respect to a particular Arcion Product and country, the Company and its affiliates shall have the perpetual, unrestricted, irrevocable, fully-paid, royalty-free

exclusive right, with rights of sublicense, to make, have made, use, sell, offer for sale, and import such Arcion Product in such country.

In conjunction with this transaction, the March 2013 payment to Arcion of $2.1 million in unregistered Common Stock was for in-process research and development and has been recorded as research and development expense in the condensed consolidated statement of operations for the six months ended June 30, 2013.

6. 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 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.

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6. Other License Agreements and Acquired Product Rights (Continued):

Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for BEMA® Fentanyl in the Kunwha Territory, while the Company will retain all other licensing rights to the Licensed Product not previously granted to third parties. Kunwha paid to the Company an upfront payment of $0.3 million (net of taxes approximating $0.25 million) and will be responsible to make certain milestone payments which could aggregate up to $1.3 million (net of taxes approximating $1.1 million).

In addition, Kunwha will pay royalties to the Company based on Net Sales (as defined in the Kunwha License Agreement) and will purchase all supplies of 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.

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 in 2010. 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 had 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 and recorded as contract revenue in 2011.

On July 29, 2013, the Company announced the regulatory approval of BEMA® Fentanyl in Taiwan, where the product will be marketed under the brand name PAINKYL . The approval in Taiwan results in a milestone payment of $0.3 million to the Company, which is expected to be received in the third quarter 2013.

Agreement with Tolmar to Purchase BEMA® Rights

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

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

On January 5, 2012, the Company and Arius Two executed a letter agreement with Tolmar and its parent company, TOLMAR Holding, Inc., whereby the parties agreed that, if Arius Two paid Tolmar $1.05 million by February 28, 2012, Tolmar would accept such payment as satisfaction in full of the remaining $2 million outstanding under the Tolmar note (pursuant to which the Company

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

acquired the North American rights to the BEMA® technology) and, upon receipt of such payment (i) the related security agreements, security interests, liens, guaranties and payment obligations with respect to such note and the assets securing its repayment would terminate, (ii) Tolmar would execute a corresponding release and (iii) neither the Company nor Arius Two will have any further payment obligations to Tolmar under the note or BEMA® acquisition documents, except with respect to certain indemnification obligations of Arius Two. Arius Two paid the $1.05 million contemplated by the letter agreement on January 6, 2012, fully satisfying the outstanding balance of the note, and Tolmar subsequently executed its final release of the related security interests contemplated by the letter agreement. As a result, the Company now owns all rights to the BEMA® technology on a worldwide basis.

7. 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. During the six months ending June 30, 2013, Biovest filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code with the United States Bankruptcy Court. On July 9, 2013, the plan became effective, which canceled all outstanding common stock. As a result, the warrants had no value as of June 30, 2013 and the reduction of value is included in derivative gain (loss) in the condensed consolidated statement of operations for the three and six months ended June 30, 2013.

8. 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.

9. Stockholders Equity:

Stock-based compensation:

During the six months ended June 30, 2013, a total of 116,242 options to purchase Common Stock with an aggregate fair market value of approximately $0.3 million were granted to Company employees. The options granted have a term of 10 years from the grant date. The options vest ratably over a three year period. The fair value of each option is amortized as compensation expense evenly through the vesting period. The fair value of each option award is estimated on the grant date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from historical volatility of the Common Stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average

for key assumptions used in determining the fair value of options granted during the six months ended June 30, 2013 follows:

Expected price volatility	80.63%
Risk-free interest rate	0.81%
Weighted average expected life in years	6 years
Dividend yield	

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9. Stockholders Equity (continued):

Option activity during the six months ended June 30, 2013 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2013	4,279,919	$ 3.70	
Granted in 2013:			
Officers and Directors			
Others	116,242	4.41	
Exercised	(5,188)	1.78	
Forfeitures	(183,431)	2.50	
Outstanding at June 30, 2013	4,207,542	$ 3.78	$ 3,541,910

Options outstanding at June 30, 2013 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.00 5.00	3,301,042	5.68	$ 3.08	
$5.01 10.00	906,500	4.17	$ 6.30	
	4,207,542			$ 3,541,910

Options exercisable at June 30, 2013 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	2,724,616	5.27	$ 3.03	
$5.01 10.00	906,500	4.17	$ 6.30	

	3,631,116		$ 2,982,037

The weighted average grant date fair value of options granted during the six months ended June 30, 2013 was $2.81. There were no options granted during the six months ended June 30, 2013 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, 2013, and changes during the six months ended June 30, 2013 is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Nonvested at January 1, 2013	853,640		
Granted	116,242		
Vested	(240,175)		
Forfeited	(153,281)		
Nonvested at June 30, 2013	576,426	$ 2.24	$ 559,873

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9. Stockholders Equity (continued):

As of June 30, 2013, there was approximately $8.5 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed through 2019.

Warrants:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. Warrants outstanding at June 30, 2013, 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	2,009,436	1.40	$ 3.88	$ 1,128,531

Midcap:

The Company issued warrants to purchase 357,356 shares of Common Stock at a price of $4.20 in connection with a loan financing in July 2013. The warrants had a fair value of $1.5 million at the date of the grant. (See Note 12 for a description of the Midcap loan transaction). These warrants are not included in the table above.

Restricted Stock Units:

During the six months ended June 30, 2013, a total of 1,078,336 restricted stock units (RSUs) with a fair market value of approximately $4.5 million were granted to members of the Company s senior management. 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 RSUs were issued under the Company s 2011 Equity Incentive Plan, as amended, and vest in equal installments over three years. This grant was in lieu of the 2012 annual option grant typically given to senior management in order to bring the percentage ownership of our senior management in line with the senior management of companies in the Company s peer group.

In addition, in June 2013, the Company issued 3,125 new hire RSUs with a fair value of $0.01 million to a board member, which vested immediately.

Preferred Stock

The Company had authorized five million blank check shares of $.001 par value convertible preferred stock. At June 30, 2013, 2,709,300 shares of Series A Preferred were outstanding.

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10. Earnings per Common Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Basic:				
Net (loss) income attributable to common stockholders	$ (13,415,011)	$ 3,782,641	$ (26,137,651)	$ 10,533,257
Weighted average common shares outstanding	37,998,610	29,669,058	37,756,309	29,615,357
Basic earnings per common share	**$ (0.35)**	**$ 0.13**	**$ (0.69)**	**$ 0.36**
Diluted:				
Effect of dilutive securities:				
Net (loss) income attributable to common stockholders	$ (13,415,011)	$ 3,782,641	$ (26,137,651)	$ 10,533,257
Adjustments to Income for Dilutive options and warrants				
	(13,415,011)	3,782,641	(26,137,651)	10,533,257
Weighted average common shares outstanding	37,998,610	29,669,058	37,756,309	29,615,357
Effect of Dilutive options and warrants		1,476,918		532,729
Diluted weighted average common shares outstanding	37,998,610	31,145,976	37,756,309	30,148,086
Diluted earnings per common share	**$ (0.35)**	**$ 0.12**	**$ (0.69)**	**$ 0.35**

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. In addition to the weighted average shares of Common Stock outstanding, common equivalent shares from stock options and warrants using the treasury stock method, are included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the six months ended June 30, 2013 and 2012, outstanding stock options and warrants of 6,216,978 and 3,047,964, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods.

The following is the total outstanding options and warrants for the six months ended June 30, 2013 and 2012, respectively.

	June 30, 2013	June 30, 2012
Options and warrants to purchase Common Stock	6,216,978	6,998,847

11. 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 the United States Patent and Trademark Office (USPTO) of reexamination proceedings and follows the recent rejection by the USPTO of all claims in all three patents asserted by MonoSol against the Company and its commercial partners for ONSOLIS®.

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11. Commitments and contingencies (continued):

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.

On January 23, 2013, the USPTO issued a Right of Appeal Notice, rejecting all claims of the 588 Patent and closing reexamination proceedings. 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. On February 22, 2013, MonoSol filed both a Notice of Appeal to the Board of Patent Appeals and Interferences and a Request for Continuing Examination of the 588 Patent. Subsequently, on July 3, 2013, the USPTO denied MonoSol s February 22, 2013 Request to Continue Examination.

Inter partes reviews, a new USPTO process to review the patentability of one or more claims of patents, was enacted in September, 2012. As such, on June 12, 2013, despite the Company s previously noted success in the prior ex parte reexaminations for the 292 and 891 patents, the Company availed themselves of this new process and filed requests for inter partes reviews on the narrowed yet reexamined patents, the 292C1 and 891C1 Patents, to challenge their validity and continue to strengthen the Company s position. This inter partes review process allows the Company to actively participate in the reviews and address any of MonoSol s arguments and representations made during the review process, which heightens the Company s ability to invalidate these patents. The Company is awaiting the USPTO s decision as to whether they will accept the Company s requests for these reviews. (See Part II, Item 1, Legal Proceedings).

12. Subsequent event:

Midcap:

On July 5, 2013, the Company, Arius One and Arius Two (the Borrowers) entered into a $20 million secured loan facility (the Loan Transaction and such loan, the Loan) with MidCap as agent and lender pursuant to the terms and conditions of the Credit Agreement. The Company received net proceeds in the aggregate amount of $19.9 million and will use the Loan proceeds for general corporate purposes or other activities of the Borrower permitted under the Credit Agreement.

In addition, pursuant to the Loan Transaction, the Company issued to MidCap a warrant (the MidCap Warrant) to purchase 357,356 unregistered shares of Common Stock, which warrant has an exercise price of $4.20 per share, the 20-day volume-weighted average share price of the Common Stock prior to the closing of the Loan. The MidCap Warrant is exercisable for a term of five (5) years and contains cashless exercise provisions and customary, stock-based anti-dilution protection provisions.

The Loan has a term of 36 months with interest only payments for the first 6 months. The interest rate is 8.45% plus a LIBOR floor of 0.5%. Upon execution of the Credit Agreement, the Company paid to MidCap a closing fee of 0.5% of the aggregate Loan amount. Upon repayment in full of the Loan, the Company is obligated to make a final payment fee equal to 3.5% of the aggregate Loan amount. In addition, the Company may prepay all or any portion of the Loan at any time subject to a prepayment premium of: (i) 5% of the Loan amount prepaid in the first year of the Loan and (ii) 3% of the Loan amount prepaid in each year thereafter. In addition, if the Company receives the second of two anticipated database lock milestone payments (the Database Lock Payments) from Endo in connection with the Endo Agreement, the Company may prepay 50% of the principal amount of the Loan then outstanding and, concurrently and at the Company s election, either: (i) pay to MidCap a cash prepayment fee of 2% of the principal amount of the Loan and all obligations thereunder outstanding as of the date of prepayment or (ii) issue to MidCap a warrant (in a form substantially similar to the MidCap Warrant) to purchase shares of Common Stock equal to 2.0% of the

prepayment amount, with the number of shares being calculated using the Black-Scholes pricing model.

The obligations of the Borrowers under the Credit Agreement are secured by a first priority lien in favor of MidCap on substantially all of the Borrowers existing and after-acquired assets, but excluding certain of the Borrowers intellectual property and general intangible assets of the Borrowers (but not any proceeds thereof). The obligations of the Company under the Loan Agreement are also secured by a first priority lien on the equity interests held by the Company in Arius One, Arius Two and BND. The Borrowers entered into customary pledge and intellectual property security agreements to evidence the security interest in favor of MidCap.

Under the Credit Agreement, the Borrowers are subject to affirmative covenants which are customary for financings of this type, including the obligations of the Borrowers to: (i) maintain good standing and governmental authorizations, (ii) provide certain information and notices to MidCap, (iii) deliver monthly and annual financial statements to MidCap, (iv) maintain insurance, (v) discharge all taxes, (vi) protect their intellectual property and (vii) generally protect the collateral granted to MidCap.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENT

FOR THE SIX MONTHS ENDED JUNE 30, 2013 AND 2012

(Unaudited)

12. Subsequent event (continued):

The Borrowers are also subject to negative covenants customary for financings of this type, including that they may not: (i) enter into a merger or consolidation or certain change of control events, (ii) incur liens on the collateral, (iii) incur additional indebtedness, (iii) dispose of any property, (iv) amend material agreements or organizational documents, (v) change their jurisdictions of organization or their organizational structures or types, (vi) declare or pay dividends (other than dividends payable solely in Common Stock), (vii) make certain investments or acquisitions, or (viii) enter into certain transactions with affiliates, in each case subject to certain exceptions provided for in the Credit Agreement, including exceptions that allow the Borrowers to acquire additional products and to enter into licenses and similar agreements provided certain conditions are met.

The Credit Agreement provides that events of default include: (i) failure to make payment of principal or interest on the Loan when required, (ii) failure to perform obligations under the Credit Agreement and related documents, (iii) defaults in other indebtedness and breaches of material agreements of the Borrowers, (iv) if any Borrower shall generally not pay its debts as such debts become due and similar insolvency matters, (v) material adverse changes to the Borrowers (subject to a 10-day notice and cure period), (vi) if the Company ceases to be a publicly-listed and reporting company, (vii) failure to receive the Database Lock Payments by June 30, 2014, and (viii) certain other events, including certain adverse actions taken by the Food and Drug Administration or other governmental authorities. Upon an event of default, the Borrower s obligations under the Credit Agreement may, or in the event of insolvency or bankruptcy will automatically, be accelerated. Upon the occurrence of any event of default, the Borrower s obligations under the Credit Agreement will bear interest at a rate equal to the lesser of: (i) 4% above the rate of interest applicable to such obligations immediately prior to the occurrence of the event of default and (ii) the maximum rate allowable under law.

TTY Biopharm:

On July 29, 2013, the Company announced the regulatory approval of ONSOLIS® in Taiwan for the management of breakthrough cancer pain in opioid tolerant, adult patients with cancer.

In Taiwan, the Company has licensed the commercialization rights to TTY, where the product will be marketed under the brand name PAINKYL . TTY will be responsible for the cost of future product commercialization in Taiwan and expects to launch PAINKYL following receipt of reimbursement pricing from the Taiwanese national healthcare system. The approval in Taiwan results in a milestone payment of $0.3 million to the Company, which is expected to be received in the third quarter 2013. Upon launch, the Company will receive a royalty on net sales.

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

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

For the three months ended June 30, 2013 compared to the three months ended June 30, 2012

Product Royalty Revenues. We recognized $0.9 million in product royalty revenue during the three months ended June 30, 2013 under our license agreement with Meda. No such revenue was reported in the corresponding period of 2012. The product royalty revenues can be attributed to the commercial launch of BREAKYL in the EU in October 2012.

Contract Revenues. We recognized $1.9 million and $16.3 million in contract revenue during the three months ended June 30, 2013 and 2012, respectively, under the Endo Agreement. The 2012 amount included a $15 million payment received from Endo in May 2012 for a milestone associated with the granting of a certain patent. We also recognized $0.05 million during both of the three months ended June 30, 2013 and 2012, in contract revenue related to previously deferred revenue under our license agreement with Meda.

Cost of Product Royalties. We recognized $0.7 million and $0.4 million in cost of product royalties during the three months ended June 30, 2013 and 2012, respectively. Both periods include minimum quarterly payments to CDC and the 2013 period also includes cost of product royalties in support of the EU commercial launch of BREAKYL .

Research and Development Expenses. During the three months ended June 30, 2013 and 2012, research and development expenses totaled $12.8 million and $6.5 million, respectively. The increase in research and development expenses can be attributed to the two pivotal pain and one safety trial underway pursuant to the Endo Agreement for our Buprenorphine chronic pain program. Also contributing to the 2013 increase was the completion of the BUNAVAIL program for the treatment of opioid dependence and compilation of the NDA, as well as $2.1 million of in-process research and development (paid in Common Stock) associated with the aforementioned license agreement with Arcion. Our scientific staff continues to work toward development and application of our BEMA® delivery technology, particularly with respect to ONSOLIS®, BEMA® Buprenorphine for chronic pain and BUNAVAIL for the treatment of opioid dependence. Funding of this research in 2013 and 2012 was obtained through contract revenue, deferred license revenue, a private placement stock offering, exercise of options by employees and directors and sales of securities. Research and development expenses generally include compensation for scientific personnel, research supplies, facility rent, manufacturing equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA® drug delivery technologies.

General and Administrative Expenses, net. During the three months ended June 30, 2013 and 2012, general and administrative expenses totaled $3.1 million and $2.2 million, respectively. General and administrative costs include legal, accounting and management wages, legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. The increase in general and administration expenses can be primarily attributed to stock compensation expense, which was $0.8 million and $0.2 million for the three months ended June 30, 2013 and 2012, respectively.

Interest Income. During the three months ended June 30, 2013 and 2012 we had interest income of $0.1 million and $0.06 million, respectively.

Derivative gain (loss). Our derivative liability consists of free standing warrants measured at their fair market value, using the Black-Scholes method. During the three months ended June 30, 2013, our stock price decreased. This is the largest component of the Black-Scholes change. As a result, our warrant liability also decreased, resulting in a $0.4 million gain. This gain was offset by a $0.03 million loss from 2 million shares of Biovest related party warrants that we wrote off. During the three months ended June 30, 2012, our stock price increased. Therefore, our derivative liability increased, resulting in a $3.2 million loss. Also included in the 2012 loss was a $0.3 million loss on the value of our former Biovest warrant.

For the six months ended June 30, 2013 compared to the six months ended June 30, 2012

Product Royalty Revenues. We recognized $0.9 million in product royalty revenue during the six months ended June 30, 2013 under our license agreement with Meda. No such revenue was reported during the corresponding period of 2012. The increase in product royalty revenues can be attributed to the commercial launch of BREAKYL in the EU in October 2012.

Research Revenues. We recognized $0.01 million of revenue related to a research and development agreement with Meda during the six months ended June 30, 2012. There was no research revenue during the six months ended June 30, 2013.

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Contract Revenues. We recognized $3.4 million and $32.8 million in contract revenue during the six months ended June 30, 2013 and 2012, respectively, under the Endo Agreement. The 2012 amount includes $15.6 million of the $30 million up-front license fee from Endo received in January 2012 ($14.4 million was recorded as deferred contract revenue), $15 million received from Endo in May 2012 for a milestone associated with the granting of a certain patent and $2.1 million in previously deferred contract revenue. We also recognized $0.1 million during both of the six months ended June 30, 2013 and 2012, in contract revenue related to previously deferred revenue under our license agreement with Meda.

Cost of Product Royalties. We recognized $1.1 million and $0.8 million in cost of product royalties during the six months ended June 30, 2013 and 2012, respectively. Both periods include minimum quarterly payments to CDC and the 2013 period also includes cost of product royalties in support of the EU commercial launch of BREAKYL .

Research and Development Expenses. During the six months ended June 30, 2013 and 2012, research and development expenses totaled $24.8 million and $11.3 million, respectively. The increase in research and development expenses can be attributed to the two pivotal pain and one safety trials underway pursuant to the Endo Agreement for our Buprenorphine chronic pain program. Also contributing to the 2013 increase was the completion of the BUNAVAIL program for the treatment of opioid dependence and compilation of the NDA, as well as $2.1 million of in-process research and development (paid in Common Stock) associated with the aforementioned license agreement with Arcion. Our scientific staff continues to work toward development and application of our BEMA® delivery technology, particularly with respect to ONSOLIS®, BEMA® Buprenorphine for chronic pain and BUNAVAIL for the treatment of opioid dependence. Funding of this research in 2013 and 2012 was obtained through contract revenue, deferred license revenue, a private placement stock offering, exercise of options by employees and directors and sales of securities. Research and development expenses generally include compensation for scientific personnel, research supplies, facility rent, manufacturing equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA® drug delivery technologies.

General and Administrative Expenses, net. During the six months ended June 30, 2013 and 2012, general and administrative expenses totaled $6 million and $5.1 million, respectively. General and administrative costs include legal, accounting and management wages, legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. The increase in general and administration expenses can be primarily attributed to stock compensation expense, which was $1.4 million and $0.7 million for the six months ended June 30, 2013 and 2012, respectively.

Interest Income. During the six months ended June 30, 2013 and 2012 we had interest income of $0.2 million and $0.1 million, respectively.

Derivative gain (loss). Our derivative liability consists of free standing warrants measured at their fair market value, using the Black-Scholes method. During the six months ended June 30, 2013, our stock price decreased. This is the largest component of the Black-Scholes change. As a result, our warrant liability also decreased, resulting in a $1.5 million gain. This gain was offset by a $0.05 million loss from 2 million shares of Biovest related party warrants that we wrote off. During the six months ended June 30, 2012, our stock price increased. Therefore, our derivative liability increased, resulting in a $5.4 million loss. This loss was offset by a $0.01 million gain on the value of our former 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 generated as a result of our worldwide license and development agreement with Meda regarding ONSOLIS® and revenue generated as a result of our January 2012 agreement with Endo regarding our BEMA® Buprenorphine product candidate. We intend to finance our research and development, commercialization efforts and our working capital needs from existing cash, royalty revenue, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

At June 30, 2013, we had cash and cash equivalents of approximately $37.4 million. We used $25.8 million of cash from operations during the six months ended June 30, 2013. As of June 30, 2013, we had stockholders equity of $27.1 million versus $49.8 million at December 31, 2012. Our existing cash as of the date of this Report (including proceeds of our $20 million loan transaction in July 2013), together with other expected cash inflows from other milestones and royalties, is anticipated by management to be sufficient to fully fund our planned level of operations through the fourth quarter of 2014.

Additional capital may be required to support commercialization activities for BUNAVAIL™, clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of our agreement with Endo), the reformulation project for and anticipated commercial relaunch of ONSOLIS®, planned development of Clonidine Topical Gel produced for painful diabetic neuropathy and general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may

be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

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Also, product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

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

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;
- sale of product royalty;
- grants and new license revenues;
- bank loans;
- equipment financing;
- public or private debt; and
- exercise of existing warrants and options.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from potential commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, any of which could have a material adverse effect on us, our financial condition and our results of operations in 2013 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

If we are unable to attract additional funds on commercially acceptable terms, it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of June 30, 2013 are as follows:

		Payments Due by Period			
	Total	**Less than**	**1-3 years**	**3-5 years**	**More than**

		1 year			5 years
Operating lease obligations	$ 206,408	$ 116,991	$ 89,417	$	$
Employment agreements	386,292	386,292			
Minimum royalty expenses*	9,750,000	1,500,000	3,000,000	3,000,000	2,250,000
Total contractual cash obligations**	$ 10,342,700	$ 2,003,283	$ 3,089,417	$ 3,000,000	$ 2,250,000

* 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.

On July 5, 2013, we entered into a $20 million secured loan facility with MidCap Financial SBIC, LP. The Loan has a term of 36 months with interest only payments for the first 6 months. The interest rate is 8.45% plus a LIBOR floor of 0.5%. (See Note 12). This obligation is not included in the table above.

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Off-Balance Sheet Arrangements

As of June 30, 2013, we had no off-balance sheet arrangements.

Effects of Inflation

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

Critical Accounting Policies

Valuation of Goodwill and Intangible Assets

Our intangible assets include goodwill, product rights, and licenses, all of which are accounted for based on GAAP related to Goodwill and Other Intangible Assets. Accordingly, goodwill is not amortized but is tested annually in December for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with limited useful lives are amortized using the straight-line method over their estimated period of benefit, ranging from eleven to thirteen years. Our carrying value of goodwill at June 30, 2013 was $2.715 million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements or the underlying patents. Our carrying value of other amortizing intangible assets at June 30, 2013 was $5.7 million, net of accumulated amortization of $5.3 million. We begin amortizing capitalized intangibles on their date of acquisition.

Impairment Testing

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

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

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

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

There were no impairment charges during the six months ended June 30, 2013 or 2012.

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.

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Revenue recognition

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents include Ultra Short Term Government Funds. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation (FDIC) covers $250,000 for substantially all depository accounts. We may from time to time have amounts on deposit in excess of the insured limits. As of June 30, 2013, we had approximately $36.9 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.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Based on this evaluation, the Certifying Officers have concluded that our disclosure controls and procedures were 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 second fiscal quarter of 2013 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.

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations (and the Liquidity and Capital Resources section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes forward-looking statements within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as projects , may , could , would , should , believes , expects , anticipates , estimates , intends , plans or similar expressions. These statements are based upon the c and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) actual sales results and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s review and/or approval and commercial launch of our products and product candidates and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1A of our 2012 Annual Report and other factors detailed from time to time in our other filings with the SEC. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Quarterly Report. We undertake no obligation to publically update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On November 2, 2010, MonoSol Rx, LLC (MonoSol) filed an action against us and our 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 BUNAVAIL™, 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.

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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 (Reexamined Patent No. 7,357,891 C1 or the 891C1 Patent). A Reexamination Certificate for MonoSol s 292 Patent in its amended form was issued on July 3, 2012 (Reexamined Patent No. 7,425,292C1 or the 292C1 Patent). 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.

Inter partes reviews, a new USPTO process to review the patentability of one or more claims of patents, was enacted in September, 2012. As such, on June 12, 2013, despite our previously noted success in the prior ex parte reexaminations for the 292 and 891 Patents, we availed ourselves of this new process and filed requests for inter partes reviews on the narrowed yet reexamined patents, the 292C1 and 891C1 Patents, to challenge their validity and continue to strengthen our position. This inter partes review process allows us to actively participate in the reviews and address any of Monosol s arguments and representations made during the review process, which heightens our ability to invalidate these patents. We are awaiting the USPTO s decision as to whether they will accept our requests for these reviews. Regardless, our assertion that our products and technologies do not infringe the original 292 and 891 Patents and, now, the reexamined 891C1 and 292C1 Patents remains the same.

Importantly, in the case of MonoSol s 588 Patent, the USPTO on July 20, 2012 issued a second Office Action closing prosecution and rejecting for a second time all claims as anticipated or obvious. It also rejected the amended claims proposed by MonoSol as unclear and lacking support. Then, on January 23, 2013, the USPTO issued a Right of Appeal Notice, rejecting all claims of the 588 Patent and closing reexamination proceedings. 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. On February 22, 2013, MonoSol filed both a Notice of Appeal to the Board of Patent Appeals and Interferences and a Request for Continuing Examination of the 588 Patent. On March 12, 2013, we filed a petition requesting the USPTO to deny Monosol s February 22, 2013 Request to Continue Examination and to allow the proceedings to go to an appeal. Subsequently, on July 3, 2013, the USPTO denied Monosol s February 22, 2013 Request to Continue Examination. With all 588 Patent claims still rejected, we are now awaiting the USPTO s next action, which would likely include the formal initiation of the appeal with the Board of Patent Appeals and Interferences.

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 us while the third has 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 891patents in light of their reissuance with fewer and narrower claims were indeed invalid and the third and final patent, 588, has had all claims rejected and appears to have had 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.

Item 1A. Risk Factors.

The Company hereby updates its risk factors to add the following risk factor relating to its July 2013 $20 million credit facility with MidCap Financial.

Our Credit Agreement with MidCap Financial SBIC, LP (MidCap) contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect under our Credit Agreement if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

In July 2013, we entered into a Credit Agreement with MidCap whereby we received a loan in the aggregate amount of $20.0 million. The agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

incur or assume certain debt;

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merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;

change the nature of our business;

change our organizational structure or type;

amend, modify or waive any of our organizational documents;

license, transfer or dispose of certain assets;

grant certain types of liens on our assets;

make certain investments;

pay cash dividends;

enter into material transactions with affiliates; and

amend or waive provisions of material agreements in certain manners.

The restrictive covenants of the Credit Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial. A breach of any of these covenants could result in an event of default under the Credit Agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the Credit Agreement occurs. In the case of a continuing event of default under the agreement, MidCap could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, proceed against the collateral in which we granted MidCap a security interest under the Credit Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the Credit Agreement are secured by all of our existing and future assets (excluding certain intellectual property).

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to make any required prepayment or repay such indebtedness at the time any such prepayment event or event of default occurs. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result.

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® until the product formulation could be modified to address two appearance issues raised by FDA following an inspection of the Aveva manufacturing facility where ONSOLIS® is produced, the FDA requested that we identify, characterize and address the formation of microscopic crystals and a slight fading of the color during the 24-month shelf life of the product. While these changes do not affect the product s underlying integrity or safety, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and product specifications before additional product can be manufactured and distributed. Therefore, the U.S. re-launch and additional manufacturing of ONSOLIS® has been postponed until such product appearance issues have been resolved.

The crystal and fading issues for ONSOLIS® were presented to the FDA at a favorable meeting in December 2012. A data generation plan to support the approval of a new formulation that resolved both issues was submitted to FDA in March 2013 and followed by initiation of manufacturing in second quarter. Submission of initial stability results for the new formulation is expected early in 2014 with approval by mid-year and re-launch of ONSOLIS® in the second half of 2014.

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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.sch	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.

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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: August 9, 2013

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

Date: August 9, 2013

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