BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
November 05, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

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

For the transition period from _____ to _____

Commission file number 001-31361

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
801 Corporate Center Drive, Suite #210	
Raleigh, NC	**27607**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

As of November 3, 2014, there were 51,301,429 shares of company Common Stock issued and 51,285,938 shares of company Common Stock outstanding.

Table of Contents

BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

TABLE OF CONTENTS

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 85,793,950	$ 23,175,809
Accounts receivable	205,229	2,794,040
Inventory	2,023,786	
Prepaid expenses and other current assets	1,435,394	630,657
Total current assets	89,458,359	26,600,506
Equipment, net	1,464,484	178,168
Idle equipment, net	2,738,898	2,844,718
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	(6,481,269)	(5,753,502)
Total other intangible assets	4,468,731	5,196,498
Other assets	235,268	470,535
Total assets	$ 101,080,740	$ 38,005,425
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 13,076,126	$ 10,415,981
Notes payable, current maturities	8,000,000	7,333,333
Deferred revenue, current	842,792	2,927,088
Derivative liabilities	12,579,418	4,315,183
Total current liabilities	34,498,336	24,991,585
Notes payable, less current maturities	6,091,296	11,844,706
Deferred revenue, long-term	5,647,989	1,281,485
Other long-term liabilities	700,000	700,000
Total liabilities	46,937,621	38,817,776
Commitments and contingencies		
Stockholders equity (deficit):		
Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,139,000 and 2,709,300 shares of Series A Non-Voting Convertible Preferred Stock	2,139	2,709

outstanding at September 30, 2014 and December 31, 2013, respectively.		
Common Stock, $.001 par value; 75,000,000 shares authorized; 50,584,518 and 38,204,384 shares issued; 50,569,027 and 38,188,893 shares outstanding at September 30, 2014 and December 31, 2013, respectively	50,585	38,204
Additional paid-in capital	242,022,624	150,506,927
Treasury stock, at cost, 15,491 shares	(47,183)	(47,183)
Accumulated deficit	(187,885,046)	(151,313,008)
Total stockholders equity (deficit)	54,143,119	(812,351)
Total liabilities and stockholders equity (deficit)	$ 101,080,740	$ 38,005,425

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Product royalties	$ 11,832	$ 924,272	$ 1,857,920	$ 1,779,373
Research and development reimbursements	1,297,761		12,067,324	
Contract revenues	512,774	2,072,590	22,471,502	5,603,516
Total Revenues:	1,822,367	2,996,862	36,396,746	7,382,889
Cost of sales	462,802	643,486	1,875,365	1,708,693
Expenses:				
Research and development	6,769,698	16,387,194	29,375,895	41,177,577
Selling, general and administrative	13,648,648	3,049,005	25,532,632	9,099,515
Total Expenses:	20,418,346	19,436,199	54,908,527	50,277,092
Loss from operations	(19,058,781)	(17,082,823)	(20,387,146)	(44,602,896)
Interest expense, net	(514,718)	(450,328)	(1,588,736)	(281,812)
Derivative (loss) gain	(5,684,893)	(917,863)	(14,630,675)	499,671
Other income (expense), net	2,134	(35,433)	34,519	(154,061)
Net loss before taxes	(25,256,258)	(18,486,447)	(36,572,038)	(44,539,098)
Income tax expense				(85,000)
Net loss attributable to common stockholders	$ (25,256,258)	$ (18,486,447)	$ (36,572,038)	$ (44,624,098)
Basic earnings per share:	$ (0.51)	$ (0.49)	$ (0.77)	$ (1.18)
Diluted earnings per share:	$ (0.51)	$ (0.49)	$ (0.77)	$ (1.18)
Weighted average common stock shares outstanding:	49,555,815	38,076,606	47,391,040	37,864,248

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)

FOR THE NINE MONTHS ENDED SEPTEMBER, 30, 2014

(Unaudited)

	Preferred Stock Series A		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	(Deficit)
Balances, January 1, 2014	2,709,300	$ 2,709	38,204,384	$ 38,204	$ 150,506,927	$ (47,183)	$ (151,313,008)	$ (812,351)
Stock-based compensation					4,857,230			4,857,230
Restricted stock awards			473,893	474	(474)			
Exercise of stock options			1,331,063	1,331	4,571,588			4,572,919
Exercise of warrants			1,099,012	1,099	4,929,697			4,930,796
Cashless exercise of warrants			218,367	219	(219)			
Shares issued pursuant to registered direct offering, net			7,500,000	7,500	58,173,672			58,181,172
Shares issued pursuant to an at the market offering, net			1,187,499	1,188	12,535,426			12,536,614
Warrant derivative liability reclassified to equity					6,366,440			6,366,440
Short swing profit return					82,337			82,337
Conversion of preferred shares to common shares	(570,300)	(570)	570,300	570				

Net loss							(36,572,038)	(36,572,038)
Balances, September 30, 2014	2,139,000	$ 2,139	50,584,518	$ 50,585	$ 242,022,624	$ (47,183)	$ (187,885,046)	$ 54,143,119

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months Ended September 30,	
	2014	**2013**
Operating activities:		
Net loss	$ (36,572,038)	$ (44,624,098)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	783,127	936,231
Debt costs	481,858	101,975
Derivative loss (gain)	14,630,675	(499,671)
Purchase of Arcion license with common stock		2,072,136
Stock-based compensation expense	4,857,230	2,487,730
Changes in assets and liabilities:		
Accounts receivable	2,588,811	(364,636)
Inventory	(2,023,786)	
Prepaid expenses and other assets	(804,738)	(131,660)
Accounts payable and accrued liabilities	2,977,872	299,974
Income tax payable		85,000
Deferred revenue	2,282,208	(5,303,516)
Net cash flows from operating activities	(10,798,781)	(44,940,535)
Investing activities:		
Purchase of equipment	(1,553,583)	(5,521)
Net cash flows from investing activities	(1,553,583)	(5,521)
Financing activities:		
Proceeds from sale of common stock	70,717,786	
Proceeds from exercise of stock options	4,572,919	347,434
Proceeds from notes payable and warrants		20,000,000
Deferred financing fees		(224,917)
Proceeds from exercise of common stock warrants	4,930,796	
Payment of notes payable	(5,333,333)	
Return of short swing profits	82,337	
Change in amounts due to related parties		(69,706)
Net cash flows from financing activities	74,970,505	20,052,811
Net change in cash and cash equivalents	62,618,141	(24,893,245)
Cash and cash equivalents at beginning of period	23,175,809	63,189,307

Cash and cash equivalents at end of period	$ 85,793,950	$ 38,296,062

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(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 September 30, 2014, 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, 2013, which are included in the Company s 2013 Annual Report on Form 10-K, filed with the SEC on March 14, 2014 (the 2013 Annual Report). The accompanying condensed consolidated balance sheet at December 31, 2013 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 has reclassified certain amounts within expenses in the Statements of Operations for the three and nine month periods ended September 30, 2013 as well as certain amounts within cash flows from operating activities in the Statements of Cash Flows for the nine months ended September 30, 2013 to conform to the current year presentation. These reclassifications had no effect on the measurement of total expenses, loss from operations, or net loss attributable to common stockholders or aggregate cash flows from operating, investing or financing activities.

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 franchise currently consists of four products or product candidates, three of which utilize the Company s 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, EU (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 TTY Biopharm Co. Ltd. (TTY)) and South Korea (licensed to Kunwha Pharmaceutical Co., Ltd. (Kunwha)).

The Company s second product using the BEMA® technology is BUNAVAIL (buprenorphine and naloxone) buccal film, which was approved by the U.S. Food and Drug Administration (FDA) in June 2014 for the maintenance

treatment of opioid dependence. The Company is commercializing BUNAVAIL with a launch scheduled for fourth quarter 2014. As with all other buprenorphine containing products for opioid dependence, the approval of BUNAVAIL carries a standard post-approval requirement by the FDA to conduct a study to determine the effect of BUNAVAIL on QT prolongation (i.e., an abnormal lengthening of the heartbeat). The clinical study results must be reported to the FDA by the end of 2016.

The Company s third product using the BEMA® technology, BEMA® Buprenorphine, is for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate and is licensed on a worldwide basis to Endo Health Solutions, Inc. (Endo). Positive study results for two pivotal Phase 3 trials for this product were reported by the Company in January and July 2014. In August 2014, the Company announced that, along with Endo, it engaged in a positive pre-New Drug Application (NDA) meeting with the FDA regarding its BEMA® Buprenorphine product.

The Company s fourth product is Clonidine Topical Gel, which is currently in Phase 3 development for the treatment of painful diabetic neuropathy (PDN), which was licensed from Arcion Therapeutics, Inc. (Arcion) in March 2013. In June 2014, the Company announced the completion of patient enrollment for the Company s Phase 3 study of Clonidine Topical Gel. In August 2014, the Company announced that it had completed a pre-specified interim analysis of the ongoing initial pivotal Phase 3 trial for Clonidine Topical Gel.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Basis of presentation (continued):

The results of operations for the three and nine month periods ended September 30, 2014 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 2013 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. 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

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)

Inventory

The Company utilizes contract manufacturers in all phases of the creation of BUNAVAIL . At September 30, 2014, inventory includes the cost of raw materials, work in process and finished goods at the Company s contract manufacturer and third party logistics provider related to the pending launch of BUNAVAIL . Inventory is stated at the lower of cost or market using the specific identification method, and cost is determined on a first-in, first-out basis. As of September 30, 2014, inventory is composed of $0.4 million of raw materials, $0.3 million of work in process and

$1.3 million of finished goods.

Equipment

Office and Manufacturing equipment are carried at cost less accumulated depreciation, which is computed on a straight-line basis over their estimated useful lives, generally three to ten years.

Due to the postponement of the U.S. re-launch of ONSOLIS® (see note 3), related manufacturing equipment, net, totaling $2.7 million has been deemed idle, and has been reclassified to idle equipment, net in the accompanying condensed consolidated balance sheets. The Company evaluates the carrying value of the idle equipment when events or changes in circumstances indicate the related carrying amount may not be recoverable. The Company has not recorded any impairment of this equipment during the nine months ended September 30, 2014.

Recent accounting pronouncements:

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers, which supersedes the revenue recognition requirements of Accounting Standards Codification (ASC) Topic 605, Revenue Recognition and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Basis of presentation (continued):

standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard will be effective for the Company in the first quarter of the year ending December 31, 2017 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. The Company is currently evaluating the impact of adoption of the new standard on its consolidated financial statements.

2. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, funded research arrangements and revenue generated as a result of its worldwide license and development agreement with Meda regarding ONSOLIS® and revenue generated as a result of its January 2012 agreement with Endo regarding its BEMA® Buprenorphine product candidate. The Company intends to finance its research and development, commercialization and working capital needs from existing cash, royalty revenue, potential sales revenue from the commercialization of BUNAVAIL , new sources of debt and equity 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 financing and operating sources during the nine months ended September 30, 2014 consisted of:

- approximately $58.2 million in net proceeds from certain institutional investors related to a definitive securities purchase agreement (see note 9);
- approximately $12.5 million in net proceeds from an at-the-market offering program utilizing the Company s universal shelf registration (see note 9);
- approximately $22.3 million in contract revenue under the Endo agreement (see note 4);

approximately $12.1 million in research and development reimbursements under the Endo agreement (see note 4);

approximately $4.6 million from the exercise of stock options; and

approximately $4.9 million from the exercise of warrants.

Significant new financing and operating sources during the year ended December 31, 2013 consisted of:

approximately $19.8 million in net proceeds from a secured loan facility from MidCap Financial SBIC, LP, as agent and lender (MidCap) (see note 7);

approximately $2.8 million in research and development reimbursements under the Endo agreement;

approximately $1.8 million in net royalties under the Meda agreements;

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

approximately $0.4 million from the exercise of stock options and warrants.

At September 30, 2014, the Company had cash and cash equivalents of approximately $85.8 million. The Company used $10.8 million of cash from operations during the nine months ended September 30, 2014. The Company believes that existing cash as of the date of this Quarterly Report, combined with anticipated revenues associated with the commercialization of BUNAVAIL and anticipated regulatory milestone payments from Endo relating to BEMA® Buprenorphine will be sufficient to fully fund the Company s planned level of operations through the end of 2015. Included in the Company s planned level of operations are: (i) commercialization activities for BUNAVAIL (ii) support of Endo s activities with BEMA® Buprenorphine relating to NDA compilation, submission and review, (iii) the clinical development of Clonidine Topical Gel, (iv) the final regulatory activities required for the resubmission of ONSOLIS® regulatory package for product reintroduction and (v) funding of general working capital requirements. Additional capital may be required to support these efforts as well as potential new product acquisitions or in-licenses, and the ability to scale up or reduce personnel and associated costs are factors considered by management throughout the product development and commercialization life cycle. However, available capital may be consumed more rapidly than currently anticipated, resulting in the need for additional funding, and there is a risk that additional funding, when and if required, may not be available at commercially favorable terms, if at all.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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 utilizing 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 2020.

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. 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 September 30, 2014, there was remaining deferred revenue of $0.9 million which was related to the Meda research and development services. As time progresses, the Company will on a quarterly basis continue to estimate the time required for ongoing obligations, and adjust the remaining deferred revenue accordingly.

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. The Company earned $1.9 million and $1.8 million in product royalty revenue for the nine months ended September 30, 2014 and 2013, respectively. The Company has incurred cost of sales related to the ONSOLIS® product of approximately $1.9 million and $1.7 million for the nine months ended September 30, 2014 and 2013, 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.

Upon delivery of the license to Meda, the Company determined that each of the undelivered obligations had stand-alone value to Meda as these post-commercialization services encompass additional clinical trials on different patient groups but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. The Company also obtained third-party evidence of fair value for the 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 has 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 have been accounted for as three separate units of accounting to include (1) product supply, (2) research and development services for the ONSOLIS® product and

(3) the combined requirements related to the remaining other service-related obligations due to Meda to include participation in committees and certain other specified services. The estimated portion of the upfront payments of approximately $1.1 million (under the Meda U.S. Agreements) and $0.1 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided through expiration of the license terms, as defined above.

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.

On March 12, 2012, the Company announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide Risk Evaluation and Mitigation Strategy (REMS) until the product formulation could be modified to address two appearance-related issues raised by the FDA during an inspection of the manufacturing facility of the Company s North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. (Aveva). Specifically, the FDA identified the formation of microscopic crystals and a fading of the color in the mucoadhesive layer during the 24-month shelf life of the product. While these changes do not affect the product s underlying integrity, safety or performance, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and product specification before additional product can be manufactured and distributed.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

The source of microcrystal formation and the potential for fading of ONSOLIS® was found to be specific to a buffer used in its formulation. This buffer and the coloring agent have both been removed in the reformulated product. As such, the Company believes the appearance issues have been resolved. The Company now has 9 months of product stability data on this formulation that shows no signs of microcrystal formation or color changes. The Company has prepared the necessary regulatory documentation that it believes the FDA will need to approve this change. The Company is working with its commercial partner, MEDA, who is responsible for the NDA and all regulatory filings including the one involving this matter. MEDA is in control of determining when this documentation will be submitted to the FDA. Once submitted, the FDA s review of the application may take up to 6 months.

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 . A final milestone payment related to the EU of $2.5 million was received 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 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 the 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 it will produce. This does not preclude royalties that the Company would owe 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.

Pursuant to the Endo Agreement, Endo has obtained all rights necessary to complete the clinical and commercial development of BEMA® Buprenorphine and to sell the product worldwide. Although Endo has obtained all such necessary rights, the Company has agreed under the Endo Agreement to be responsible for the completion of certain clinical trials regarding BEMA® Buprenorphine (and providing clinical trial materials for such trials) necessary to submit a NDA to the FDA in order to obtain approval of BEMA® Buprenorphine in the U.S., in each case pursuant to a development plan set forth in the Endo Agreement (as it may be amended pursuant to the Endo Agreement). The Company is responsible for development activities through the filing of the NDA in the U.S., while Endo is

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

Pursuant to the Endo Agreement, the Company has received (or expects 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);

$15 million for enhancement of intellectual property rights (earned in May 2012);

$20 million for full enrollment in two clinical trials ($10 million earned in January 2014 and $10 million earned in June 2014);

$10 million upon FDA acceptance of filing NDA;

up to $50 million upon regulatory approval;

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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

4. Endo License and Development Agreement (continued):

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, the Company determined that the Endo Agreement is a multi-deliverable arrangement 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 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, the 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 payment was assigned to this deliverable because the Company determined the deliverable to be perfunctory. 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 of $14.4 million is being recognized as those services are performed. The Company estimates that such clinical development services will extend into the first half of 2015. Based on the estimated proportion of those services performed through

September 30, 2014, $5.2 million was recognized as revenue in fiscal year 2012, $6.3 million was recognized as revenue in fiscal year 2013 and $2.3 million was recognized as contract revenue during the nine months ended September 30, 2014 in the accompanying condensed statements of operations. As a result, $0.6 million remains deferred at September 30, 2014.

The Company analyzed the milestone payments noted above 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 and therefore has and will recognize revenue when milestones are earned.

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 timeframe 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, and therefore was recognized as revenue when the milestone was earned.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

4. Endo License and Development Agreement (continued):

On January 23, 2014, the Company announced positive top-line results from its pivotal Phase 3 efficacy study of BEMA® Buprenorphine in opioid- naive subjects. The locking of the database for the opioid naive study has triggered a $10 million milestone payment from Endo per the Company s licensing agreement. Such payment was received during February 2014 and has been recorded as contract revenue in the accompanying 2014 condensed consolidated statement of operations.

On June 25, 2014, the database for the pivotal Phase 3 efficacy study of BEMA® Buprenorphine in opioid-experienced patients was locked. As a result, the locking of the database triggered a $10 million milestone payment from Endo per the Company s license agreement. Such payment was received during July 2014 and has been recorded as contract revenue in the accompanying 2014 condensed consolidated statement of operations.

In August 2014, the Company announced that along with Endo, it engaged in a positive pre-NDA meeting with the FDA regarding the BEMA® Buprenorphine product.

The remaining milestone payments are expected to be recognized as revenue as they are achieved, except that one milestone is contingently refundable for a period of time. Revenue related to such contingently refundable 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 occur under the terms of the Endo Agreement.

The Company is reimbursed by Endo for certain contractor costs when these costs go beyond set thresholds as outlined in the Endo Agreement. Endo reimburses the Company for this spending at cost and the Company receives no mark-up or profit. The gross amount of these reimbursed research and development costs are reported as research and development reimbursement revenue in the accompanying consolidated statements of operations. The Company acts as a principal, has discretion to choose suppliers, bears credit risk and may perform part of the services required in the transactions. Therefore, these reimbursements are treated as revenue to the Company. The actual expenses creating the reimbursements are reflected as research and development expense.

Beginning in March 2014, total reimbursable contractor costs exceeded a set threshold, at which point all such expenses are to be borne at a rate of 50% by Endo and 50% by the Company. In connection with the Endo Agreement, Endo has continued to reimburse the Company for 100% of such costs, with 50% thereof to be taken as a credit against potential future milestones associated with achievement of certain regulatory events. At September 30, 2014, the Company has recorded $4.8 million of such prepayments, as deferred revenue, long term in the accompanying condensed consolidated balance sheet. During the nine months ended September 30, 2014, the Company recognized $12.1 million of reimbursable expenses related to its Endo agreement, which is recorded as revenue and shown as research and development reimbursements on the accompanying condensed consolidated statements of operations.

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 PDN 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 with a fair market value of $2.1 million, which shares are subject to a nine month lock-up and certain limitations on sales 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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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 to 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 accompanying condensed consolidated statement of operations for the nine months ended September 30, 2013.

On April 3, 2014, the Company announced the enrollment of the first patient in the RHAPSODY Study, a Phase 3 clinical trial of the Clonidine Topical Gel for the treatment of painful diabetic neuropathy. On June 26, 2014, the Company announced that it completed randomization of all patients required based on the initial planned sample size for the study.

On August 6, 2014, the Company announced that it has completed a pre-specified interim analysis. The purpose of the interim analysis was to allow for a sample size adjustment if necessary to maintain appropriate statistical power to detect a treatment effect between Clonidine Topical Gel and placebo. As a result of the interim analysis, a total of approximately 80 additional patients will be added to the ongoing trial in an effort to maintain 90% power to detect a statistically significant difference between Clonidine Topical Gel and placebo.

This will extend patient enrollment until year-end with top-line results expected near the end of the first quarter of 2015.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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 expiration of the patents, or July 23, 2027, whichever is later.

Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for BEMA® Fentanyl in the Kunwha Territory, while the Company 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 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 resulted in a milestone payment of $0.3 million to the Company, which was received in the third quarter 2013 and recorded as contract revenue in 2013.

7. MidCap Secured Loan Facility:

On July 5, 2013, the Company 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 and Security Agreement, dated as of July 5, 2013 (as amended on July 3, 2014 with an effective date of June 29, 2014), among the Borrowers and MidCap (the Credit Agreement). The Company received net proceeds in the aggregate amount of $19.8 million and has 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 years and contains cashless exercise provisions and customary, anti-dilution protection provisions. The proceeds of the secured loan facility were allocated to the note payable and Midcap warrants (which qualified for equity accounting) based on their relative fair values, as follows:

Note payable	$ 19,013,648
MidCap warrant	986,352
Total proceeds	$ 20,000,000

The resulting debt discount is being amortized to interest expense over the 3 year life of the loan.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

7. MidCap Secured Loan Facility (continued):

The fair value of the warrants was determined based upon the Black Scholes valuation model using the following key assumptions:

Market price of stock	$ 4.41
Term of warrant	5 years
Volatility	81.05%
Risk free interest rate	2.9%

The Loan has a term of 36 months with interest only payments until February 1, 2014. The interest rate is 8.45% plus a LIBOR floor of 0.5% (total of 8.95% at September 30, 2014 and December 31, 2013). 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. The 3.5% exit fee has been recorded as deferred loan costs, the current portion of which is included in prepaid expenses and other current assets and the long-term portion in other assets. Additionally, the liability associated with the exit fee has been recorded in other long-term liability in the accompanying condensed consolidated balance sheets. The assets associated with this exit fee are accreted to interest expense through the maturity of the Midcap Loan. 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.

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, but not limited to, 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.

The Borrowers are also subject to negative covenants customary for financings of this type, including, but not limited to, that without the prior consent of Midcap, 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 and (vii) 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 or (ii) the maximum rate allowable under law.

The balance of the secured loan facility due to MidCap as of September 30, 2014 is $14.7 million, and is recorded in the accompanying condensed consolidated balance sheet, net of unamortized discount of $0.6 million. Effective June 29, 2014, the Company and MidCap amended the Credit Agreement to (i) remove the failure to receive the database lock payments by June 30, 2014 as an event of default and (ii) delete the ability of the Company to prepay a portion of the Loan with the database lock payments.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

7. MidCap Secured Loan Facility (continued):

The following table represents future maturities of the MidCap obligation as of September 30, 2014:

Years ending September 30,	
2015	8,000,000
2016	6,666,667
Total maturities	14,666,667
Unamortized discount	(575,371)
Total Midcap obligation	$ 14,091,296

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.

The following table summarizes assets and liabilities measured at fair value on a recurring basis at September 30, 2014 and December 31, 2013, respectively:

	September 30, 2014				**December 31, 2013**			
	Level 1	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Fair Value Measurements Using:								

Liabilities				
Derivative liabilities- free standing warrants	$ $ 12,579,418	$ $ 12,579,418	$ $ 4,315,183	$ $ 4,315,183

The table below provides a reconciliation of the beginning and ending balances for the liabilities measured at fair value using observable inputs (Level 2). The table reflects net gains and losses for all financial liabilities categorized as Level 2 as of September 30, 2014 and December 31, 2013.

	$	Number of Warrants
Liabilities:		
Warrant liability as of December 31, 2013	$ 4,315,183	1,999,436
Decrease due to exercise of warrants	(6,366,440)	(1,099,011)
Increase in fair value of warrants	14,630,675	
Warrant liability as of September 30, 2014	$ 12,579,418	900,425

The derivative (loss) gain recognized in the condensed consolidated statements of operations reflects the change in fair value of these warrant liabilities.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

9. Stockholders Equity:

Stock-based compensation

During the nine months ended September 30, 2014, a total of 152,265 options to purchase Common Stock with an aggregate fair market value of approximately $1 million were granted to Company employees. The options granted have a term of 10 years from the grant date and vest ratably over a three year period. The fair value of each option is amortized as compensation expense evenly through the vesting period. The fair value of each option award is estimated on the grant date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from historical volatility of the Common Stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average for key assumptions used in determining the fair value of options granted during the nine months ended September 30, 2014 follows:

Expected price volatility	74.7-78.05%
Risk-free interest rate	1.00-1.58%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the nine months ended September 30, 2014 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2014	4,192,927	$ 3.82	
Granted in 2014:			
Officers and Directors			
Others	152,265	9.41	
Exercised	(1,337,878)	3.48	
Forfeitures			
Outstanding at September 30, 2014	3,007,314	$ 4.26	$ 38,598,170

Options outstanding at September 30, 2014 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	2,059,390	5.25	$ 3.10	
$5.01 10.00	905,344	4.01	$ 6.44	
$10.01-15.00	23,744	9.82	$ 12.44	
$15.01-20.00	18,836	9.99	$ 15.95	
	3,007,314			$ 38,598,170

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

9. Stockholders Equity (continued):

Options exercisable at September 30, 2014 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	1,725,513	4.69	$ 2.98	
$5.01 10.00	740,000	2.84	$ 6.35	
$10.01-15.00				
$15.01-20.00				
	2,465,513			$ 32,321,327

The weighted average grant date fair value of options granted during the nine months ended September 30, 2014 was $6.77. There were no options granted during the nine months ended September 30, 2014 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, 2014, and changes during the nine months ended September 30, 2014 is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Nonvested at January 1, 2014	614,468		
Granted	152,265		
Vested	(224,932)		
Forfeited			
Nonvested at September 30, 2014	541,801	$ 3.33	$ 6,276,843

As of September 30, 2014, there was approximately $11.3 million of unrecognized compensation cost related to non-vested share-based compensation awards, including options and restricted stock units (RSUs) granted. These costs will be expensed through 2017.

On July 17, 2014, the Company held its 2014 Annual Meeting of Stockholders (the Annual Meeting). During the Annual Meeting, stockholders approved the amendment to the Company s 2011 Equity Incentive Plan to increase the number of shares of common stock authorized for issuance under the plan by 2,000,000 shares from 6,800,000 to 8,800,000.

Warrants

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. Warrants outstanding at September 30, 2014, 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	900,425	0.56	$ 3.12	$ 12,578,937

During the nine months ended September 30, 2014, approximately 1.1 million shares of Common Stock underlying warrants were exercised for proceeds to the Company of $4.9 million. Also during the nine months ended September 30, 2014, there were 357,356 shares of Common Stock underlying a warrant exercised on a cashless basis, which resulted in a net issuance of 218,367 shares to the warrant holder.

In October, 2014, 0.6 million shares of Common Stock underlying warrants were exercised for proceeds to the Company of approximately $1.9 million.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

9. Stockholders Equity (continued):

Common Stock

In November 2013, the Company filed a shelf registration statement which registered up to $75 million of the Company s securities for potential future issuance, and such registration statement was declared effective on December 18, 2013. Concurrent with the filing of such registration statement, the Company established an at-the-market offering program utilizing the universal shelf registration for up to $15 million of Common Stock. Cantor Fitzgerald & Co. is the placement agent for such offering program. In January 2014, the Company sold 658,489 shares of Common Stock under such offering program for approximate net proceeds of $3.9 million. In September and October 2014, the Company sold 529,010 and 116,911 shares of Common Stock, respectively, under such offering program for approximate net proceeds of $8.6 million and $1.9 million, respectively.

On February 7, 2014, the Company entered into a definitive Securities Purchase Agreement with certain institutional investors relating to a registered direct offering by the Company of 7,500,000 shares of the Company s Common Stock, par value $.001 per share. The shares were sold at a price of $8.00 per share, yielding net offering proceeds of $58.2 million. The offering price per share was determined based on an approximately 3.1% discount to the closing price of the Common Stock on February 7, 2014.

During the nine months ended September 30, 2014, Company employees, directors and affiliates exercised approximately 1.3 million stock options, with net proceeds to the Company of approximately $4.6 million.

Preferred Stock

The Company has authorized five million blank check shares of $.001 par value convertible preferred stock. During the nine months ended September 30, 2014, 570,300 shares of Series A Preferred stock converted to common stock. At September 30, 2014, 2,139,000 shares of Series A Preferred were outstanding.

Earnings Per Share

During the nine months ended September 30, 2014 and 2013, outstanding stock options, warrants and convertible preferred stock of 6 million and 9.2 million, respectively, were not included in the computation of diluted earnings per share, because to do so would have had an antidilutive effect.

Recovery of Stockholder Short Swing Profit

In February 2014, three executive officers of the Company paid a total of approximately $0.08 million to the Company, representing the disgorgement of short swing profits under Section 16(b) under the Exchange Act. The

amount was recorded as additional paid-in capital.

Restricted Stock Units

During the nine months ended September 30, 2014, a total of 995,619 RSUs were granted to members of the Company s senior management, with a fair market value of approximately $8.8 million. 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.

During the nine months ended September 30, 2014, a total of 110,000 RSUs were granted to members of the Company s board of directors, with a fair market value of approximately $1.5 million. These RSUs were issued under the Company s 2011 Equity Incentive Plan, as amended, and vest in equal installments over one year. Additionally, there were 15,000 RSUs granted to two new board members, with a market value of approximately $0.2 million. These RSUs were issued under the Company s 2011 Equity Incentive Plan, as amended, and vest in 2015.

Also during the nine months ended September 30, 2014, the following RSUs vested; 1) a total of 359,446 RSUs that were previously granted in 2013 to members of the Company s senior management with a fair market value of approximately $3.2 million, 2) a total of 55,000 RSUs that were previously granted in 2013 to members of the Company s board of directors with a fair market value of approximately $0.7 million and 3) a total of 55,000 RSUs that were granted in 2014 to members of the Company s board of directors with a fair market value of approximately $0.7 million. These RSUs were issued under the Company s 2011 Equity Incentive Plan, as amended.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

9. Stockholders Equity (continued):

Performance Long Term Incentive Plan

In December 2012, the Company s Board of Directors (the Board) approved the BDSI Performance Long Term Incentive Plan (LTIP). The LTIP is designed as an incentive for the Company s senior management to generate revenue for the Company. The LTIP consists of RSUs (which are referred to in this context as Performance RSUs) which are rights to acquire shares of Common Stock. All Performance RSUs granted under the LTIP will be granted under the Company s 2011 Equity Incentive Plan (as the same may be amended, supplemented or superseded from time to time) as Performance Compensation Awards under such plan. The participants in the LTIP are either named executive officers or senior officers of the Company.

The term of the LTIP began with the Company s fiscal year ended December 31, 2012 and lasts through the fiscal year ended December 31, 2019. The total number of Performance RSUs covered by the LTIP is 1,078,000, of which 978,000 were awarded in 2012 (with 100,000 Performance RSUs being reserved for future hires). The Performance RSUs under the LTIP did not vest upon granting, but instead are subject to potential vesting each year over the 8 year term of the LTIP depending on the achievement of revenue by the Company, as reported in its Annual Report on Form 10-K. During the nine months ended September 30, 2014, a total of 4,447 RSUs vested, subject to performance criteria.

10. Commitments and contingencies:

Litigation Related To ONSOLIS®

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®.

On March 26, 2014, the Company participated in an oral hearing for the appeal, in which both parties presented arguments before the Patent Trial & Appeal Board (PTAB). On April 17, 2014 the PTAB issued a Decision on Appeal affirming the Examiner s rejection (and confirming the invalidity) of all the claims of the 588 Patent. MonoSol did not request a rehearing by the May 17, 2014 due date for making such a request and did not appeal the Decision to the Federal Court of Appeals by the June 17, 2014 due date for making such an appeal. Therefore, the Company expects the USPTO to issue a Certificate of Reexamination cancelling the 588 Patent claims, which should happen before the end of 2014.

Importantly, in the case of MonoSol s 588 Patent, at the conclusion of the reexamination proceedings (and its appeals process), on April 17, 2014, the PTAB issued a Decision on Appeal affirming the Examiner s rejection (and confirming the invalidity) of all the claims of the 588 Patent. MonoSol did not request a rehearing by the May 17, 2014 due date for making such a request and did not further appeal the Decision to the Federal Court of Appeals by the June 17, 2014 due date for making such an appeal. Subsequently, on August 5, 2014, the USPTO issued a Certificate of Reexamination cancelling the 588 Patent claims.

Based on the Company s original assertion that its 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 the Company while the third has had all claims rejected by the USPTO, the Company remains very confident in its original stated position regarding this matter. Thus far, the Company has proven that the original 292 and 891 patents in light of their reissuance with fewer and narrower claims were indeed invalid and the third and final patent, the 588 patent, was invalid as well with all its claims cancelled. Given the outcomes of the 292, 891 and 588 reexamination proceedings, the possibility exists that the stay on the case could be lifted. If this occurs, the Company will continue to defend this case vigorously and seek a dismissal, but ultimately, the Company anticipates that MonoSol s claims against the Company will be rejected.

Litigation Related To BUNAVAIL™

On October 29, 2013, Reckitt Benckiser, Inc. RB Pharmaceuticals Limited, and MonoSol RX, LLC (collectively, the RB Plaintiffs) filed an action against the Company relating to the Company s BUNAVAIL product in the United States District Court for the Eastern District of North Carolina for alleged patent infringement. BUNAVAIL is a proposed treatment for opioid dependence. The RB Plaintiffs claim that the formulation for BUNAVAIL , which has never been disclosed publicly, infringes its patent (United States Patent No. 8,475,832). The Company strongly refutes as without merit the RB Plaintiffs assertion of patent infringement and will vigorously defend the lawsuit.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

10. Commitments and contingencies (continued):

On January 31, 2014, the Company filed in Court a motion for stay pending the outcome of the inter partes review proceedings. The Court scheduled a hearing on the motion to dismiss and motion to stay had been scheduled for April 25, 2014. At the Court hearing, both the RB Plaintiffs and the Company had the opportunity to present arguments to the Court on the pending motions.

On May 21, 2014 the Court granted the Company s motion to dismiss. In doing so, the Court dismissed the case in its entirety. The RB Plaintiffs did not appeal the Court Decision by the June 21, 2014 due date and therefore, the dismissal will stand and the RB Plaintiffs lose the ability to challenge the Court Decision in the future. The possibility exists, however, that the RB Plaintiffs could file another suit alleging infringement of the 832 Patent. If this occurs, based on the Company s original position that its BUNAVAIL product does not infringe the 832 Patent, the Company would defend the case vigorously (as the Company has done so previously), and the Company anticipates that such claims against the Company ultimately would be rejected.

On September 20, 2014, based upon the Company s position and belief that its BUNAVAIL product does not infringe any patents owned by the RB Plaintiffs, the Company proactively filed a declaratory judgment action in the United States District Court for the Eastern District of North Carolina, requesting the Court to make a determination that the Company s BUNAVAIL product does not infringe the RB Plaintiffs 832 Patent, US Patent No. 7,897,080 (080 Patent) and US Patent No. 8,652,378 (378 Patent). With the DJ Action, there is an automatic stay in proceedings. The RB Plaintiffs may request that the stay be lifted, but they have the burden of showing that the stay should be lifted. For the 832 Patent, the January 15, 2014 IPR was instituted and all challenged claims were rejected for both anticipation and obviousness. For the 080 Patent, all claims remain rejected in an inter partes reexamination and the reexamination is currently in the appeals process, with the oral hearing scheduled for November 5, 2014. For the 378 Patent, an IPR was filed on June 1, 2014. As in prior litigation proceedings, the Company believes these IPR and the reexamination filings will provide support for maintaining the stay until the IPR and reexamination proceedings conclude.

On September 22, 2014, the RB Plaintiffs filed an action against the Company (and its commercial partner) relating to the Company s BUNAVAIL product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL , whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent (U.S. Patent No. 8,765,167) (167 Patent). As with prior actions by the RB Plaintiffs, the Company believes this is another anticompetitive attempt by the RB Plaintiffs to distract the Company s efforts from commercializing BUNAVAIL . The Company strongly refutes as without merit the RB Plaintiffs assertion of patent infringement and will vigorously defend the lawsuit. In this regard, on October 28, 2014, the Company recently filed multiple IPR requests on the 167 Patent demonstrating that certain claims of such patent 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.

20

Table of Contents

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

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

For the three months ended September 30, 2014 compared to the three months ended September 30, 2013

Product Royalty Revenues. We recognized $0.01 million and $0.9 million in product royalty revenue during the three months ended September 30, 2014 and 2013, respectively, under our license agreement with Meda AB (Meda). The product royalty revenues can be attributed to a percentage of net sales revenue of the BREAKYL product under our license agreement with Meda. The decrease in product royalty revenues during the three months ended September 30, 2014 can be attributed to lower BREAKYL sales during the third quarter 2014 as compared to the third quarter of 2013.

***Research and Development Reimbursements*.** We recognized $1.3 million of reimbursable revenue related to our agreement with Endo Health Solutions, Inc. (Endo) during the three months ended September 30, 2014. There was no such reimbursable revenue in the corresponding period of 2013. The research and development reimbursements can be attributed to certain research and development expenses, the aggregate of which exceeds $45 million that are related to the Buprenorphine chronic pain program and are reimbursable from Endo.

Contract Revenues. We recognized a total of $0.5 million and $2.1 million in related deferred contract revenue during the three months ended September 30, 2014 and 2013, respectively, the majority of which relate to the Endo license agreement as well as $0.3 million in contract revenue during the three months ended September 30, 2013 under the TTY Biopharm Co. Ltd. (TTY) agreement. The decrease in contract revenues during the three months ended September 30, 2014 can be attributed to lower research and development spending during the third quarter 2014 as compared to the third quarter of 2013.

Cost of Sales. We recognized $0.5 million and $0.6 million in cost of sales during each of the three months ended September 30, 2014 and 2013, respectively. Both periods include minimum quarterly payments to CDC and BREAKYL cost of sales.

Research and Development Expenses. During the three months ended September 30, 2014 and 2013, research and development expenses totaled $6.8 million and $16.4 million, respectively. Our scientific staff continues to work toward development and application of our BEMA® delivery technology, which includes ONSOLIS®, BEMA® Buprenorphine for chronic pain and BUNAVAIL for the treatment of opioid dependence. Research and development expenses generally include contractor services, compensation for scientific personnel and other costs directly related to the development and application of drug technologies. Research and Development expenses decreased during the three months ended September 30, 2014 because the BEMA® Buprenorphine study for Opioid Naïve patients was finished in early 2014. In addition, BUNAVAIL clinical trials were completed prior to 2014.

Selling, General and Administrative Expenses. During the three months ended September 30, 2014 and 2013, selling, general and administrative expenses totaled $13.6 million and $3 million, respectively. Selling, general and administrative costs include commercialization costs anticipating the BUNAVAIL launch, legal, accounting and

management wages, and consulting and professional fees, travel costs, and stock compensation expenses. The increase in selling, general and administrative expenses during the three months ended September 30, 2014 can be attributed to marketing and sales expenses in preparation for the launch of BUNAVAIL , U.S. Food and Drug Administration (FDA) product fees and patent expense in the third quarter of 2014.

Interest expense, net. During the three months ended September 30, 2014 we had net interest expense of $0.5 million, consisting of $0.35 million of scheduled interest payments and $0.16 million of related amortization of discount and loan costs related to the July 2013 long term debt secured loan facility. During the three months ended September 30, 2013 we had net interest expense of $0.5 million, consisting of $0.4 million of scheduled interest payments and $0.1 million of related amortization of discount and loan costs related to the July 2013 long term debt secured loan facility, offset by interest income of $0.01 million.

Derivative (loss) gain. Our derivative liability consists of free standing warrants measured at their fair market value, using the Black-Scholes model. During the three months ended September 30, 2014, our stock price increased, which is the largest component of the Black-Scholes change. As a result, our derivative liability also increased, resulting in a $5.7 million charge to income. During the three months ended September 30, 2013, our stock price also increased, and the volatility used in the calculation increased. As a result, our warrant liability increased, resulting in a $0.9 million charge to income.

Table of Contents

For the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013

Product Royalty Revenues. We recognized $1.9 million and $1.8 million in product royalty revenue during the nine months ended September 30, 2014 and 2013, respectively, under our license agreement with Meda. Product royalty revenue is earned through sales of BREAKYL in Europe.

Research and Development Reimbursements. We recognized $12.1 million of reimbursable revenue related to our agreement with Endo during the nine months ended September 30, 2014. There was no such reimbursable revenue in the corresponding period of 2013. The research and development reimbursements can be attributed to certain research and development expenses, the aggregate of which exceeds $45 million that are related to the Buprenorphine chronic pain program and reimbursable from Endo.

Contract Revenues. We recognized a total of $22.5 million and $5.6 million in contract revenue during the nine months ended September 30, 2014 and 2013, respectively, the majority of which relate to the milestones in connection with the Endo license agreement as well as $0.3 million in contract revenue during the nine months ended September 30, 2013 under the TTY agreement. The increase in contract revenues during the nine months ended September 30, 2014 can be attributed to two $10 million milestone payments received from Endo regarding two Phase 3 study database locks associated with the BEMA® Buprenorphine chronic pain program with Endo.

Cost of Sales. We recognized $1.9 million and $1.7 million in cost of sales during the nine months ended September 30, 2014 and 2013, respectively. Both periods include minimum quarterly payments to CDC and the 2013 period also includes cost of sales in support of the commercial launch of BREAKYL . The increase in cost of sales during the nine months ended September 30, 2014 can be attributed to the addition of BUNAVAIL cost of sales.

Research and Development Expenses. During the nine months ended September 30, 2014 and 2013, research and development expenses totaled $29.4 million and $41.2 million, respectively. Contributing to the lower 2014 expenses were the completion of the BUNAVAIL program for the treatment of opioid dependence and compilation of the NDA, and a 2013 charge of $2.1 million for in-process research and development (paid in Common Stock) associated with our license agreement with Arcion Therapeutics, Inc. (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. 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.

Selling, General and Administrative Expenses. During the nine months ended September 30, 2014 and 2013, selling, general and administrative expenses totaled $25.5 million and $9.1 million, respectively. Selling, 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 selling, general and administration expenses can be attributed to BUNAVAIL commercialization efforts, FDA product fees and patent costs in 2014.

Interest expense, net. During the nine months ended September 30, 2014 we had net interest expense of $1.6 million, consisting of $1.2 million of scheduled interest payments and $0.5 million of related amortization of discount and loan costs related to the July 2013 secured loan facility from MidCap, offset by interest income of $0.07 million. During the nine months ended September 30, 2013, we had net interest expense of $0.3 million, consisting of $0.4 million of scheduled interest payments and $0.1 million of related amortization of discount and loan costs related to the July 2013 secured loan facility from MidCap, offset by interest income of $0.2 million.

Derivative (loss) gain. Our derivative liability consists of free standing warrants measured at their fair market value, using the Black-Scholes model. During the nine months ended September 30, 2014, our stock price increased, which is the largest component of the Black-Scholes change. As a result, our warrant liability also increased, resulting in a $14.6 million charge to income. During the nine months ended September 30, 2013, our stock price decreased. Therefore, our derivative liability decreased, resulting in a $0.5 million gain.

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, 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 and working capital needs from existing cash, royalty revenue, new sources of debt and equity 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.

Table of Contents

At September 30, 2014, we had cash and cash equivalents of approximately $85.8 million. We used $10.8 million of cash from operations during the nine months ended September 30, 2014. We believe that existing cash as of the date of this Quarterly Report, combined with anticipated revenues associated with the commercialization of BUNAVAIL and anticipated regulatory milestone payments from Endo relating to BEMA® Buprenorphine will be sufficient to fully fund our planned level of operations through the end of 2015. Included in our planned level of operations are: (i) commercialization activities for BUNAVAIL (ii) support of Endo s activities with BEMA® Buprenorphine relating to NDA compilation, submission and review, (iii) the clinical development of Clonidine Topical Gel, (iv) the final regulatory activities required for the resubmission of ONSOLIS® regulatory package for product reintroduction and (v) funding of general working capital requirements.

Additional capital may be required to support these efforts as well as potential new product acquisitions or in-licenses, and the ability to scale up or reduce personnel and associated costs are factors considered by management throughout the product development and commercialization life cycle. However, available capital may be consumed more rapidly than currently anticipated, resulting in the need for additional funding, and there is a risk that additional funding, when and if required, may not be available at commercially favorable terms, if at all.

Accordingly, we may need to potentially 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 2014 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 September 30, 2014 are as follows:

		Payments Due by Period			
		Less than			More than
	Total	**1 year**	**1-3 years**	**3-5 years**	**5 years**
Operating lease obligations	$ 59,611	$ 59,611	$	$	$
Employment agreements	1,317,141	1,317,141			
Secured loan facility	14,666,667	8,000,000	6,666,667		
Interest on secured loan facility	1,274,546	997,262	277,284		
Secured loan exit fee	700,000		700,000		
Minimum royalty expenses*	7,875,000	1,500,000	3,000,000	3,000,000	375,000
Total contractual cash obligations**	$ 25,892,965	$ 11,874,014	$ 10,643,951	$ 3,000,000	$ 375,000

Table of Contents

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

** Endo has worldwide rights to market, upon FDA approval, our BEMA® Buprenorphine product. Under our agreement with Endo, among other deliverables, we are required to conduct and pay for certain specific clinical trials and, in connection with such specific trials, provide clinical trial materials, as outlined in a mutually agreed development plan. The costs for such trials and materials will depend on the size and scope of the specified trials. The Endo agreement does not specify minimums in terms of the cost of the trials, but does provide for a cost sharing arrangement under which we will be responsible for a material amount of such costs, up to a certain threshold, whereupon Endo will be responsible for a significantly less amount of such costs (if any are incurred), up to second threshold amount, and thereafter, costs (if any are incurred) will be shared equally by us and Endo.

Off-Balance Sheet Arrangements

As of September 30, 2014, 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 generally accepted accounting principles in the United States of America (GAAP). 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, as discussed below. The carrying value of goodwill at September 30, 2014 was $2.7 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. The carrying value of other amortizing intangible assets at September 30, 2014 was $4.5 million, net of accumulated amortization of $6.5 million. We begin amortizing capitalized intangibles on their date of acquisition.

Impairment Testing

Goodwill is tested for impairment annually in December or more frequently if impairment indicators are present. Our impairment test is performed at the reporting unit level. The Financial Accounting Standards Board (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. Should our qualitative impairment assessment not be conclusive, we perform a traditional two-step quantitative impairment test.

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.

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

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

There were no impairment charges during the nine months ended September 30, 2014 or 2013.

Table of Contents

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 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.

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 the financial statement 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 Government T-Bills. 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 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 September 30, 2014, we had approximately $85.6 million of cash, 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our third fiscal quarter of 2014 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

Limitations on the Effectiveness of Internal Controls

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

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations (and the Liquidity and Capital Resources section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes forward-looking statements within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as projects, may, could, would, should, believes, expects, anticipates, estimates, intends, plans or These statements are based upon the current beliefs and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) actual sales results (including the results of the commercial launch of BUNAVAIL) 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 2013 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.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Litigation Related To ONSOLIS®

On November 2, 2010, 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.

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 USPTO. 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. 7,357,891C1 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. On November 13, 2013, the USPTO decided not to institute the two inter partes reviews for the 891C1 and 292C1 Patents. The USPTO s decision was purely on statutory grounds and based on a technicality (in that the IPRs were not filed within what the UPSTO determined to be the statutory period) rather than substantive grounds. Thus, even though the inter partes reviews were not instituted, the USPTO decision preserves our right to raise the same arguments at a later time (e.g., during litigation). 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.

Table of Contents

Importantly, in the case of MonoSol s 588 Patent, at the conclusion of the reexamination proceedings (and its appeals process), on April 17, 2014, the PTAB issued a Decision on Appeal affirming the Examiner s rejection (and confirming the invalidity) of all the claims of the 588 Patent. MonoSol did not request a rehearing by the May 17, 2014 due date for making such a request and did not further appeal the Decision to the Federal Court of Appeals by the June 17, 2014 due date for making such an appeal. Subsequently, on August 5, 2014, the USPTO issued a Certificate of Reexamination cancelling the 588 Patent claims.

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 891 patents in light of their reissuance with fewer and narrower claims were indeed invalid and the third and final patent, the 588 patent, was invalid as well with all its claims cancelled. Given the outcomes of the 292, 891 and 588 reexamination proceedings, the possibility exists that the stay on the case could be lifted. If this occurs, we will continue to defend this case vigorously and seek a dismissal, but ultimately, we anticipate that MonoSol s claims against us will be rejected.

Litigation Related To BUNAVAIL

On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol (collectively, the RB Plaintiffs) filed an action against us relating to our BUNAVAIL product in the United States District Court for the Eastern District of North Carolina for alleged patent infringement. BUNAVAIL is a proposed treatment for opioid dependence. The RB Plaintiffs claim that the formulation for BUNAVAIL , which has never been disclosed publicly, infringes its patent (United States Patent No. 8,475,832) (the 832 Patent).

We believe that this action is in response to a 2013 decision wherein the FDA recently ruled in favor of our position in two Citizen Petitions filed by the RB Plaintiffs that sought to prevent the FDA from accepting and filing our NDA for BUNAVAIL . The two Citizen Petitions, filed on December 2, 2011 and August 13, 2013, respectively, included requests that the FDA refuse to accept for filing any NDAs submitted using the 505 (b)(2) regulatory pathway for buprenorphine/naloxone products consisting of a polymer film for application to the buccal mucosal membranes (such as BUNAVAIL), unless such application references the NDA for Suboxone® (buprenorphine/naloxone) sublingual film (and not the Suboxone® sublingual tablet NDA). Suboxone® is an approved product for opioid dependence. The requirement to reference the Suboxone® film formulation, which is under patent exclusivity with Orange Book-listed patents, including the 832 Patent, was aimed at delaying the eventual approval of BUNAVAIL . FDA did not agree with these arguments and in its decision on September 18, 2013, it denied the requests and subsequently, accepted and filed the BUNAVAIL NDA.

We believe that the RB Plaintiff s claim of patent infringement has no more validity than the recently rejected Citizen Petitions, but is being used as another anticompetitive attempt to distract us in our efforts toward commercializing BUNAVAIL . In the meantime, we strongly refute as without merit the RB Plaintiffs assertion of patent infringement and will vigorously defend the lawsuit.

On December 13, 2013, we filed a motion to dismiss RB Plaintiff s suit based on insufficient pleadings and lack of standing. In response, RB Plaintiffs filed its opposition to our motion to dismiss on January 22, 2014. We filed our reply to RB s opposition to our motion to dismiss on February 10, 2014.

On January 15, 2014, we filed a request for inter partes review (IPR) in the USPTO of the 832 Patent demonstrating that certain claims of such patent 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.

On January 31, 2014, we filed in Court a motion for stay pending the outcome of the inter partes review proceedings. The Court scheduled a hearing on the motion to dismiss and motion to stay had been scheduled for April 25, 2014. At the Court hearing, both the RB Plaintiffs and we had the opportunity to present arguments to the Court on the pending motions.

On May 21, 2014 the Court granted our motion to dismiss. In doing so, the Court dismissed the case in its entirety. The RB Plaintiffs did not appeal the Court Decision by the June 21, 2014 due date and therefore, the dismissal will stand and the RB Plaintiffs lose the ability to challenge the Court Decision in the future. The possibility exists, however, that the RB Plaintiffs could file another suit alleging infringement of the 832 Patent. If this occurs, based on our original position that our BUNAVAIL product does not infringe the 832 Patent, we would defend the case vigorously (as we have done so previously), and we anticipate that such claims against us ultimately would be rejected.

Table of Contents

On September 20, 2014, based upon our position and belief that our BUNAVAIL product does not infringe any patents owned by the RB Plaintiffs, we proactively filed a declaratory judgment action in the United States District Court for the Eastern District of North Carolina, requesting the Court to make a determination that our BUNAVAIL product does not infringe the RB Plaintiffs 832 Patent, US Patent No. 7,897,080 (080 Patent) and US Patent No. 8,652,378 (378 Patent). With the DJ Action, there is an automatic stay in proceedings. The RB Plaintiffs may request that the stay be lifted, but they have the burden of showing that the stay should be lifted. For the 832 Patent, the January 15, 2014 IPR was instituted and all challenged claims were rejected for both anticipation and obviousness. For the 080 Patent, all claims remain rejected in an inter partes reexamination and the reexamination is currently in the appeals process, with the oral hearing scheduled for November 5, 2014. For the 378 Patent, an IPR was filed on June 1, 2014. As in prior litigation proceedings, we believe these IPR and the reexamination filings will provide support for maintaining the stay until the IPR and reexamination proceedings conclude.

On September 22, 2014, the RB Plaintiffs filed an action against us (and our commercial partner) relating to our BUNAVAIL product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL , whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent (U.S. Patent No. 8,765,167) (167 Patent). As with prior actions by the RB Plaintiffs, we believe this is another anticompetitive attempt by the RB Plaintiffs to distract our efforts from commercializing BUNAVAIL . We strongly refute as without merit the RB Plaintiffs assertion of patent infringement and will vigorously defend the lawsuit. In this regard, on October 28, 2014, we recently filed multiple IPR requests on the 167 Patent demonstrating that certain claims of such patent 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.

Item 1A. Risk Factors.

1. The following risk factor is intended to update and replace the risk factor captioned ***We will be subject to risks if we seek to develop our own sales force*** appearing in the 2013 Annual Report in order to account for our BUNAVAIL commercial activities.

BUNAVAIL is the first product that we have elected to commercialize. If we are unable to adequately develop, implement, or manage our sales, marketing and distribution capabilities, either on our own or through third parties who perform these functions, our commercialization efforts for BUNAVAIL or any future product we may commercialize would not produce the desired results, which would hurt our revenues and results of operations.

Prior to our decision to commercialize BUNAVAIL , we have relied on third parties to manage sales and marketing efforts for us, including Meda for ONSOLIS® and, if BEMA® Buprenorphine is approved, Endo. We therefore have little experience as a company in commercializing a product, and our sales, marketing and distribution capabilities are new. As such, we may not achieve success in marketing and promoting BUNAVAIL , or any other products we develop or acquire in the future or products we may commercialize through the exercise of co-promotion rights. Specifically, in order to optimize the commercial potential of BUNAVAIL , we must execute upon our commercialization plan effectively and efficiently. In addition, we must continually assess and modify our commercialization plan in order to adapt to the promotional response. Further, we must continue to focus and refine our marketing campaign to ensure a clear and understandable physician-patient dialogue around BUNAVAIL as an appropriate therapy. In addition, we must provide our sales forces with the highest quality training, support, guidance and oversight in order for them to effectively promote BUNAVAIL . If we fail to perform these commercial functions in the highest quality manner, BUNAVAIL will not achieve its maximum commercial potential or any level of success at all. With respect to BUNAVAIL , we rely on our agreement with Quintiles, who is responsible for providing our sales force on an outsourced basis. Should our relationship with Quintiles deteriorate or if our agreement with Quintiles is terminated, our sales efforts with BUNAVAIL would likely suffer materially and we may not be able to

keep or reconstitute our sales force. In addition, sales and marketing efforts could be negatively impacted by the delay or failure to obtain additional supportive clinical trial data for our products, as is the requirement for BUNAVAIL . The deterioration or loss of our sales force would materially and adversely impact our ability to generate sales revenue, which would hurt our results of operations. Finally, we are competing and expect to compete with other companies that currently have extensive and well-funded marketing and sales operations, and our marketing and sales efforts may be unable to compete against these other companies, which would also hurt our results of operations.

2. The following risk factor is intended to update the risk factor captioned ***If users of our products and product candidates are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our proposed formulations or products may be limited and we may not achieve material revenues*** appearing in the 2013 Annual Report in order to account for our BUNAVAIL commercial activities.

Table of Contents

If users of our products and product candidates are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our proposed formulations or products may be limited and we may not achieve material revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals and related laws, rules and regulations could materially harm our business, financial conditions, results of operations or stock price. Moreover, the passage of the Patient Protection and Affordable Care Act in 2010, and efforts to amend or repeal such law, has created significant uncertainty relating to the scope of government regulation of healthcare and related legal and regulatory requirements, which could have an adverse impact on sales of our products.

The ability of Meda to sell ONSOLIS® and our ability to commercialize BUNAVAIL will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Consumers and third-party payers are increasingly challenging the prices charged for drugs and medical services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

3. The following risk factor is intended to update the risk factor captioned ***Government and other efforts to reform the healthcare industry could have adverse effects on our company, including the inability of users of our current and future approved products to obtain adequate reimbursement from third-party payers, which could lead to diminished market acceptance of, and revenues from, such products*** appearing in the 2013 Annual Report in order to account for our BUNAVAIL commercial activities.

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

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

The Healthcare Reform Legislation contains a number of provisions that are expected to impact our business and operations or those of our commercial partners, including provisions governing enrollment in federal healthcare programs, reimbursement and discount programs and fraud and abuse prevention and control. The impact of these

programs on our business is presently uncertain and may have unexpected consequences for our company. For example, expansion of health insurance coverage under the Health Reform Legislation may result in a reduction in uninsured patients and increase in the number of patients with access to healthcare that have either private or public program coverage, and subsequently prescription drug coverage, including coverage for those products currently approved or in development by us or our partners. However, this outcome, along with any other potential benefits of the Health Reform Legislation which could prove a benefit for us or our commercial partners, is uncertain and may not occur.

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

Table of Contents

Furthermore, the ability of Meda to sell ONSOLIS® (once it is reformulated and placed back on the market in the U.S. and Canada) and our ability to commercialize BUNAVAIL and our product candidates with partners such as Endo or otherwise will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers, managed care, and other organizations and may all result in lower prices for or rejection of our products, which could further have a material adverse effect on our revenues (royalty or otherwise) and results of operations.

4. The following risk factor is intended to update the risk factor captioned ***We have limited manufacturing experience and therefore depend on third parties to formulate and manufacture our products. We may not be able to secure or maintain the manufacture of sufficient quantities or at an acceptable cost necessary to successfully commercialize or continue to sell our products*** appearing in the 2013 Annual Report in order to account for our BUNAVAIL commercial activities.

We have limited manufacturing experience and therefore depend on third parties to formulate and manufacture our products. We may not be able to secure or maintain the manufacture of sufficient quantities or at an acceptable cost necessary to successfully commercialize or continue to sell our products.

Our management s expertise has primarily been in the areas of research and development, formulation development and clinical trial phases of pharmaceutical product development. Our management s experience in the manufacturing of pharmaceutical products is more limited and we have limited equipment and no facilities of our own from which these activities could be performed. Therefore, we are fully dependent on third parties for our formulation development, manufacturing and the packaging of our products. This is particularly true with respect to ARx LLC (ARx), the primary manufacturer of our approved and commercialized product, BUNAVAIL . We also rely on Aveva Drug Delivery Systems, Inc. (Aveva), the manufacturer of ONSOLIS® in the U.S., and LTS Lohmann Therapie-Systeme AG (LTS), the manufacturer for BREAKYL in the E.U. This reliance exposes us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to formulate sufficient product to conduct clinical trials and maintain adequate supplies to meet market demand for our products.

Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay or limit production, which could leave our commercial partners with inadequate supplies of product to sell, especially when regulatory requirements or customer demand necessitate the need for additional product supplies. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes, and the inability of third party manufacturers like ARx, Aveva and LTS to consistently supply quality product when required would have a material adverse effect on our ability to commercialize and sell our products.

These risks associated with reliance on key third party manufacturers was demonstrated in March 2012, when Meda temporarily suspended distribution of ONSOLIS® following discussions with the FDA regarding certain appearance issues with the product. Specifically, the FDA raised concerns about two appearance issues with ONSOLIS® following an inspection of Aveva s manufacturing facility. On March 12, 2012, we announced the postponement of the U.S. and Canadian relaunch of ONSOLIS® until the product formulation can be modified to address these issues. Therefore, ONSOLIS® is not currently being marketed in the US and Canada and the relaunch and additional manufacturing of ONSOLIS® for those jurisdictions has been postponed until such product issues have been resolved. Any future manufacturing interruptions or related supply issues could have an adverse effect on our company, including loss of sales and royalty revenue and claims by or against us or our partners for breach of contract.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Table of Contents

Item 5. Other Information.

Update on Relaunch Activities in the U.S. for ONSOLIS®

On March 12, 2012, we announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide REMS until the product formulation could be modified to address two appearance-related issues raised by FDA during an inspection of the manufacturing facility of our North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. Specifically, the FDA identified the formation of microscopic crystals and a fading of the color in the mucoadhesive layer during the 24-month shelf life of the product. While these changes do not affect the product s underlying integrity, safety or performance, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and product specification before additional product can be manufactured and distributed.

The source of microcrystal formation and the potential for fading of ONSOLIS® was found to be specific to a buffer used in its formulation. This buffer and the coloring agent have both been removed in the reformulated product. As such, we believe the appearance issues have been resolved. We now have 9 months of product stability data on this formulation that shows no signs of microcrystal formation or color changes. We have prepared the necessary regulatory documentation that we believe the FDA will need to approve this change. We are working with our commercial partner, MEDA, who is responsible for the NDA and all regulatory filings including the one involving this matter. MEDA is in control of determining when this documentation will be submitted to the FDA. Once submitted, the FDA s review of the application may take up to 6 months.

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.

32

Table of Contents

SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: November 5, 2014

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

(Principal Executive Officer)

Date: November 5, 2014

By: /s/ Ernest R. De Paolantonio
Ernest R. De Paolantonio, Secretary and

Chief Financial Officer (Principal Accounting Officer)