BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 09, 2014
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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 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 May 7, 2014, there were 48,458,361 shares of company Common Stock issued and 48,442,870 shares of company Common Stock outstanding.

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**BioDelivery Sciences International, Inc. and Subsidiaries**

**Quarterly Report on Form 10-Q**

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**AS OF MARCH 31, 2014 AND DECEMBER 31, 2013**

| | March 31, 2014 (unaudited) | December 31, 2013 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 88,199,418 | $ 23,175,809 |
| Accounts receivable | 2,531,429 | 2,794,040 |
| Prepaid expenses and other current assets | 703,426 | 630,657 |
| Total current assets | 91,434,273 | 26,600,506 |
| Equipment, net | 235,061 | 178,168 |
| Idle equipment, net (note 1) | 3,301,112 | 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 | (5,996,091) | (5,753,502) |
| Total other intangible assets | 4,953,909 | 5,196,498 |
| Other assets | 392,112 | 470,535 |
| Total assets | $ 103,031,467 | $ 38,005,425 |
| **LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 8,844,483 | $ 10,415,981 |
| Notes payable, current maturities | 7,333,334 | 7,333,333 |
| Deferred revenue, current (notes 3 and 4) | 1,924,861 | 2,927,088 |
| Derivative liabilities (note 8) | 7,470,271 | 4,315,183 |
| Total current liabilities | 25,572,949 | 24,991,585 |
| Notes payable, less current maturities | 9,926,903 | 11,844,706 |
| Deferred revenue, long-term | 2,217,506 | 1,281,485 |
| Other long-term liabilities | 700,000 | 700,000 |
| Total liabilities | 38,417,358 | 38,817,776 |
| Commitments and contingencies (note 10) | | |
| Stockholders equity (deficit): | | |
| Preferred Stock, $.001 par value; 5,000,000 shares authorized in 2014 and 2013; 2,709,300 shares of Series A Non-Voting Convertible Preferred Stock | 2,709 | 2,709 |

| | | |
|---|---|---|
| outstanding in 2014 and 2013 | | |
| Common Stock, $.001 par value; 75,000,000 shares authorized in 2014 and 2013; 48,165,551 and 38,204,384 shares issued; 48,150,060 and 38,188,893 shares outstanding in 2014 and 2013, respectively | 48,166 | 38,204 |
| Additional paid-in capital | 220,567,836 | 150,506,927 |
| Treasury stock, at cost, 15,491 shares, 2014 and 2013 | (47,183) | (47,183) |
| Accumulated deficit | (155,957,419) | (151,313,008) |
| Total stockholders equity (deficit) | 64,614,109 | (812,351) |
| Total liabilities and stockholders equity (deficit) | $ 103,031,467 | $ 38,005,425 |

See notes to condensed consolidated financial statements

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(Unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2014** | **2013** |
| Revenues: | | |
| Product royalty revenues | $ 953,990 | $ |
| Research and development reimbursements | 8,451,979 | |
| Contract revenues | 11,283,833 | 1,621,977 |
| Total revenues: | 20,689,802 | 1,621,977 |
| Cost of product royalty revenues | 725,597 | 375,000 |
| Expenses: | | |
| Research and development | 14,623,221 | 12,032,168 |
| General and administrative | 4,622,024 | 2,910,256 |
| Related party general and administrative | 6,000 | 16,500 |
| Total expenses: | 19,251,245 | 14,958,924 |
| Income (loss) from operations | 712,960 | (13,711,947) |
| Interest (expense) income, net | (555,245) | 72,510 |
| Derivative (loss) gain | (4,825,458) | 1,024,951 |
| Other income (expense), net | 23,332 | (23,154) |
| Loss before taxes | (4,644,411) | (12,637,640) |
| Income tax expense | | (85,000) |
| Net loss attributable to common stockholders | $ (4,644,411) | $ (12,722,640) |
| Basic and diluted loss per share | $ (0.11) | $ (0.34) |
| Weighted average common stock shares outstanding | 44,035,288 | 37,511,326 |

See notes to condensed consolidated financial statements

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014**

**(Unaudited)**

| | Preferred Stock Series A | | Common Stock | | Additional Paid-In | Treasury | Accumulated | Total Stockholders |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Stock | Deficit | Equity |
| **Balances, January 1, 2014** | 2,709,300 | $ 2,709 | 38,204,384 | $ 38,204 | $ 150,506,927 | $ (47,183) | $ (151,313,008) | $ (812,351) |
| Stock-based compensation | | | | | 1,146,566 | | | 1,146,566 |
| Restricted stock awards | | | 363,893 | 364 | (364) | | | |
| Exercise of stock options | | | 826,236 | 826 | 2,558,898 | | | 2,559,724 |
| Exercise of warrants | | | 515,000 | 515 | 2,574,486 | | | 2,575,001 |
| Cashless exercise of warrants | | | 97,549 | 98 | (98) | | | |
| 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 | | | 658,489 | 659 | 3,855,042 | | | 3,855,701 |
| Warrant derivative liability reclassified to equity | | | | | 1,670,370 | | | 1,670,370 |
| Short swing profit return | | | | | 82,337 | | | 82,337 |
| Net loss | | | | | | | (4,644,411) | (4,644,411) |
| **Balances, March 31, 2014** | 2,709,300 | $ 2,709 | 48,165,551 | $ 48,166 | $ 220,567,836 | $ (47,183) | $ (155,957,419) | $ 64,614,109 |

See notes to condensed consolidated financial statements

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(Unaudited)**

| | Three months Ended March 31, | |
|---|---|---|
| | **2014** | **2013** |
| Operating activities: | | |
| Net loss | $ (4,644,411) | $ (12,722,640) |
| Adjustments to reconcile net loss to net cash flows from operating activities: | | |
| Depreciation and amortization | 331,520 | 366,161 |
| Accretion of debt discount | 82,198 | |
| Derivative loss (gain) | 4,825,458 | (1,024,951) |
| Purchase of Arcion license | | 2,072,136 |
| Stock-based compensation expense | 1,146,566 | 584,166 |
| Changes in assets and liabilities: | | |
| Accounts receivable | 262,611 | 293,192 |
| Prepaid expenses and other assets | (72,769) | (254,063) |
| Accounts payable and accrued expenses | (1,253,771) | (1,299,423) |
| Income tax payable | | 85,000 |
| Deferred revenue | (66,206) | (1,621,977) |
| Net cash flows from operating activities | 611,196 | (13,522,399) |
| Investing activities: | | |
| Purchase of equipment | (841,522) | |
| Net cash flows from investing activities | (841,522) | |
| Financing activities: | | |
| Proceeds from sale of securities | 62,036,873 | |
| Proceeds from exercise of stock options | 2,559,724 | |
| Proceeds from exercise of common stock warrants | 2,575,001 | |
| Payment of notes payable | (2,000,000) | |
| Return of short swing profits | 82,337 | |
| Net cash flows from financing activities | 65,253,935 | |
| Net change in cash and cash equivalents | 65,023,609 | (13,522,399) |
| Cash and cash equivalents at beginning of period | 23,175,809 | 63,189,307 |
| Cash and cash equivalents at end of period | $ 88,199,418 | $ 49,666,908 |

See notes to condensed consolidated financial statements

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(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 March 31, 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 is a specialty pharmaceutical company that is leveraging its novel and proprietary patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics. The Company is focusing on developing products to meet unmet patient needs in the areas of pain management and addiction.

The Company s pain franchise currently consists of four products, three of which utilize the patented BioErodible MucoAdhesive ( BEMA ) drug delivery technology, a thin film applied to the inner lining of the cheek. ONSOLIS® (fentanyl buccal soluble film) is approved in the U.S., Canada, E.U. (where it is marketed as BREAKYL) and Taiwan (where it is marketed as PAINKYL ), for the management of breakthrough pain in opioid tolerant, adult patients with cancer. The commercial rights to ONSOLIS® are licensed to Meda AB ( Meda ) for all territories worldwide except for Taiwan (licensed to TTY Biopharm Co. Ltd. ( TTY )) and South Korea (licensed to Kunwha Pharmaceutical Co., Ltd. ( Kunwha )). The Company s second pain product using the BEMA® technology, BEMA® Buprenorphine, is in Phase 3 clinical trials for the treatment of moderate to severe chronic pain and is licensed on a worldwide basis to Endo Health Solutions, Inc. ( Endo ). Additionally, in October 2013, the U.S. Food and Drug Administration ( FDA ) accepted the Company s New Drug Application for BUNAVAIL (buprenorphine naloxone buccal film), a high dose formulation of buprenorphine in combination with naloxone for the maintenance treatment of opioid dependence. FDA s decision on the BUNAVAIL New Drug Application ( NDA ) is due in June 2014. The Company s fourth pain product in

development is Clonidine Topical Gel for the treatment of painful diabetic neuropathy, which was licensed from Arcion Therapeutics, Inc. ( Arcion ) in March 2013.

The results of operations for the three month period ended March 31, 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.

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(Unaudited)**

**1. Basis of presentation (continued):**

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) |

*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 3 to ten years.

Due to the postponement of the U.S. re-launch of ONSOLIS® (note 3), related manufacturing equipment, net, totaling $2.8 million has been deemed idle, and has been reclassified to idle equipment, net in the accompanying condensed consolidated balance sheet as of March 31, 2014. During the three months ended March 31, 2014, $0.5 million of additions to idle equipment, net, is related to manufacturing equipment that will be used for the expected commercialization of BUNAVAIL that have not yet been placed into service. 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 three months ended March 31, 2014.

**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, 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 three months ended March 31, 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 $3.9 million in net proceeds utilizing a universal shelf registration (see note 9);
- approximately $11.2 million in contract revenue under the Endo agreement (see note 4);
- approximately $8.5 million in research and development reimbursements under the Endo agreement;
- approximately $0.3 million in net royalties under the Meda agreements;
- approximately $2.6 million from the exercise of stock options; and
- approximately $2.6 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.

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(Unaudited)**

**2. Liquidity and management s plans (continued):**

In April 2014, a warrant holder exercised 283,871 shares of common stock underlying a warrant for proceeds to the Company of $1.4 million.

At March 31, 2014, the Company had cash and cash equivalents of approximately $88.2 million. The Company generated $0.6 million of cash from operations during the three months ended March 31, 2014. As of March 31, 2014, the Company had stockholders equity of $64.6 million, versus deficit of $(0.8) million at December 31, 2013. The Company s existing cash, together with other expected cash inflows from other milestones and royalties, are anticipated to be sufficient to fully fund the Company s operations through the second quarter of 2015.

Additional capital may be required to support commercialization activities for BUNAVAIL , the clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of the Company s agreement with Endo), the clinical development of Clonidine Topical Gel for painful diabetic neuropathy, the reformulation project for and anticipated commercial relaunch of ONSOLIS® and for general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. There can be no assurance that additional funding, when and if required, will be available at commercially available terms, if at all.

**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 March 31, 2014, there was remaining deferred revenue of $1.2 million which was related to the Meda research and development services. As time progresses, the Company will continue to estimate the time required for ongoing obligations, and adjust the remaining deferred revenue accordingly on a quarterly basis.

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. The Company earned $1.0 million in product royalty revenue for the three months ended March 31, 2014. No such revenue was reported for the corresponding period of 2013. The Company has incurred cost of product royalty revenue of approximately $0.7 million and $0.4 million for the three months ended March 31, 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 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.

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(Unaudited)**

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

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 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 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.

The source of microcrystal formation and the potential for fading of the product was found to be specific to a buffer used in the manufacturing process for ONSOLIS®. ONSOLIS® has been reformulated and the Company s believes the appearance issues have been resolved. Meda, the Company s commercial partner, is working to determine the content and timing of the submission to FDA. Once submitted, FDA s review of the application may take up to 6 months. If the submission is made before mid-2014, and approved by FDA, the relaunch could occur by the end of 2014; otherwise, the relaunch would move to sometime in 2015.

On May 21, 2012, the Company announced receipt of a pre-launch milestone payment of $2.5 million from Meda in conjunction with the first country registration and pricing approval for BREAKYL (tradename for ONSOLIS® in the EU). A final milestone payment related to the EU of $2.5 million was paid at the time of commercial launch, which occurred in October 2012. BREAKYL is commercialized in the EU by Meda.

On September 13, 2012, the Company executed a Manufacturing, Supply, and License Agreement, effective April 26, 2012, with 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 they 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 is expected to receive upon satisfaction of applicable conditions) the following payments (some portion(s) of which will be utilized by the Company to support its development obligations under the Endo Agreement with respect to BEMA® Buprenorphine):

$30 million non-refundable upfront license fee (received January 17, 2012);

up to an aggregate of $95 million in six separate potential milestone payments based on the following pre-defined events: (i) enhancement of intellectual property rights (two milestones aggregating $35 million in potential milestone payments,

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(Unaudited)**

**4. Endo License and Development Agreement (continued):**

including a May 2012 receipt of $15 million upon issuance of a certain patent covering the product), (ii) clinical development (two milestones aggregating $20 million in potential milestone payments) and (iii) regulatory events (two milestones aggregating $40 million in potential milestone payments);

up to an aggregate of $55 million based on the achievement of four separate post-approval sales thresholds; and

sales-based royalties in a particular percentage range on U.S. sales of BEMA® Buprenorphine, and royalties in a lesser range on sales outside the United States, subject to certain restrictions and adjustments.

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

At the inception of the Endo arrangement, 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. In April 2012, the patent being sought by the Company was granted as described further below, and in May 2012, the applicable intellectual property milestone payment of $15 million was received and recognized as revenue. The amount allocated to the license was recognized as revenue in January 2012.

The portion of the upfront license fee allocated to the clinical development services deliverable ($14.4 million) is being recognized as those services are performed. The Company estimates that such clinical development services will extend into the first half of 2015. Based on the estimated proportion of those services performed through March 31, 2014, $5.2 million was recognized as revenue in fiscal year 2012, $6.3 million was recognized as revenue in fiscal year 2013 and $1.2 million was recognized as revenue during the three months ended March 31, 2014. As a result, $1.7 million remains deferred at March 31, 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.

The term of the Endo Agreement shall last, on a country-by-country basis, until the later of: (i) 10 years from the date of the first commercial sale of BEMA® Buprenorphine in a particular country or (ii) the date on which the last valid claim of the Company s patents covering BEMA® Buprenorphine in a particular country has expired or been invalidated. The Endo Agreement shall be subject to termination: (i) by Endo, at any time, upon a specific amount of prior written notice to the Company, (ii) by Endo and the Company

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**4. Endo License and Development Agreement (continued):**

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 received.

The remaining milestone payments are expected to be recognized as revenue as and if they are achieved, except that one milestone is contingently refundable for a period of time. Revenue related to 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 accrue 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 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 total potential future milestones of $50 million associated with achievement of certain regulatory events. During the three months ended March 31, 2014, the Company received $1.2 million of such prepayments, which have been recorded as deferred revenue, long term in the accompanying condensed consolidated 2014 balance sheet. During three months ended March 31, 2014, the Company recognized $8.5 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.

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.

**5. Arcion License Agreement:**

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

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

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

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

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

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**5. Arcion License Agreement (continued):**

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

All milestone payments due 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 2013 condensed consolidated statement of operations.

**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).

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

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

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

*TTY License and Supply Agreement*

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

On November 7, 2011, the Company announced that TTY had submitted an NDA for marketing authorization of BEMA® Fentanyl to the Taiwan Food and Drug Administration. This triggered a milestone payment to the Company of approximately $0.3 million, which was received November 2011 and recorded as contract revenue in 2011.

On July 29, 2013, the Company announced the regulatory approval of BEMA® Fentanyl in Taiwan, where the product will be marketed under the brand name PAINKYL . The approval in Taiwan 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, Arius One and Arius Two (the Borrowers ) entered into a $20 million secured loan facility (the Loan Transaction and such loan, the Loan ) with MidCap as agent and lender pursuant to the terms and conditions of the Credit Agreement. The Company received net proceeds in the aggregate amount of $19.9 million and will use the Loan proceeds for general corporate purposes or other activities of the Borrower permitted under the Credit Agreement.

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

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 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

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**7. MidCap Secured Loan Facility (continued):**

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. In addition, if the Company receives the second of two anticipated database lock milestone payments (the Database Lock Payments ) from Endo in connection with the Endo Agreement, the Company may prepay 50% of the principal amount of the Loan then outstanding and, concurrently and at the Company s election, either: (i) pay to MidCap a cash prepayment fee of 2% of the principal amount of the Loan and all obligations thereunder outstanding as of the date of prepayment or (ii) issue to MidCap a warrant (in a form substantially similar to the MidCap Warrant) to purchase shares of Common Stock equal to 2.0% of the prepayment amount, with the number of shares being calculated using the Black-Scholes pricing model.

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

Under the Credit Agreement, the Borrowers are subject to affirmative covenants which are customary for financings of this type, including, 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, (vii) failure to receive the Database Lock Payments by June 30, 2014, and (viii) certain other events, including certain adverse actions taken by the Food and Drug Administration or other governmental authorities. Upon an event of default, the Borrower s obligations under the Credit Agreement may, or in the event of insolvency or bankruptcy will automatically, be accelerated. Upon the occurrence of any event of default, the Borrower s obligations under the Credit Agreement will bear interest at a rate equal to the lesser of: (i) 4% above the rate of interest applicable to such obligations immediately prior to the occurrence of the event of default or (ii) the maximum rate allowable under law. The balance of the secured loan facility due to MidCap as of March 31, 2014 is $17.3 million, and is recorded in the accompanying condensed consolidated March 31, 2014 balance sheet, net of unamortized discount of $0.7 million.

The following table represents future maturities of the MidCap obligation as of March 31, 2014:

| **Years ending March 31,** | |
|---|---|
| 2014 | $ 7,333,334 |
| 2015 | 8,000,000 |
| 2016 | 2,666,666 |
| | |
| Total maturities | 18,000,000 |
| Unamortized discount | (739,763) |
| | |
| Total Midcap obligation | $ 17,260,237 |

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**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 March 31, 2014 and December 31, 2013, respectively:

| | March 31, 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 | $ | $ 7,470,271 | $ | $ 7,470,271 | $ | $ 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 March 31, 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 | (1,670,370) | (515,000) |
| Increase in fair value of warrants | 4,825,458 | |
| Warrant liability as of March 31, 2014 | $ 7,470,271 | 1,484,436 |

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

**9. Stockholders Equity:**

*Stock-based compensation:*

During the three months ended March 31, 2014, a total of 109,685 options to purchase Common Stock with an aggregate fair market value of approximately $0.6 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 three months ended March 31, 2014 follows:

| | |
|---|---|
| Expected price volatility | 76.23-78.05% |
| Risk-free interest rate | 1.58% |
| Weighted average expected life in years | 6 years |
| Dividend yield | |

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**9. Stockholders Equity (continued):**

Option activity during the three months ended March 31, 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 | 109,685 | 7.63 | |
| Exercised | (826,236) | 3.10 | |
| Forfeitures | | | |
| Outstanding at March 31, 2014 | 3,476,376 | $ 4.12 | $ 15,034,087 |

Options outstanding at March 31, 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 | 2,429,532 | 5.64 | $ 3.13 | |
| $5.01 10.00 | 1,046,844 | 4.37 | $ 6.42 | |
| | 3,476,376 | | | $ 15,034,087 |

Options exercisable at March 31, 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 | 2,051,682 | 5.08 | $ 3.01 | |
| $5.01 10.00 | 881,500 | 3.36 | $ 6.33 | |
| | 2,933,182 | | | $ 12,998,927 |

The weighted average grant date fair value of options granted during the three months ended March 31, 2014 was $5.13. There were no options granted during the three months ended March 31, 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 three months ended March 31, 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 | 109,685 | | |
| Vested | (180,959) | | |
| Forfeited | | | |
| Nonvested at March 31, 2014 | 543,194 | $ 3.29 | $ 2,035,160 |

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**9. Stockholders Equity (continued):**

As of March 31, 2014, there was approximately $14.6 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.

*Warrants:*

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. Warrants outstanding at March 31, 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 | 1,663,114 | 1.23 | $ 3.56 | $ 8,121,117 |

During the three months ended March 31, 2014, a total of 515,000 shares of Common Stock underlying warrants were exercised for proceeds to the Company of $2.6 million. Also during the three months ended March 31, 2014, there were 178,678 shares of Common Stock underlying a warrant exercised on a cashless basis, which resulted in a net exercise of 97,549 shares to the warrant holder.

*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. Concurrently 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.

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 three months ended March 31, 2014, Company employees, directors and affiliates exercised approximately 0.8 million stock options, with net proceeds to the Company of approximately $2.6 million.

*Preferred Stock*

The Company has authorized five million blank check shares of $.001 par value convertible preferred stock. At March 31, 2014, 2,709,300 shares of Series A Preferred were outstanding.

*Restricted Stock Units:*

During the three months ended March 31, 2014, a total of 997,500 restricted stock units ( 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.

Also during the three months ended March 31, 2014, a total of 359,446 RSUs that were previously granted to members of the Company s senior management vested. Such vested RSUs had a fair market value of approximately $3.2 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.

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(Unaudited)**

**9. Stockholders Equity (continued):**

*Performance Long Term Incentive Plan*

In December 2012, the Company s Board of Directors 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 our Annual Report on Form 10-K. During the three months ended March 31, 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 ). The Company is now awaiting a decision from the PTAB on MonoSol s appeal of the USPTO s rejection of all the claims of the 588 Patent. On April 17, 2014, the PTAB issued

a Decision on Appeal affirming the USPTO s rejection (and confirming the invalidity) of all the claims of the 588 Patent. MonoSol has one month from the PTAB Decision date to request a rehearing and two months from the PTAB Decision date to appeal the Decision to the Federal Court of Appeals.

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 their 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, 588, has had all claims rejected and appears to have had a similar fate. Importantly, the Company will continue to defend this case vigorously, and anticipates that MonoSol s claims against the Company will ultimately 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.

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. The Company is presently awaiting a decision from the Court on the motions.

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**BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**(Unaudited)**

**11. Subsequent events:**

On April 3, 2014, the Company announced the enrollment of the first patient in the RHAPSODY Study, a Phase 3 clinical trial of the Company s Clonidine Topical Gel product for the treatment of painful diabetic neuropathy.

On May 6, 2014, the Company announced the randomization of more than half of the planned number of patients required for its ongoing initial Phase 3 study of Clonidine Topical Gel, the Company s proposed treatment for painful diabetic neuropathy (PDN). An interim analysis of the study, which will be based on the first 50% of patients entering the study, is now anticipated to occur in the third quarter of 2014.

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

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

**For the three months ended March 31, 2014 compared to the three months ended March 31, 2013**

***Product Royalty Revenues***. We recognized $1.0 million in product royalty revenue during the three months ended March 31, 2014 under our license agreement with Meda. No such revenue was reported in the corresponding period of 2013. The product royalty revenues can be attributed to a percentage of net sales revenue of the ONSOLIS® product under our license agreement with Meda.

***Research and Development Reimbursements.*** We recognized $8.5 million of reimbursable revenue related to our agreement with Endo during the three months ended March 31, 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 $11.3 million and $1.6 million in contract revenue during the three months ended March 31, 2014 and 2013, respectively, under our license agreement with Endo. We also recognized $0.05 million during each of the three months ended March 31, 2014 and 2013, in contract revenue related to previously deferred revenue under our license agreement with Meda. The increase in contract revenues during the three months ended March 31, 2014 can be attributed to the $10 million milestone payment received from Endo associated with a Phase III study database lock.

***Cost of Product Royalty Revenues***. We recognized $0.7 million and $0.4 million in cost of product royalties during the three months ended March 31, 2014 and 2013, respectively. Both periods include minimum quarterly payments to CDC.

***Research and Development Expenses***. During the three months ended March 31, 2014 and 2013, research and development expenses totaled $14.6 million and $12 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. We also began development activities for Topical Clonidine Gel for painful diabetic neuropathy. 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 increased during the three months ended March 31, 2014 due to Buprenorphine Chronic Pain clinical trial expenses. The opioid experienced trial and long term safety study included more patients when compared to last year at this time due to expansion of both studies. However, it should be noted that approximately $8.5 million of this expense is reimbursable by Endo and such reimbursement have been recorded as revenue and shown as research and development reimbursements for the three months ended March 31, 2014.

***General and Administrative Expenses, net***. During the three months ended March 31, 2014 and 2013, general and administrative expenses totaled $4.6 million and $2.9 million, respectively. 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 general and administrative expenses during the three months ended March 31, 2014 can be attributed to marketing and sales expense in preparation of a BUNAVAIL launch in the second half of 2014.

***Interest (expense) income, net***. During the three months ended March 31, 2014 we had net interest expense of $0.6 million, consisting of $0.4 million of scheduled interest payments and $0.2 million of related amortization of discount and loan costs related to the July 2013 secured loan facility from MidCap, offset by interest income of $0.04 million. During the three months ended March 31, 2013, we had interest income, dividends and gains of $0.05 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 March 31, 2014, our stock price increased by $2.55. This is the largest component of the Black-Scholes change. As a result, our derivative liability also increased, resulting in a $4.8 million charge to income. During the three months ended March 31, 2013, our stock price decreased, and the volatility used in the calculation also decreased. As a result, our warrant liability decreased, resulting in a $1 million gain. This gain was partially offset by a $0.02 million loss from the cancellation in 2013 of 2 million previously owned Biovest options.

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**Liquidity and Capital Resources**

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, funded research arrangements, revenue 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.

At March 31, 2014, we had cash and cash equivalents of approximately $88.2 million. We generated approximately $0.6 million of cash from operations during the three months ended March 31, 2014. As of March 31, 2014, we had stockholders equity of approximately $64.6 million versus a deficit of approximately $(0.8) million at December 31, 2013. We believe that our existing cash as of the date of this Quarterly Report, together with other expected cash inflows from other milestones and royalties, is sufficient to fully fund our planned level of operations through the second quarter of 2015.

Additional capital may be required to support our commercialization activities for BUNAVAIL , or should BUNAVAIL not be approved, to fund any additional requirements the FDA may request prior to considering it for approval, clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of our agreement with Endo), our clinical development of Clonidine Topical Gel for painful diabetic neuropathy, the reformulation project for and anticipated commercial relaunch of ONSOLIS® and for general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. There can be no assurance that additional funding, when and if required, will be available at commercially available terms, if at all.

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

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

public equity markets;

private equity financings;

commercialization agreements and collaborative arrangements;

sale of product royalty;

grants and new license revenues;

bank loans;

equipment financing;

public or private debt; and

exercise of existing warrants and options.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from potential commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, any of which could have a material adverse effect on us, our financial condition and our results of operations in 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.

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***Contractual Obligations and Commercial Commitments***

Our contractual obligations as of March 31, 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 | $ 119,223 | $ 119,223 | $ | $ | $ |
| Employment agreements | 1,224,347 | 1,224,347 | | | |
| Secured loan facility | 18,000,000 | 7,333,334 | 10,666,666 | | |
| Interest on secured loan facility | 2,052,037 | 1,363,218 | 688,819 | | |
| Minimum royalty expenses* | 8,625,000 | 1,500,000 | 3,000,000 | 3,000,000 | 1,125,000 |
| Total contractual cash obligations** | $ 30,020,607 | $ 11,540,122 | $ 14,355,485 | $ 3,000,000 | $ 1,125,000 |

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

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

***Off-Balance Sheet Arrangements***

As of March 31, 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 GAAP related to Goodwill and Other Intangible Assets. Accordingly, goodwill is not amortized but is tested annually in December for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with limited useful lives are amortized using the straight-line method over their estimated period of benefit, ranging from eleven to thirteen years. Our carrying value of goodwill at March 31, 2014 was $2.715

million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements or the underlying patents. Our carrying value of other amortizing intangible assets at March 31, 2014 was $5 million, net of accumulated amortization of $6 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 FASB issued ASU 2011-08, Testing Goodwill for Impairment . The update allows us to qualitatively assess whether the fair value of a reporting unit is less than its carrying amount, and is effective for fiscal years beginning after December 15, 2011. 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.

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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 three months ended March 31, 2014 or 2013.

***Stock-Based Compensation and other stock based valuation issues (derivative accounting)***

We account for stock-based awards to employees and non-employees in accordance with generally accepted accounting principles related to share based payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our Common Stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide the service in exchange for the award. We use the Black-Scholes options-pricing model to determine the fair value of stock option and warrant grants. We also use the Black-Scholes option pricing model as the primary basis for valuing our derivative liabilities and assets at each reporting date (both embedded and free-standing derivatives). The underlying assumptions used in this determination are primarily the same as are used in the determination of stock-based compensation previously discussed except contractual lives of the derivative instruments are utilized rather than expected option terms as previously discussed.

***Revenue recognition***

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

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

***Interest rate risk***

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents include Ultra Short Term Government Funds. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation 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 March 31, 2014, we had approximately $88 million, which exceed these insured limits.

***Foreign currency exchange risk***

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

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

As of the end of the period covered by this Quarterly Report, the Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer (the Certifying Officers ), conducted evaluations of our disclosure controls and procedures. As defined under Sections 13a 15(e) and 15d 15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act ), the term disclosure controls and procedures means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded,

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processed, summarized and reported, within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer s management, including the Certifying Officers, to allow timely decisions regarding required disclosures.

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

*Changes in Internal Control over Financial Reporting*

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

*Limitations on the Effectiveness of Internal Controls*

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

**CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS**

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations (and the Liquidity and Capital Resources section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes forward-looking statements within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as projects, may, could, would, should, believes, expects, anticipates, estimates, intends, plans or 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 any 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.

**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.

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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.

Importantly, in the case of MonoSol s 588 Patent, the USPTO on July 20, 2012 issued a second Office Action closing prosecution and rejecting for a second time all claims as anticipated or obvious. It also rejected the amended claims proposed by MonoSol as unclear and lacking support. Then, on January 23, 2013, the USPTO issued a Right of Appeal Notice, rejecting all claims of the 588 Patent and closing reexamination proceedings. This action confirms that all claims of this patent are also invalid, but unlike 292 and 891, the USPTO has not found that any amended or narrower claims should be granted. On February 22, 2013, MonoSol filed both a Notice of Appeal to the Board of Patent Appeals and Interferences and a Request for Continuing Examination of the 588 Patent. On March 12, 2013, we filed a petition requesting the USPTO to deny MonoSol s February 22, 2013 Request to Continue Examination and to allow the proceedings to go to an appeal. Subsequently, on July 3, 2013, the USPTO denied MonoSol s February 22, 2013 Request to Continue Examination. After reviewing MonoSol s Appeal Brief (filed June 24, 2013) and our Respondent s Brief (filed July 24, 2013), the USPTO formally initiated the appeals process with the Examiner s Answer on August 8, 2013, which affirmed the rejection of all the claims in the 588 Patent. On March 26, 2014, we 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

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issued a Decision on Appeal affirming the Examiner s rejection (and confirming the invalidity) of all the claims of the 588 Patent. MonoSol has one month from the PTAB Decision date to request a rehearing and two months from the PTAB decision date to appeal the Decision to the Federal Court of Appeals.

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, 588, has had all claims rejected and appears to have had a similar fate. Importantly, we will continue to defend this case vigorously, and we anticipate that MonoSol s claims against us will ultimately be rejected.

*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 this is another anticompetitive attempt by the RB Plaintiffs to distract our efforts from commercializing BUNAVAIL .

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 . We look forward to the FDA s review of the BUNAVAIL NDA as it moves toward the June 7, 2014 PDUFA date when we expect a response from FDA on our NDA for 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 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. We are now awaiting a decision from the Court on the motions.

**Item 1A. Risk Factors.**

No update.

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

None.

**Item 3. Defaults upon Senior Securities.**

None.

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**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

*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 the product was found to be specific to a buffer used in the manufacturing process for ONSOLIS®. ONSOLIS® has been reformulated and we believe the appearance issues have been resolved. Meda, our commercial partner, is working to determine the content and timing of the submission to FDA. Once submitted, FDA s review of the application may take up to 6 months. If the submission is made before mid-2014, and approved by FDA, the relaunch could occur by years end, otherwise, the relaunch would move to sometime 2015.

*Agreement with Quintiles*

On September 25, 2013, we entered into a Master Services Agreement with Quintiles Commercial US, Inc. ( Quintiles ) under which we choose Quintiles to support our commercial sales and related efforts for BUNAVAIL. Initially, we were not required to undertake any material outlays under this agreement. On March 27, 2014, we agreed with Quintiles on a scope of work for the BUNAVAIL project, which solidified the relationship, thus making the Master Services Agreement more meaningful to our company. Under the Master Services Agreement as modified by the scope of work, we agreed with Quintiles on the economic arrangements for the project as well as other customary provisions, including provisions relating to termination and indemnification.

**Item 6. Exhibits.**

| Number | Description |
|---|---|
| 10.1 | Master Services Agreement, dated September 25, 2013, between the Company and Quintiles Commercial US, Inc. + |
| 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.

\+ Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.

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**SIGNATURES**

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 9, 2014

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

(Principal Executive Officer)

Date: May 9, 2014

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

Chief Financial Officer (Principal Accounting Officer)