BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 11, 2015
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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, 2015**

¨ **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.)** |
| **4131 ParkLake Ave., Suite 225** | |
| **Raleigh, NC** | **27612** |
| **(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 8, 2015, there were 52,418,518 shares of company Common Stock issued and 52,403,027 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**

**(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)**

**(Unaudited)**

| | March 31, 2015 | December 31, 2014 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 63,459 | $ 70,472 |
| Accounts receivable, net | 3,031 | 3,141 |
| Inventory | 2,550 | 1,828 |
| Prepaid expenses and other current assets | 2,704 | 2,882 |
| Total current assets | 71,744 | 78,323 |
| Property and equipment, net | 3,948 | 3,890 |
| Goodwill | 2,715 | 2,715 |
| Other intangible assets, net | 3,984 | 4,226 |
| Other assets | 78 | 157 |
| Total assets | $ 82,469 | $ 89,311 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 14,512 | $ 14,429 |
| Notes payable, current maturities | 8,000 | 8,000 |
| Deferred revenue, current | 7,075 | 6,772 |
| Total current liabilities | 29,587 | 29,201 |
| Notes payable, less current maturities, net | 2,256 | 4,173 |
| Deferred revenue, long-term | 45 | 841 |
| Other long-term liabilities | 734 | 700 |
| Total liabilities | 32,622 | 34,915 |
| Commitments and contingencies (Notes 6 and 10) | | |
| Stockholders equity: | | |
| Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,093,155 and 2,139,000 shares of Series A Non-Voting Convertible Preferred Stock outstanding at March 31, 2015 and December 31, 2014, respectively. | 2 | 2 |
| Common Stock, $.001 par value; 75,000,000 shares authorized; 52,381,638 and | 53 | 52 |

| | | |
|---|---|---|
| 51,603,070 shares issued; 52,366,147 and 51,587,579 shares outstanding at March 31, 2015 and December 31, 2014, respectively | | |
| Additional paid-in capital | 263,563 | 259,920 |
| Treasury stock, at cost, 15,491 shares | (47) | (47) |
| Accumulated deficit | (213,724) | (205,531) |
| Total stockholders equity | 49,847 | 54,396 |
| Total liabilities and stockholders equity | $ 82,469 | $ 89,311 |

See notes to condensed consolidated financial statements

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

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)**

**(Unaudited)**

| | Three months ended March 31, | |
|---|---|---|
| | 2015 | 2014 |
| Revenues: | | |
| Product sales | $ 677 | $ |
| Product royalty revenues | 194 | 954 |
| Research and development reimbursements | 775 | 8,452 |
| Contract revenue | 11,408 | 11,284 |
| Total revenues | 13,054 | 20,690 |
| Cost of sales | 1,124 | 726 |
| Expenses: | | |
| Research and development | 6,549 | 14,623 |
| Selling, general and administrative | 13,181 | 4,628 |
| Total expenses | 19,730 | 19,251 |
| (Loss) income from operations | (7,800) | 713 |
| Interest expense, net | (420) | (555) |
| Derivative loss | | (4,825) |
| Other income, net | 27 | 23 |
| Net loss attributable to common stockholders | $ (8,193) | $ (4,644) |
| Basic earnings per share | $ (0.16) | $ (0.11) |
| Diluted earnings per share | $ (0.16) | $ (0.11) |
| Weighted average common stock shares outstanding | 51,908,844 | 44,305,288 |

See notes to condensed consolidated financial statements

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

**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY**

**(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)**

**(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, 2015** | 2,139,000 | $ 2 | 51,603,070 | $ 52 | $ 259,920 | $ (47) | $ (205,531) | $ 54,396 |
| Stock-based compensation | | | | | 3,507 | | | 3,507 |
| Restricted stock awards | | | 694,269 | 1 | (1) | | | |
| Exercise of stock options | | | 38,454 | | 131 | | | 131 |
| Short swing profit return | | | | | 6 | | | 6 |
| Conversion of preferred shares to common shares | (45,845) | | 45,845 | | | | | |
| Net loss | | | | | | | (8,193) | (8,193) |
| **Balances, March 31, 2015** | 2,093,155 | $ 2 | 52,381,638 | $ 53 | $ 263,563 | $ (47) | $ (213,724) | $ 49,847 |

See notes to condensed consolidated financial statements

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

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

| | Three months ended March 31, | |
|---|---|---|
| | **2015** | **2014** |
| Operating activities: | | |
| Net loss | $ (8,193) | $ (4,644) |
| Depreciation | 85 | 11 |
| Accretion of debt discount | 162 | 161 |
| Amortization of intangible assets | 242 | 243 |
| Derivative loss | | 4,825 |
| Stock-based compensation expense | 3,507 | 1,147 |
| Changes in assets and liabilities: | | |
| Accounts receivable | 109 | 262 |
| Inventories | (722) | |
| Prepaid expenses and other assets | 177 | (73) |
| Accounts payable and accrued expenses | 127 | (1,255) |
| Deferred revenue | (499) | (66) |
| Net cash flows from operating activities | (5,005) | 611 |
| Investing activities: | | |
| Purchase of equipment | (144) | (842) |
| Net cash flows from investing activities | (144) | (842) |
| Financing activities: | | |
| Proceeds from sales of securities | | 62,037 |
| Proceeds from exercise of stock options | 131 | 2,560 |
| Proceeds from exercise of common stock warrants | | 2,575 |
| Payment on note payable | (2,001) | (2,000) |
| Return of short swing profits | 6 | 82 |
| Net cash flows from financing activities | (1,864) | 65,254 |
| Net change in cash and cash equivalents | (7,013) | 65,023 |
| Cash and cash equivalents at beginning of year | 70,472 | 23,176 |
| **Cash and cash equivalents at end of year** | **$ 63,459** | **$ 88,199** |

| | | |
|---|---|---|
| Cash paid for interest | $ 269 | $ 432 |

See notes to condensed consolidated financial statements

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

## 1. Organization, basis of presentation and summary of significant policies:

*Overview*

BioDelivery Sciences International Inc., together with its subsidiaries (collectively, the Company or BDSI ) 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 accompanying unaudited consolidated financial statements include all adjustments (consisting of normal and recurring adjustments) necessary for a fair presentation of these financial statements. The consolidated balance sheet at December 31, 2014 has been derived from the Company s audited consolidated financial statements included in its annual report on Form 10-K for the year ended December 31, 2014. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ( GAAP ) have been condensed or omitted pursuant to the Securities and Exchange Commission ( SEC ) rules and regulations. It is suggested that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2014.

Operating results for the three month period ended March 31, 2015 are not necessarily indicative of results for the full year or any other future periods.

As used herein, the Company s common stock, par value $.001 per share, is referred to as the Common Stock .

*Use of estimates in financial statements*

The preparation of the accompanying condensed consolidated financial statements requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and assumptions.

*Inventory*

Inventories are stated at the lower of cost or market value with costs determined on the first-in, first-out method. Inventory consists of raw materials, work in process and finished goods. Raw materials include active pharmaceutical ingredient ( API ) for a product to be manufactured, work in process includes the bulk inventory of laminate prior to being packaged for sale, and finished goods include pharmaceutical products ready for commercial sale.

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales. There were no allowances recorded at March 31, 2015.

*Deferred revenue*

Consistent with the Company s revenue recognition policy, deferred revenue represents cash received in advance for licensing fees, consulting, research and development services, related supply agreements and product sales. Such payments are reflected as deferred revenue until recognized under the Company s revenue recognition policy. Deferred revenue is classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date.

*Revenue recognition*

*Product Sales*- The Company recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for rebates, price adjustments, chargebacks, prompt payment and other discounts. When the Company cannot reasonably estimate the amount of future product returns, it defers revenues until the risk of product return has been substantially eliminated.

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**1. Organization, basis of presentation and summary of significant policies (continued):**

As of March 31, 2015 and December 31, 2014, the Company had $1.0 million and $0.8 million of deferred revenue related to sales to wholesalers for which future returns could not be reasonably estimated at the time of sale. Deferred revenue is recognized when the product is sold to the end user, based upon prescriptions filled. To estimate product sold to end users, the Company relies on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sales to customers. Deferred revenue is recorded net of estimated allowances for rebates, price adjustments, chargebacks, prompt payment and other discounts. Estimated allowances are recorded and classified as accrued liabilities in the accompanying balance sheets as of March 31, 2015 and December 31, 2014 (Note 4).

*Product Returns*- Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the products within an 18-month period that begins six months prior to and ends twelve months subsequent to expiration of the products. The Company does not believe it has sufficient experience with BUNAVAIL® to estimate its returns at time of exfactory sales. When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated which is at the time the product is sold to the end user.

*Rebates*- The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program s administrator.

*Price Adjustments and Chargebacks*- The Company s estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the Company s listed prices of its products. In the event that the sales mix to third-party payers is different from the Company s estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it had estimated and such differences may be significant.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. The Company has voucher programs for BUNAVAIL® whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company s completed programs. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

*Prompt Payment Discounts*- The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 37 days after the invoice date depending on the customer and the products purchased.

*Deferred Cost of Sales*

The Company defers its cost of sales in connection with BUNAVAIL® sales at time of ex-factory sales. These costs are recognized when the product is sold to the end user. The Company had $0.9 million and $0.7 million of deferred costs of sales at March 31, 2015 and December 31, 2014, respectively, which are included in other current assets in the accompanying condensed consolidated balance sheets.

*Cost of Sales*

The cost of sales attributable to the production of BUNAVAIL® includes raw materials, production costs at our two contract manufacturing sites, quality testing directly related to the product, and depreciation on equipment that we have purchased to produce BUNAVAIL®. It also includes any batches not meeting specifications and raw material yield loss. Yield losses and batches not meeting specifications are expensed as incurred. Cost of sales is recognized as actual product is sold through to the end user. During the three months ended March 31, 2015, the Company wrote down $0.2 million of inventory to lower of cost or market, which is recorded as cost of sales in the accompanying condensed consolidated statement of operations.

The cost of sales attributable to the production of ONSOLIS® and BREAKYL includes all costs related to creating the product at the Company s contract manufacturing locations in the U.S. and Germany. The Company s contract manufacturers bill the Company for the final product, which includes materials, direct labor costs, and certain overhead costs as outlined in applicable supply agreements. Cost of sales also includes royalty expenses that the Company owes to third parties.

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**1. Organization, basis of presentation and summary of significant policies (continued):**

*Recent accounting pronouncements*

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers, which supersedes the revenue recognition requirements of Accounting Standards Codification ( ASC ) Topic 605, Revenue Recognition and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard will be effective for the Company in the first quarter of the year ending December 31, 2017 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. The Company is currently evaluating the impact of adoption of the new standard on its consolidated financial statements.

**2. Liquidity and management s plans:**

At March 31, 2015, the Company had cash and cash equivalents of approximately $63.5 million. The Company used $5 million of cash from operations during the three months ended March 31, 2015 and had stockholders equity of $49.8 million, versus $54.4 million at December 31, 2014. The Company has sufficient cash to manage the business into early 2016, although this assumes that the Company does not accelerate the development of other opportunities available to the Company or otherwise face unexpected events, costs or contingencies, any of which could affect the Company s cash requirements.

Additional capital will likely be required to support the Company s ongoing commercialization activities for BUNAVAIL®, the reformulation project for and anticipated commercial relaunch of ONSOLIS®, the development of Clonidine Topical Gel and Buprenorphine Depot Injection or other products which may be acquired or licensed by the Company, and general working capital requirements. Based on product development timelines and agreements with the Company s development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all.

**3. Inventory:**

The following table represents the components of inventory as of:

| | March 31, 2015 | December 31, 2014 |
|---|---|---|
| Raw materials & supplies | $ 580 | $ 544 |
| Work-in-process | 1,296 | 523 |
| Finished goods | 674 | 761 |
| Total inventories | $ 2,550 | $ 1,828 |

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**4. Accounts payable and accrued liabilities:**

The following table represents the components of accounts payable and accrued liabilities as of:

| | March 31, 2015 | December 31, 2014 |
|---|---|---|
| Accounts payable | $ 10,038 | $ 9,072 |
| Accrued price adjustments | 1,629 | 1,094 |
| Accrued rebates | 122 | 231 |
| Accrued chargebacks | 23 | 14 |
| Accrued compensation and benefits | 737 | 945 |
| Accrued royalties | 382 | 770 |
| Accrued other | 1,581 | 2,303 |
| Total accounts payable and accrued expenses | $ 14,512 | $ 14,429 |

**5. Property and Equipment:**

Property and equipment, summarized by major category, consist of the following as of:

| | March 31, 2015 | December 31, 2014 |
|---|---|---|
| Idle equipment | $ 3,798 | $ 3,758 |
| Machinery & equipment | 1,360 | 1,354 |
| Computer equipment & software | 348 | 344 |
| Office furniture & equipment | 178 | 110 |
| Leasehold improvements | 34 | 9 |
| Total | 5,718 | 5,575 |
| Less accumulated depreciations | (1,770) | (1,685) |
| Total property, plant & equipment, net | $ 3,948 | $ 3,890 |

Depreciation expense for the periods ended March 31, 2015 and March 31, 2014, was approximately $0.09 million and $0.1 million, respectively.

**6. License and Development Agreements:**

The Company periodically enters into license and development agreements to develop and commercialize its products. The arrangements typically are multi-deliverable arrangements that are funded through upfront payments, milestone payments, royalties and other forms of payment to the Company. The Company s most significant license and development agreements are as follows:

***Meda License, Development and Supply Agreements***

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

On March 12, 2012, the Company announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide Risk Evaluation and Mitigation Strategy ( REMS ) until the product formulation could be modified to address two appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of the color in the mucoadhesive layer, raised by the FDA during an inspection of the Company s North American manufacturing partner for

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**6. License and Development Agreements (continued):**

***Meda License, Development and Supply Agreements***

ONSOLIS®, Aveva Drug Delivery Systems, Inc. ( Aveva ). While the appearance issues 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 its specification before it can be manufactured and distributed. The source of microcrystal formation and the potential for fading of the color in the mucoadhesive layer of ONSOLIS® was found to be specific to a buffer used in its formulation. The Company modified the formulation and as of the date of this report has 12 months of stability data on the reformulated product that shows no signs of microcrystal formation or color changes.

The Company determined that, upon inception of both the U.S. and EU Meda arrangements, all deliverables were considered one combined unit of accounting. As such, all cash payments from Meda that were related to these deliverables were initially 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 delivered 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 in fiscal year 2009. On January 27, 2015, the Company announced that it had entered into an assignment and revenue sharing agreement with Meda to return to the Company the marketing authorization for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. Following return of the US marketing authorization from Meda, the Company submitted a prior approval supplement for the new formulation to the FDA in March 2015 that provided responses to earlier questions and requests. The FDA s review of the application may take up to 6 months; therefore, it is possible to have a decision before the end of 2015. In connection with the return of the U.S. marketing authorization by Meda to the Company in January 2015, the remaining U.S. related deferred revenue of $1.0 million was recorded as contract revenue during the three months ended March 31, 2015.

***Endo License and Development Agreement***

In January 2012, the Company entered into a License and Development Agreement with Endo Health Solutions, Inc. ( Endo ) pursuant to which the Company granted Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company s BELBUCA product and to complete U.S. development of such product candidate for purposes of seeking FDA approval (the Endo Agreement ). BELBUCA is for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Pursuant to the Endo Agreement, Endo has obtained all rights necessary to complete the clinical and commercial development of BELBUCA 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 BELBUCA (and providing clinical trial materials for such trials) necessary to submit a New Drug Application ( NDA ) to the FDA in order to obtain approval of BELBUCA in the U.S.). 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 BELBUCA on a worldwide basis. In addition, Endo is responsible for all filings required in order to obtain regulatory approval of BELBUCA .

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 BELBUCA ):

$30 million non-refundable upfront license fee (earned in January 2012);

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

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

$10 million upon FDA acceptance of filing NDA (earned in February 2015);

$50 million upon regulatory approval;

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

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

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**6. License and Development Agreements (continued):**

***Endo License and Development Agreement***

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 was a multi-deliverable arrangement with three deliverables: (1) the license rights related to BELBUCA , (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. 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 did not separately account for the CTM deliverable, but considers it part of the clinical development services deliverable.

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

Based on this analysis, $15.6 million of the up-front license fee was allocated to the license (which was estimated to have a value significantly in excess of $30 million), and $14.4 million to clinical development services (which is inclusive of the cost of CTM). Although the intellectual property component was considered a separate deliverable, no distinct amount of the up-front payment was assigned to this deliverable because the Company determined the deliverable to be perfunctory. The amount allocated to the license was recognized as revenue in fiscal year 2012. The

portion of the upfront license fee allocated to the clinical development services deliverable of $14.4 million is being recognized as those services are performed. The Company estimated that such clinical development services will extend into the first half of 2015. Such services were completed by March 2015 and resulted in the recognition of the remaining deferred revenue balance of $0.4 million during the three months ended March, 31, 2015 as compared to $1.2 million for the comparable period in the prior year.

The Company concluded that each of the performance based milestones are substantive and, therefore, revenue has and will be recognized when milestones are earned.

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

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

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**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**6. License and Development Agreements (continued):**

***Endo License and Development Agreement***

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

Beginning in March 2014, total reimbursable contractor costs exceeded a set threshold, at which point all such expenses are to be borne at a rate of 50% by Endo and 50% by the Company. Endo has continued to reimburse the Company for 100% of such costs, with 50% thereof to be taken as a credit against potential future milestones associated with achievement of certain regulatory events. During the three months ended March 31, 2015, the Company received $0.8 million of such prepayments, which have been recorded as deferred revenue, current in the accompanying condensed consolidated balance sheet. During the three months ended March 31, 2015, the Company recognized $0.8 million of reimbursable expenses related to its Endo agreement, which and is recorded as research and development reimbursement revenue on the accompanying 2015 condensed consolidated statement of operations.

On December 23, 2014, the Company, along with Endo, announced the submission of a NDA for BELBUCA to the FDA, which was accepted February 23, 2015.

**7. License Obligations:**

***Arcion License Agreement***

On March 26, 2013, the Company entered into a license agreement with Arcion Therapeutics, Inc. (the Arcion Agreement ) pursuant to which Arcion granted 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) for the treatment of painful diabetic neuropathy ( PDN ) and other indications (the Arcion Products ).

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

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 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.

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 (to see if C-fiber function is present in the skin by determining if subjects experience pain, and to determine pain intensity if present) 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.

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**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**7. License Obligations (continued):**

***Arcion License Agreement***

In addition to the milestones set forth above, the Company will pay royalties to Arcion based upon sales of Arcion Products by the Company, its affiliate and sub-licensees (if any), all as defined in the Arcion Agreement.

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.

On March 30, 2015, the Company announced that the primary efficacy endpoint in the Company s Phase 3 clinical study of Clonidine Topical Gel for PDN compared to placebo for the treatment of PDN did not meet statistical significance. Certain secondary endpoints showed statistically significant improvement over the placebo. In addition, a strong safety profile for the product was observed. Based on the Company s ongoing analysis, the Company believes that the data from this study supports continued development of this product. The Company s analysis showed an unusually high placebo response in the cohort of patients that entered the trial following its previously announced interim analysis of the study. Generally speaking, the Company believes there may be study design features that might be able to mitigate this response in all patients that would enter a subsequent study of Clonidine Topical Gel, and the Company is presently considering these features as it evaluates the potential for additional study of this product candidate. The Company is therefore currently in the process of determining what the next steps in the development pathway should be and whether its decision may require FDA consultation. One possibility is that the Company would do a small scale study that takes into account the design features that the Company believes could mitigate the placebo

response the Company saw in its initial Phase 3 trial. If the Company decides to pursue this type of study or any next study, it would not likely occur before fourth quarter of 2015.

***Evonik Development and Exclusive License Option Agreement:***

On October 27, 2014, the Company entered into a definitive Development and Exclusive License Option Agreement (the Development Agreement ) with Evonik Corporation, ( Evonik ) to develop and commercialize an injectable, extended release, microparticle formulation of buprenorphine for the treatment of opioid dependence (the Product ). Under the Development Agreement, the Company also has the right to pursue development of the Product for pain management.

Under the Development Agreement, Evonik has also granted to the Company two exclusive options to acquire exclusive worldwide licenses, with rights of sublicense, to certain patents and other intellectual property rights of Evonik to develop and commercialize certain products containing buprenorphine. If such options are exercised, such licenses would be memorialized in the License Agreement (as defined below).

Pursuant to the Development Agreement, Evonik is responsible for using commercially reasonable efforts to develop a formulation for the Product in accordance with a work plan mutually agreed upon by the parties (the Project ). Should the Project proceed past the Product formulation stage, Evonik also has the right to manufacture clinical and commercial supplies of Product, such manufacturing arrangement to be negotiated by the Parties in good faith in a formal License and Supply Agreement(s) (the License Agreement ), with such License Agreement covering Evonik s intellectual property rights to be entered into between the parties if certain conditions are met and terms are mutually agreed upon.

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**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**7. License Obligations (continued):**

***Evonik Development and Exclusive License Option Agreement:***

Should Evonik and Company enter into the License Agreement following the attainment of a Phase 1 ready formulation for one or both of the opioid dependence or pain management indications, the Company would pay Evonik certain non-refundable, non-creditable one-time payment in conjunction with certain future regulatory filings and approvals and royalties on net sales of Product.

The Development Agreement contains customary termination provisions, and the Company may additionally terminate the Development Agreement at any time after the completion of certain enumerated tasks as provided in the Development Agreement, for any reason or no reason, by providing written notice of termination to Evonik. Upon termination of the Development Agreement, Evonik will be paid any amounts owed to Evonik in accordance with the Estimated Budget for work that has been performed under the Development Agreement through the effective date of termination, including any reasonable, documented, non-cancelable third party costs and any reasonable, documented wind-down costs reasonably incurred by Evonik in connection with the Project. Should Company terminate for reasons other than for a material, uncured breach by Evonik or Evonik s bankruptcy, Evonik shall have the right to use any and all data and intellectual property generated under the Project for any purpose.

**8. Note Payable:**

On July 5, 2013, the Company entered into a $20 million secured loan facility (the Loan or Credit Agreement ) with MidCap Financial SBIC, LP ( MidCap ). The Company received net proceeds in the aggregate amount of $19.8 million and used the Loan proceeds for general corporate purposes or other activities of the Company permitted under the Credit Agreement.

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 March 31, 2015 and December 31, 2014). 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. The liability associated with the exit fee has been recorded in other long-term liability in the accompanying condensed consolidated balance sheets. The deferred loan costs associated with this exit fee are amortized to interest expense over the three year life of the loan. In addition, the Company may prepay all or

any portion of the Loan at any time subject to a prepayment premium of 3% of the Loan amount prepaid in each year thereafter the first year.

The obligations of the Company under the Credit Agreement are secured by a first priority lien in favor of MidCap on substantially all of the Company s existing and subsequently acquired assets, but excluding certain intellectual property and general intangible assets (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 in the Company s subsidiaries.

The Company is subject to affirmative covenants including, but not limited to, the obligations 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 Company is also subject to negative covenants including, but not limited to, that without the prior consent of Midcap, the Company 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 Company to acquire additional products and to enter into licenses and similar agreements provided certain conditions are met.

The balance of the Loan as of March 31, 2015 is $10.3 million, and is recorded in the accompanying condensed consolidated balance sheet, net of unamortized discount of $0.4 million.

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**(U.S. DOLLARS, IN THOUSANDS)**

**(Unaudited)**

**9. Stockholders Equity:**

*Stock-based compensation*

During the three months ended March 31, 2015, a total of 87,693 options to purchase Common Stock with an aggregate fair market value of approximately $0.8 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. During the three months ended March 31, 2015, stock-based compensation expense was recorded as $0.8 million in research and development and $2.7 million in selling, general and administrative, in the accompanying 2015 condensed consolidated statement of operations. 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, 2015 follows:

| | |
|---|---|
| Expected price volatility | 73.29% |
| Risk-free interest rate | 1.37% |
| Weighted average expected life in years | 6 years |
| Dividend yield | |

Option activity during the three months ended March 31, 2015 was as follows:

| | Number of Shares | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at January 1, 2015 | 3,196,100 | $ 4.32 | |
| Granted in 2015: | | | |
| Officers and Directors | | | |
| Others | 87,693 | 13.17 | |
| Exercised | (38,454) | 3.41 | |

| | | | |
|---|---|---|---|
| Forfeitures | (71,237) | 10.22 | |
| Outstanding at March 31, 2015 | 3,174,102 | $ 5.39 | $ 18,025 |

As of March 31, 2015, options exercisable totaled 2,633,424. There was approximately $40.3 million of unrecognized compensation cost related to non-vested share-based compensation awards, including options and restricted stock units ( RSUs ) granted. These costs will be expensed through 2018.

*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, 2015 totaled 284, with an exercise price of $3.12 per share.

*Earnings Per Share*

During the three months ended March 31, 2015 and 2014, outstanding stock options, RSUs, warrants and convertible preferred stock of 9.4 million and 10.7 million, respectively, were not included in the computation of diluted earnings per share, because to do so would have had an antidilutive effect.

*Recovery of Stockholder Short Swing Profit*

In February 2015, an executive officer of the Company paid a total of approximately $0.006 million to the Company, representing the disgorgement of short swing profits under Section 16(b) under the Exchange Act. The amount was recorded as additional paid-in capital.

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**(Unaudited)**

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

*Restricted Stock Units*

During the three months ended March 31, 2015, approximately 2.1 million RSUs were granted to members of the Company s senior management, with a fair market value of approximately $30.8 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.

Restricted stock activity during the three months ended March 31, 2015 was as follows:

| | Number of Restricted Shares | Weighted Average Fair Market Value Per RSU |
|---|---|---|
| Outstanding at January 1, 2015 | 2,849,076 | $ 6.08 |
| Granted in 2015: | | |
| Executive officers | 2,102,615 | 14.63 |
| Directors | | |
| Vested | (694,269) | 14.39 |
| Forfeitures | (65,853) | 11.69 |
| Outstanding at March 31, 2015 | 4,191,569 | $ 10.12 |

**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®.

Based on the Company s original assertion that its proprietary manufacturing process for ONSOLIS® does not infringe on patents held by MonoSol, and the denial and subsequent narrowing of the claims on the two reissued patents MonoSol has asserted against the Company while the third has had all claims rejected by the USPTO, the Company remains very confident in its original stated position regarding this matter. Thus far, the Company has proven that the original 292 and 891 patents in light of their reissuance with fewer and narrower claims were indeed invalid and the third and final patent, the 588 patent, was invalid as well with all its claims cancelled.

Given the outcomes of the 292, 891 and 588 reexamination proceedings, at a January 22, 2015 status meeting, the Court decided to lift the stay and grant the Company s request for the case to proceed on an expedited basis with a Motion for Summary Judgment to dismiss the action. In doing so, the Judge denied MonoSol s request for full litigation proceedings (including, for example, discovery and claim construction proceedings). The Company filed its motion for summary judgment on March 13, 2015 and briefing took place during March. The Court indicated it would rule on the Company s summary judgment motion without an oral hearing. The Company expects a decision within the first half of 2015. Based upon the outcome from reexaminations and the Court s grant of the Company s request for the proceedings to move directly to a motion for summary judgment, the Company believes it will prevail and the case will be dismissed. However, if this does not occur and the case proceeds to trial, the Company will continue to defend this case vigorously and seek a dismissal at trial. Ultimately, whether now with the motion for summary judgment proceedings or later with trial proceedings, the Company anticipates that MonoSol s claims against the Company will be rejected.

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**(Unaudited)**

**10. Commitments and contingencies: (continued):**

*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 September 20, 2014, based upon the Company s position and belief that its BUNAVAIL® product does not infringe any patents owned by the RB Plaintiffs, the Company proactively filed a declaratory judgment action in the United States District Court for the Eastern District of North Carolina, requesting the Court to make a determination that its BUNAVAIL® product does not infringe the RB Plaintiffs 832 Patent, US Patent No. 7,897,080 ( 080 Patent) and US Patent No. 8,652,378 ( 378 Patent). With the declaratory judgment, there is an automatic stay in proceedings. The RB Plaintiffs may request that the stay be lifted, but they have the burden of showing that the stay should be lifted. For the 832 Patent, the January 15, 2014 IPR was instituted and all challenged claims were rejected for both anticipation and obviousness. For the 080 Patent, all claims have been rejected in an inter partes reexamination and the rejection of all claims as invalid over the prior art has been affirmed on appeal by the PTAB in a decision dated March 27, 2015. For the 378 Patent, an IPR was filed on June 1, 2014, but an IPR was not instituted. However, in issuing its November 5, 2014 decision not to institute the IPR, the PTAB construed the claims of the 378 Patent narrowly. As in prior litigation proceedings, the Company believes these IPR and the reexamination filings will provide support for maintaining the stay until the IPR and reexamination proceedings conclude. Indeed, given the PTAB s narrow construction of the claims of the 378 Patent, the Company filed a motion to withdraw the 378 Patent from the case on December 12, 2014. In addition, the Company also filed a joint motion to continue the stay (with RB Plaintiffs) in the proceedings on the same day. Both the motion to withdraw the 378 Patent from the proceedings and motion to continue the stay were granted.

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

certain claims of such patent were anticipated by or obvious in the light of prior art references, including prior art references not previously considered by the USPTO, and thus, invalid. On December 12, 2014, the Company filed a motion to transfer the case from New Jersey to North Carolina and a motion to dismiss the case against the Company s commercial partner. An oral hearing on these motions was set for March 2, 2015, however, the Court has decided to move forward without an oral hearing and the Company is awaiting their decision. The Court can still ultimately decide to hold an oral hearing on a later date.

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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.*

**Overview**

*Strategy*

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of approved therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. We have developed and are continuing to develop pharmaceutical products aimed principally in the areas of pain management and addiction.

Our strategy is to:

- Focus our commercial and development efforts in the areas of pain management and addiction within the U.S. pharmaceutical marketplace;
- Identify and acquire rights to products that we believe have potential for near-term regulatory approval through the FDA s 505(b)(2) approval process, or are already approved;
- Market our products through specialty sales teams by primarily focusing on high-prescribing U.S. physicians in pain and addiction.

We believe this strategy will allow us to increase our revenues, improve our margins and profitability and enhance stockholder value.

*First Quarter 2015 Highlights*

- On January 27, 2015, we announced that we had entered into an assignment and revenue sharing agreement with Meda to return to us the marketing authorization for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. Following return of the US marketing authorization from Meda, we submitted a prior approval supplement for the new formulation to the FDA in March that provided responses to earlier questions and requests. The FDA s review of the application may take up to 6 months; therefore, it is possible to have a decision before the end of 2015.

On February 23, 2015, the New Drug Application (or NDA) for our BELBUCA product (which is partnered with Endo) was accepted by the FDA.

In March, 2015, we received a $10 million milestone from Endo upon FDA acceptance of filing our BELBUCA NDA.

In March 2015, we reported that our first Phase III trial for Clonidine Topical Gel did not meet its primary efficacy endpoint, although several secondary endpoints were met. As described further below, we are current engaged in ongoing analysis of the data set in an effort to determine next steps with the overall program for this product.

*Opportunities and Trends*

Our franchise currently consists of five products, two of which are approved by the FDA and three of which are in development. Three of these five products utilize our patented BEMA® thin film drug delivery technology.

ONSOLIS® is approved in the U.S., Canada, EU (where it is marketed as BREAKYL ) and Taiwan (where it is marketed as PAINKYL ), for the management of breakthrough pain in opioid tolerant, adult patients with cancer. The commercial rights to ONSOLIS® are licensed to Meda for all territories worldwide except for Taiwan (licensed to TTY) and South Korea (licensed to Kunwha).

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Our second product using the BEMA® technology is BUNAVAIL® (buprenorphine and naloxone) buccal film, which was approved by the FDA in June 2014 for the maintenance treatment of opioid dependence. We are commercializing BUNAVAIL® ourselves and launched the product during the fourth quarter 2014. As with all other buprenorphine containing products for opioid dependence, the approval of BUNAVAIL® carries a standard post-approval requirement by the FDA to conduct a study to determine the effect of BUNAVAIL® on QT prolongation (i.e., an abnormal lengthening of the heartbeat). The clinical study results must be reported to the FDA by the end of 2016.

Our third product using the BEMA® technology, BELBUCA , is for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. This product is licensed on a worldwide basis to Endo. On December 23, 2014, we announced along with Endo the submission of a NDA for BELBUCA (BEMA® Buprenorphine) to the FDA, which was accepted February 23, 2015, with a decision due from the FDA in October, 2015.

Our fourth product is Clonidine Topical Gel, which is currently in Phase 3 development for the treatment of painful diabetic neuropathy (or PDN), which we licensed from Arcion in March 2013. In June 2014, we announced the completion of patient enrollment for our Phase 3 study of Clonidine Topical Gel. In August 2014, we announced our completion of a pre-specified interim analysis of the ongoing initial pivotal Phase 3 trial for Clonidine Topical Gel, at which point we re-opened enrollment to complete recruitment. On March 30, 2015, we announced that the primary efficacy endpoint in our Phase 3 clinical study of Clonidine Topical Gel for PDN compared to placebo for the treatment of PDN did not meet statistical significance. Certain secondary endpoints showed statistically significant improvement over the placebo. In addition, a strong safety profile for the product was observed. Based on our ongoing analysis, we believe that the data from this study supports continued development of this product. Our analysis showed an unusually high placebo response in the cohort of patients that entered the trial following our previously announced interim analysis of the study. Generally speaking, we believe there may be study design features that might be able to mitigate this response in all patients that would enter a subsequent study of Clonidine Topical Gel, and we are presently considering these features as we evaluate the potential for additional study of this product candidate. We are therefore currently in the process of determining what the next steps in the development pathway should be and whether our decision may require FDA consultation. One possibility is that we would do a small scale study that takes into account the design features that we believe could mitigate the placebo response we saw in our initial Phase 3 trial. If we decide to pursue this type of study or any next study, it would not likely occur before fourth quarter of 2015.

Our fifth product is Buprenorphine Depot Injection, which is in development as an injectable, extended release, microparticle formulation of buprenorphine for the treatment of opioid dependence and chronic pain, the rights to which we secured when we entered into a definitive development and exclusive license option agreement from Evonik in October 2014. This product candidate is current in the pre-clinical stage of development.

As we focus on the growth of our existing products and other product candidates, we also continue to position ourselves to execute upon the licensing and acquisition opportunities that will drive our next phase of growth. Our organization is fully committed to this effort, and we believe we will be successful in executing upon our corporate strategy in ways that will drive this future growth.

In order to do so, we will need to continue to maintain our strategic direction, manage and deploy our available cash efficiently and strengthen our alliance and partner relationships. We believe these actions, combined with the experience and expertise of our management team, position us well to drive the future growth of our revenue and income.

We expect to continue research and development of pharmaceutical products and related drug delivery technologies, some of which will be funded by our commercialization agreements. We will continue to seek additional license agreements, which may include upfront payments. We anticipate that funding for the next several years will come primarily from milestone payments and royalties from Meda and Endo, revenues from sales of BUNAVAIL®, potential sale of securities and collaborative research agreements, including those with pharmaceutical companies.

*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 Risk Evaluation and Mitigation Strategy ( REMS ) until the product formulation could be modified to address two appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of the color in the mucoadhesive layer, raised by the FDA during an inspection of our North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. ( Aveva ). While the appearance issues 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 its specification before it can be manufactured and distributed. The source of microcrystal formation and the potential for fading of the color in the mucoadhesive layer of ONSOLIS® was found to be specific to a buffer used in its formulation. We modified the formulation and as of the date of this report have 12 months of stability data on the reformulated product that shows no signs of microcrystal formation or color changes.

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On January 27, 2015, we announced that we had entered into an assignment and revenue sharing agreement with Meda to return to us the marketing authorization for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. Following return of the US marketing authorization from Meda, we submitted a prior approval supplement for the new formulation to the FDA in March that provided responses to earlier questions and requests. FDA s review of the application may take up to 6 months; therefore, it is possible to have a decision before the end of 2015.

Our supply agreement with Aveva will expire on October 15, 2015. We will seek alternative manufacturing arrangements for ONSOLIS® in the U.S. in the event we are able to secure a new commercial partner for the product.

**Results of Operations**

**Comparison of the three months ended March 31, 2015 and 2014**

***Product Sales.*** We recognized $0.7 million in product sales during the three months ended March 31, 2015 from the launch of BUNAVAIL®. There were no product sales during the three months ended March 31, 2014.

***Product Royalty Revenues***. We recognized $0.2 million and $1.0 million in product royalty revenue during the three months ended March 31, 2015 and 2014, respectively, under our license agreement with Meda. The product royalty revenues can be attributed to a percentage of net sales of the BREAKYL product under our license agreement with Meda. The decrease is due to lower sales of BREAKYL during the three months ended March 31, 2015 as compared to March 31, 2014.

***Research and Development Reimbursements*.** We recognized $0.8 million and $8.5 million of reimbursable revenue related to our agreement with Endo during the three months ended March 31, 2015 and 2014, respectively. The research and development reimbursements can be attributed to certain research and development expenses, the aggregate of which exceeds $45 million and is related to the BELBUCA program and reimbursable from Endo. The decrease is due to the completion of the BELBUCA development program during the first quarter of 2015.

***Contract Revenues***. We recognized $10.4 million and $11.3 million in contract revenue during the three months ended March 31, 2015 and 2014, respectively, under our license agreement with Endo. We also recognized $1.0 million and $0.05 million during the three months ended March 31, 2015 and 2014, in contract revenue related to previously deferred revenue under our license agreement with Meda.

***Cost of Sales*.** We incurred $1.1 million and $0.7 million in cost of sales during the three months ended March 31, 2015 and 2014, respectively. Cost of sales during the three months ended March 31, 2015 was related primarily to BUNAVAIL®, which includes $0.7 million of product cost, lower to cost or market adjustment and depreciation, as well as quarterly minimum royalty payments to CDC IV, LLC (or CDC), which provided early funding for this product, of $0.4 million. Cost of sales during the three months ended March 31, 2014 was composed of BREAKYL cost of sales of $0.3 million as well as quarterly minimum royalty payments to CDC of $0.4 million.

***Expenditures for Research and Development Programs***

***BUNAVAIL®***

We incurred research and development expenses for BUNAVAIL® of approximately $0.7 million for three months ended March 31, 2015 and approximately $1.7 million for the three months ended March 31, 2014. We have incurred approximately $28.0 million in the aggregate since inception of our development of this product. BUNAVAIL® was

approved by the FDA in 2014. Therefore, BUNAVAIL® research and development expenses in 2014 and 2015 primarily consist of manufacturing process development and stability work prior to approval.

***BELBUCA***

We incurred research and development expenses for BELBUCA of approximately $2.1 million for the three months ended March 31, 2015 and approximately $11.8 million for the three months ended March 31, 2014. Aggregate expenses approximate $113.5 million since inception of our development of this product candidate. Our expense obligations for this product candidate were detailed in our license and development agreement with Endo. Since our license agreement with Endo in 2012, a portion of these expenses were reimbursed by Endo. Our expenses for this product over such periods consisted primarily of three large clinical trials addressing the efficacy and safety of the product, along with formulation and manufacturing development.

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***Clonidine Topical Gel***

We incurred research and development expenses for Clonidine Topical Gel of approximately $3.6 million for the three months ended March 31, 2015 and approximately $1.06 million for the three months ended March 31, 2014, and have incurred approximately $15.9 million in the aggregate since inception of our development of this product candidate. Our expenses for this product candidate over such periods consisted mainly of Phase 2 and Phase 3 trials testing the efficacy of the product and performing a long term safety study.

***Buprenorphine Depot Injection***

We incurred research and development expenses for Buprenorphine Depot Injection of approximately $0.07 million for the three months ended March 31, 2015 and $0.0 million for the three months ended March 31, 2014, and have incurred approximately $0.5 million in the aggregate since inception of our development of this product candidate. Our expenses on Buprenorphine Depot Injection have been for development of analytical methods and initial formulations for animal testing.

***Selling, General and Administrative Expenses***. During the three months ended March 31, 2015 and 2014, general and administrative expenses totaled $13.2 million and $4.6 million, respectively. General and administrative costs include commercialization costs for BUNAVAIL , 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, 2015 can principally be attributed to the launch of BUNAVAIL in November 2014 and its ongoing commercialization.

***Interest expense, net***. During the three months ended March 31, 2015, we had net interest expense of $0.4 million, consisting of $0.26 million of scheduled interest payments and $0.16 million of related amortization of discount and loan costs related to the July 2013 secured loan facility from MidCap. 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 MidCap, offset by interest income of $0.04 million.

***Derivative loss***. There was no derivative related activity during the three months ended March 31, 2015 which compared to a $4.8 million charge to income for the three month ended March 31, 2014 that consisted of free standing warrants measured at their fair market value, using the Black-Scholes model.

**Liquidity and Capital Resources**

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from secured debt facilities, short-term borrowings or convertible notes, funded research arrangements and 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 BELBUCA product candidate. We intend to finance our research and development, commercialization and working capital needs from existing cash, royalty revenue, sales revenue from the commercialization of BUNAVAIL®, new sources of debt and equity financing, existing and new licensing and commercial partnership agreements and, potentially, through the exercise of outstanding common stock options and warrants to purchase common stock.

At March 31, 2015, we had cash and cash equivalents of approximately $63.5 million. We used $5 million of cash from operations during the three months ended March 31, 2015 and had stockholders equity of $49.8 million, versus $54.4 million at December 31, 2014. We have sufficient cash to manage the business into early 2016, although this assumes that we do not accelerate the development of other opportunities available to us or otherwise face unexpected

events, costs or contingencies, any of which could affect our cash requirements.

Additional capital will likely be required to support our ongoing commercialization activities for BUNAVAIL®, the reformulation project for and anticipated commercial relaunch of ONSOLIS®, development of Clonidine Topical Gel and Buprenorphine Depot Injection or other products which we may acquire or license, and general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding.

Accordingly, we may need 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;

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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 2015 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

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

***Contractual Obligations and Commercial Commitments***

Our contractual obligations as of March 31, 2015 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 | $ 2,410,472 | $ 132,026 | $ 649,809 | $ 1,043,663 | $ 584,974 |
| Secured loan facility | 10,666,669 | 6,000,000 | 4,666,669 | | |
| Purchase obligations** | 398,608 | 170,832 | 227,776 | | |
| Interest on secured loan facility | 688,825 | 638,108 | 50,717 | | |
| Minimum royalty expenses*** | 7,125,000 | 1,500,000 | 3,000,000 | 2,625,000 | |
| Total contractual cash obligations**** | $ 21,289,574 | $ 8,440,966 | $ 8,594,971 | $ 3,668,663 | $ 584,974 |

* This amount represents obligations through the end of the calendar year ended December 31, 2015.

** Purchase obligations are primarily related to long term contracts for minimum services from commercial vendors.

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

**** We signed a commercialization agreement with Endo in January 2012. Endo will have worldwide rights to market our BELBUCA product. In return for milestone payments and royalties, we are required to conduct and pay for certain clinical trials as outlined in a mutually agreed development plan. These costs will depend on the size and scope of the required trials. The Endo agreement does not specify minimums in terms of the cost of the trials.

***Off-Balance Sheet Arrangements***

As of March 31, 2015, 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**

Our consolidated financial statements have been prepared in accordance with GAAP. For information regarding our critical accounting policies and estimates, please refer to Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates contained in our annual report on Form 10-K for the year ended December 31, 2014. There have been not material changes to the critical accounting policies previously disclosed in that report.

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

***Interest rate risk***

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents include Government T-Bills. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments.

***Foreign currency exchange risk***

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

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

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

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.

Based on this evaluation, the Certifying Officers have concluded that our disclosure controls and procedures were effective.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during our first fiscal quarter of 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS**

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations (and the Liquidity and Capital Resources section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes forward-looking statements within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as projects, may, could, would, should, believes, expects, anticipates, estimates, intends, plans or These statements are based upon the current beliefs and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) actual sales results (including the results of the commercial launch of BUNAVAIL ) and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s review and/or approval and commercial launch of our products and product candidates and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking

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statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1A of our 2014 Annual Report and other factors detailed from time to time in our other filings with the SEC. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Quarterly Report. We undertake no obligation to publically update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings.

*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 (the 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 BELBUCA or BUNAVAIL®, but rather only the manner in which ONSOLIS®, which incorporates the BEMA® technology, is manufactured. Pursuant to its complaint, MonoSol is seeking an unspecified amount of damages, attorney s fees and an injunction preventing future infringement of MonoSol s patents.

We strongly refute as without merit MonoSol s assertion of patent infringement, which relates to our confidential, proprietary manufacturing process for ONSOLIS®. On February 23, 2011, we filed our initial answer in this case. In our answer, we stated our position that our products, methods and/or components do not infringe MonoSol s 588 Patent because they do not meet the limitations of any valid claim of such patent. Moreover, in our answer, we stated our position that MonoSol s 588 Patent is actually invalid and unenforceable for failure to comply with one or more of the requirements of applicable U.S. patent law.

On September 12, 2011, we filed a request for inter partes reexamination in the 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 292 C1 and 891 C1 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 891 C1 and 292 C1 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 891 C1 and 292 C1 Patents remains the same.

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

Based on our original assertion that our proprietary manufacturing process for ONSOLIS® does not infringe on patents held by MonoSol, and the denial and subsequent narrowing of the claims on the two reissued patents MonoSol has asserted against us while the third has had all claims rejected by the USPTO, we remain very confident in our original stated position regarding this matter. Thus far, we have proven that the original 292 and 891 patents in light of their reissuance with fewer and narrower claims were indeed invalid and the third and final patent, the 588 patent, was invalid as well with all its claims cancelled. Given the outcomes of the 292, 891 and 588 reexamination proceedings, at a January 22, 2015 status meeting, the Court decided to lift the stay and grant our request for the case to proceed on an expedited basis with a Motion for Summary Judgment to dismiss the action. In doing so, the Judge denied MonoSol s request for full litigation proceedings (including, for example, discovery and claim construction proceedings). We filed our motion for summary judgment on March 13, 2015 and briefing took place during March. The Court indicated it would rule on our summary judgment motion without an oral hearing. We expect a decision during the first half of 2015. Based upon the outcome from reexaminations and the Court s grant of our request for the proceedings to move directly to a motion for summary judgment, we believe we will prevail and the case will be dismissed. However, if this does not occur and the case proceeds to trial, we will continue to defend this case vigorously and seek a dismissal at trial. Ultimately, whether now with the motion for summary judgment proceedings or later with trial proceedings, we anticipate that MonoSol s claims against us will be rejected.

*Litigation Related To BUNAVAIL®*

On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol (collectively, the RB Plaintiffs) filed an action against us relating to our BUNAVAIL® product in the United States District Court for the Eastern District of North Carolina for alleged patent infringement. BUNAVAIL® is a drug approved for the maintenance treatment of 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).

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

On September 20, 2014, based upon our position and belief that our BUNAVAIL® product does not infringe any patents owned by the RB Plaintiffs, we proactively filed a declaratory judgment action in the United States District Court for the Eastern District of North Carolina, requesting the Court to make a determination that our BUNAVAIL® product does not infringe the RB Plaintiffs 832 Patent, US Patent No. 7,897,080 ( 080 Patent) and US Patent No. 8,652,378 ( 378 Patent). With the declaratory judgment, there is an automatic stay in proceedings. The RB Plaintiffs may request that the stay be lifted, but they have the burden of showing that the stay should be lifted. For the 832 Patent, the January 15, 2014 IPR was instituted and all challenged claims were rejected for both anticipation and obviousness. For the 080 Patent, all claims have been rejected in an inter partes reexamination and the rejection of all

claims as invalid over the prior art has been affirmed on appeal by the PTAB in a decision dated March 27, 2015. For the 378 Patent, an IPR was filed on June 1, 2014, but an IPR was not instituted. However, in issuing its November 5, 2014 decision not to institute the IPR, the PTAB construed the claims of the 378 Patent narrowly. As in prior litigation proceedings, we believe these IPR and the reexamination filings will provide support for maintaining the stay until the IPR and reexamination proceedings conclude. Indeed, given the PTAB s narrow construction of the claims of the 378 Patent, we filed a motion to withdraw the 378 Patent from the case on December 12, 2014. In addition, we also filed a joint motion to continue the stay (with RB Plaintiffs) in the proceedings on the same day. Both the motion to withdraw the 378 Patent from the proceedings and motion to continue the stay were granted.

On September 22, 2014, the RB Plaintiffs filed an action against us (and our commercial partner) relating to our BUNAVAIL® product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL®, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent (U.S. Patent No. 8,765,167) ( 167 Patent). As with prior actions by the RB Plaintiffs, we believe this is another anticompetitive attempt by the RB Plaintiffs to distract our efforts from commercializing BUNAVAIL®. We strongly refute as without merit the RB Plaintiffs assertion of patent infringement and will vigorously defend the lawsuit. In this regard, on October 28, 2014, we filed multiple IPR requests on the 167 Patent demonstrating that certain claims of such patent were anticipated by or obvious in the light of prior art references, including prior art references not previously considered by the USPTO, and thus, invalid. On December 12, 2014, we filed a motion to

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transfer the case from New Jersey to North Carolina and a motion to dismiss the case against our commercial partner. An oral hearing on these motions was set for March 2, 2015, however, the Court has decided to move forward without an oral hearing and we are awaiting their decision. The Court can still ultimately decide to hold an oral hearing on a later date.

**Item 1A. Risk Factors.**

The following risk factor is intended to update and replace the risk factor captioned ***Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approvals.*** appearing in the 2014 Annual Report in order to account for our March 30, 2015 announcement of the results of our Phase 3 study of Clonidine Topical Gel.

Data already obtained, or data we may obtain in the future, from non-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later non-clinical studies and clinical trials. Moreover, non-clinical and clinical data are susceptible to multiple and varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry, including those involved in competing drug delivery technologies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the product candidate, resulting in delays to commercialization, and could materially harm our business. In addition, our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing. Finally, if any of our clinical trials do not meet their primary endpoints, or for a variety of other reasons, we may be required to conduct additional clinical trials in order to progress development of the subject product. These additional trials would be costly and time-consuming, and would divert resources from other projects.

The foregoing risks were evidenced by the failure of our Phase 3 trial for BELBUCA for the treatment of moderate to severe chronic pain to meet its primary endpoint, which we announced September 2011. These risks were further evidenced in that, on March 30, 2015, we announced that the primary efficacy endpoint in the Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of PDN did not meet statistical significance.

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

None.

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

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

| Number | Description |
|---|---|
| 31.1 | Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302 (*) |
| 31.2 | Certification of Chief Financial Officer Pursuant To Sarbanes-Oxley Section 302 (*) |
| 32.1 | Certification Pursuant To 18 U.S.C. Section 1350 (*) |
| 32.2 | Certification Pursuant To 18 U.S.C. Section 1350 (*) |
| 101.ins | XBRL Instance Document |
| 101.sch | XBRL Taxonomy Extension Schema Document |
| 101.cal | XBRL Taxonomy Calculation Linkbase Document |
| 101.def | XBRL Taxonomy Definition Linkbase Document |
| 101.lab | XBRL Taxonomy Label Linkbase Document |
| 101.pre | XBRL Taxonomy Presentation Linkbase Document |

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* A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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**SIGNATURES**

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 11, 2015

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

(Principal Executive Officer)

Date: May 11, 2015

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

Chief Financial Officer (Principal Accounting Officer)