BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
November 09, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

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 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 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
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

As of November 8, 2016, there were 54,133,511 shares of company Common Stock issued and 54,118,020 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)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,682	$ 83,560
Accounts receivable, net	3,089	2,488
Inventory	4,018	2,558
Prepaid expenses and other current assets	4,470	3,933
Total current assets	56,259	92,539
Property and equipment, net	4,253	4,262
Goodwill	2,715	2,715
Other intangible assets, net	2,528	3,256
Total assets	$ 65,755	$ 102,772
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 18,839	$ 19,501
Notes payable, current maturities, net	11,446	6,707
Deferred revenue, current	1,922	1,875
Derivative liability	100	
Total current liabilities	32,307	28,083
Notes payable, less current maturities, net	17,726	22,168
Deferred revenue, long-term	20,000	20,000
Other long-term liabilities	825	825
Total liabilities	70,858	71,076
Commitments and contingencies (Notes 7 and 12)		
Stockholders (deficit) equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,093,155 shares of Series A Non-Voting Convertible Preferred Stock outstanding at September 30, 2016 and December 31, 2015	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 54,133,511 and 52,730,799 shares issued; 54,118,020 and 52,715,308 shares outstanding at September 30, 2016 and December 31, 2015, respectively	54	53
Additional paid-in capital	289,287	274,891

Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(294,399)	(243,203)
Total stockholders (deficit) equity	(5,103)	31,696
Total liabilities and stockholders (deficit) equity	$ 65,755	$ 102,772

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product sales	$ 2,009	$ 1,155	$ 6,221	$ 2,665
Product royalty revenues	1,065	25	2,393	689
Research and development reimbursements	497	55	501	909
Contract revenues			2,500	11,759
Total Revenues:	3,571	1,235	11,615	16,022
Cost of sales	2,314	1,699	8,958	5,443
Expenses:				
Research and development	4,402	4,473	13,786	15,527
General and administrative	12,054	14,715	37,606	41,185
Total Expenses:	16,456	19,188	51,392	56,712
Loss from operations	(15,199)	(19,652)	(48,735)	(46,133)
Interest expense, net	(786)	(785)	(2,477)	(1,732)
Derivative gain	14		36	
Other (expense) income, net	(6)	(2)	(20)	21
Net loss	$ (15,977)	$ (20,439)	$ (51,196)	$ (47,844)
Basic and diluted loss per share:	$ (0.30)	$ (0.39)	$ (0.96)	$ (0.92)
Weighted average common stock shares outstanding, basic and diluted:	53,767,099	52,542,715	53,531,770	52,286,757

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS (DEFICIT) 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 (Deficit)
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Equity
Balances, January 1, 2016	2,093,155	$ 2	52,730,799	$ 53	$ 274,891	$ (47)	$ (243,203)	$ 31,696
Stock-based compensation					11,600			11,600
Exercise of stock options			147,425		297			297
Vesting of restricted stock awards			592,066					
Common stock issuance upon retirement			663,221	1	2,459			2,460
Equity financing costs					40			40
Net loss							(51,196)	(51,196)
Balances, September 30, 2016	2,093,155	$ 2	54,133,511	$ 54	$ 289,287	$ (47)	$ (294,399)	$ (5,103)

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)

	Nine months ended September 30,	
	2016	**2015**
Operating activities:		
Net loss	$ (51,196)	$ (47,844)
Depreciation	325	248
Accretion of debt discount	297	400
Amortization of intangible assets	728	728
Derivative liability	100	
Stock-based compensation expense	11,600	12,703
Changes in assets and liabilities:		
Accounts receivable	(601)	1,734
Inventories	(1,460)	(59)
Prepaid expenses and other assets	(537)	(727)
Accounts payable and accrued expenses	(662)	477
Deferred revenue	47	(377)
Net cash flows from operating activities	(41,359)	(32,717)
Investing activities:		
Purchase of equipment	(316)	(619)
Net cash flows from investing activities	(316)	(619)
Financing activities:		
Equity financing costs	40	(40)
Proceeds from exercise of stock options	297	480
Proceeds from issuance of common stock	2,460	
Proceeds from exercise of common stock warrants		1
Payment on note payable		(3,335)
Proceeds from notes payable		20,667
Payment of deferred financing fees		(486)
Return of short swing profits		6
Net cash flows from financing activities	2,797	17,293
Net change in cash and cash equivalents	(38,878)	(16,043)

Cash and cash equivalents at beginning of year	83,560	70,472
Cash and cash equivalents at end of period	**$ 44,682**	**$ 54,429**
Cash paid for interest	$ 2,045	$ 1,201

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 developing and commercializing, either on its 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. The Company is focusing on developing products to meet unmet patient needs in the areas of pain management and addiction.

The accompanying unaudited condensed consolidated financial statements include all adjustments (consisting of normal and recurring adjustments) necessary for a fair presentation of these financial statements. The condensed consolidated balance sheet at December 31, 2015 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, 2015. 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, 2015. The Company has made certain reclassifications in this report s footnote tables for the year ending December 31, 2015 to conform to the current period presentation. This reclassification had no effect on the measurement of total expenses, loss from operations, or net loss.

Operating results for the three and nine month periods ended September 30, 2016 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.

Principles of consolidation

The condensed consolidated financial statements include the accounts of the Company, Arius Pharmaceuticals, Inc. (Arius), Arius Two, Inc. (Arius Two) and Bioral Nutrient Delivery, LLC (BND). For each period presented, BND has been an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

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 condensed 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 the active pharmaceutical ingredients required 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 as of September 30, 2016 or December 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.

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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):

Revenue recognition

Net Product Sales

Product Sales- The Company generally recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. For products that it commercializes on its own (currently only the Company s BUNAVAIL® product), the Company sells such 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 and prompt payment 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.

As of September 30, 2016 and December 31, 2015, the Company had $1.9 million in each period, respectively, 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 as revenue 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 expenses in the accompanying balance sheets as of September 30, 2016 and December 31, 2015 (see Note 4).

Product Returns- Consistent with industry practice, the Company offers contractual return rights that allow its customers to return product within an 18-month period that begins six months prior to and ends twelve months after the expiration of the products. The Company does not believe it has sufficient experience with BUNAVAIL® to estimate its returns at time of ex-factory 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 through 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 actual redemption rates 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.

Gross to Net Accruals- A significant majority of the Company s gross to net accruals are the result of its voucher program, commercial contracts and Medicaid rebates, with the majority of those programs having an accrual to payment cycle of anywhere from one to three months. In addition to this relatively short accrual to payment cycle, the Company receives daily information from its wholesalers regarding their sales of BUNAVAIL® and actual on hand inventory levels. During the quarter ended September 30, 2016, the Company s three largest wholesalers accounted for approximately 91% of the Company s voucher and Medicaid accruals. The Company believes that consistently working with these three large wholesalers enables the Company to execute more accurate provisioning procedures. Consistent with pharmaceutical industry practice, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products. However, since the Company does not have sufficient experience with measuring returns, at the time of ex-factory sales, the Company records revenue when the risk of product return has been substantially eliminated.

Once the Company has adequate experience with measuring returns, it will then be able to record sales ex-factory.

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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):

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 through to the end user. The Company had $1.9 million and $1.7 million of deferred costs of sales as of September 30, 2016 and December 31, 2015, respectively. These costs are included in other current assets in the accompanying condensed consolidated balance sheets.

Cost of Sales

For BUNAVAIL®, cost of sales includes raw materials, production costs at the Company s two contract manufacturing sites, quality testing directly related to the product, and depreciation on equipment 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.

Cost of sales also includes the direct costs attributable to the production of the Company s BREAKYLand PAINKYL products, which are not self-commercialized by the Company, including 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.

Fair value of financial assets and liabilities

The Company measures the fair value of financial assets and liabilities in accordance with GAAP, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. GAAP also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. GAAP describes three levels of inputs that may be used to measure fair value:

Level 1 quoted prices in active markets for identical assets or liabilities

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

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

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) 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. In July 2015, the FASB agreed to defer the effective date of the standard from January 1, 2017 to January 1, 2018, with an option that permits companies to adopt the standard as early as the original effective date. Early application prior to the original effective date is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers* (Topic 606): Identifying Performance Obligations and Licensing. ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. These ASUs apply to all companies that enter into contracts with customers to transfer goods or services. These two ASUs are effective for public entities for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, but not before interim and annual reporting periods beginning after December 15, 2016. Entities have the choice to apply these ASUs either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. The Company is currently evaluating the requirements of these standards and has not yet determined the impact on its condensed consolidated financial statements.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

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

The FASB s new leases standard, ASU 2016-02 *Leases* (Topic 842), was issued on February 25, 2016. ASU 2016-02 is intended to improve financial reporting about leasing transactions. The ASU affects all companies and other organizations that lease assets such as real estate, airplanes, and manufacturing equipment. The ASU will require organizations that lease assets referred to as Lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. An organization is to provide disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements concerning additional information about the amounts recorded in the financial statements. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new ASU will require

both types of leases (i.e. operating and capital leases) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases. The leasing standard will be effective for calendar year-end public companies beginning after December 15, 2018. Public companies will be required to adopt the new leasing standard for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption will be permitted for all companies and organizations upon issuance of the standard. For calendar year-end public companies, this means an adoption date of January 1, 2019 and retrospective application to previously issued annual and interim financial statements for 2018 and 2017. Lessees with a large portfolio of leases are likely to see a significant increase in balance sheet assets and liabilities. The Company is currently in the process of evaluating the impact that this new leasing ASU will have on its condensed consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification (ASC) Topic 718, Compensation Stock Compensation. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of the ASU on its condensed consolidated financial statements.

2. Liquidity and management s plans:

At September 30, 2016, the Company had cash and cash equivalents of approximately $44.7 million. The Company used $38.9 million of cash during the nine months ended, September 30, 2016 and had stockholders deficit of $5.1 million, versus stockholders equity of $31.7 million at December 31, 2015. Based on the Company s current operational plan and budget, the Company expects that it has sufficient cash to manage its business into the third quarter of 2017, although this estimation assumes that the Company does not accelerate the development of existing product candidates, or acquire other drug development opportunities 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 anticipated commercial relaunch of ONSOLIS®, the continued development of Clonidine Topical Gel and Buprenorphine Depot Injection, or other products which may be acquired or licensed by the Company, and for 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 lifecycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding from any source (including, without limitation, milestone, royalty or other payments from commercialization agreements as well as equity or debt financings) may be unavailable on favorable terms, if at all.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

3. Inventory:

The following table represents the components of inventory as of:

	September 30, 2016	December 31, 2015
Raw materials & supplies	$ 995	$ 443
Work-in-process	1,979	1,216
Finished goods	1,044	899
Total inventories	$ 4,018	$ 2,558

4. Accounts payable and accrued liabilities:

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

	September 30, 2016	December 31, 2015
Accounts payable	$ 10,533	$ 10,177
Accrued price adjustments	442	317
Accrued rebates	4,120	4,471
Accrued chargebacks	15	65
Accrued compensation and benefits	2,314	1,917
Accrued royalties	410	431
Accrued clinical trial costs	128	584
Accrued manufacturing costs	200	183
Accrued sales and marketing costs	8	880
Accrued other	669	476
Total accounts payable and accrued expenses	$ 18,839	$ 19,501

5. Property and Equipment:

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

	September 30, 2016	December 31, 2015
Machinery & equipment	$ 4,434	$ 580
Computer equipment & software	463	460
Office furniture & equipment	202	200
Leasehold improvements	53	53
Idle equipment	1,440	4,983
Total	6,592	6,276
Less accumulated depreciation	(2,339)	(2,014)
Total property, plant & equipment, net	$ 4,253	$ 4,262

Depreciation expense for the nine month periods ended September 30, 2016 and September 30, 2015, was approximately $0.3 million and $0.2 million, respectively. Depreciation expense for the three month periods ended September 30, 2016 and September 30, 2015, was approximately $0.1 million and $0.08 million, respectively.

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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:

The Company has periodically entered into license and development agreements to develop and commercialize certain of 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.

Meda License, Development and Supply Agreements

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® in the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. Following the return of the U.S. marketing authorization from Meda, the Company submitted a prior approval supplement for the new formulation to the FDA in March 2015, which was approved in August 2016. 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 nine months ended September 30, 2015. There was no remaining U.S.-related contract revenue to record during the nine months ended September 30, 2016. On February 27, 2016, the Company entered into an extension of the assignment and revenue sharing agreement to extend the period until December 31, 2016.

Efforts to extend the Company s supply agreement with its ONSOLIS® manufacturer, Aveva, which is now a subsidiary of Apotex, Inc., were unsuccessful and the agreement expired. However, the Company identified an alternate supplier and requested guidance from the FDA on the specific requirements for obtaining approval to supply product from this new vendor. Based on the Company s current estimates, the Company will submit the necessary documentation to the FDA for qualification of the new manufacturer in early 2017, thus allowing for the reintroduction of ONSOLIS® by mid-2017.

On May 11, 2016, the Company and Collegium Pharmaceutical, Inc. (Collegium) executed a definitive License and Development Agreement (the License Agreement) under which the Company has granted the exclusive rights to develop and commercialize ONSOLIS® in the U.S. to Collegium. See Collegium License and Development Agreement below.

Collegium License and Development Agreement

On May 11, 2016, the Company and Collegium executed a License Agreement under which the Company granted Collegium the exclusive rights to develop and commercialize ONSOLIS® in the U.S.

Under the terms of the License Agreement, Collegium will be responsible for the manufacturing, distribution, marketing and sales of ONSOLIS® in the U.S. The Company is obligated to use commercially reasonable efforts to continue the transfer of manufacturing to the anticipated manufacturer for ONSOLIS® and to submit a corresponding Prior Approval Supplement (the Supplement) to the FDA with respect to the current NDA for ONSOLIS®. Following

approval of the Supplement, the NDA and manufacturing responsibility for ONSOLIS® (including the manufacturing relationship with the Company s manufacturer, subject to the Company entering into an appropriate agreement with such manufacturer that is acceptable and assignable to Collegium) will be transferred to Collegium.

Financial terms of the License Agreement include:

- a $2.5 million upfront non-refundable payment, payable to the Company within 30 days of execution of the License Agreement (received June 2016);
- reimbursement to the Company for a pre-determined amount of the remaining expenses associated with the ongoing transfer of the manufacturing of ONSOLIS®;
- $4 million payable to the Company upon first commercial sale of ONSOLIS® in the U.S;
- up to $17 million in potential payments to the Company based on achievement of certain performance and sales milestones; and
- upper-teen percent royalties payable by Collegium to the Company based on various annual U.S. net sales thresholds, subject to customary adjustments and the royalty sharing arrangements described below.

The License Agreement also contains customary termination provisions that include a right by either party to terminate upon the other party s uncured material breach, insolvency or bankruptcy, as well as in the event a certain commercial milestone is not met.

ONSOLIS® was originally licensed to, and launched in the U.S. by, Meda. In January 2015, the Company entered into an assignment and revenue sharing agreement (the ARS Agreement) with Meda pursuant to which Meda transferred the marketing authorizations for ONSOLIS® in the United States back to the Company. Under the ARS Agreement, financial terms were established that enable

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6. License and Development Agreements (continued):
Collegium License and Development Agreement (continued)

Meda to share a significant portion of the proceeds of milestone and royalty payments received by the Company from any new North American partnership for ONSOLIS® that may be executed by the Company. The execution of the License Agreement between the Company and Collegium also required the execution of a definitive termination agreement between the Company and Meda embodying those royalty-sharing terms, returning ONSOLIS®-related assets and rights in the U.S., Canada, and Mexico to the Company, and including certain other provisions. In addition, the Company s royalty obligations to CDC IV, LLC (CDC) and its assignees will remain in effect. CDC provided funding for the development of ONSOLIS® in the past.

Endo License and Development Agreement

In January 2012, the Company entered into a License and Development Agreement with Endo Pharmaceuticals, 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 used 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.

The remaining milestone payments owed pursuant to the Endo Agreement are expected to be recognized as revenue as they are achieved, except that $20 of the $50 million regulatory approval milestone received in November 2015. Such amount is associated with the Patent Life Extension and is contingently refundable from 2020 to 2027. The $20 million will be earned over the extended 84 month patent period as it is contingently refundable pending a generic product commercially launched in the U.S. during the patent extension period. Sales threshold payments and sales-based royalties will be recognized as they accrue under the terms of the Endo Agreement.

The Company is reimbursed by Endo for certain contractor costs when these costs go beyond set thresholds as outlined in the Endo Agreement. Endo reimburses the Company for this spending at cost and the Company receives no mark-up or profit. The gross amount of these reimbursed research and development costs are reported as research and development reimbursement revenue in the accompanying condensed 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 have been 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 by Endo as a credit against potential future milestones associated with achievement of certain regulatory events. During the nine months ended September 30, 2016 and 2015, the Company recognized $0.01 and $0.09 million, respectively, of reimbursable expenses related to the Endo Agreement, which is recorded as research and development reimbursement revenue on the accompanying condensed consolidated statement of operations. During the three months ended September 30, 2016 and 2015, the Company recognized $0.01 and $0.06 million, respectively, of reimbursable expenses related to the Endo Agreement, which is recorded as research and development reimbursement revenue on the accompanying condensed consolidated statement of operations.

On December 23, 2014, the Company and Endo announced the submission of an NDA for BELBUCA to the FDA, which was accepted February 23, 2015. On October 26, 2015, the Company and Endo announced that on October 23, 2015, the FDA approved BELBUCA. The FDA approval of BELBUCA triggered a milestone payment to the Company from Endo of $50 million pursuant to the Endo Agreement, less approximately $6 million of cumulative pre-payments. The Company received payment of such milestone in November 2015. The Company has deferred the aforementioned $20 million of the $50 million milestone payment.

On February 22, 2016, the Company and Endo announced the commercial availability of BELBUCA buccal film. BELBUCA, distributed and promoted by Endo, is now available nationwide.

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 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).

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7. License Obligations (continued):
Arcion License Agreement (continued)

On March 30, 2015, the Company announced that the primary efficacy endpoint in its initial Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of PDN did not meet statistical significance, although certain secondary endpoints showed statistically significant improvement over placebo. Final analysis of the study identified a sizeable patient population with a statistically significant improvement in pain score vs placebo. Following thorough analysis of the data and identification of the reasons behind the study results, the Company initiated a second study. The study incorporated significant learnings from previously conducted studies and involved tightened and additional inclusion criteria to improve assay sensitivity, reduce bias and ensure compliance with enrollment criteria. On August 4, 2016, the Company announced that it had reached its target number of subjects to be randomized in its multi-center, double-blind, placebo-controlled Phase 2b study assessing the efficacy and safety of Clonidine Topical Gel in the treatment of PDN. Based on the timing of randomization of the last patient, the Company now expects topline results of the study will be available by the end of 2016, which puts it six to eight weeks ahead of schedule.

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 Evonik Product). Under the Development Agreement, the Company also has the right to pursue development of the Evonik Product for pain management and 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 Evonik License Agreement (as defined below).

Upon execution of the Development Agreement and the delivery by Evonik to the Company of certain data and results achieved by Evonik from prior work performed by Evonik relating to the Product, the Company is obligated to pay to Evonik an initial, non-refundable, non-creditable, one-time payment as well as development service fees for work to be completed, which together totals up to $2.16 million in accordance with an estimated budget set out in the Development Agreement (the Estimated Budget) for the mutually agreed Project. Evonik shall not bill the Company for amounts greater than the Estimated Budget unless change orders are executed by both parties. As of September 30, 2016, the Company has paid $2.85 million toward the Estimated Budget in addition to executed change orders.

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

This product candidate is currently in the pre-clinical stage of development with plans underway for an Investigational New Drug Application submission in early 2017.

8. Other license agreements and acquired product rights:

TTY License and Supply Agreement

On October 7, 2010, the Company announced a license and supply agreement with TTY Biopharm Co., Ltd. (TTY) for the exclusive rights to develop and commercialize BEMA® Fentanyl in the Republic of China, Taiwan. The agreement results in potential milestone payments to the Company of up to $1.3 million, which include an initial upfront one-time non-refundable payment of $0.3 million that was received in 2010. In addition, the Company will receive an ongoing royalty based on net sales. TTY will be responsible for the regulatory filings of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. The term of the agreement with TTY is for the

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8. Other license agreements and acquired product rights (continued):
TTY License and Supply Agreement

period from October 4, 2010 until the date fifteen years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

On February 4, 2016 and June 30, 2016, the Company received separate payments of $0.24 million each from TTY and on October 4, 2016 a payment of $0.4 million, all which related to royalties based on PAINKYL product purchased in Taiwan by TTY of PAINKYL.

9. Note Payable (MidCap Loan):
On May 29, 2015, the Company entered into a $30 million secured loan facility (the Loan) with MidCap Financial Trust, as agent and lender (MidCap), pursuant to the terms and conditions of the Amended and Restated Credit and Security Agreement, dated as of May 29, 2015 (the Credit Agreement), between the Company and MidCap. The Credit Agreement is a restatement, amendment and modification of a prior Credit and Security Agreement, dated as of July 5, 2013 (the Prior Agreement), between the Company, MidCap Financial SBIC, LLP, a predecessor to MidCap, and certain lenders thereto. The Credit Agreement restructures, renews, extends and modifies the obligations under the Prior Agreement and the other financing documents executed in connection with the Prior Agreement (the Prior Loan). The Company received net Loan proceeds in the aggregate amount of approximately $20.1 million and will use the Loan proceeds for general corporate purposes or other activities of the Company permitted under the Credit Agreement.

The Loan (as amended in May 2016 and as described below) has a term of 42 months, with interest only payments for the first 19 months. The interest rate is 8.45% plus a LIBOR floor of 0.5% (total of 8.95% at September 30, 2016), with straight line amortization of principal payments commencing on June 1, 2016, in an amount equal to $1.3 million per month. Upon execution of the Credit Agreement, the Company paid to MidCap a closing fee from the prior loan of approximately $0.4 million. Upon repayment in full of the Loan, the Company is obligated to make a final payment fee equal to 2.75% of the aggregate Loan amount. The 2.75% exit fee has been recorded as deferred loan costs, the current portion of which is included in notes payable, current maturities, net and the long-term portion is in note payable, less current maturities, net, being amortized over the life of the loan. The amounts payable are recorded as other long-term liabilities.

In addition, the Company may prepay all or any portion of the Loan at any time subject to a prepayment premium of: (i) 5% of the Loan amount prepaid in the first year following the execution of the Credit Agreement and (ii) 3% of the

Loan amount prepaid in each year thereafter.

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

Under the Credit Agreement, the Company is subject to affirmative covenants which are customary for financings of this type, including, but not limited to, the obligations of the Company to: (i) maintain good standing and governmental authorizations, (ii) provide certain information and notices to MidCap, (iii) deliver quarterly and annual financial statements to MidCap, (iv) maintain insurance, property and books and records, (v) discharge all taxes, (vi) protect its intellectual property and (vii) generally protect the collateral granted to MidCap.

The Company is also subject to negative covenants customary for financings of this type, including, but not limited to, that it may not: (i) enter into a merger or consolidation or certain change of control events without complying with the terms of the Credit Agreement, (ii) incur liens on the collateral, (iii) incur additional indebtedness, (iv) dispose of any property, (v) amend material agreements or organizational documents, (vi) change its business, jurisdictions of organization or its organizational structures or types, (vii) declare or pay dividends (other than dividends payable solely in Common Stock), (viii) make certain investments or acquisitions except under certain circumstances as set forth in the Credit Agreement, or (ix) enter into certain transactions with affiliates, in each case subject to certain exceptions provided for in the Credit Agreement. Notwithstanding the foregoing, the Credit Agreement amends certain negative covenants contained in the Prior Agreement such that (i) licensing and acquisitions are added as permitted business activities of the Company and (ii) the Company is no longer required to obtain the prior written consent of MidCap for any in-licensing, product

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9. Note Payable (MidCap Loan) continued:

or entity acquisitions by the Company by way of merger or consolidation, so long as no event of default has occurred and certain financial metrics are adhered to.

The Credit Agreement provides for several events of default under the Loan. Upon the occurrence of any event of default, the Company s obligations under the Credit Agreement will bear interest at a rate equal to the lesser of: (i) 4% above the rate of interest applicable to such obligations immediately prior to the occurrence of the event of default and (ii) the maximum rate allowable under law.

The debt discount is related to warrants on the Prior Loan, which was amended in 2015. The discount is being amortized to interest expense over the life of the amended loan. On May 5, 2016, the Company entered into an amendment to the Credit Agreement between the Company, MidCap and the lenders thereto (the Lenders) extending the interest only period of the Loan through the end of 2016. Beginning on January 1, 2017, the principal amount owed under the Loan will then be amortized over the remaining 23 months of the Loan. In association with the extension of the interest only period, the Lenders were issued warrants to purchase a total of 84,986 shares of Common Stock at an exercise price of $3.53 per share.

The balance of the Loan as of September 30, 2016 is $29.2 million, and is recorded in the accompanying condensed consolidated balance sheet, net of unamortized discount of $0.8 million.

10. Derivative Financial Instruments:

The Company generally does not use derivative instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair value of its financial instruments. However, certain other financial instruments, such as warrants and embedded conversion features that are indexed to the Company s Common Stock, are classified as liabilities when either: (a) the holder possesses rights to a net-cash settlement or (b) physical or net-share settlement is not within the control of the Company. In such instances, net-cash settlement is assumed for financial accounting and reporting, even when the terms of the underlying contracts do not provide for net-cash settlement. Such financial instruments are initially recorded at fair value estimated on the settlement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate, and then adjusted to fair value at the close of each reporting period.

The following table summarizes assets and liabilities measured at fair value on a recurring basis at September 30, 2016 and December 31, 2015, respectively:

	September 30, 2016				December 31, 2015			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Fair Value Measurements Using:								
Liabilities								
Derivative liabilities- free standing warrants	$	$ 100	$	$ 100	$	$	$	$

The table below provides a reconciliation of the beginning and ending balances for the liabilities measured at fair value using observable inputs (Level 2). The table reflects net gains and losses for all financial liabilities categorized as Level 2 as of September 30, 2016 and December 31, 2015.

	$	Number of Warrants
Liabilities:		
Warrant liability as of December 31, 2015	$	
Increase due to issuance of warrants	136	84,986
Decrease due to fair value of warrants	(36)	
Warrant liability as of September 30, 2016	$ 100	84,986

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

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11. Stockholders Equity:

Stock-based compensation

During the nine months ended September 30, 2016, a total of 481,303 options to purchase Common Stock, with an aggregate fair market value of approximately $1.6 million, were granted to Company employees, directors and contractors. The options granted have a term of 10 years from the grant date and vest ratably over a three year period for employees and contractors and options for directors vest half upon issuance and the remaining half the following year. The fair value of each option is amortized as compensation expense evenly through the vesting period.

The Company s stock-based compensation expense is allocated between research and development and selling, general and administrative as follows:

	Three months ended,		Nine months ended,	
Stock-based compensation expense	**September 30, 2016**	**September 30, 2015**	**September 30, 2016**	**September 30, 2015**
Research and Development	$ 0.5	$ 1.1	$ 2.1	$ 3.1
Selling, General and Administrative	$ 3.6	$ 3.9	$ 9.5	$ 9.6

The fair value of each option award is estimated on the grant date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from historical volatility of the Common Stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average for key assumptions used in determining the fair value of options granted during the nine months ended September 30, 2016 follows:

Expected price volatility	62.36% - 82.38%
Risk-free interest rate	0.56% - 1.70%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the nine months ended September 30, 2016 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2016	3,397,529	$ 5.42	
Granted in 2016			
Officers and Directors	95,000	2.34	
Others	386,303	3.49	
Exercised	(147,425)	2.01	
Forfeitures	(394,898)	9.06	
Outstanding at September 30, 2016	3,336,509	$ 4.83	$ 459

As of September 30, 2016, options exercisable totaled 2,559,949. There was approximately $17.2 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 2019.

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11. Stockholders Equity (continued):

Earnings Per Share

During the nine months ended September 30, 2016 and 2015, outstanding stock options, RSUs, warrants and convertible preferred stock of 10,196,872 and 9,582,513, respectively, were not included in the computation of diluted earnings per share, because to do so would have had an antidilutive effect. During the three months ended September 30, 2016 and 2015, outstanding stock options, RSUs, warrants and convertible preferred stock of 9,986,447 and 9,743,687, respectively, were not included in the computation of diluted earnings per share, because to do so would have had an antidilutive effect.

Restricted Stock Units

During the nine months ended September 30, 2016, 1,406,000 restricted stock units (RSUs) were granted to the Company s executive officers, directors and employees, with a fair market value of approximately $4.6 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 for the executive officers, vest in equal installments over two years for directors and vest in the following year for employees. Of the aforementioned RSUs granted during the nine months ended September 30, 2016, 40,000 were granted to certain Company employees as performance-based RSUs, which vest when certain profitability thresholds are achieved, as defined by the Compensation Committee of the Company s Board of Directors (the Compensation Committee).

Restricted stock activity during the nine months ended September 30, 2016 was as follows:

	Number of Restricted Shares	Weighted Average Fair Market Value Per RSU
Outstanding at January 1, 2016	4,298,154	$ 10.23
Granted:		
Executive officers	913,000	3.80
Directors	185,000	2.43
Employees	308,000	2.32

Vested	(592,066)		2.68
Forfeitures	(640,291)		11.47
Outstanding at September 30, 2016	4,471,797	$	9.28

Common Stock

On December 16, 2015, the Company and Dr. Andrew Finn entered into a retirement agreement (the Retirement Agreement) setting forth their mutual understandings regarding Dr. Finn s retirement from the Company. Pursuant to the Retirement Agreement, all unvested RSUs previously issued under the Company s equity incentive plans and held by Dr. Finn as of the retirement date were cancelled and, in lieu thereof, Dr. Finn was awarded a one-time issuance of shares of Common Stock based upon a net present valuation of the cancelled RSUs as set forth in the Retirement Agreement (which resulted in an issuance in January 2016 of 513,221 shares of Common Stock).

Following its review of the Company s corporate performance for 2015, the Compensation Committee of the Board of Directors approved in early 2016, equity awards for 2015 in the form of RSUs to its named executive officers (including Dr. Finn) and other senior executives in amounts at or below the 25th% percentile of the Company s peer group. Dr. Finn, who retired on December 31, 2015, received an immediate award of 150,000 shares of Common Stock in fulfillment of the Company s contractual obligation to him under the Retirement Agreement. Such shares were issued in March 2016.

Warrants

During the nine months ended September 30, 2016, the Company granted warrants to purchase 84,986 shares of Common Stock at an exercise price of $3.53 per share to Midcap and its affiliates in connection with the Company s extension agreement with MidCap. As of September 30, 2016, 84,986 warrants remain outstanding.

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12. Commitments and contingencies:

Litigation Related To ONSOLIS®

On November 2, 2010, MonoSol Rx, LLC (MonoSol) filed an action against the Company and its commercial partners for ONSOLIS® in the Federal District Court of New Jersey (DNJ) for alleged patent infringement and false marking. The Company was formally served in this matter on January 19, 2011. MonoSol claims that the Company s manufacturing process for ONSOLIS®, which has never been disclosed publicly and which the Company and its partners maintain as a trade secret, infringes its patent (United States Patent No. 7,824,588) (the 588 Patent).

In November 2011, the United States Patent and Trademark Office (USPTO) rejected all 191 claims of MonoSol s 588 Patent. On January 20, 2012, the Company 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. The USPTO granted the requests for reexamination with respect to MonoSol s 292 and 891 Patents. In its initial office action in each, the USPTO rejected every claim in each patent.

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

Based on the Company s original assertion that its proprietary manufacturing process for ONSOLIS® does not infringe on patents held by MonoSol, and the denial and subsequent narrowing of the claims on the two reissued patents MonoSol has asserted against the Company while the third has had all claims rejected by the USPTO, the Company remains very confident in its original stated position regarding this matter. Thus far, the Company has proven that the original 292 and 891 patents in light of their reissuance with fewer and narrower claims were indeed invalid and the third and final patent, the 588 patent, was invalid as well with all its claims cancelled. Given the outcomes of the 292, 891 and 588 reexamination proceedings, 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. On September 25, 2015, the Hon. Freda L. Wolfson granted the Company s motion for summary judgment and ordered the case closed. The Company was found to be entitled to absolute intervening rights as to both patents in suit, the 292 and 891 patents, and its ONSOLIS® product is not liable for infringing the patents prior to July 3, 2012 and August 21, 2012, respectively. In October 2015, MonoSol appealed the decision of the court to the Federal Circuit. The Company had no reason to

believe the outcome would be different and would vigorously defend the appeal. MonoSol filed an appeal with the Federal Circuit and has subsequently decided to withdraw the appeal.

On February 25, 2016, MonoSol filed an Unopposed Motion for Voluntary Dismissal of Appeal, which was granted by the court on February 26, 2016 and the case was dismissed. Thus, the district court s grant of the Summary Judgement of Intervening Rights will stand. The possibility exists, however, that MonoSol could file another suit alleging infringement of the 292 and 891 patents. The Company believes ONSOLIS® and its other products relying on the BEMA® technology, including BUNAVAIL® and BELBUCA , do not infringe any amended, reexamined claim from either patent after those dates.

Litigation Related To BUNAVAIL®

On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol (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 (EDNC) for alleged patent infringement. BUNAVAIL® is a method of 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).

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 EDNC requesting the Court to make a determination that the Company s BUNAVAIL® product does not infringe the RB Plaintiffs 832 Patent, US Patent No. 7,897,080 (the 080 Patent) and US Patent No. 8,652,378 (the 378 Patent).

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12. Commitments and contingencies (continued):

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 *inter partes* review before the USPTO (an IPR) was instituted and in June 2015, all challenged claims were rejected for both anticipation and obviousness. In August 2015, the RB Plaintiffs filed an appeal to the Federal Circuit. The Federal Circuit affirmed the USPTO s decision, and the RB Plaintiffs then filed a Petition for Panel Rehearing and for Rehearing En Banc, which was denied. A mandate issued on October 25, 2016, pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure, meaning that a petition for certiorari to the Supreme Court is no longer possible for the RB Plaintiffs. The 832 IPR was finally resolved with the invalidation of claims 15-19. 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. In May 2015, the RB Plaintiffs filed a response after the decision to which the Company filed comments. In December 2015, the Board denied MonoSol s request to reopen prosecution, but provided MonoSol an opportunity to file a corrected response. MonoSol filed the request in December 2015 and the Company subsequently filed comments on December 23, 2015. PTAB issued a communication on July 7, 2016 denying MonoSol s request to reopen prosecution of the rejections of all claims over the prior art. All claims remain finally rejected, and the additional rejections of the claims was maintained. 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 its 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 (the 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. On December 12, 2014, the Company filed motions to transfer the case from New Jersey to North Carolina and to dismiss the case against the Company s commercial partner. The Court issued an opinion on July 21, 2015 granting the Company s motion to transfer the venue to the Eastern District of North Carolina (EDNC), but denying the Company s motion to dismiss the case against the Company s commercial partner as moot. The Company has also filed a Joint Motion to Stay the case

in North Carolina at the end of April 2016, which was granted by the court on May 5, 2016. Thus, the case is now stayed until a final resolution of the 167 IPRs in the USPTO. The Company will continue to vigorously defend this case in the EDNC.

In a related matter, 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 light of prior art references, including prior art references not previously considered by the USPTO, and thus, invalid. The USPTO instituted three of the four IPR requests and the Company filed a request for rehearing for the non-instituted IPR. The final decisions finding all claims patentable were issued in March 2016 and the Company filed a Request for Reconsideration in the USPTO in April 2016, which was denied in September 2016 and any appeal thereof to Court of Appeals for the Federal Circuit would be due in November 2016. While the claims were upheld in the opinion, BUNAVAIL® was found to not infringe the claims of the 167 patent.

On January 22, 2014, MonoSol filed a Petition for IPR on US Patent No. 7,579,019 (the 019 Patent). The Petition asserted that the claims of the 019 Patent are alleged to be unpatentable over certain prior art references. The IPR was instituted on August 6, 2014. An oral hearing was held in April 2015 and a decision upholding all seven claims was issued August 5, 2015. In September 2015, MonoSol requested that the USPTO rehear the IPR. The Company will continue to vigorously defend its 019 patent. The Company expects the USPTO to issue a decision in the second half of 2016.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

12. Commitments and contingencies (continued):

Actavis

On February 8, 2016, the Company received a purported notice relating to a Paragraph IV certification from Actavis Laboratories UT, Inc. (Actavis) seeking to find invalid three Orange Book listed patents (the Patents) relating specifically to BUNAVAIL®. The Paragraph IV certification relates to an Abbreviated New Drug Application (the ANDA) filed by Actavis with the FDA for a generic formulation of BUNAVAIL®. The Patents subject to Actavis certification are U.S. Patent Nos. 7,579,019 (the 019 Patent), 8,147,866 and 8,703,177. The Company believes that Actavis claims of invalidity of the Patents are wholly without merit and, as the Company has done in the past, intends to vigorously defend its intellectual property. The Company is highly confident that the Patents are valid, as evidenced in part by the fact that the 019 Patent has already been the subject of an unrelated IPR before the USPTO under which the Company prevailed and all claims of the 019 Patent survived. Although there is a pending request for rehearing of the final IPR decision regarding the 019 Patent pending at the USPTO, the Company believes the USPTO s decision will be upheld. Under the Food Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the Hatch-Waxman Amendments), after receipt of a valid Paragraph IV notice, the Company may, and in this case plans to, bring a patent infringement suit in federal district court against Actavis within 45 days from the date of receipt of the certification notice. On March 18, 2016 the Company filed a complaint in Delaware against Actavis, thus the Company is entitled to receive a 30 month stay on FDA s ability to give final approval to any proposed products that reference BUNAVAIL®. The 30 month stay is expected to preempt any final approval by FDA on Actavis s ANDA until at least August of 2018. The court has rescheduled a claim construction hearing (Markman hearing) from December 12, 2016 to March 3, 2017. A five (5) day trial is scheduled to begin on October 2, 2017. In addition, given the FDA approval of BUNAVAIL®, we are entitled to three years of market exclusivity for BUNAVAIL® ending in June 2017. In addition, given the FDA approval of BUNAVAIL®, the Company is entitled to three years of market exclusivity for BUNAVAIL® ending in June 2017. Given this timeframe, Actavis s action is not unexpected. In addition, the Company has additional pending intellectual property which, if issued, would be capable of extending the patent life of all three of our BEMA®-related products, including BUNAVAIL®, and would potentially be listed in the Orange Book.

During the normal course of business, the Company accrues additional expenses for certain legal matters from time to time, including legal matters related to the protection and enforcement of the Company s intellectual property. The amounts accrued for such legal matters are recorded within accrued expenses on the balance sheet.

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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 505(b)(2) approval process of the U.S Food and Drug Administration (FDA) or are already FDA approved;
- Market our products through specialty sales teams by primarily focusing on high-prescribing U.S. physicians working with patients in the pain and addiction space.

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

2016 Highlights For the Third Quarter and Beyond

- On July 11, 2016, we announced we had signed an agreement with a significant managed care provider providing preferred access to BUNAVAIL® for the maintenance treatment of opioid dependence.
- On September 19, 2016, we announced we had secured three new managed care contracts for BUNAVAIL® in plans where BUNAVAIL® was previously non-formulary or in a non-preferred position.

On September 30, 2016, we reported that according to the Substance Abuse and Mental Health Services Administration, 1,665 clinicians have applied for and were granted waivers to prescribe buprenorphine for the treatment of opioid dependence at the increased limit of 275 prescriptions from the previous 100 prescription limit.

On October 24, 2016, we announced the addition of our BUNAVAIL® as a preferred drug to the Texas Medicaid formulary from its previous non-formulary status.

Our Products and Related Trends

Our product portfolio currently consists of five products. As of the date of this report, three products are approved by the FDA and two are in development. Three of these five products utilize our patented BEMA® thin film drug delivery technology.

BUNAVAIL® was approved by the FDA in June 2014 for the maintenance treatment of opioid dependence. BUNAVAIL® uses our BEMA® technology combined with the Schedule III narcotic buprenorphine in tandem with naloxone, an opioid antagonist. We are commercializing BUNAVAIL® ourselves and launched the product during the fourth quarter of 2014. We have been actively engaged in efforts to optimize our commercialization of BUNAVAIL® and with particular emphasis in 2016, to better align costs with revenue and reduce spending. To this end, effective as of May 2016, we reduced the size and altered the structure of our sales force to better focus

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on the most profitable territories in the country where BUNAVAIL® has or is in the best position to obtain marketplace growth. This resulted in a reduction in sales territories and sales and marketing expenditures. We will seek to continue to grow BUNAVAIL® market share by focusing sales efforts in the highest growth territories over time, by using recently published data evidencing diversion (i.e., the illicit use of a legally prescribed controlled substance) associated with the market leader s product and, by highlighting the other attributes of BUNAVAIL® as we seek to win exclusive or preferred status in additional managed care contracts. We also believe there will be an opportunity to introduce more patients to BUNAVAIL® following the official lifting of a long-standing limit from 100 to 275 (as outlined in the final ruling by the Department of Health and Human Services and effective on August 8, 2016), the number of patients per physician that can be treated at any given time with buprenorphine. We will continue to closely monitor commercial efforts and seek to increase revenue and profitability, as well as evaluate all options available to preserve the long term prospects for and maximize the value of BUNAVAIL®. Separately, 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).

BELBUCA (which also uses our BEMA® technology) is for the management of chronic 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 Pharmaceuticals, Inc. (Endo). On October 26, 2015, we announced with Endo that the FDA approved BELBUCA. BELBUCA was launched by Endo in February 2016, and the commercialization of this product may trigger additional future payments from Endo if certain sales milestones are met. We are also entitled to receive tiered royalties that start in the mid-teens on net sales of BELBUCA. We continue to have ongoing contact with Endo including Joint Development and Joint Commercial Committee meetings with senior management to monitor progress of Endo s sales and marketing efforts. The launch has been more challenging, as previously disclosed, because of the increased scrutiny of prescribing opioids driven by the Centers for Disease Control and Prevention guideline changes issued in March 2016. The difference that Belbuca offers over the Schedule II opioids, such as Oxycodone, Hydrocodone, Morphine, etc., including less addition and abuse potential along with a ceiling effect on respiratory depression make it the opioid of choice.

ONSOLIS® is approved in the U.S., the 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. ONSOLIS® utilizes our BEMA® thin film drug delivery technology in combination with the narcotic fentanyl. The commercial rights to ONSOLIS® were originally licensed to Meda AB (Meda) in 2006 and 2007 for all territories worldwide except for Taiwan (where it is licensed to TTY). The marketing authorization for ONSOLIS® was returned to us in early 2015 as part of an assignment and revenue sharing agreement with Meda for the United States, Canada and Mexico. Such agreement also facilitated the approval of a new formulation of ONSOLIS® in the U.S. On May 11, 2016, our Company and Collegium executed a License Agreement under which we granted to Collegium the exclusive rights to develop and commercialize ONSOLIS® in the U.S.

Clonidine Topical Gel is a non-BEMA® product which is currently in Phase 3 development for the treatment of painful diabetic neuropathy (PDN). We licensed this product from Arcion in March 2013. On March 30, 2015, we announced that the primary efficacy endpoint in our initial Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of PDN did not meet statistical significance,

although certain secondary endpoints showed statistically significant improvement over placebo. Final analysis of the study identified a sizeable patient population with a statistically significant improvement (n=158; p<0.02) in pain score vs placebo. Following thorough analysis of the data and identification of the reasons behind the study results, we initiated a second study. Such current study incorporates significant learnings from previously conducted studies and involves tightened and additional inclusion criteria to improve assay sensitivity, reduce bias and ensure compliance with enrollment criteria. On August 4, 2016, we announced that we had reached our target number of subjects to be randomized in our multi-center, double-blind, placebo-controlled Phase 2b study assessing the efficacy and safety of Clonidine Topical Gel in the treatment of PDN. Based on the timing of randomization of the last patient, we now expect topline results of the study will be available by the end of this year, which puts it six to eight weeks ahead of schedule.

Buprenorphine Depot Injection 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 currently in the pre-clinical stage of development with plans underway for an Investigational New Drug Application (IND) submission in early 2017.

As we focus on the growth of our existing products and other product candidates, we also continue to actively explore licensing and acquisition opportunities that will facilitate future growth. In order to do so, we will need to continue to maintain our strategic direction, manage and deploy our available cash and human capital effectively and strengthen our alliances and partner relationships. We believe these actions, combined with the experience and expertise of our management team, position us well to deliver future growth of our revenue and income.

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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, and as previously reported we have since worked with FDA to reformulate ONSOLIS® to address these issues. In August 2015, we announced the FDA approval of the new formulation.

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 the return of the U.S. marketing authorization from Meda, we submitted a prior approval supplement for the new formulation to the FDA in March 2015, which was approved in August 2016. On February 27, 2016, we entered into an extension of the assignment and revenue sharing agreement to extend the agreement through December 31, 2016.

Efforts to extend our supply agreement with our ONSOLIS® manufacturer, Aveva, which is now a subsidiary of Apotex, Inc., were unsuccessful and the agreement expired. However, we identified an alternate supplier and requested guidance from the FDA on the specifics required for obtaining approval to supply product from this new vendor. Based on our current estimates, we believe that we will submit the necessary documentation to the FDA for qualification of the new manufacturer in early 2017, which would allow for the reintroduction of ONSOLIS by mid-2017.

On May 11, 2016, our Company and Collegium executed the License Agreement under which we have granted to Collegium the exclusive rights to develop and commercialize ONSOLIS® in the U.S.

Under the terms of the License Agreement, Collegium will be responsible for the manufacturing, distribution, marketing and sales of ONSOLIS® in the U.S. We are obligated to use commercially reasonable efforts to continue the transfer of manufacturing to our anticipated manufacturer for ONSOLIS® and to submit a corresponding Prior Approval Supplement (the Supplement) to the FDA with respect to the current NDA for ONSOLIS®. Following approval of the Supplement, the NDA and manufacturing responsibility for ONSOLIS® (including the manufacturing relationship with our manufacturer, subject to us entering into an appropriate agreement with such manufacturer that is acceptable and assignable to Collegium) will be transferred to Collegium.

Results of Operations

Comparison of the three months ended September 30, 2016 and 2015

Product Sales. We recognized $2.0 million and $1.2 million in product sales during the three months ended September 30, 2016 and 2015, respectively. The improvement in quarter ended September 30, 2016 is from increased sales of BUNAVAIL® and lower associated gross to net deductions as a result of lower Medicaid utilization under our managed care.

Product Royalty Revenues. We recognized $1.1 million and $0.03 million in product royalty revenue during the three months ended September 30, 2016 and 2015, respectively. For the three months ended September 30, 2016, $0.4 million can be attributed to higher net sales of BREAKYL under our license agreement with Meda and $0.3 million from net sales of BELBUCA under our license agreement with Endo. For the same period in 2016, we also recognized $0.4 million in product royalty revenue for PAINKYL under our license agreement with TTY. For the three months

ended September 30, 2015, we recognized $0.03 million in net sales of BREAKYL under our license agreement with Meda.

Research and Development Reimbursements. We recognized $0.5 million and $0.06 million of reimbursable revenue during the three months ended September 30, 2016 and 2015, respectively. Higher research and development reimbursements during the three months ended September 30, 2016 can be attributed to certain reimbursements related to our license agreement with Collegium.

Cost of Sales. We incurred $2.3 million and $1.7 million in cost of sales during the three months ended September 30, 2016 and 2015, respectively. Cost of sales during the three months ended September 30, 2016 was $1.6 million for BUNAVAIL®, which includes product cost, royalties paid, lower of cost or market adjustment, and depreciation. Additionally, we incurred a total of $0.4 million in quarterly minimum payments and royalty payments to CDC IV, LLC and NB Athyrium LLC (which we refer to collectively as CDC). Cost of sales during the three months ended September 30, 2016 also included $0.2 million and $0.06 million related to BREAKYL and PAINKYL, respectively. Cost of sales during the three months ended September 30, 2015 was $1.2 million for BUNAVAIL®, which includes product cost, royalties paid, lower of cost or market adjustment and depreciation. Additionally, we paid a total of $0.4 million in quarterly minimum and royalty payments to CDC. The Cost of sales during the three months ended September 30, 2015 also included $0.1 million related to BREAKYL.

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Expenditures for Research and Development Programs

BUNAVAIL®

We incurred research and development expenses for BUNAVAIL® of approximately $1.3 million for the three months ended September 30, 2016 and approximately $1.9 million for the three months ended September 30, 2015. We have incurred approximately $37.6 million in the aggregate since inception of development of this product. BUNAVAIL® was approved by the FDA in 2014. Quarterly BUNAVAIL® research and development expenses primarily consist of qualification of a second manufacturer of BUNAVAIL® and allocated wages and compensation.

BELBUCA

We incurred research and development expenses for BELBUCA of approximately $0.3 million for the three months ended September 30, 2015. No such expenses were incurred for the three months ended September 30, 2016. Aggregate expenses approximate $114.2 million since inception of our development of this product. Our expense obligations for this product are 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. Expenses in 2015 consisted primarily of three large clinical trials addressing the efficacy and safety of the product, along with formulation, manufacturing development and allocated wages and compensation. BELBUCA was approved by the FDA in 2015.

ONSOLIS®

We incurred research and development expenses for ONSOLIS® of approximately $0.1 million for the three months ended September 30, 2016. There were no such expenses incurred during the three months ended September 30, 2015. We have incurred approximately $1.0 million in the aggregate since inception of this product. Our expenses for this product for 2016 and 2015 consisted mainly of development work in support of the reformulation of ONSOLIS® that was approved by the FDA in August 2015 and allocated wages and compensation.

Clonidine Topical Gel

We incurred research and development expenses for Clonidine Topical Gel of approximately $1.9 million for the three months ended September 30, 2016 and approximately $1.6 million for the three months ended September 30, 2015, and have incurred approximately $26.8 million in the aggregate since inception of development. Our expenses for this product candidate over such periods consisted mainly of several clinical trials testing the efficacy of the product, a Long-Term Safety Study and allocated wages and compensation.

Buprenorphine Depot Injection

We incurred research and development expenses for Buprenorphine Depot Injection of approximately $1.1 million for the three months ended September 30, 2016 and $0.8 million for the three months ended September 30, 2015, and have incurred approximately $6.2 million in the aggregate since inception of development. Our 2016 and 2015 expenses for this product candidate consisted of pre-clinical formulation and manufacturing development in anticipation of filing an IND in 2016. Also included were allocated wages and compensation.

Selling, General and Administrative Expenses. During the three months ended September 30, 2016 and 2015, selling, general and administrative expenses totaled $12.1 million and $14.7 million, respectively. Such expenses include commercialization costs for BUNAVAIL®, legal, accounting and management wages, and consulting and professional fees, travel costs and stock compensation expenses. During the normal course of business, we accrue additional

expenses for certain legal matters from time to time, including legal matters related to the protection and enforcement of our intellectual property. The amounts accrued for such legal matters are recorded within accrued expenses on the balance sheet.

During the three months ended September 30, 2016 and 2015, selling, general and administrative expenses included $3.6 million and $3.9 million of stock compensation expenses, respectively. This is primarily composed of restricted stock expense to our executive management and board of directors.

Interest expense, net. During the three months ended September 30, 2016, we had net interest expense of $0.8 million, consisting of $0.7 million of scheduled interest payments and $0.01 million of related amortization of discount, all related to the July 2013 secured loan facility from MidCap. During the three months ended September 30, 2015, we had net interest expense of $0.8 million, consisting of $0.7 million of scheduled interest payments and $0.1 million of related amortization of discount and loan costs related to MidCap.

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Derivative gain. Our derivative liability consists of free standing warrants measured at their fair market value, using the Black-Scholes model. During the three months ended September 30, 2016, our stock price increased by $0.34. This is the largest component of the Black-Scholes change. However, due to volatility, our derivative liability decreased, resulting in a $0.01 million credit to income. There were no derivatives or associated warrants granted or exercised during the three months ended September 30, 2015.

Comparison of the nine months ended September 30, 2016 and 2015

Product Sales. We recognized $6.2 million and $2.7 million in product sales during the nine months ended September 30, 2016 and 2015, respectively. The 2016 increase is from higher sales of BUNAVAIL® and lower associated gross to net deductions as a result of lower Medicaid utilization under our managed care contract and lower voucher program costs.

Product Royalty Revenues. We recognized $2.4 million and $0.7 million in product royalty revenue during the nine months ended September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2016, $1.3 million can be attributed to higher net sales of BREAKYL under our license agreement with Meda and $0.3 million from net sales of BELBUCA under our license agreement with Endo. During the nine months ended September 30, 2016, we also recognized $0.9 million in product royalty revenue under our license agreement with TTY. During the nine months ended September 30, 2015, $0.6 million in product royalty revenues can be attributed to net sales of BREAKYL. We also recognized $0.07 million in product royalty revenue during the nine months ended September 30, 2015 under our license agreement with TTY.

Research and Development Reimbursements. We recognized $0.5 million and $0.9 million of reimbursable revenue during the nine months ended September 30, 2016 and 2015, respectively. Research and development reimbursements during the nine months ended September 30, 2016 can be attributed to certain reimbursements related to our license agreement with Collegium. Research and development reimbursements during the nine months ended September 30, 2015 can be attributed to certain research and development expense reimbursements from Endo for BELBUCA. The BELBUCA development program was completed during the first quarter of 2015.

Contract Revenues. We recognized $2.5 million and $11.8 million in contract revenue during the nine months ended September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2016, contract revenue can be attributed to the execution of our license agreement with Collegium which includes a $2.5 million upfront payment. For the nine months ended September 30, 2015, contract revenue included a $10 million milestone payment from Endo upon FDA acceptance of filing the BELBUCA NDA. We also recognized $1.5 million during the nine months ended September 30, 2015 in contract revenue related to previously deferred revenue under our license agreement with Meda. We further earned $0.3 million in contract revenue during the nine months ended September 30, 2015 under our license agreement with Kunwha. The decrease in contract revenue during the nine months ended September 30, 2016 can be attributed to no additional milestone payments being received or earned during that period.

Cost of Sales. We incurred $9.0 million and $5.4 million in cost of sales during the nine months ended September 30, 2016 and 2015, respectively. Cost of sales during the nine months ended September 30, 2016 was $5.3 million for BUNAVAIL®. Such product costs include manufacturing, royalties, lower of cost or market adjustment and depreciation. Additionally, we paid a total of $3.0 million in royalty payments to CDC and to Meda of aforementioned existing agreements. Cost of sales during the nine months ended September 30, 2016 also includes $0.5 million and $0.1 million related to BREAKYL and PAINKYL, respectively. Cost of sales during the nine months ended September 30, 2015 was related primarily to BUNAVAIL®, which includes $3.1 million of product cost, $0.1 million in lower of cost or market adjustment and depreciation, $0.8 million for batches not meeting specifications and raw material yield loss. Also included in the prior year period were $0.3 million in cost of sales related to BREAKYL and

royalty payments to CDC of $1.1 million.

Expenditures for Research and Development Programs

BUNAVAIL®

We incurred research and development expenses for BUNAVAIL® of approximately $4.1 million for nine months ended September 30, 2016 and approximately $3.8 million for the nine months ended September 30, 2015. We have incurred approximately $37.6 million in the aggregate since inception of our development of this product. BUNAVAIL® was approved by the FDA in 2014. BUNAVAIL® research and development expenses for the first nine months of 2016 and the corresponding period in 2015 primarily consist of qualification of a second manufacturer of BUNAVAIL® and allocated wages and compensation.

BELBUCA

We incurred research and development expenses for BELBUCA of approximately $2.7 million for the nine months ended September 30, 2015. No such expenses were incurred for the nine months ended September 30, 2016. Aggregate expenses approximate $114.2 million since inception of our development of this product. Our expense obligations for this product are detailed

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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. Expenses in 2015 consisted primarily of nine large clinical trials addressing the efficacy and safety of the product, along with formulation, manufacturing development and allocated wages and compensation. BELBUCA was approved by the FDA in 2015.

ONSOLIS®

We incurred research and development expenses for ONSOLIS® of approximately $0.7 million for the nine months ended September 30, 2016. There were no such expenses incurred during the nine months ended September 30, 2015. We have incurred approximately $1.0 million in the aggregate since inception of this product. Our expenses for this product for 2016 and 2015 consisted mainly of development work in support of the reformulation of ONSOLIS® that was approved by the FDA in August 2015 and allocated wages and compensation.

Clonidine Topical Gel

We incurred research and development expenses for Clonidine Topical Gel of approximately $6.0 million for the nine months ended September 30, 2016 and approximately $7.3 million for the nine months ended September 30, 2015, and have incurred approximately $26.8 million in the aggregate since inception of development. Our expenses for this product candidate over such periods consisted mainly of several clinical trials testing the efficacy of the product, a Long-Term Safety Study and allocated wages and compensation.

Buprenorphine Depot Injection

We incurred research and development expenses for Buprenorphine Depot Injection of approximately $3.0 million for the nine months ended September 30, 2016 and $1.5 million for the nine months ended September 30, 2015, and have incurred approximately $6.2 million in the aggregate since inception of development. Our 2016 and 2015 expenses for this product candidate consisted of pre-clinical formulation and manufacturing development in anticipation of filing an IND in 2016. Also included were allocated wages and compensation.

Selling, General and Administrative Expenses. During the nine months ended September 30, 2016 and 2015, selling, general and administrative expenses totaled $37.6 million and $41.2 million, respectively. Such expenses include commercialization costs for BUNAVAIL®, legal, accounting and management wages, and consulting and professional fees, travel costs, and stock compensation expenses. During the normal course of business, we accrue additional expenses for certain legal matters from time to time, including legal matters related to the protection and enforcement of our intellectual property. The amounts accrued for such legal matters are recorded within accrued expenses on the accompanying condensed balance sheet.

During the nine months ended September 30, 2016 and 2015, selling, general and administrative expenses included $9.5 million and $9.6 million of stock compensation expenses, respectively. This is primarily composed of restricted stock expense to our executive management and board of directors.

Interest expense, net. During the nine months ended September 30, 2016, we had net interest expense of $2.5 million, consisting of $2.2 million of scheduled interest payments, $0.2 million of related amortization of discount and loan costs and $0.1 million in warrant interest expense, all related to the July 2013 secured loan facility from MidCap. During the nine months ended September 30, 2015, we had net interest expense of $1.7 million, consisting of $1.3 million of scheduled interest payments and $0.4 million of related amortization of discount and loan costs related to our secured loan facility from Midcap.

Derivative gain. Our derivative liability consists of free standing warrants measured at their fair market value, using the Black-Scholes model. During the nine months ended September 30, 2016, our stock price decreased by $2.09. This is the largest component of the Black-Scholes change. As a result, our derivative liability also decreased, resulting in a $0.04 million credit to income. There were no derivatives or associated warrants granted or exercised during the nine months ended September 30, 2015.

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®, revenue generated as a result of our January 2012 agreement with Endo regarding our newly FDA approved BELBUCA product and revenue generated as a result of our May 2016 license and development agreement with Collegium to develop ONSOLIS® in the U.S. We intend to finance our research and development, commercialization and working capital needs from existing cash, royalty revenue, sales revenue from the

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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 September 30, 2016, we had cash and cash equivalents of approximately $44.7 million. We used $38.9 million of cash during the nine months ended September 30, 2016 and had stockholders deficit of $5.1 million at September 30, 2016, versus stockholders equity $31.7 million at December 31, 2015. We expect that we will have sufficient cash to manage our business into the third quarter of 2017, although this estimation assumes we do not accelerate the development of existing product candidates, or acquire other, drug development opportunities 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 anticipated commercial relaunch and manufacturing 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;

grants and new license revenues;

bank loans;

equipment financing;

public or private debt; and

exercise of existing warrants or options to purchase our common stock.

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 2016 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

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

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Contractual Obligations and Commercial Commitments

Our contractual obligations as of September 30, 2016 are as follows (in thousands):

	Payments Due by Period				
		Less than			More than
	Total	1 year*	1-3 years	3-5 years	5 years
Operating lease obligations	$ 2,055	$ 330	$ 687	$ 725	$ 313
Secured loan facility	30,000	11,739	18,261		
Interest on secured loan facility	4,254	2,366	1,888		
Minimum royalty expenses**	4,875	1,500	3,000	375	
Total contractual cash obligations***	$ 41,184	$ 15,935	$ 23,836	$ 1,100	$ 313

* This amount represents obligations through the end of the calendar year ending December 31, 2016.

** Minimum royalty expenses represent a contractual floor that we are obligated to pay CDC and NB Athyrium LLC (or CDC) 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 and therefore no amounts are included herein.

Off-Balance Sheet Arrangements

As of September 30, 2016, 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 condensed 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, 2015. There have not been material changes to the critical accounting policies previously disclosed in that report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

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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 third quarter of 2016 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 our continuing commercial efforts with BUNAVAIL®) and royalty or milestone payments, if any (including potential royalty payments from Endo on sales of BELBUCA), (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s review and/or approval and commercial launch of our products and product candidates and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1A of our 2015 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 September 12, 2011, we filed a request for *inter partes* reexamination in the United States Patent and Trademark Office (USPTO) of MonoSol s 588 Patent demonstrating that all claims of such patent were anticipated by or obvious in the light of prior art references, including several prior art references not previously considered by the USPTO, and thus invalid. On September 16, 2011, we filed a motion for stay pending the outcome of the reexamination proceedings, which subsequently was granted.

In November 2011, the USPTO 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. The USPTO granted the requests for reexamination with respect to MonoSol s 292 and 891 Patents. In its initial office action in each, the USPTO rejected every claim in each patent.

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.

On June 12, 2013, despite our previously noted success in the prior ex parte reexaminations for the 292 and 891 Patents, we filed requests for *inter partes* reviews (IPRs) on the narrowed yet reexamined patents, the 292 C1 and 891 C1 Patents, to challenge their validity and continue to strengthen our position. On November 13, 2013, the USPTO decided not to institute the two IPRs 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 IPRs 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.

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

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while the third has had all claims rejected by the USPTO, we remain 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. On September 25, 2015, the Honorable Freda L. Wolfson granted our motion for summary judgment and ordered the case closed. We were found to be entitled to absolute intervening rights as to both patents in suit, the 292 and 891 patents and our ONSOLIS® product is not liable for infringing the patents prior to July 3, 2012 and August 21, 2012, respectively. In October 2015, MonoSol appealed the decision of the court to the Federal Circuit. We have no reason to believe the outcome will be different and we will vigorously defend the appeal. MonoSol filed an appeal with the Federal Circuit and has subsequently decided to withdraw the appeal. On February 25, 2016, MonoSol filed an Unopposed Motion For Voluntary Dismissal Of Appeal, which was granted by the court on February 26, 2016 and the case dismissed. Thus, the district court s grant of the Summary Judgement of Intervening Rights will stand. In addition, the possibility exists that MonoSol could file another suit alleging infringement of the 292 and 891 patents. We believe ONSOLIS® and our other products relying on the BEMA® technology, including BUNAVAIL® and BELBUCA, do not infringe any amended, reexamined claim from either patent after those dates.

Litigation Related To BUNAVAIL®

RB and MonoSol

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 (EDNC) 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 in June 2015, all challenged claims were rejected for both anticipation and obviousness. In August 2015, the RB Plaintiffs filed an appeal to the Federal Circuit. The Federal Circuit affirmed the USPTO s decision, and the RB Plaintiffs then filed a Petition for Panel Rehearing and for Rehearing En Banc, which was denied. A mandate issued on October 25, 2016, pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure, meaning that a petition for certiorari to the Supreme Court is no longer possible for the RB Plaintiffs. The 832 IPR was finally resolved with the invalidation of claims 15-19. 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. In May 2015, the RB Plaintiffs filed a response after the decision to which we filed comments. In December 2015, the PTAB denied MonoSol s request to reopen prosecution, but provided MonoSol an opportunity to file a corrected response. MonoSol filed the request in December 2015 and we subsequently filed comments on December 23, 2015. The PTAB issued a communication on July 7, 2016 denying MonoSol s request to reopen prosecution of the rejections of all claims over the prior art. All claims remain finally rejected, and the additional rejections of the claims was maintained. 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

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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. On December 12, 2014, we filed a motion to transfer the case from New Jersey to North Carolina and a motion to dismiss the case against our commercial partner. The Court issued an opinion on July 21, 2015 granting our motion to transfer the venue to the Eastern District of North Carolina (ENDC) but denying our motion to dismiss the case against our commercial partner as moot. We have also filed a Joint Motion to Stay the case in North Carolina at the end of April 2016, which was granted by the court on May 5, 2016. Thus, the case is now stayed until a final resolution of the 167 IPRs in the USPTO. We will continue to vigorously defend this case in the EDNC.

In a related matter, 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 light of prior art references, including prior art references not previously considered by the USPTO, and thus, invalid. The USPTO instituted three of the four IPR requests and we filed a request for rehearing for the non-instituted IPR. The final decisions finding all claims patentable were issued in March 2016 and we filed a Request for Reconsideration in the USPTO in April 2016, which was denied in September 2016 and any appeal thereof to Court of Appeals for the Federal Circuit would be due in November 2016. While the claims were upheld in the opinion, BUNAVAIL® was found to not infringe the claims of the 167 patent.

On January 22, 2014, MonoSol filed a Petition for IPR on US Patent No. 7,579,019 (the 019 Patent). The Petition asserted that the claims of the 019 Patent are alleged to be unpatentable over certain prior art references. The IPR was instituted on August 6, 2014. An oral hearing was held in April 2015 and a decision upholding all seven claims was issued August 5, 2015. In September 2015, MonoSol requested that the USPTO rehear the IPR. We will continue to vigorously defend our 019 patent. We expect the USPTO to issue a decision in the second half of 2016.

Actavis

On February 8, 2016, we received a purported notice relating to a Paragraph IV certification from Actavis Laboratories UT, Inc. (Actavis) seeking to find invalid three Orange Book listed patents (the Patents) relating specifically to BUNAVAIL®. The Paragraph IV certification relates to an Abbreviated New Drug Application (the ANDA) filed by Actavis with the U.S Food and Drug Administration (FDA) for a generic formulation of BUNAVAIL®. The Patents subject to Actavis certification are U.S. Patent Nos. 7,579,019 (the 019 Patent), 8,147,866 and 8,703,177.

We believe that Actavis claims of invalidity of the Patents are wholly without merit and, as we have done in the past, we intend to vigorously defend our intellectual property. We are highly confident that the Patents are valid, as evidenced in part by the fact that the 019 Patent has already been the subject of an unrelated IPR before the USPTO under which we prevailed and all claims of the 019 Patent survived. Although there is a pending request for rehearing of the final IPR decision regarding the 019 Patent pending at the USPTO, we believe the USPTO s decision will be upheld. Under the Food Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the Hatch-Waxman Amendments), after receipt of a valid Paragraph IV notice, we may, and in this case did, bring a patent infringement suit in federal district court against Actavis within 45 days from the date of receipt of the certification notice. On March 18, 2016, we filed a complaint in Delaware against Actavis, thus we are entitled to receive a 30 month stay on the FDA s ability to give final approval to any proposed products that reference BUNAVAIL®. The 30 month stay is expected to preempt any final approval by the FDA on Actavis ANDA until at least August of 2018. The court has rescheduled a claim construction hearing (Markman hearing) from December 12, 2016 to March 3, 2017. A five (5) day trial is scheduled to begin on October 2,

2017. Given the FDA approval of BUNAVAIL®, we are entitled to three years of market exclusivity for BUNAVAIL® ending in June 2017. Given this timeframe, Actavis action is not unexpected. In addition, we have additional pending intellectual property which, if issued, would be capable of extending the patent life of all three of our BEMA®-related products, including BUNAVAIL®, and would potentially be listed in the Orange Book.

Litigation related to BELBUCA

On November 4, 2016, we became aware of a purported ANDA filing relating to BELBUCA but we have not yet received a Paragraph IV notice from the ANDA filer. Once we receive a Paragraph IV notice, if appropriate, we plan to initiate litigation within the 45-day Hatch Waxman window to uphold BELBUCA s intellectual property.

Item 1A. Risk Factors.

None.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

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Item 4. Mine Safety Disclosures.

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

* 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: November 9, 2016

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

Vice Chairman
(Principal Executive Officer)

Date: November 9, 2016

By: /s/ Ernest R. De Paolantonio
Ernest R. De Paolantonio, Secretary, Treasurer and Chief Financial Officer (Principal Accounting Officer)