BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 15, 2017
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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 March 31, 2017

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
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 May 15, 2017, there were 55,341,463 shares of company Common Stock issued and 55,325,972 shares of company Common Stock outstanding.

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BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash	$ 35,219	$ 32,019
Accounts receivable, net	7,102	3,569
Inventory	8,145	3,368
Prepaid expenses and other current assets	3,942	4,136
Total current assets	54,408	43,092
Property and equipment, net	4,549	4,230
Goodwill	2,715	2,715
BELBUCA® license and distribution rights intangible	45,000	
Other intangible assets, net	918	2,285
Total assets	$ 107,590	$ 52,322
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 30,521	$ 18,174
Deferred revenue, current		1,716
Total current liabilities	30,521	19,890
Notes payable, less current maturities, net	34,800	29,272
Deferred revenue, long-term		20,000
Other long-term liabilities	4,050	825
Total liabilities	69,371	69,987
Commitments and contingencies (Notes 11 and 14)		
Stockholders 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 both March 31, 2017 and December 31, 2016, respectively.	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 55,341,463 and 54,133,511 shares issued; 55,325,972 and 54,118,020 shares outstanding at	55	54

March 31, 2017 and December 31, 2016, respectively.		
Additional paid-in capital	300,225	292,667
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(262,016)	(310,341)
Total stockholders equity (deficit)	38,219	(17,665)
Total liabilities and stockholders equity (deficit)	$ 107,590	$ 52,322

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three Months Ended March 31,	
	2017	**2016**
Revenues:		
Product sales	$ 7,795	$ 2,102
Product royalty revenues	1,661	934
Research and development reimbursements	22	4
Contract revenues	20,000	
Total Revenues:	29,478	3,040
Cost of sales	5,645	2,550
Expenses:		
Research and development	2,671	5,377
Selling, general and administrative	13,259	13,055
Total Expenses:	15,930	18,432
Income (loss) from operations	7,903	(17,942)
Interest expense, net	(2,886)	(778)
Other expense, net		(13)
Bargain purchase gain	27,336	
Income (loss)	$ 32,353	$ (18,733)
Income tax benefit	15,972	
Net income (loss) attributable to common stockholders	$ 48,325	$ (18,733)
Basic		
Basic income (loss) per share:	$ 0.89	$ (0.36)
Weighted average common stock shares outstanding:	54,519,574	52,230,648
Diluted		
Diluted income (loss) per share:	$ 0.87	$ (0.36)

Diluted weighted average common stock shares outstanding:	55,431,628	52,230,648

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)

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

(Unaudited)

	Preferred Stock Series A		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balances, January 1, 2017	2,093,155	$ 2	54,133,511	$ 54	$ 292,667	$ (47)	$ (310,341)	$ (17,665)
Stock-based compensation					3,070			3,070
Restricted stock awards			1,207,952	1	(1)			
Issuance of warrants					4,489			4,489
Net income							48,325	48,325
Balances, March 31, 2017	2,093,155	$ 2	55,341,463	$ 55	$ 300,225	$ (47)	$ (262,016)	$ 38,219

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

	Three months ended March 31,	
	2017	**2016**
Operating activities:		
Net income (loss)	$ 48,325	$ (18,733)
Depreciation	111	86
Accretion of debt discount and loan costs	1,040	99
Amortization of intangible assets	1,369	243
Stock-based compensation expense	3,070	4,111
Deferred income taxes	(15,972)	
Bargain purchase gain	(27,336)	
Changes in assets and liabilities:		
Accounts receivable	(3,531)	356
Inventories, net of effect of acquisition	633	(2,263)
Prepaid expenses and other assets	194	118
Accounts payable and accrued expenses, net of effect of acquisition	4,811	(438)
Deferred revenue	(21,716)	(235)
Net cash flows from operating activities	(9,002)	(16,656)
Investing activities:		
Purchase of equipment		(236)
Net cash flows from investing activities		(236)
Financing activities:		
Proceeds from notes payable	45,000	
Payment of notes payable	(30,000)	
Payment of deferred financing fees	(2,798)	
Equity financing costs		40
Proceeds from exercise of stock options		225
Proceeds from issuance of common stock		2,460
Net cash flows from financing activities	12,202	2,725
Net change in cash and cash equivalents	3,200	(14,167)
Cash and cash equivalents at beginning of year	32,019	83,560

Cash and cash equivalents at end of period	**$ 35,219**	**$ 69,393**
Cash paid for interest	$ 946	$ 679

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

SUPPLEMENTAL CASH FLOW INFORMATION

(U.S. DOLLARS IN THOUSANDS EXCEPT SHARE DATA)

Non-cash Financing and Investing Activities:

The Company recorded the fair value of the bargain purchase price of the BELBUCA® acquisition totaling $27.3 million to income during the three months ended March 31, 2017 in accordance with US GAAP (note 7).

The Company recorded the fair value of warrants totaling $4.5 million to equity with an offsetting amount to Notes payable in connection with the CRG term loan during the three months ended March 31, 2017 in accordance with US GAAP (note 12).

See notes to 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, 2016 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, 2016. 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, 2016.

Operating results for the three month periods ended March 31, 2017 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 in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates. The Company reviews all significant estimates affecting the consolidated financial statements on a recurring basis and records the effect of any necessary adjustments prior to their issuance. Significant estimates of the Company include: revenue

recognition, sales allowances such as returns of product sold, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales commissions, amortization, stock-based compensation, determination of fair values of assets and liabilities in connection with business combinations, and deferred income taxes.

Reacquisition of BELBUCA®

On December 7, 2016, the Company entered into an agreement (the Termination Agreement) with Endo Pharmaceuticals, Inc. (Endo) terminating Endo s licensing of rights to the Company s BELBUCA® (buprenorphine) buccal film product (BELBUCA®). The closing of the Termination Agreement, and the formal termination of the BELBUCA® license to Endo and closing of the transactions further described below occurred on January 6, 2017 (see note 7, Business Combinations and Asset Acquisitions).

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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):

Inventory

Other than the inventory purchased from Endo which is stated at fair value, inventories are stated at the lower of cost or net realized value with costs determined for each batch under the first-in, first-out method and specifically allocated to remaining inventory. Inventory consists of raw materials, work in process and finished goods. Raw materials include amounts of active pharmaceutical ingredient for a product to be manufactured, work in process includes the bulk inventory of laminate (the Company s drug delivery film) 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. The Company recorded $0.2 million in inventory allowances as of March 31, 2017. There were no allowances recorded as of December 31, 2016.

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 and related supply agreements. 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.

The Company, until January 1, 2017, deferred sales of its BUNAVAIL® (buprenorphine and naloxone) buccal film, Schedule 3 (CIII) product (BUNAVAIL®) and recognized such revenue when the product was sold through to the end user. There were no product sales of BELBUCA® before January 2017.

Revenue recognition

Net product sales

Beginning in the first quarter of 2017, the Company has determined that it has sufficient experience with BELBUCA® and BUNAVAIL® to estimate its returns at time of ex-factory sales. The Company recognizes revenue when it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (a) persuasive evidence of an arrangement exists; (b) delivery has occurred or services have been rendered; (c) the Company s price to the buyer is fixed or determinable; and (d) collectability is reasonably assured. The

Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company recognizes revenue from sales transactions where the buyer has the right to return the product at the time of sale only if (1) the Company s price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the Company, or the buyer is obligated to pay the Company and the obligation is not contingent on resale of the product, (3) the buyer s obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from any provided by the Company, (5) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. The Company recognizes product sales net of estimated allowances for rebates, price adjustments, returns, chargebacks and prompt payment discounts. Given the sufficient experience with BELBUCA® and BUNAVAIL®, the Company can reasonably estimate the amount of future product returns, and therefore, the risk of estimating product return has been substantially eliminated. The effect in income from operations and on net income is that the Company is able to recognize revenue earlier on the sell-in method, net of a provision for estimated returns, since the Company can record revenue once sold to the wholesaler rather than waiting until the product is sold to the end user on a sell-through basis.

The Company establishes allowances for estimated rebates, chargebacks and product returns based on numerous qualitative and quantitative factors, including:

the number of and specific contractual terms of agreements with customers;

estimated levels of inventory in the distribution channel;

historical rebates, chargebacks and returns of products;

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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):

direct communication with customers;

anticipated introduction of competitive products or generics;

anticipated pricing strategy changes by the Company and/or its competitors;

analysis of prescription data gathered by a third-party prescription data provider;

the impact of changes in state and federal regulations; and

the estimated remaining shelf life of products.

In its analyses, the Company uses prescription data purchased from a third-party data provider to develop estimates of historical inventory channel sell-through. The Company utilizes an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, management develops an estimate of the quantity of product in the channel which may be subject to various rebate, chargeback and product return exposures. To estimate months of ending inventory in the Company s distribution channel, the Company divides estimated ending inventory in the distribution channel by the Company s recent prescription data, not taking into account any future anticipated demand growth beyond the succeeding quarter. Monthly for each product line, the Company prepares an internal estimate of ending inventory units in the distribution channel by adding estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. This is done for each product line by applying a rate of historical activity for rebates, chargebacks and product returns, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated to be in the distribution channel.

Product Returns- Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the products within an 18-month period that begins six months prior to and ends twelve months subsequent to expiration of the products.

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 BELBUCA® and 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 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 the wholesalers regarding their sales of the Company s products and actual on hand inventory levels of its products. During the three months ended March 31, 2017, the three large wholesalers account for approximately 92% of the Company voucher and Medicaid accruals. This enables the Company to execute accurate provisioning procedures. Consistent with the pharmaceutical industry, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products.

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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):

Cost of sales

Cost of sales includes the direct costs attributable to the production of BREAKYL (the Company s out-licensed breakthrough cancer pain therapies). It includes all costs related to creating the product at the Company s contract manufacturing location in Germany. The Company s contract manufacturer bills 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.

For BELBUCA® and BUNAVAIL®, cost of sales includes raw materials, production costs at the Company s three contract manufacturing sites, quality testing directly related to the products, and depreciation on equipment that the Company has purchased to produce BELBUCA® and BUNAVAIL®. It also includes any batches not meeting specifications and raw material yield losses. Yield losses and batches not meeting specifications are expensed as incurred. Prior to January 1, 2017, cost of sales was recognized as actual product was sold through to the end user. Beginning January 1, 2017, cost of sales is recognized when sold to the wholesaler.

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 in the process of evaluating the impact that this new ASU will have on its condensed consolidated financial statements.

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

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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 accounting policies (continued):

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 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 has adopted this ASU in the first quarter of 2017; however, the adoption of the ASU had no significant impact on its condensed consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. The amendments in this update provide a screen to determine when an integrated set of assets and activities (a set) is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. The new guidance will be effective for the Company beginning on January 1, 2018 and early adoption is permitted. The Company is evaluating the impact of the adoption of the new guidance on its condensed consolidated financial statements.

In January 2017, the FASB issued ASU Update No. 2017-04, Intangibles Goodwill and Other (Topic 350): Simplifying the Test of Goodwill Impairment. This ASU simplifies the accounting for goodwill impairment for all entities by requiring impairment charges to be based on the first step of the goodwill impairment test under ASC 350. Under previous guidance, if the fair value of a reporting unit is lower than its carrying amount (Step 1), an entity calculates any impairment charge by comparing the implied fair value of goodwill with its carrying amount (Step 2). The implied fair value of goodwill is calculated by deducting the fair value of all assets and liabilities of the reporting unit from the reporting unit s fair value as determined in Step 1. To determine the implied fair value of goodwill, entities estimate the fair value of any unrecognized intangible assets (including in-process research and development) and any corporate-level assets or liabilities that were included in the determination of the carrying amount and fair value of the reporting unit in Step 1. Under this new guidance if a reporting unit s carrying value exceeds its fair value,

an entity will record an impairment charge based on that difference with such impairment charge limited to the amount of goodwill in the reporting unit. This ASU does not change the guidance on completing Step 1 of the goodwill impairment test. An entity will still be able to perform today s optional qualitative goodwill impairment assessment before determining whether to proceed to Step 1. This ASU will be applied prospectively and is effective for annual and interim impairment test performed in periods beginning after December 15, 2019 for public business enterprises. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. 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 March 31, 2017, the Company had cash of approximately $35.2 million. The Company generated $3.2 million of cash during the three months ended March 31, 2017 and had stockholders equity of $38.2 million, versus stockholders deficit of $17.7 million at December 31, 2016. The Company expects that it has sufficient cash to manage the business as currently planned into the second half of 2018. This estimation assumes that the Company does not accelerate the development of existing, or acquire other drug development opportunities or otherwise face unexpected events, costs or contingencies, any of which could affect the Company s cash requirements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

2. Liquidity and management s plans (continued):

Additional capital will be required to support the commercialization of the Company s reacquired BELBUCA® product, ongoing commercialization activities for BUNAVAIL®, the reformulation project for and the anticipated commercial relaunch of ONSOLIS® (which is out-licensed to Collegium Pharmaceutical, Inc. (Collegium) in the US), the continued development of 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 life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all.

3. Inventory:

The following table represents the components of inventory as of:

	March 31, 2017	December 31, 2016
Raw materials & supplies	$ 1,854	$ 978
Work-in-process	2,526	1,660
Finished goods	3,765	730
Total inventories	$ 8,145	$ 3,368

4. Accounts payable and accrued liabilities:

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

	March 31, 2017	December 31, 2016

Accounts payable	$ 12,381	$ 9,397
Accrued price adjustments	1,420	592
Accrued returns	760	
Accrued acquisition consideration	7,536	
Accrued rebates	4,228	3,842
Accrued chargebacks	52	10
Accrued compensation and benefits	1,574	2,052
Accrued royalties	586	518
Accrued clinical trial costs	397	615
Accrued legal costs	1,109	490
Accrued manufacturing costs	200	200
Accrued sales and marketing costs		193
Accrued other	278	265
Total accounts payable and accrued expenses	$ 30,521	$ 18,174

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5. Property and equipment:

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

	March 31, 2017	December 31, 2016
Machinery & equipment	$ 4,907	$ 4,476
Computer equipment & software	464	464
Office furniture & equipment	202	202
Leasehold improvements	53	53
Idle equipment	1,486	1,486
Total	7,112	6,681
Less accumulated depreciation	(2,563)	(2,451)
Total property, plant & equipment, net	$ 4,549	$ 4,230

Depreciation expense was approximately $0.1 million and $0.09 million for the three month periods ended March 31, 2017 and 2016, respectively.

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. The Company s most significant license and development agreements are as follows:

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 year ended December 31, 2015. There was no remaining U.S.-related contract revenue

to record during the year ended December 31, 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, which terminated on May 11, 2016 upon the signing of the Termination and Revenue Sharing Agreement (the Agreement).

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 the second half of 2017.

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

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6. License and development agreements (continued):

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;

$3 million payable to the Company related to ONSOLIS® patent milestone (earned March 2017 but payable by Collegium to the Company first half of 2018);

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

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6. License and development agreements (continued):

Endo license and development agreement (continued)

Pursuant to the Endo Agreement, the Company has received the following payments:

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

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

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

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

$50 million upon regulatory approval, earned in October 2015 and received in November 2015. Of the $50 million received in November 2015, $20 million related to a patent extension and was recorded as deferred revenue because all or a portion of such $20 million was contingently refundable to Endo if a third party generic product was introduced in the U.S. during the patent extension period from 2020 to 2027. However, due to the Company and Endo entering into a Termination Agreement on December 7, 2016 which terminated the BELBUCA® license to Endo effective January 6, 2017, the deferred $20 million was recognized as revenue during the three months ended March 31, 2017 in the accompanying condensed consolidated statement of operations (see note 7).

7. Business combination and asset acquisitions:

On December 7, 2016, the Company entered into an agreement (the Termination Agreement) with Endo terminating Endo s licensing of rights for BELBUCA®. The closing of the Termination Agreement, and the formal termination of the BELBUCA® license to Endo and closing of the transactions further described below to be undertaken in connection therewith (the Endo Closing), occurred on January 6, 2017.

At the Endo Closing, the Company purchased from Endo the following assets (the Assets): (i) current BELBUCA® product inventory, raw material and work-in-progress, (ii) material manufacturing contracts related to BELBUCA®, (iii) BELBUCA®-related domain names and trademarks (including the BELBUCA® trademark), (iv) BELBUCA®-related manufacturing equipment, and (v) all pre-approval regulatory submissions, including any Investigational New Drug Applications and New Drug Applications, regulatory approvals and post-approval regulatory submissions concerning BELBUCA®. The purchase price for the Assets (the Asset Purchase Price) is equal to the sum of (i) the aggregate book value of the portion of the transferred product inventory forecasted to be used or sold by the Company, (ii) the aggregate book value of the raw material and work-in-progress inventory, and (iii) the assumption of any assumed liabilities. Upon the Endo Closing, the Company accepted transfer of the Assets and assumed and agreed to discharge when due all applicable liabilities assumed by the Company, which consisted of post-closing obligations for liabilities and payments associated with the Assets, the assumed contracts related to the Assets and applicable taxes (with the obligation for pre-closing and other certain liabilities resulting from the acts or omissions of Endo being retained by Endo).

The Asset Purchase Price, together with all other payments (including a non-compete covenant payment) due to Endo under the Termination Agreement, will be paid to Endo in cash in four quarterly installments on the last calendar day of each quarter in 2017. Furthermore, the Company is not responsible for future royalties or milestone payments to Endo and Endo is not obligated to any future milestone payments to the Company. The Termination Agreement contains customary representations and warranties and mutual releases and indemnification.

At the Endo Closing, the Company and Endo entered into a Transition Services Agreement which governed the post-closing rights and responsibilities of the Company and Endo in connection with the license termination and the transfer of the Assets to the Company. Under this agreement, the Company and Endo agreed to the handling of transition matters such as managing customer contracts, BELBUCA® price reporting, payments, returns and rebates, and customer and managed care relations. In connection therewith, Endo has agreed to provide to the Company an agreed upon number of work hours to be provided by Endo personnel during the transition for certain of these transition services and other assistance with respect to the transition of BELBUCA® to the Company.

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7. Business combination and asset acquisitions (continued):

The BELBUCA® acquisition was accounted for as a business combination in accordance with ASC No. 805, *Business Combinations* which, among other things, requires assets acquired and liabilities assumed to be measured at their acquisition date fair values. The purchase price allocation is preliminary with respect to taxes and certain accruals and includes the use of estimates based on information that was available to management at the time these unaudited condensed consolidated financial statements were prepared. The Company believes the estimates used are reasonable and the significant effects of the BELBUCA® acquisition are properly reflected. However, the estimates are subject to change as additional information becomes available and is assessed by the Company.

Asset acquisition BELBUCA®

The following table summarizes the consideration paid to acquire BELBUCA® and the estimated values of assets acquired and liabilities assumed in the accompanying condensed consolidated balance sheet based on their fair values on January 6, 2017 (the date of the Endo Closing):

Asset purchase price:	
Deferred cash consideration to Endo	$ 7,536
Total asset purchase price	$ 7,536
Estimated fair value of assets acquired:	
Current BELBUCA® product inventory and work-in process	$ 5,412
BELBUCA®-related manufacturing equipment	432
License and distribution rights intangible assets	45,000
Deferred tax liability	(15,972)
Amount attributable to assets acquired	$ 34,872
Bargain purchase gain	$ (27,336)

Inventories acquired included raw materials, work-in-progress and finished goods. The fair value of the acquired finished goods inventory was estimated by adjusting the anticipated selling price costs to sell and an appropriate profit on selling activities. For work-in-process, in addition to those inputs used to estimate the fair value of finished goods,

the cost and estimated profit on completing the manufacturing are also included. The fair value of the raw materials represent cost to acquire the materials from suppliers.

The fair value of the equipment was determined by consultations with a third-party equipment vendor, which considered replacement cost and equipment condition. The equipment will be depreciated over seven years based on its estimated remaining useful life.

The fair value of the license and distribution intangible assets were estimated primarily using the income method, which starts with a forecast of all expected future cash flows. Some of the more significant assumptions inherent in the development of intangible asset values, from the perspective of a market participant, include: the amount and timing of projected future cash flows (including net revenue, cost of sales, commercial expenses, research and development costs and working capital requirements) as well as estimated contributory asset charges; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset s life cycle and the competitive trends impacting the asset, among other factors. The license and distribution rights intangible assets will be amortized over ten years, which approximates the current, remaining patent life of the BELBUCA® intellectual property.

As a result of the business combination, the Company recognized a deferred tax liability of $16.0 million. This deferred tax liability was netted against its deferred tax assets as of March 31, 2017. Because a full valuation allowance has been provided against the Company s deferred tax assets as it is considered more likely than not that they will not be utilized, the Company released a corresponding amount of its valuation allowance during the three months ended March 31, 2017 and recognized a $16.0 million tax benefit in the accompanying condensed consolidated statement of operations.

The Company recorded the asset acquisition as a bargain purchase gain of $27.3 million in the accompanying condensed consolidated statement of operations.

Pro forma impact of acquisition

The following pro forma combined results of operations are provided for the year ended December 31, 2016, as though the BELBUCA® acquisition had been completed as of January 1, 2016. These supplemental pro forma results of operations are provided for illustrative purposes only and do not purport to be indicative of the actual results that would have been achieved by the combined

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7. Business combination and asset acquisitions (continued):

company for the periods presented or that may be achieved by the combined company in the future. The pro forma results of operations do not include any cost savings or other synergies that resulted, or may result, from the BELBUCA® acquisition or any estimated costs that will be incurred to integrate the BELBUCA® product line, nor do they reflect the bargain purchase gain recognized. Future results may vary significantly from the results in this pro forma information because of future events and transactions, as well as other factors.

(in thousands, except per share data)

	2016* (unaudited)
Revenue	$ 25,010
Net loss	$ (201,769)
Pro forma net loss per common share	
Basic	$ (3.76)
Diluted	$ (3.76)

The Company s historical financial information was adjusted to give effect to the pro forma events that were directly attributable to the BELBUCA® acquisition and factually supportable. The unaudited pro forma consolidated results include historical revenues and expenses of assets acquired in the acquisition with the following adjustments:

Adjustment to recognize incremental amortization expense based on the fair value of intangibles acquired;

Adjustment to recognize incremental depreciation expense for equipment acquired in the acquisition.

*BELBUCA® was launched February 22, 2016, and therefore, results as of March 31, 2016 were not readily available.

The Company has recognized net product sales for BELBUCA® subsequent to the Endo Closing on January 7, 2017 in the amount of $4.6 million. Non-recurring transaction costs related to the acquisition for the year ended December 31, 2016 were minimal. These non-recurring transaction costs have been excluded from the pro forma results in the above table.

8. License obligations:

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.

This product candidate is currently in the pre-clinical stage of development. An Investigational New Drug Application (IND) for the treatment of opioid dependence was filed in the fourth quarter 2016 and plans are underway to file a pain IND in 2017.

9. 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 upfront 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 filing of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. The term of the agreement with TTY is for the period from October 4, 2010 until the date fifteen 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, the Company received a payment of $0.2 million from TTY, which related to royalties based on product purchased in Taiwan by TTY of PAINKYL which is recorded in the accompanying condensed consolidated statement of operations for the three months ended March 31, 2016. There were no payments received during the three months ended March 31, 2017.

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10. 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 that certain Amended and Restated Credit and Security Agreement, dated as of May 29, 2015 (the Credit Agreement), between the Company and MidCap.

On February 21, 2017, the Company entered into a term loan agreement (the Term Loan Agreement) with CRG Servicing LLC (CRG), as administrative agent and collateral agent, and the lenders named in the Term Loan Agreement (the Lenders). The Company utilized approximately $29.4 million of the initial loan proceeds to repay all of the amounts owed by the Company under its existing Amended and Restated Loan and Security Agreement, dated May 29, 2015, with MidCap (the Prior Agreement). Upon the repayment of all amounts owed by the Company under the Prior Agreement, all commitments under the Prior Agreement have been terminated and all security interests granted by the Company and its subsidiary guarantors (the Subsidiary Guarantors) under the Prior Agreement have been released (see note 11). The warrants issued to MidCap in May 2016 related to the extension of the interest only period were not terminated and are outstanding as of March 31, 2017. During the three months ended March 31, 2017, $0.7 million of deferred loan costs were expensed and recorded as interest expense in the accompanying condensed consolidated statement of operations.

11. Term loan agreement (CRG):

Pursuant to the Term Loan Agreement, the Company borrowed $45.0 million from the Lenders as of the Closing Date, and may be eligible to borrow up to an additional $30.0 million in two tranches of $15.0 million each contingent upon achievement of certain conditions, including: (i) in the case of the first tranche, representing the second potential draw under the Loan Agreement (the Second Draw), satisfying both (a) certain minimum net revenue thresholds on or before September 30, 2017 or December 31, 2017 and (b) a certain minimum market capitalization threshold for a period of time prior to the funding of the Second Draw (provided, that if the Company does not achieve the minimum net revenue thresholds necessary for the Second Draw but does achieve a certain minimum market capitalization threshold for a period of time prior to December 31, 2017, the Company would be eligible for a Second Draw funding in the amount of $5.0 million); and (ii) in the case of the second tranche, representing the third potential draw under the Loan Agreement (the Third Draw), satisfying both (a) certain minimum net revenue thresholds on or before June 30, 2018 or September 30, 2018 and (b) a certain minimum market capitalization threshold for a period of time prior to the funding of the Third Draw.

The Company intends to use the remainder of the initial proceeds under the Term Loan Agreement (after deducting loan origination costs and broker and other fees) of approximately $13.7 million, plus any additional amounts that may be borrowed in the future, for general corporate purposes and working capital.

The Term Loan Agreement has a six-year term with three years of interest-only payments (which can be extended to four years if the Company achieves certain net revenue and market capitalization thresholds prior to December 31, 2019), after which quarterly principal and interest payments will be due through the December 31, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of 12.50%, 3.5% of which (i.e., a resultant 9.0% rate) may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. On each borrowing date (including the Closing Date), the Company is required to pay CRG a financing fee based on the loan drawn on that date. The Company is also required to pay the Lenders a final payment fee equivalent to 9% of the original loan amount upon repayment of the Loans in full, in addition to prepayment amounts described below.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice to the Lenders subject to a certain prepayment fees during the first five years of the term (which fees are

lowered over time) and no prepayment fee thereafter. In certain circumstances, including a change of control and certain asset sales or licensing transactions, the Company is required to prepay all or a portion of the loan, including the applicable prepayment premium of on the amount of the outstanding principal to be prepaid.

As security for its obligations under the Term Loan Agreement, on the funding date of the initial borrowing, the Company and the Subsidiary Guarantors entered into a security agreement with CRG whereby the Company and the Subsidiary Guarantors granted to CRG, as collateral agent for the Lenders, a lien on substantially all of its assets including intellectual property (subject to certain

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11. Term loan agreement (CRG) (continued):

exceptions). The Term Loan Agreement requires the Company to maintain minimum cash and cash equivalents balance and, each year through the end of 2022, to meet a minimum net annual revenue threshold. In the event that the Company does not meet the minimum net annual revenue threshold, then the Company can satisfy the requirement for that year by raising two (2) times the shortfall by way of raising equity or subordinated debt.

The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including covenants that limit or restrict the Company s ability to, among other things (but subject in each case to negotiated exceptions), incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into transactions with affiliates, pay dividends or make distributions, license intellectual property rights on an exclusive basis or repurchase stock.

The Term Loan Agreement includes customary events of default that include, among other things, non-payment, inaccuracy of representations and warranties, covenant breaches, a material adverse change (as defined in the Term Loan Agreement), cross default to material indebtedness or material agreements, bankruptcy and insolvency, material judgments and a change of control. The occurrence and continuance of an event of default could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.00% per annum will apply on all outstanding obligations during the existence of an event of default under the Term Loan Agreement.

The amount disclosed in Notes payable, less current maturities, in the accompanying condensed consolidated balance sheets for year ended December 31, 2016 reflects the February 21, 2017 repayment of loan obligations to MidCap Financial Trust and the simultaneous entry into a term loan agreement with CRG Servicing LLC.

The following table represents future maturities of the CRG obligation as of March 31, 2017:

2017	$
2018	
2019	
2020	15,000
2021	15,000
2022	15,162
Total maturities	$ 45,162

Unamortized discount and loan costs	(10,362)
Total CRG obligation	$ 34,800

12. Stockholders equity:
Stock-based compensation

During the three months ended March 31, 2017, a total of 615,155 options to purchase Common Stock, with an aggregate fair market value of approximately $1.2 million, were granted to Company employees. The options granted have a term of 10 years from the grant date and vest ratably over a three year period. The fair value of each option is amortized as compensation expense evenly through the vesting period.

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

	Three months ended,	
Stock-based compensation expense	**March 31, 2017**	**March 31, 2016**
Research and Development	$ 401	$ 1,128
Selling, General and Administrative	$ 2,669	$ 2,983

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.

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12. Stockholders equity (continued):

Expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average for key assumptions used in determining the fair value of options granted during the three months ended March 31, 2017 follows:

Expected price volatility	62.34% -79.88%
Risk-free interest rate	1.90% - 1.94%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the three months ended March 31, 2017 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2017	3,468,991	$ 4.14	
Granted in 2017			
Officers and Directors			
Others	615,155	1.87	
Exercised			
Forfeitures	(186,387)	5.27	
Outstanding at March 31, 2017	3,897,759	$ 3.73	$ 31

As of March 31, 2017, options exercisable totaled 2,612,869. There was approximately $11.9 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 2020.

Restricted stock units

During the three months ended March 31, 2017, 2,060,000 RSUs were granted to the Company s executive officers and employees, with a fair market value of approximately $3.7 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. One-half of such RSUs are time-based and one-half are performance based and all vest over a three-year period. The performance-based RSUs provide for vesting if specified predetermined net revenue and operating income goals are achieved with respect to the annual fiscal years 2017 through 2019. These RSUs were granted over the plan allotment of our 2011 Equity Incentive Plan and will require approval during the 2017 annual stockholder meeting.

	Number of Restricted Shares	Weighted Average Fair Market Value Per RSU
Outstanding at January 1, 2017	4,584,297	$ 7.29
Granted:		
Executive officers	1,640,000	1.80
Directors		
Employees	420,000	1.80
Vested	(1,207,952)	2.04
Forfeitures	(84,000)	3.14
Outstanding at March 31, 2017	5,352,345	$ 4.69

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12. Stockholders equity (continued):

Warrants

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements.

In connection with the initial borrowing made under the Loan Agreement on February 21, 2017, the Company issued to CRG and certain of its affiliates five separate warrants to purchase an aggregate of 1,701,583 shares of the Company s common stock (the CRG Warrants). The CRG Warrants are exercisable any time prior to February 21, 2027 at a price of $2.38 per share, with typical provisions for cashless exercise and stock-based anti-dilution protection. The exercise of the CRG Warrants could have a dilutive effect to the Company s common stock to the extent that the market price per share of the Company s common stock, as measured under the terms of the CRG Warrants, exceeds the exercise price of the CRG Warrants. CRG is also entitled to receive a smaller amount of similar warrants concurrently with the funding, if applicable, of the Second Draw and the Third Draw.

The fair value of each warrant grant 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 warrants.

Expected term of warrants 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 warrants granted during the three months ended March 31, 2017 follows:

Expected price volatility	78.39%
Risk-free interest rate	1.92%
Weighted average expected life in years	6 years
Dividend yield	

Warrant activity during the three months ended March 31, 2017 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2017	84,986	$ 3.53	
Granted in 2017	1,701,583	2.38	
Exercised			
Forfeitures			
Outstanding at March 31, 2017	1,786,569	$ 2.43	$

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13. Earnings per common share:

The following table reconciles the numerators and denominators of the basic and diluted loss per share computations (in thousands, except per share data).

	March 31, 2017	March 31, 2016
Basic:		
Net income (loss)	$ 48,235	$ (18,733)
Weighted average common shares outstanding	54,519,574	52,230,648
Basic income (loss) per common share	$ 0.89	$ (0.36)
Diluted:		
Effect of dilutive securities:		
Net income (loss)	$ 48,235	$ (18,733)
	48,235	(18,733)
Weighted average common shares outstanding	54,519,574	52,230,648
Effect of dilutive options and warrants	912,054	
Diluted weighted average common shares outstanding	55,431,628	52,230,648
Diluted income (loss) per common share	$ 0.87	$ (0.36)

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. In addition to the weighted average shares of Common Stock outstanding, common equivalent shares from stock options, RSUs and warrants using the treasury stock method, are included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the three months ended March 31, 2017 and 2016, outstanding stock options, RSUs and warrants of 10,124,619 and 10,113,296, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods.

The following is the total outstanding options and warrants for the three months ended as follows:

	March 31, 2017	March 31, 2016
Options, RSUs and warrants to purchase Common Stock	11,036,673	10,113,296

14. Commitments and contingencies:

Litigation related to ONSOLIS®

On November 2, 2010, MonoSol filed an action against the Company and its commercial partners for ONSOLIS® in the Federal District Court of New Jersey (the DNJ) for alleged patent infringement and false marking. The Company was formally served in this matter on January 19, 2011. MonoSol claimed that our 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). Of note, the BEMA® technology itself was 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 was seeking an unspecified amount of damages, attorney s fees and an injunction preventing future infringement of MonoSol s patents.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

14. Commitments and contingencies (continued):

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 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 Honorable 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 the Company s 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 were prepared to vigorously defend the appeal. MonoSol, however, 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 stands. The possibility exists that MonoSol could file another suit alleging infringement of the 292 and 891 patents. The Company continues to believe, however, that ONSOLIS® and its other products relying on the BEMA® technology, including BUNAVAIL® and BELBUCA®, do not infringe any amended, reexamined claim from either patent.

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 the Company relating to its BUNAVAIL® product in the United States District Court for the Eastern District of North Carolina (EDNC) 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 the Company s motion to dismiss.

In doing so, the Court dismissed the case in its entirety. The RB Plaintiffs did not appeal the Court Decision by the June 21, 2014 due date and therefore, the dismissal will stand and the RB Plaintiffs lose the ability to challenge the Court Decision in the future. The possibility exists, however, that the RB Plaintiffs could file another suit alleging

infringement of the 832 Patent. If this occurs, based on the Company s original position that its BUNAVAIL® product does not infringe the 832 Patent, the Company would defend the case vigorously (as the Company has done so previously), and the company anticipates that such claims against them ultimately would be rejected.

On September 20, 2014, based upon the Company s position and belief that its BUNAVAIL® product does not infringe any patents owned by the RB Plaintiffs, the Company proactively filed a declaratory judgment action in the EDNC, requesting the Court to make a determination that its BUNAVAIL® product does not infringe the RB Plaintiffs 832 Patent, US Patent No. 7,897,080 (080 Patent) and US Patent No. 8,652,378 (378 Patent). With the declaratory judgment, there is an automatic stay in proceedings. The RB Plaintiffs may request that the stay be lifted, but they have the burden of showing that the stay should be lifted. For the 832 Patent, the January 15, 2014 IPR was instituted and 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

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(Unaudited)

14. Commitments and contingencies (continued):

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. On January 31, 2017, the PTAB issued a final decision maintaining an additional new ground of rejection in addition to the previous grounds of invalidity. As such, all claims remain finally rejected on multiple grounds. MonoSol failed to appeal the final decision and all claims were cancelled in a reexamination certificate issued May 9, 2017. 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 the Company (and its 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 (167 Patent). As with prior actions by the RB Plaintiffs, the Company believes this is another anticompetitive attempt by the RB Plaintiffs to distract our 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 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 the Company s motion to transfer the venue to the ENDC but denying its 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.

On January 13, 2017, MonoSol filed a complaint in the United States District Court for the District of New Jersey alleging BELBUCA® infringes the 167 patent. In lieu of answering the complaint, the Company filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC on March 1, 2017. Briefing on the motions will be completed by May 22, 2017. The Company strongly refutes as without merit MonoSol s assertion of patent infringement and will vigorously defend the lawsuit.

Teva Pharmaceuticals (formerly Actavis)

On February 8, 2016, the Company received a 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 (the 866 Patent) and 8,703,177 (the 177 Patent). 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 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, the Company filed a complaint in Delaware against Actavis, thus the Company is 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.

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(Unaudited)

14. Commitments and contingencies (continued):

On January 31, 2017, the Company received a notice relating to a Paragraph IV certification from Teva Pharmaceuticals USA (Teva) relating to Teva s ANDA on additional strengths of BUNAVAIL®. Teva s parent company, Teva Pharmaceuticals Ltd., recently acquired Actavis through an acquisition. The Company anticipates bringing suit against Teva and its parent company on these additional strengths within 45 days from the receipt of the notice.

A five (5) day bench trial is currently scheduled to begin on December 4, 2017.

Litigation related to BELBUCA®

The Company received notices regarding Paragraph IV certifications from Teva on November 8, 2016, November 10, 2016, and December 22, 2016, seeking to find invalid two Orange Book listed patents (the Patents) relating specifically to BELBUCA®. The Paragraph IV certifications relate to three ANDAs filed by Teva with the FDA for a generic formulation of BELBUCA®. The Patents subject to Teva s certification are U.S. Patent Nos. 7,579,019 (the 019 Patent) and 8,147,866 (the 866 Patent). Under the Hatch-Waxman Amendments, after receipt of a valid Paragraph IV notice, the Company may, and in this case did, bring a patent infringement suit in federal district court against Teva within 45 days from the date of receipt of the certification notice. The Company filed complaints in Delaware against Teva on December 22, 2016 and February 3, 2017, thus the Company is entitled to receive a 30 month stay on the FDA s ability to give final approval to any proposed products that reference BELBUCA®. The 30 month stay is expected to preempt any final approval by the FDA on Teva s ANDA Nos. 209704 and 209772 until at least May of 2019 and for Teva s ANDA No. 209807 until at least June of 2019.

A five (5) day bench trial is currently scheduled to begin on November 19, 2018.

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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. Our 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 our 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 and profitability and enhance stockholder value.

First Quarter and Recent Highlights

- On January 9, 2017, we announced the closing of our previously announced agreement with Endo Pharmaceuticals, Inc. (Endo) terminating Endo s licensing of rights for BELBUCA® As a result of the closing, the worldwide rights to BELBUCA® have now been transferred back to us.
- On February 23, 2017, we announced that we had entered into a senior credit facility with affiliates of CRG LP (CRG), a healthcare-focused investment firm, to retire our existing credit facility and provide

additional working capital for the company. After paying off our loan with MidCap, we netted approximately $13.7 million.

On March 31, 2017, we announced that two important patents were granted extending patent protection around all three of our approved products, BELBUCA®, BUNAVAIL® and ONSOLIS®, further strengthening our overall intellectual property position.

On May 2, 2017, we announced that the FDA has approved a Supplemental New Drug Application (sNDA) for BUNAVAIL® revising the indication to include the use of BUNAVAIL® for the initiation of buprenorphine treatment for opioid dependence.

Our Products and Related Trends

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

BELBUCA® is indicated 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 was licensed on a worldwide basis to Endo. On October 26, 2015, we announced with Endo that the FDA approved BELBUCA®. BELBUCA® was

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launched by Endo in February 2016. On December 7, 2016, we entered into an agreement with Endo terminating Endo s licensing of rights for BELBUCA®. This followed a strategic decision made by Endo to discontinue commercial efforts in the branded pain business. On January 6, 2017, we announced the closing of the transaction to reacquire the license to BELBUCA® from Endo. As a result, the worldwide rights to BELBUCA® were transferred back to us. Going forward, we are not responsible for future royalties or milestone payments to Endo and Endo will not be obligated to any future milestone payments to us. Behind a revised commercialized plan based on market research conducted primarily by Endo that took into consideration the current climate for prescribing opioids for chronic pain, we are initially leveraging our existing sales force to capitalize on commercial synergies with BUNAVAIL® for a focused commercial approach targeting identified healthcare providers which we believe create the potential to incrementally grow BELBUCA® sales without the requirement of significant resources. We also will explore other options for longer-term growth for BELBUCA®. In mid-January 2017, we completed the expansion and training of our sales force, allowing for promotion of BELBUCA® to commence in late January. BELBUCA® and BUNAVAIL® are supported by a field force of approximately sixty-five sales representatives and five regional sales managers. 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 guidelines issued in March 2016. The difference that BELBUCA® offers over the Schedule II opioids, such as oxycodone, hydrocodone, morphine, etc., include less addiction and abuse potential along with a ceiling effect on respiratory depression. These differences we believe make it the opioid of choice.

BUNAVAIL® was approved by the FDA in June 2014 for the maintenance treatment of opioid dependence. BUNAVAIL® uses our BEMA® technology combined with 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® with particular emphasis in 2016 on better aligning 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 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).

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 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, we executed a License Agreement with Collegium under which we granted to Collegium the exclusive rights to develop and commercialize ONSOLIS® in the U.S.

Sustained Release Buprenorphine 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. In 2015, we completed initial development work and preclinical studies which have resulted in the identification of a formulation we believe is capable of providing 30 days of continuous buprenorphine treatment. During a pre-IND meeting with FDA in November 2015, FDA requested an additional study to assess the fate of the polymers used in the formulation. In 2016, we completed this study as well as additional preclinical work and other activities to support a planned Phase 1 clinical study. We submitted an Investigational New Drug application (or IND) for this product candidate to FDA in December 2016.

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

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

On March 12, 2012, we announced the postponement of the U.S. relaunch of ONSOLIS® following the initiation of the class-wide REMS until the product formulation could be modified to address two appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of the color in the mucoadhesive layer, raised by the FDA during an inspection of our North American manufacturing partner for ONSOLIS®, Aveva which is now a subsidiary of Apotex. While the appearance issues did not affect the product s underlying integrity, safety or performance, the FDA believed that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and its specification before it can be manufactured and distributed. The source of microcrystal formation and the potential for fading of ONSOLIS® was found to be specific to a buffer used in its formulation. We modified the formulation and submitted a prior approval supplement that responded to FDA questions and led to FDA approval of the new formulation of ONSOLIS® in August 2015.

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 authorizations for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico.

On May 11, 2016, we announced the signing of a licensing agreement under which we granted the exclusive rights to develop and commercialize in the U.S. to Collegium. Under terms of the agreement, Collegium will be responsible for the manufacturing, distribution, marketing and sales of ONSOLIS® in the U.S. Both companies are collaborating on the ongoing transfer of manufacturing, which includes submission of a Prior Approval Supplement FDA. Upon approval of the Supplement, the NDA and manufacturing responsibility will be transferred to Collegium. Financial terms of our agreement with Collegium include a $2.5 million upfront non-refundable payment, a $4 million payment upon first commercial sale, $3 million payable to us related to ONSOLIS® patent milestone, up to $17 million in potential payments based on achievement of performance and sales milestones, and upper-teen percent royalties based on various annual U.S. net sales thresholds. Meda shares in the proceeds of our partnership with Collegium, and the completion of this transaction with Collegium required the execution of a definitive termination agreement between us and Meda embodying those royalty-sharing terms and certain other provisions. Meda continues to commercialize ONSOLIS® under the brand name BREAKYL in the E.U.

Efforts to extend our supply agreement with our ONSOLIS® manufacturer Aveva have been unsuccessful and the agreement expired. However, we have identified an alternate supplier and requested guidance from the FDA on the specifics required for obtaining approval to supply product from this new vendor. This will in part help us to better determine when ONSOLIS® may be available to the marketplace through our partnership with Collegium. Based on our current estimates, we believe that we will submit the necessary documentation to FDA for qualification of the new manufacturer in the second half of 2017.

Results of Operations

Comparison of the three months ended March 31, 2017 and 2016

Product Sales. We recognized $7.8 million and $2.1 million in product sales during the three months ended March 31, 2017 and 2016, respectively. The increase is principally due to the reacquisition of BELBUCA® during the three months ended March 31, 2017, which resulted in increased sales from our internal sales force, along with sales of BUNAVAIL®. Also included in the aforementioned product sales during the three months ended March 31, 2017 is $1.7 million of revenue recorded as a result of changing to the sell-in method as of January 1, 2017, which related to units of BUNAVAIL® shipped prior to January 1, 2017.

Product Royalty Revenues. We recognized $1.7 million and $0.9 million in product royalty revenue during the three months ended March 31, 2017 and 2016, respectively. Of the aforementioned amounts, $0.8 million and $0.7 million, respectively, can be attributed to a percentage of net sales of the BREAKYL product under our license agreement with Meda. Also, during the three months ended march 31, 2017, we recognized $0.7 million in product royalty revenue related to BELBUCA® under our prior agreement with Endo and $0.2 million in PAINKYL product royalty revenue in each of the three months ended March 31, 2017 and 2016, respectively, under our license agreement with TTY. The increase is due to higher sales of BREAKYL during the three months ended March 31, 2017 as compared to March 31, 2016, as well as BELBUCA® Endo royalties in 2017.

***Research and Development Reimbursements*.** We recognized $0.02 million of reimbursable revenue related to our agreement with Collegium during the three months ended March 31, 2017. We recognized $0.004 million of reimbursable revenue related to our agreement with Endo during the three months ended March 31, 2016.

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Contract Revenues. We recognized $20.0 million of deferred revenue during the first quarter of 2017. No such revenue was recognized in the corresponding prior year period. The $20.0 million recognized in 2017 was received in November 2015 as partial payment from Endo for the BELBUCA® NDA approval and was deferred because it was contingently refundable to Endo if a third party generic product was introduced in the U.S. during the patent extension period from 2020 to 2027. However, we entered into a Termination Agreement with Endo on December 7, 2016 which terminated the BELBUCA® license to Endo effective January 6, 2017. The deferred $20 million was recognized as revenue during the three months ended March 31, 2017. There was no such contract revenue during the three months ended March 31, 2016.

Cost of Sales. We incurred $5.6 million and $2.6 million in cost of sales during the three months ended March 31, 2017 and 2016, respectively. Cost of sales during the three months ended March 31, 2017 was related primarily to BELBUCA® and BUNAVAIL®, which included $4.9 million of product cost, royalties paid, lower of cost or net realized value, and depreciation. Additionally, we paid a total of $0.4 million in quarterly minimum royalty payments to CDC IV, LLC (CDC). Cost of sales during the three months ended March 31, 2017 also included $0.2 million and $0.04 million related to BREAKYL and PAINKYL, respectively. Cost of sales during the three months ended March 31, 2016 was related primarily to BUNAVAIL®, which included $2.0 million of product cost, royalties paid, lower of cost or net realized value, and depreciation. Additionally, we paid a total of $0.4 million in quarterly minimum royalty payments to CDC. Cost of sales during the three months ended March 31, 2016 also included $0.2 million and $0.04 million related to BREAKYL and PAINKYL, respectively.

Expenditures for Research and Development Programs

BELBUCA®

We incurred research and development expenses for BELBUCA® of approximately $0.18 million for the three months ended March 31, 2017. No such expenses were incurred for the three months ended March 31, 2016. Aggregate expenses approximate $114.38 million since inception of our development of this product candidate. 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.

BUNAVAIL®

We incurred research and development expenses for BUNAVAIL® of approximately $1.15 million for three months ended March 31, 2017 and approximately $1.6 million for the three months ended March 31, 2016. We have incurred approximately $39.85 million in the aggregate since inception of our development of this product. BUNAVAIL® was approved by the FDA in 2014. Therefore, BUNAVAIL® research and development expenses primarily consist of qualification of a 2nd manufacturer of BUNAVAIL® and allocated wages and compensation.

ONSOLIS®

We incurred research and development expenses for ONSOLIS® of approximately $0.07 million for the three months ended March 31, 2017 and approximately $0.4 million for the three months ended March 31, 2016. We have incurred approximately $1.87 million in the aggregate since inception of our development of this product. Our expenses for this product for 2017 and 2016 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.

Buprenorphine Depot Injection

We incurred research and development expenses for Buprenorphine Depot Injection of approximately $1.13 million for the three months ended March 31, 2017 and $0.6 million for the three months ended March 31, 2016, and have incurred approximately $10.03 million in the aggregate since inception of development. Our 2017 and 2016 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.

Clonidine Topical Gel

We incurred research and development expenses for Clonidine Topical Gel of approximately $0.14 million for the three months ended March 31, 2017 and approximately $2.7 million for the three months ended March 31, 2016, and have incurred approximately $27.44 million in the aggregate since inception of development. Our expenses for this former product candidate during

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2016 consisted mainly of several clinical trials testing the efficacy of the product, a Long-Term Safety Study and allocated wages and compensation. On December 13, 2016, we announced that the Phase 2b study failed to show a statistically significant difference in pain relief between Clonidine Topical Gel and placebo, and as a result we have no further plans for development of Clonidine Topical Gel. Minimal expenses in 2017 consisted of the winding down of the product candidate which included allocated wages and compensation.

Selling, General and Administrative Expenses. During the three months ended March 31, 2017 and 2016, general and administrative expenses totaled $13.3 million and $13.1 million, respectively, which the 2017 amount includes $1.1 million of amortization expense related to the reacquisition of BELBUCA®. Selling, general and administrative costs include commercialization costs for BELBUCA® and BUNAVAIL®, legal, accounting and management wages, and consulting and professional fees, travel costs, stock compensation expenses and amortization of the license and distribution rights intangible from the reacquisition of BELBUCA®.

Interest expense, net. During the three months ended March 31, 2017, we had net interest expense of $2.9 million, consisting of $0.4 million of scheduled interest payments and $0.3 million of related amortization of discount and loan costs related to the February 2017 term loan agreement from CRG. In addition, we had remaining $0.5 million of scheduled interest payments and $1.7 million of related amortization of discount, loan costs and loan pay off related to the July 2013 secured loan facility from MidCap, which was paid off with the CRG term loan. During the three months ended March 31, 2016, we had net interest expense of $0.8 million, consisting of $0.62 million of scheduled interest payments and $0.16 million of related amortization of discount and loan costs related to the July 2013 secured loan facility from MidCap.

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, funded research arrangements and revenue generated as a result of our worldwide license and development agreement with Meda regarding ONSOLIS® and revenue generated as a result of our January 2012 agreement with Endo regarding our BELBUCA® product. We intend to finance our research and development, commercialization and working capital needs from existing cash, royalty revenue, earnings from the commercialization of BELBUCA® and BUNAVAIL®, new sources of debt and equity financing, existing and new licensing and commercial partnership agreements and, potentially, through the exercise of outstanding common stock options and warrants to purchase common stock.

At March 31, 2017, we had cash and cash equivalents of approximately $35.2 million. We generated $3.2 million of cash during the three months ended March 31, 2017 and had stockholders equity of $38.2 million at March 31, 2017, versus stockholders deficit of $17.7 million at December 31, 2016. We believe we have sufficient cash to manage the business under our current operating plan into the second half of 2018. This assumes that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements

Additional capital may be required to support our commercialization activities for BELBUCA® and BUNAVAIL®, our planned development of buprenorphine depot injection, the reformulation project for and anticipated commercial relaunch of ONSOLIS® and general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

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

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

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;
- sale of product royalty;

grants and new license revenues;

bank loans;

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equipment financing;

public or private debt; and

exercise of existing warrants and options.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from 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, either of which could have a material adverse effect on us, our financial condition and our results of operations during 2017 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

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

Contractual Obligations and Commercial Commitments

Our contractual obligations as of March 31, 2017 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	$ 1,890	$ 334	$ 696	$ 735	$ 125
Secured loan facility	45,000		3,750	30,000	11,250
Interest on secured loan facility	24,973	5,703	11,422	7,133	715
Minimum royalty expenses**	4,125	1,500	2,625		
Total contractual cash obligations***	$ 75,988	$ 7,537	$ 18,493	$ 37,868	$ 12,090

* This amount represents obligations through the end of the calendar year ended December 31, 2017.

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

Off-Balance Sheet Arrangements

As of March 31, 2017, 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, 2016. As of January 1, 2017, we made a change to an accounting estimate in revenue recognition to recognize revenue on the sell-in method.

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.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our first quarter of 2017 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 BELBUCA® and BUNAVAIL®), (ii) the application and availability of corporate funds and our need for future funds, (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s review and/or approval and commercial activities for our products and product candidates and regulatory filings related to the same or (iv) the

results of our ongoing intellectual property litigations and patent office proceedings, may differ significantly from those set forth or anticipated 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 2016 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 claimed 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 was 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 was seeking an unspecified amount of damages, attorney s fees and an injunction preventing future infringement of MonoSol s patents.

We strongly refuted 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 while the third has had all claims rejected by the USPTO, we remain confident in our original stated position regarding this matter. Thus far,

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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 had no reason to believe the outcome would be different and were prepared to vigorously defend the appeal. MonoSol, however, 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 stands. The possibility exists that MonoSol could file another suit alleging infringement of the 292 and 891 patents. We continue to believe, however, that ONSOLIS® and our other products relying on the BEMA® technology, including BUNAVAIL® and BELBUCA®, do not infringe any amended, reexamined claim from either patent.

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. On January 31, 2017, the PTAB issued a final decision maintaining an additional new ground of rejection in addition to the previous grounds of invalidity. As such, all claims remain finally rejected on multiple grounds. MonoSol failed to appeal the final decision and all claims were cancelled in a reexamination certificate issued May 9, 2017.

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.

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On September 22, 2014, the RB Plaintiffs filed an action against us (and our commercial partner) relating to our BUNAVAIL® product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL®, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent U.S. Patent No. 8,765,167 (167 Patent). As with prior actions by the RB Plaintiffs, we believe this is another anticompetitive attempt by the RB Plaintiffs to distract our efforts from commercializing BUNAVAIL®. We strongly refute as without merit the RB Plaintiffs assertion of patent infringement and will vigorously defend the lawsuit. 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 appealed to Court of Appeals for the Federal Circuit (Fed. Cir.) in November 2016. The appeal is currently proceeding in the Federal Circuit with our Appeal Brief due March 31, 2017. Regardless of the outcome of the appeal, we believe that BUNAVAIL® will be found not to 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 PTAB rehear the IPR. On December 19, 2016, the PTAB issued a final decision denying MonoSol s request for rehearing. MonoSol did not file a notice of appeal to the Federal Circuit by February 20, 2017, therefore, PTAB s decision upholding all claims of our 019 patent will be final and unappealable.

On January 13, 2017, MonoSol filed a complaint in the United States District Court for the District of New Jersey alleging BELBUCA® infringes the 167 patent. In lieu of answering the complaint, we filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC on March 1, 2017. Briefing on the motions will be completed by May 22, 2017. We strongly refute as without merit MonoSol s assertion of patent infringement and will vigorously defend the lawsuit.

Teva Pharmaceuticals (formerly Actavis)

On February 8, 2016, we received a 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 (the 866 Patent) and 8,703,177 (the 177 Patent). 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.

We have asserted three different patents against Actavis, the 019 patent, the 866 patent, and the 177 patent. Actavis did not raise non-infringement positions with regard to the 019 and the 866 patents in its Paragraph IV certification. Actavis did raise a non-infringement position on the 177 patent due to its assertion that the backing layer for its generic product does not have a pH within the claimed range claimed in the patent. We asserted in our complaint that Actavis infringed the 177 patent either literally or under the doctrine of equivalents.

We believe that Actavis is unlikely to prevail on its claims that the 019, 866, and 177 Patents are invalid, and, as we have done in the past, intend to vigorously defend our intellectual property. Each of the three patents carry the presumption of validity and, the 019 Patent has already been the subject of an unrelated IPR before the USPTO under which we, and all claims of the 019 Patent survived. MonoSol s request for rehearing of the final IPR decision regarding the 019 Patent was denied by the USPTO on December 19, 2016. MonoSol did not file a timely appeal at the Federal Circuit.

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On December 20, 2016 the USPTO issued U.S. Patent No. 9,522,188 (the 188 patent), and this patent was properly listed in the Orange Book as covering the BUNAVAIL® product. On February 23, 2017 Actavis sent a Paragraph IV certification adding the 9,522,188 to its ANDA. An amended Complaint will be filed, adding the 188 patent to the current litigation.

Finally, on January 31, 2017, we received a notice relating to a Paragraph IV certification from Teva Pharmaceuticals USA (Teva) relating to Teva s ANDA on additional strengths of BUNAVAIL®. Teva s parent company, Teva Pharmaceuticals Ltd., recently acquired Actavis through an acquisition. We anticipate bringing suit against Teva and its parent company on these additional strengths within 45 days from the receipt of the notice.

A five (5) day bench trial is currently scheduled to begin on December 4, 2017.

Litigation related to BELBUCA®

We received notices regarding Paragraph IV certifications from Teva on November 8, 2016, November 10, 2016, and December 22, 2016, seeking to find invalid two Orange Book listed patents (the Patents) relating specifically to BELBUCA®. The Paragraph IV certifications relate to three ANDAs filed by Teva with the FDA for a generic formulation of BELBUCA®. The Patents subject to Teva s certification are U.S. Patent Nos. 7,579,019 (the 019 Patent) and 8,147,866 (the 866 Patent). Under 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 Teva within 45 days from the date of receipt of the certification notice. We filed complaints in Delaware against Teva on December 22, 2016 and February 3, 2017, 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 BELBUCA®. The 30 month stay is expected to preempt any final approval by the FDA on Teva s ANDA Nos. 209704 and 209772 until at least May of 2019 and for Teva s ANDA No. 209807 until at least June of 2019.

We have asserted two different patents against Teva, the 019 Patent and the 866 Patent. Teva did not contest infringement of the claims of the 019 Patent and also did not contest infringement of the claims of the 866 Patent that cover BELBUCA® in its Paragraph IV certifications.

We believe that Teva is unlikely to prevail on its claims that the 019 and 866 Patents are invalid, and, as we have done in the past, intends to vigorously defend our intellectual property. Both of the patents carry the presumption of validity, and 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. MonoSol s request for rehearing of the final IPR decision regarding the 019 Patent was denied by the USPTO on December 19, 2016. MonoSol did not file a timely appeal at the Federal Circuit.

A five (5) day bench trial is currently scheduled to begin on November 19, 2018.

Item 1A. Risk Factors.

No update.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

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Item 6. Exhibits.

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

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

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SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 15, 2017

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

(Principal Executive Officer)

Date: May 15, 2017

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

Chief Financial Officer (Principal Accounting Officer)