BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 10, 2018
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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, 2018

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, a smaller reporting company or an emerging growth company. See definition of large accelerated filer , accelerated filer and smaller reporting company , or emerging growth 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 10, 2018, there were 59,288,804 shares of company Common Stock issued and 59,273,313 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, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	$ 12,090	$ 21,195
Accounts receivable, net	8,123	8,852
Inventory, net	5,441	6,091
Prepaid expenses and other current assets	2,828	3,610
Total current assets	28,482	39,748
Property and equipment, net	3,621	3,778
Goodwill	2,715	2,715
BELBUCA® license and distribution rights intangible asset, net	39,375	40,500
Other intangible assets, net	1,196	1,360
Total assets	$ 75,389	$ 88,101
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 20,335	$ 26,149
Total current liabilities	20,335	26,149
Notes payable, net	48,285	47,660
Other long-term liabilities	5,415	5,415
Total liabilities	74,035	79,224
Commitments and contingencies (Note 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, 2018 and December 31, 2017, respectively	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 58,646,522 and 55,904,072 shares issued; 58,631,031 and 55,888,581 shares outstanding at March 31, 2018 and December 31, 2017, respectively	59	56
Additional paid-in capital	316,970	313,922
Treasury stock, at cost, 15,491 shares	(47)	(47)

Accumulated deficit	(315,630)	(305,056)
Total stockholders equity	1,354	8,877
Total liabilities and stockholders equity	$ 75,389	$ 88,101

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,	
	2018	**2017**
Revenues:		
Product sales	$ 9,838	$ 7,795
Product royalty revenues	440	1,661
Research and development reimbursements		22
Contract revenue	1,003	20,000
Total revenues	11,281	29,478
Cost of sales	3,415	5,645
Expenses:		
Research and development	2,484	2,671
Selling, general and administrative	13,505	13,259
Total expenses	15,989	15,930
(Loss) income from operations	(8,123)	7,903
Interest expense, net	(2,505)	(2,886)
Bargain purchase gain		27,336
Other expense, net	(7)	
(Loss) income before income taxes	$ (10,635)	$ 32,353
Income tax (expense) benefit	(74)	15,972
Net (loss) income attributable to common stockholders	$ (10,709)	$ 48,325
Basic:		
Weighted average common stock shares outstanding	58,062,997	54,519,574
Basic (loss) earnings per share	$ (0.18)	$ 0.89
Diluted:		
Diluted weighted average common stock shares outstanding	58,062,997	55,431,628

Diluted (loss) earnings per share	$	(0.18)	$	0.87

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

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

(Unaudited)

	Preferred Stock Series A		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Equity
Balances, January 1, 2018	2,093,155	$ 2	55,904,072	$ 56	$ 313,922	$ (47)	$ (305,056)	$ 8,877
Stock-based compensation					2,921			2,921
Stock option exercise			63,295		130			130
Restricted stock awards			1,038,957	1	(1)			
Common stock issuance upon retirement			1,640,198	2	(2)			
Cumulative effect of accounting change							135	135
Net loss							(10,709)	(10,709)
Balances, March 31, 2018	2,093,155	$ 2	58,646,522	$ 59	$ 316,970	$ (47)	$ (315,630)	$ 1,354

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,	
	2018	**2017**
Operating activities:		
Net (loss) income	$ (10,709)	$ 48,325
Adjustments to reconcile net (loss) income to net cash flows from operating activities		
Depreciation	230	111
Accretion of debt discount and loan costs	625	1,040
Amortization of intangible assets	1,289	1,369
(Benefit) provision for inventory obsolescence	(66)	153
Stock-based compensation expense	2,921	3,070
Deferred income taxes		(15,972)
Bargain purchase gain		(27,336)
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	864	(2,662)
Inventories	716	480
Prepaid expenses and other assets	782	194
Accounts payable and accrued expenses	(3,413)	3,942
Deferred revenue		(21,716)
Net cash flows used in operating activities	(6,761)	(9,002)
Investing activities:		
BELBUCA® acquisition	(1,951)	
Purchase of equipment	(73)	
Net cash flows used in investing activities	(2,024)	
Financing activities:		
Proceeds from notes payable		45,000
Proceeds from exercise of stock options	130	
Payment on note payable		(30,000)
Payment of deferred financing fees	(450)	(2,798)
Net cash flows (used in) provided by financing activities	(320)	12,202
Net change in cash and cash equivalents	(9,105)	3,200
Cash and cash equivalents at beginning of period	21,195	32,019

Cash and cash equivalents at end of period	**$ 12,090**	**$ 35,219**
Cash paid for interest	$ 1,880	$ 946

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 Operating, Financing and Investing Activities:

The Company recorded the fair value of an accumulated total of 1,640,198 shares of common stock issued to officers who retired from the Company during the three months ended March 31, 2018 totaling approximately $4.3 million to expense in accordance with accounting principles generally accepted in the United States (GAAP).

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 GAAP (see note 7, Business Combinations and Asset Acquisitions).

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) 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, 2017 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, 2017. Certain footnote disclosures normally included in financial statements prepared in accordance with 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, 2017.

Operating results for the three month period ended March 31, 2018 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 bonuses, stock-based compensation, determination of fair values of assets and liabilities in connection with business combinations, and deferred income taxes.

Inventory

Inventories are stated at the lower of cost or net realizable 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 reserved $0.2 million for inventory obsolescence as of both March 31, 2018 and December 31, 2017.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

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

Revenue recognition

Product sales

As discussed further below in Recent accounting pronouncements-adopted, effective January 1, 2018 the Company adopted Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (Topic 606) and began recognizing revenue under the new accounting guidance on that date. Under the new accounting guidance, the Company recognizes revenue on product sales when control of the promised goods is transferred to its customers in an amount that reflects the consideration expected to be received in exchange for transferring those goods. The Company accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. When determining whether the customer has obtained control of the goods, the Company considers any future performance obligations. Generally, there is no post-shipment obligations on product sold.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Topic 606. A contract s transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The Company s product sales contracts have a single performance obligation as the promise to transfer the individual goods is not separately identifiable from other promises in the contracts and, therefore, not distinct. The Company s performance obligations are satisfied at a point in time.

Adjustments to product sales

The Company recognizes product sales net of estimated allowances for rebates, price adjustments, returns, chargebacks and prompt payment discounts. A significant majority of the Company s adjustments to gross product revenues are the result of accruals for its commercial contracts, retail consumer subsidy programs, and Medicaid rebates.

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;

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 (shipments less returns) 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 considering any future anticipated demand growth. 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. In addition, the Company receives daily information from the wholesalers regarding their sales and actual on hand inventory levels of the Company s products. This enables the Company to execute accurate provisioning procedures.

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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):

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 after expiration of the products. The accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products.

Rebates-The liability for 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. If the sales mix to third-party payers is different from the Company s estimates, the Company will pay higher or lower total price adjustments and/or chargebacks than it had estimated.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include certain product incentives to pharmacy customers whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these programs based on the actual redemption rates as reported to the Company by a third-party claims processing organization. The Company accounts for the costs of these special 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 a specified number days after the invoice date, depending on the agreement with the customer.

Cost of sales

Cost of sales includes the direct costs attributable to the production of BELBUCA® and BUNAVAIL®. It 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 which are expensed as incurred. Cost of sales also includes royalty expenses that the Company owes to third parties.

Reclassification

Certain amounts were reclassified between Provision for inventory obsolescence, Accounts receivable, Inventories and Accounts payable and accrued expenses in the Condensed Consolidated Statement of Cash Flows for the three

months ended March 31, 2017 to conform to current year presentation. These reclassifications had no effect on the previously reported net cash flows from operations, activities or net losses.

Recent accounting pronouncements-adopted

In the first quarter of 2018, the Company adopted Topic 606. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The Company applied the five-step method outlined in the ASU to all revenue streams and elected the modified retrospective implementation method. The additional disclosures required by Topic 606 have been included in Note 2.

Recent accounting pronouncements-issued, not yet adopted

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

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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):

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 new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019 but may be adopted earlier. The Company expects to adopt this standard beginning in 2019. The Company does not expect that this standard will have a material impact on its condensed consolidated statements of operations, but the Company does expect that upon adoption, this standard will impact the carrying value of its assets and liabilities on its condensed consolidated balance sheets as a result of the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. In addition, the standard will require that the Company update its systems, processes and controls it uses to track, record and account for its lease portfolio.

2. Revenue from contracts with customers:

Effective January 1, 2018, the Company adopted Topic 606. The Company elected to apply the standard and all related ASUs using the modified retrospective method beginning January 1, 2018. The Company applied this guidance only to those contracts that were not completed at the date of adoption. As a result of adoption, the cumulative impact to the Company s retained earnings at January 1, 2018 was $0.1 million. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods. The Company expects the impact of the adoption of the new standard on its existing contracts to be immaterial to the Company s net income on an ongoing basis, however additional disclosures have been added in accordance with the ASU.

The Company does not anticipate any significant changes in the timing or amount of revenue recognized for the Company s product sales and related gross-to-net adjustments under ASC 606. The Company s net product sales continue to be recognized when delivery has occurred, and its gross-to-net adjustments are estimated and recorded in the accounting period related to when sales occur in the manner fundamentally consistent with the Company s prior accounting methodology.

Under the new standard, timing for recognition of certain contract revenue may be accelerated such that a portion of revenue will be estimated and recognized in revenue earlier than the previous accounting standards. During the three

months ended March 31, 2018, the Company recorded milestone revenue for contracts that are not due until between years 2020-2023. This financing component is recorded as a cumulative effect adjustment and the receivables were discounted for time value of money.

The main types of revenue contracts are:

Product sales -Product sales amounts relate to sales of BELBUCA® and BUNAVAIL®. These sales are recognized as revenue when control is transferred to the wholesaler in an amount that reflects the consideration expected to be received.

Product royalty revenues- Product royalty revenue amounts are based on sales revenue of BELBUCA® under the Company s license agreement with Purdue Pharma, the PAINKYLproduct under the Company s license agreement with TTY and the BREAKYL product under the Company s license agreement with Meda. Product royalty revenues are recognized when control of the product is transferred to the license partner in an amount that reflects the consideration expected to be received. Supplemental sales-based product royalty revenue may also be earned upon the subsequent sale of the product at agreed upon contractual rates.

Contract revenue -Contract revenue amounts are related to milestone payments under the Company s license agreements with its partners including any associated financing component.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

2. Revenue from contracts with customers (continued):

The impact of adoption of ASC 606 on the Company s condensed consolidated balance sheet and condensed consolidated statement of operations as of and for the three months ended March 31, 2018 follows (in thousands):

	Condensed Consolidated Balance Sheet March 31, 2018		
	As reported	Balances without adoption of ASC 606	Effect of Adoption
Accounts receivable, net	$ 8,123	$ 7,798	$ 325
Accumulated deficit	$ (315,630)	$ (315,955)	$ 325

	Condensed Consolidated Statement of Operations Three months ended March 31, 2018		
	As reported	Balances without adoption of ASC 606	Effect of Adoption
Total revenues	$ 11,281	$ 11,091	$ 190
Net loss attributable to common stockholders	$ (10,709)	$ (10,899)	$ 190

The cumulative effect of the changes made to the Company s condensed consolidated balance sheet from the modified retrospective adoption of ASC 606 was as follows (in thousands):

	Balance at December 31, 2017	Adjustment due to implementation of ASC 606	Balance at January 1, 2018
Accounts receivable, net	$ 8,852	$ 135	$ 8,987

Accumulated deficit	$ (305,056)	$ 135	$ (304,921)

The beginning and ending balances of the Company s accounts receivables with customers from contracts during the periods presented is as follows (in thousands):

	Balance at January 1, 2018	Three months ended March 31, 2018	Balance at March 31, 2018
Accounts receivable with customers	$ 8,987	$ (864)	$ 8,123

3. Liquidity and management s plans:

At March 31, 2018, the Company had cash of approximately $12.1 million. The Company used $6.8 million of cash in operations during the three months ended March 31, 2018 and had stockholders equity of $1.4 million, versus stockholders equity of $8.9 million at December 31, 2017. The Company expects that it has sufficient cash to manage the business as currently planned into the second quarter of 2019, which assumes either access to an additional $15 million of loan proceeds through the Company s term loan with CRG Servicing LLC (CRG) if the Company satisfies the third draw requirements (see note 10), and/or further assumes the Company s ability to access to the equity markets if the Company chooses (or a combination of both debt and equity, if available) that would provide sufficient capital necessary to support the continued commercialization of BELBUCA® and BUNAVAIL®.

Additionally, beginning April 2018, the Company has the ability to access to its previously established at-the-market offering program utilizing the universal shelf registration for up to $40 million of Common Stock. The Company s cash on hand estimation therefore assumes the availability of the foregoing capital sources and further assumes that the Company does not otherwise face unexpected events, costs or contingencies, any of which could affect the Company s cash requirements from time to time.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

3. Liquidity and management s plans (continued):

Additional capital will be required to support the continued commercialization of the Company s BELBUCA® and BUNAVAIL® products, the reformulation project for and the anticipated commercial relaunch of ONSOLIS®, the potential continued development of Buprenorphine Extended Release 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, which could leave the Company without adequate capital resources.

4. Inventory:

The following table represents the components of inventory as of:

	March 31, 2018	December 31, 2017
Raw materials & supplies	$ 1,100	$ 1,338
Work-in-process	3,663	3,135
Finished goods	855	1,861
Obsolescence reserve	(177)	(243)
Total inventories	$ 5,441	$ 6,091

5. Accounts payable and accrued liabilities:

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

	March 31,	December 31,

	2018	2017
Accounts payable	$ 9,712	$ 12,236
Accrued rebates	6,133	5,648
Accrued compensation and benefits	1,768	3,472
Accrued acquisition costs	583	2,311
Accrued returns	622	915
Accrued royalties	526	488
Accrued clinical trial costs	274	234
Accrued legal	164	216
Accrued other	553	629
Total accounts payable and accrued liabilities	$ 20,335	$ 26,149

6. Property and equipment:

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

	March 31, 2018	December 31, 2017
Machinery & equipment	$ 5,495	$ 5,428
Computer equipment & software	405	399
Office furniture & equipment	169	169
Leasehold improvements	44	44
Idle equipment	766	766
Total	6,879	6,806
Less accumulated depreciation and amortization	(3,258)	(3,028)
Total property and equipment, net	$ 3,621	$ 3,778

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

6. Property and equipment (continued):

Depreciation and amortization expense was approximately $0.2 million and $0.1 million for the three month periods ended March 31, 2018 and 2017, respectively.

7. 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 significant license and development agreements are as follows:

Meda license, development and supply agreements

In August 2006 and September 2007, the Company entered into certain agreements with Meda AB (Meda) a subsidiary of Mylan N.V., a Swedish company to develop and commercialize the Company s ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered utilizing the Company s BEMA® technology. The agreements related to the United States, Mexico and Canada (Meda U.S. Agreements) and to certain countries in Europe (Meda EU Agreements). They carry license terms that commenced on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration date of the last to expire Orange Book listed patents which currently is July 23, 2027.

On March 12, 2012, the Company announced the postponement of the U.S. relaunch of ONSOLIS® following the initiation of the class-wide Risk Evaluation and Mitigation Strategy (REMS) until the product formulation could be modified to address two appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of the color in the mucoadhesive layer, and as previously reported the Company has since worked with FDA to reformulate ONSOLIS® to address these issues. In August 2015, the Company announced the FDA approval of the new formulation. The Company identified a new supplier and requested guidance from the FDA on specific requirements for obtaining approval to supply product from this new vendor. Based on the Company s current estimates, the Company will be able to submit the necessary documentation to the FDA for qualification of the new manufacturer during 2018.

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. 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).

Simultaneously on May 11, 2016, the Company and Collegium Pharmaceutical Inc. (Collegium) executed a definitive License and Development Agreement (the License Agreement) under which the Company had granted to Collegium the exclusive rights to develop and commercialize ONSOLIS® in the U.S. Under the terms of the License Agreement, Collegium was responsible for the manufacturing, distribution, marketing and sales of ONSOLIS® in the U.S. However, on December 8, 2017, the Company received the required 90-day notice from Collegium regarding termination of the License Agreement and the effective date of termination was March 8, 2018. The Company is assessing its commercial options for ONSOLIS®.

Endo license and development agreement

In January 2012, the Company entered into a License and Development Agreement with Endo Pharmaceuticals, Inc. (Endo) pursuant to which the Company granted Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company s BELBUCA® product and to complete U.S. development of such product candidate for purposes of seeking FDA approval (the Endo Agreement). BELBUCA® is for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA approved BELBUCA® in October 2015.

However, due to the Company and Endo entering into a termination agreement effective January 6, 2017 (the Termination Agreement) which terminated the BELBUCA® license to Endo, the Company recognized $20 million of previously deferred revenue in January 2017. (See note 8, Business Combinations and BELBUCA® Acquisition).

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8. Business combination and BELBUCA® acquisition:

On December 7, 2016, the Company and Endo entered into the Termination Agreement to terminate Endo s licensing rights for BELBUCA®. The transaction closed on January 6, 2017. At the closing date, the Company purchased from Endo the following net assets (the net assets): (i) current BELBUCA® product inventory 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 net assets (the Asset Purchase Price) was 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 work-in-progress inventory, and (iii) the assumption of any assumed liabilities. Together with the Asset Purchase Price, pursuant to the terms of the Termination Agreement, the Company paid to Endo a fee in the amount of $5 million in consideration for (i) Endo s agreement not to compete for a period of two years from the closing date of the termination agreement and (ii) Endo s waiver of its right to sell product for twelve months following the closing of the termination agreement.

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. Determining the fair value of certain acquired assets and liabilities is subjective in nature and often involves the use of significant estimates and assumptions, including, but not limited to, the selection of appropriate valuation methodology, projected revenue, expenses and cash flows, weighted average cost of capital, discount rates, and estimates of terminal values. The Company believes the estimates used were reasonable and the significant effects of the BELBUCA® acquisition were properly reflected.

The following table summarizes the consideration paid to acquire BELBUCA® and the estimated values of assets acquired and liabilities assumed in the accompanying 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)

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.

During the three months ended March 31, 2017, the Company recorded the asset acquisition as a bargain purchase gain of $27.3 million in the accompanying condensed consolidated statement of operations.

9. License agreements and acquired product rights:

Purdue license and supply agreement:

On July 12, 2017, the Company, along with Purdue Pharma, an Ontario limited partnership (Purdue), announced that they had executed an exclusive agreement granting to Purdue the licensing, distribution, marketing and sale rights related to BELBUCA® in Canada. Financial terms of the Purdue agreement include: (i) total upfront and other cash milestone payments (relating to marketing authorization transfer and certain other marketing- and sales-related milestones) of up to an aggregate of CAD 4.5 million, including approximately CAD 1.5 million (0.5 million CAD and 1.0 million CAD received August 2017 and October 2017, respectfully); (ii) a low double digit percent royalty payable quarterly by Purdue to the Company based on Canadian net sales of BELBUCA®, which

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9. License agreements and acquired product rights (continued):

royalty rate is subject to adjustment in certain circumstances; (iii) an annual royalty fee commencing a period of time after the commercial launch of BELBUCA® in Canada, which fee is creditable against royalties payable by Purdue and subject to reduction in certain circumstances; and (iv) payment by Purdue of certain costs incurred to obtain and transfer the marketing authorization for BELBUCA® in Canada, a portion of which will be reimbursed by the Company as a reduction of royalties payable by Purdue.

On January 30, 2018, the Company and Purdue announced that BELBUCA® is now commercially available in Canada. The first commercial sale of BELBUCA® in Canada triggered a milestone payment to the Company from Purdue in the amount of CAD 1 million (US $0.8 million), which the Company received and recognized as revenue in March 2018.

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.

During the three months ended March 31, 2018, the Company received cumulative payments of $0.4 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. There were no payments received during the three months ended March 31, 2017.

10. Notes payable:

On February 21, 2017, the Company entered into a term loan agreement (the Term Loan Agreement) with 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 under the Term Loan Agreement to repay all the amounts owed by the Company under the MidCap Credit Agreement (Midcap). During the three months ended March 31, 2017, $0.7 million of deferred loan costs arising out of the MidCap Credit Agreement were expensed and

recorded as interest expense in the accompanying consolidated statement of operations.

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. On December 26, 2017, the Company was eligible and elected to receive the Second Draw for gross proceeds of $15.0 million.

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.

We may prepay all or a portion of the outstanding principal and accrued unpaid interest under the 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

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10. Notes payable (continued):

transactions, we are 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.

The following table represents future maturities of the CRG obligation as of March 31, 2018:

2018	$
2019	
2020	20,054
2021	20,054
2022	20,054
Total maturities	$ 60,162
Unamortized discount and loan costs	(11,877)
Total CRG obligation	$ 48,285

11. Segment reporting:

The Company s business is classified as a single reportable segment.

However, the following table presents net sales by product:

	Three months ended March 31,	
	2018	**2017**
BELBUCA®	$ 8,024	$ 4,555
BUNAVAIL®	1,814	3,240
Net product sales	$ 9,838	$ 7,795

12. Stockholders equity:

Stock-based compensation

During the three months ended March 31, 2018, a total of 618,174 options to purchase Common Stock, with an aggregate fair market value of approximately $1.5 million, were granted to Company employees. Options granted to employees 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:

Stock-based compensation expense	2018	2017
Research and development	$ 1,052	$ 401
Selling, general and administrative	$ 1,869	$ 2,669

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.

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.

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12. Stockholders equity (continued):

The key assumptions used in determining the fair value of options granted during the three months ended March 31, 2018 follows:

Expected price volatility	60.41%-68.77%
Risk-free interest rate	2.05%-2.60%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the three months ended March 31, 2018 was as follows:

	Number of shares	Weighted average exercise price per share	Aggregate intrinsic value
Outstanding at January 1, 2018	2,712,954	$ 2.98	$ 1,190
Granted in 2018:			
Employees	618,174	2.50	
Exercised	(63,295)	2.05	
Forfeitures	(201,989)	4.64	
Outstanding at March 31, 2018	3,065,844	$ 2.80	$ 292

As of March 31, 2018, options exercisable totaled 1,769,300. There was approximately $4.9 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 2021.

Restricted stock units

During the three months ended March 31, 2018, 1,155,611 RSUs were granted to the Company s executive officers and employees, with a fair market value of approximately $2.5 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 (the EIP).

Of the aforementioned 2018 RSU grants, 292,500 are time-based and 292,500 are performance based, all of which vest over a three-year period. Performance-based RSUs vest if specified predetermined net revenue and operating income goals are achieved with respect to the annual fiscal years 2018 through 2020. Actual performance relative to the predetermined performance measures are evaluated independently at the end of each fiscal year and the number of awards that will vest will be based upon the percentage of the individual performance measure achieved relative to the predetermined target. This allows for partial vesting relative to separate performance measures.

Pursuant to retirement agreements of certain Company senior staff, the remaining 570,611 RSUs terminated and immediately were issued into shares of Common Stock.

Restricted stock activity during the three months ended March 31, 2018 was as follows:

	Number of restricted shares	Weighted average fair market value per RSU
Outstanding at January 1, 2018	4,706,895	$ 5.20
Granted:		
Executive officers	463,129	2.10
Directors	375,305	2.18
Employees	317,177	2.10
Vested	(1,038,957)	2.35
Forfeitures	(235,110)	2.52
Conversions	(1,640,198)	2.68
Outstanding at March 31, 2018	2,948,241	$ 3.02

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12. Stockholders equity (continued):

Warrants

The Company has granted warrants to purchase shares of Common Stock.

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. A cumulative total of 2,136,020 shares underlying warrants to purchase Common Stock are outstanding as of March 31, 2018 with a weighted average exercise price of $2.60 per share.

13. Earnings per common share:

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

	March 31, 2018	March 31, 2017
Basic:		
Net (loss) income attributable to common stockholders	$ (10,709)	$ 48,325
Weighted average common shares outstanding	58,062,997	54,519,574
Basic (loss) earnings per common share	$ (0.18)	$ 0.89
Diluted:		
Effect of dilutive securities:		
Net (loss) income attributable to common stockholders	(10,709)	48,325
Adjustment to income for dilutive options and warrants		

	(10,709)	48,325
Weighted average common shares outstanding	58,062,997	54,519,574
Effect of dilutive options and warrants		912,054
Diluted weighted average common shares outstanding	58,062,997	55,431,628
Diluted (loss) earnings per common share	$ (0.18)	$ 0.87

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. Common equivalent shares from stock options, RSUs, warrants and convertible preferred stock using the treasury stock method, are also included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the three months ended March 31, 2018 and 2017, outstanding stock options, RSUs, warrants and convertible preferred stock of 10,243,260 and 10,124,619, 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.

14. Commitments and contingencies:

The Company is involved from time to time in routine legal matters incidental to our business. Based upon available information, the Company believes that the resolution of such matters will not have a material adverse effect on its condensed consolidated financial position or results of operations. Except as discussed below, the Company is not the subject of any pending legal proceedings and, to the knowledge of management, no proceedings are presently contemplated against the Company by any federal, state or local governmental agency.

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14. Commitments and contingencies (continued):

Litigation related to BUNAVAIL®

RB and Aquestive Therapeutics (formerly MonoSol Rx)

On September 22, 2014, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and Aquestive Therapeutics, Inc. (Aquestive) (collectively, the RB Plaintiffs) the RB Plaintiffs filed an action against the Company (and the Company s commercial partner) relating to the Company s BUNAVAIL® product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL®, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent U.S. Patent

No. 8,765,167 (the 167 Patent). The Company believes this is an anticompetitive attempt by the RB Plaintiffs to distract the Company s efforts from commercializing BUNAVAIL®. 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 its commercial partner. The Court issued an opinion on July 21, 2015 granting the Company s motion to transfer the venue to the Eastern District of North Carolina (ENDC) but denying the Company s motion to dismiss the case against the Company s commercial partner as moot. The Company has also filed a Joint Motion to Stay the case in North Carolina at the end of April 2016, which was granted by the court on May 5, 2016. Thus, the case is now stayed until a final resolution of the 167 IPRs in the United States Patent and Trademark Office (USPTO).

In a related matter, on October 28, 2014, the Company filed multiple IPR requests on the 167 Patent demonstrating that certain claims of such patent were anticipated by or obvious in light of prior art references, including prior art references not previously considered by the USPTO, and thus, invalid. The USPTO instituted three of the four IPR requests and the Company filed a request for rehearing for the non-instituted IPR. The final decisions finding all claims patentable were issued in March 2016 and the Company filed a Request for Reconsideration in the USPTO in April 2016, which was denied in September 2016 and appealed to Court of Appeals for the Federal Circuit (Fed. Cir.) in November 2016. The appeal is currently proceeding in the Federal Circuit with final briefing completed August 7, 2017 and oral argument held February 7, 2018. The Company anticipates receiving a final decision from the Federal Circuit sometime in 2018.

On January 13, 2017, Aquestive 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. Briefing on the motions was completed on June 21, 2017. On July 25, 2017, the Court administratively terminated the case pending the parties submission of a joint stipulation of transfer because the District of New Jersey was an inappropriate venue. This case has been transferred to Delaware District Court. On October 31, 2017 the Company filed motions to dismiss the complaint and,

in the alternative, to transfer the case to the EDNC. Briefing on the motions was completed on December 1, 2017. The Company anticipates receiving a final decision from the District Court in the 2nd quarter of 2018. The Company strongly refutes as without merit Aquestive s assertion of patent infringement and will vigorously defend the lawsuit.

Litigation related to BELBUCA®

Teva Pharmaceuticals USA (formerly Actavis)

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 related to three ANDAs filed by Teva with the FDA for a generic formulation of BELBUCA®. The Patents subject to Teva s certification were the 019 Patent and the 866 Patent. Under the Hatch-Waxman Amendments, after receipt of a valid Paragraph IV notice, the Company brought a patent infringement suit in federal district court against Teva USA 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 were 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 was 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.

In February 2018, we announced that we had entered into a settlement agreement with Teva that resolved our BELBUCA® patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the settlement agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we have granted Teva a non-exclusive license (for which we will receive no current or future payments) that permits Teva to first begin selling the generic version of our BELBUCA® product in the U.S. on January 23, 2027 or earlier under certain circumstances (including, for example, upon (i) the

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14. Commitments and contingencies (continued):

delisting of the patents-in-suit from the U.S. FDA Orange Book, (ii) the granting of a license by us to a third party to launch another generic form of BELBUCA® at a date prior to January 23, 2027, or (iii) the occurrence of certain conditions regarding BELBUCA® market share).

2018 Arkansas Opioid Litigation

On March 15, 2018, the State of Arkansas, and certain counties and cities in that State, filed an action in the Circuit Court of Arkansas, Crittenden County against multiple manufacturers, distributors, retailers, and prescribers of opioid analgesics, including the Company. The Company was served with the complaint on April 27, 2018. The complaint specifically alleges that the Company licensed its branded fentanyl buccal soluble film ONSOLIS® to Collegium, and Collegium is also named as a defendant in the lawsuit. ONSOLIS® is not presently sold in the United States and the license agreement with Collegium was terminated prior to Collegium launching ONSOLIS® in the United States. The lawsuit seeks to recoup the past and prospective public health costs allegedly associated with the abuse of opioids in Arkansas from the defendants and seeks punitive and treble damages, attorneys fees, costs and expenses, and pre-and post-judgment interest under a variety of legal theories including negligence/gross negligence, common law public nuisance, civil conspiracy, and violations of Arkansas statutes. The Company denies the allegations in the lawsuit and intends to vigorously defend against them.

15. Subsequent events:

On May 8, 2018, Herm Cukier was appointed Chief Executive Officer and a member of the Board of Directors of the Company. In connection with his appointment, the Company and Mr. Cukier entered into an employment agreement, dated May 2, 2018, for an initial two-year term, starting on May 8, 2018, automatically renewable for one-year terms, unless either party gives notice of non-extension to the other party at least 60 days prior to the end of the applicable term. The employment agreement provides for the following compensation terms for Mr. Cukier: (i) Base salary of $0.57 million per annum, (ii) an annual cash bonus in an amount no less than fifty-five percent (55%) of the base salary (iii) a signing bonus in the amount of $0.05 million); (iv) an initial incentive stock option to purchase Eight Hundred Thousand (800,000) shares of the Common Stock under the Company s 2011 EIP; and (v) Two Hundred Thousand (200,000) RSUs under the Company s 2011 EIP.

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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 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;
- 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; and
- 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,

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

First Quarter and Recent Highlights

- On January 30, 2018, we announced that BELBUCA® is now commercially available in Canada via our exclusive agreement with Purdue (Canada). This milestone triggered a payment in the amount of CAD 1 million, (US $0.8 million) which we received March 2018.
- On February 6, 2018, we announced that we had entered into a Settlement Agreement with Teva that resolves our previously reported BELBUCA® patent litigation against Teva pending in the United States District Court for the District of Delaware.

On May 7, 2018, we announced the appointment of Herm Cukier as our new Chief Executive Officer and member of our board of directors, effective as of May 8, 2018.

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 originally licensed on a worldwide basis to Endo. On October 26, 2015, we announced with Endo that the FDA approved BELBUCA®. BELBUCA® was 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. Behind a revised commercialization plan based on market research conducted primarily by Endo that took into consideration the current climate for prescribing opioids for chronic pain, we are leveraging our existing sales force to capitalize on commercial synergies with BUNAVAIL®. This effort is a focused commercial approach targeting identified healthcare providers which we believe create the potential to incrementally grow BELBUCA® sales without the requirement for significant resources. We also will explore other options for longer-term growth for BELBUCA®. In mid-February 2017, we completed the expansion and training of our sales force, allowing for promotion of BELBUCA® to commence in full in late February. We further expanded our sales force beginning of January 2018 to support the commercialization efforts. BELBUCA® and BUNAVAIL® are currently supported by a field force of approximately

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eighty-five sales representatives and nine regional sales managers. As previously disclosed, the launch has been more challenging because of the increased scrutiny over the prescribing of opioids that is 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. The approval of BELBUCA® carries a standard post-approval requirement by the FDA to conduct a study to determine the effect of BELBUCA® on QT prolongation (i.e. an abnormal lengthening of the heartbeat). Also required is a study assessing the safety and efficacy of BELBUCA® in pediatric patients and participation in a consortium with other holders of NDAs for long-acting opioids to assess and better understand the risk of abuse, misuse, addiction and overdose with opioids. Prescription sales of BELBUCA have significantly increased since promotion began.

BUNAVAIL® was approved by the FDA in June 2014 and is indicated for the 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 reducing spending. We will seek to continue to manage our BUNAVAIL® business by focusing sales efforts on those healthcare providers who have been prescribers of BUNAVAIL. And we will continue to use published data evidencing diversion (i.e., the illicit use of a legally prescribed controlled substance) associated with the market leader s product and highlight the other attributes of BUNAVAIL® as we seek to win additional managed care contracts. We also believe there will be an opportunity to introduce more patients to BUNAVAIL® with the lifting of the long-standing limit from 100 to 275 (as outlined in the final ruling by HHS and effective on August 8, 2016), the number of patients per physician that can be treated at any given time with buprenorphine and more recent legislation allowing nurse practitioners and physician assistants to prescribe buprenorphine for opioid dependence. 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.

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, a subsidiary of Mylan N.V., 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. We are currently assessing our commercial options for ONSOLIS®.

Buprenorphine Extended Release 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 the FDA in November 2015, the 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 (IND) for this product candidate to the FDA in December 2016.

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 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 was responsible for the manufacturing, distribution, marketing and sales of ONSOLIS® in the U.S. Meda continues to commercialize ONSOLIS® under the brand name

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BREAKYL in the E.U. However, on December 8, 2017, Collegium provided us the required 90-day notice regarding termination of the license and development agreement for ONSOLIS® between us and Collegium. The license and development agreement for ONSOLIS® between us and Collegium formally ended on March 8, 2018. We are working with Collegium to transfer the assets back to us and a final resolution of financial matters.

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 and help assist us as we seek a new commercial partnership arrangement. Based on our current estimates, we believe that we will submit the necessary documentation to FDA for qualification of the new manufacturer during 2018.

Results of Operations

Comparison of the three months ended March 31, 2018 and 2017

Product Sales. We recognized $9.8 million and $7.8 million in product sales during the three months ended March 31, 2018 and 2017, respectively. The increase is due to increased sales of BELBUCA® from our internal sales force. 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 $0.4 million and $1.7 million in product royalty revenue during the three months ended March 31, 2018 and 2017, respectively. We recognized $0.4 million and $0.2 million in PAINKYL product royalty revenue during the three months ended March 31, 2018 and 2017, respectively, under our license agreement with TTY. 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 $0.8 million related to a percentage of net sales of the BREAKYL product under our license agreement with Meda. The decrease is due to the reacquisition BELBUCA® in January 2017 from Endo, which net sales are now shown under product sales.

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. There was no such reimbursable revenue during the three months ended March 31, 2018. The decrease is due to the program termination by Collegium.

Contract Revenues. We recognized $1.0 million as contract revenue in a milestone payment under our license agreement from Purdue related to BELBUCA® in Canada during the three months ended March 31, 2018. We also recognized $20.0 million of deferred revenue during the three months ended March 31, 2017. 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.

Cost of Sales. We incurred $3.4 million and $5.6 million in cost of sales during the three months ended March 31, 2018 and 2017, respectively. Cost of sales during the three months ended March 31, 2018 was related primarily to BELBUCA® and BUNAVAIL®, which included $2.9 million of product cost, royalties paid, lower of cost or net realized value, depreciation and yield adjustments. 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, 2018 also included $0.02 million and $0.1 million related to BREAKYL and PAINKYL, 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. During the three months ended March 31, 2017, we recognized approximately $1.6 million of expense related to previously deferred BUNAVAIL® cost of sales as a result of changing from the sell through to the sell in method of recognizing revenue. Additionally, during the three months ended March 31, 2017, we expensed approximately $0.9 million related to the fair value of purchased BELBUCA® inventory from Endo. We did not record any deferred cost of sales nor fair value adjustments during the three months ended March 31, 2018.

Selling, General and Administrative Expenses. During the three months ended March 31, 2018 and 2017, general and administrative expenses totaled $13.5 million and $13.3 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®.

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Interest expense, net. During the three months ended March 31, 2018, we had net interest expense of $2.5 million, consisting of $1.9 million of scheduled interest payments and $0.6 million of related amortization of discount and loan costs related to the February 2017 term loan agreement from CRG. 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.

Revenues

The following table summarizes net product sales for the three month periods ended March 31 in thousands:

	Three months ended March 31,	
	2018	**2017**
BELBUCA®	$ 8,024	$ 4,555
% of net product sales	82%	58%
BUNAVAIL®	1,814	3,240
% of net product sales	18%	42%
Net product sales	$ 9,838	$ 7,795

Expenditures for Research and Development Programs

Our research and development expenditures for our approved products and product candidates as of March 31 are as follows in thousands:

	Three Months Ended March 31,		Cumulative through March 31,
	2018	**2017**	**2018**
BELBUCA®	$ 1,752	$ 183	$ 124,449
BUNAVAIL®	95	1,152	40,980
ONSOLIS®	431	67	3,485
Buprenorphine ER Injection	206	138	9,991
Clonidine Topical Gel*		1,131	27,519

* Clonidine Topical Gel product candidate was discontinued in December 2016. Expenses thereafter consist of the winding down of the product candidate which includes allocated wages and compensation.

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

license and development agreements. We intend to finance our commercialization, research and development and working capital needs from existing cash, royalty revenue, earnings from the continued commercialization of BELBUCA® and BUNAVAIL®, our term loan with CRG (assuming we achieve the conditions for additional funding under such loan), potential 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, 2018, we had cash of approximately $12.1 million. We used $6.8 million of cash in operations during the three months ended March 31, 2018 and had stockholders equity of $1.4 million, versus stockholders equity of $8.9 million at December 31, 2017. We expect that we have sufficient cash to manage the business as currently planned into the second quarter of 2019, which assumes either access to an additional $15 million of loan proceeds through our term loan with CRG if we satisfy the third draw requirements, and/or further assumes our ability to access to the equity markets if we choose (or a combination of both debt and equity, if available) that would provide sufficient capital necessary to support the continued commercialization of BELBUCA® and BUNAVAIL®. Additionally, beginning April 2018, we have the ability to access to our previously established at-the-market offering program utilizing the universal shelf registration for up to $40 million of Common Stock. Our cash on hand estimation therefore assumes the availability of the foregoing capital sources and further assumes that we do not otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements from time to time.

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Additional capital will be required to support the continued commercialization of our BELBUCA® and BUNAVAIL® products, the reformulation project for and the anticipated commercial relaunch of ONSOLIS®, the potential continued development of Buprenorphine Extended Release Injection or other products which may be acquired or licensed by us, and for general working capital requirements. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all, which could leave our company without adequate capital resources.

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

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

public equity markets;

private equity financings;

commercialization agreements and collaborative arrangements;

sale of product royalty;

grants and new license revenues;

bank loans;

equipment financing;

public or private debt; and

exercise of existing warrants and options.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from 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 in 2018 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.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of March 31, 2018 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	$ 1,556	$ 343	$ 715	$ 498	$
Secured loan facility	60,162		25,068	35,094	
Interest on secured loan facility	25,762	7,625	13,684	4,453	
Minimum royalty expenses**	2,625	1,500	1,125		
Total contractual cash obligations	$ 90,105	$ 9,468	$ 40,592	$ 40,045	$

* This amount represents obligations through the end of the calendar year ending December 31, 2018.

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

Off-Balance Sheet Arrangements

As of March 31, 2018, 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.

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Critical Accounting Policies

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, 2017 (the 2017 Annual Report) and Note 1 of the accompanying condensed consolidated financial statements 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 and may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros, CAD 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, Euro, CAD or other applicable currencies, or by weak economic conditions in Europe, Canada or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, our management, with the participation of our Principal 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 2018 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

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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 2017 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 publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

We are involved from time to time in routine legal matters incidental to our business. Based upon available information, we believe that the resolution of such matters will not have a material adverse effect on our condensed consolidated financial position or results of operations. Except as discussed below, we are not the subject of any pending legal proceedings and, to the knowledge of management, no proceedings are presently contemplated against us by any federal, state or local governmental agency.

Litigation related to ONSOLIS®

In 2010, Aquestive Therapeutics (formerly MonoSol Rx) (Aquestive) 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. Aquestive claimed that our manufacturing process for ONSOLIS®, which has never been disclosed publicly and which we and our partners maintain as a trade secret, infringed on its US Patent No. 7,824,588 (the 588 Patent). Later, two more patents were added to the action, US Patent No. 7,357,891 (the 891 Patent) and US Patent No. 7,425,292 (the 292 Patent).

We challenged all three patents in *inter partes* reexamination proceedings, and the claims of all three patents were substantially narrowed and/or invalidated. A Reexamination Certificate for the 891 Patent in its amended form was issued August 21, 2012. A Reexamination Certificate for the 292 Patent in its amended form was issued on July 3, 2012. A Certificate of Reexamination cancelling every claim in the 588 Patent was issued on August 5, 2014.

Therefore, we were found to be entitled to absolute intervening rights as to 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 and the case was dismissed. The possibility exists that Aquestive could file another suit alleging infringement of the 292 and 891 Patents. However, 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®

Indivior (formerly RB Pharmaceuticals Ltd.) and Aquestive Therapeutics (formerly MonoSol Rx)

On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and Aquestive (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 (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 US Patent No. 8,475,832 (the 832 Patent). On May 21, 2014, the Court granted our motion to dismiss.

On September 20, 2014, we proactively filed a declaratory judgment action in the United States District Court for the EDNC requesting the Court to make a determination that our BUNAVAIL® product does not infringe the 832 Patent, US Patent No. 7,897,080 (the 080 Patent) and US Patent No. 8,652,378 (the 378 Patent). We invalidated the 080 Patent in its entirety in an *inter partes* reexamination proceeding. We invalidated all relevant claims of the 832 Patent in an *inter partes* review (IPR) proceeding. And, in an IPR proceeding for the 378 Patent, in its decision not to institute the IPR proceeding the PTAB construed the claims of the 378 Patent narrowly. Shortly thereafter, by joint motion of the parties, the 378 Patent was subsequently removed from the action.

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 (the 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 our motion, this case was transferred to the Eastern District of North Carolina. A Joint Motion to Stay the case was granted and the case is now stayed until a final resolution of the 167 IPRs discussed directly below. We will continue to vigorously defend this case.

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On October 28, 2014, we filed multiple IPR petitions on certain claims of the 167 Patent. The USPTO instituted three of the four IPR petitions. The PTAB upheld the claims and denied collateral estoppel applied to the PTAB decision in March 2016. This case is currently on appeal to Court of Appeals for the Federal Circuit. The USPTO intervened with respect to whether collateral estoppel applied to the PTAB. The Federal Circuit did not issue an affirmance without opinion after the February 7, 2018 oral argument. As such, we anticipate receiving a decision from the Federal Circuit sometime in 2018.

On January 22, 2014, Aquestive initiated an IPR on the 019 Patent, which was instituted. The PTAB upheld all claims of our 019 Patent in 2015 and this decision was not appealed by Aquestive.

On January 13, 2017, Aquestive 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. Briefing on the motions was completed on June 21, 2017. On July 25, 2017, the Court administratively terminated the case pending the parties submission of a joint stipulation of transfer because the District of New Jersey was an inappropriate venue. This case has been transferred to Delaware District Court. On October 31, 2017 we filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC. Briefing on the motions was completed on December 1, 2017. We anticipate receiving a final decision from the District Court in the 2nd quarter of 2018. We strongly refute as without merit Aquestive s assertion of patent infringement and will vigorously defend the lawsuit.

Teva Pharmaceuticals USA (formerly Actavis)

On February 8, 2016, we received a notice relating to a Paragraph IV certification from Teva Pharmaceuticals USA (Teva) (formerly Actavis) seeking to find invalid three Orange Book listed patents (the Patents) relating specifically to BUNAVAIL®. The Paragraph IV certification related to an Abbreviated New Drug Application (the ANDA) filed by Teva with the U.S Food and Drug Administration (FDA) for a generic formulation of BUNAVAIL®. The Patents subject to Teva s certification were the 019 Patent, 8,147,866 (the 866 Patent) and 8,703,177 (the 177 Patent).

On March 18, 2016, we asserted three different patents against Teva, the 019 Patent, the 866 Patent, and the 177 Patent. Teva did not raise non-infringement positions about the 019 and the 866 Patents in its Paragraph IV certification. Teva did raise a non-infringement position on the 177 Patent but we asserted in our complaint that Teva infringed the 177 Patent either literally or under the doctrine of equivalents.

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 Teva sent a Paragraph IV certification adding the 9,522,188 to its ANDA. An amended Complaint was filed, adding the 188 Patent to the litigation.

On January 31, 2017, we received a notice relating to a Paragraph IV certification from Teva relating to Teva s ANDA on additional strengths of BUNAVAIL® and on March 16, 2017, we brought suit against Teva and its parent company on these additional strengths. On June 20, 2017, the Court entered orders staying both BUNAVAIL® suits at the request of the parties.

On May 23, 2017, the USPTO issued U.S. Patent 9,655,843 (the 843 Patent), and this patent was properly listed in the Orange Book as covering the BUNAVAIL® product.

Finally, on October 12, 2017, we announced that we had entered into a settlement agreement with Teva that resolved our BUNAVAIL® patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As

part of the Settlement Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we have entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BUNAVAIL® in the U.S. on July 23, 2028 or earlier under certain circumstances. Other terms of the agreement are confidential.

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 were the 019 Patent and the 866 Patent. We filed complaints in Delaware against Teva on December 22, 2016 and February 3, 2017in which we asserted against Teva the 019 Patent and the 866 Patent. Teva did not contest infringement of the claims of the 019 Patent and did not contest infringement of the claims of the 866 Patent.

The 019 Patent had already been the subject of an unrelated IPR before the USPTO under which we prevailed, and all claims of the 019 Patent survived. Aquestive s request for rehearing of the final IPR decision regarding the 019 Patent was denied by the USPTO on December 19, 2016. Aquestive did not file a timely appeal at the Federal Circuit.

On May 23, 2017, the USPTO issued U.S. Patent 9,655,843 (the 843 Patent), and this patent was properly listed in the Orange Book as covering the BELBUCA® product.

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On August 28, 2017, the Court entered orders staying both BELBUCA® suits at the request of the parties.

In February 2018, we announced that we had entered into a settlement agreement with Teva that resolved our BELBUCA® patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the settlement agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we have granted Teva a non-exclusive license (for which we will receive no current or future payments) that permits Teva to first begin selling the generic version of our BELBUCA® product in the U.S. on January 23, 2027 or earlier under certain circumstances (including, for example, upon (i) the delisting of the patents-in-suit from the U.S. FDA Orange Book, (ii) the granting of a license by us to a third party to launch another generic form of BELBUCA® at a date prior to January 23, 2027, or (iii) the occurrence of certain conditions regarding BELBUCA® market share). Other terms of the Agreement are confidential.

2018 Arkansas Opioid Litigation

On March 15, 2018, the State of Arkansas, and certain counties and cities in that State, filed an action in the Circuit Court of Arkansas, Crittenden County against multiple manufacturers, distributors, retailers, and prescribers of opioid analgesics, including our company. We were served with the complaint on April 27, 2018. The complaint specifically alleges that we licensed its branded fentanyl buccal soluble film ONSOLIS® to Collegium Pharmaceutical Inc. (Collegium), and Collegium is also named as a defendant in the lawsuit. ONSOLIS® is not presently sold in the United States and the license agreement with Collegium was terminated prior to Collegium launching ONSOLIS® in the United States. The lawsuit seeks to recoup the past and prospective public health costs allegedly associated with the abuse of opioids in Arkansas from the defendants and seeks punitive and treble damages, attorneys fees, costs and expenses, and pre-and post-judgment interest under a variety of legal theories including negligence/gross negligence, common law public nuisance, civil conspiracy, and violations of Arkansas statutes. We deny the allegations in the lawsuit and intend to vigorously defend against them.

Item 1A. Risk Factors.

Actions of activist shareholders could be disruptive and potentially costly and the possibility that activist shareholders may seek changes that conflict with our strategic direction could cause uncertainty about the strategic direction of our business.

Activist investors may attempt to effect changes in our strategic direction and how our company is governed or may seek to acquire control over our company. Some investors (commonly known as activist investors) seek to increase short-term stockholder value by advocating corporate actions such as financial restructuring, increased borrowing, special dividends, stock repurchases, or even sales of assets or the entire company. Activist campaigns can also seek to change the composition of our board of directors, and campaigns that contest or conflict with our strategic direction could have an adverse effect on our results of operations and financial condition as responding to proxy contests and other actions by activist shareholders can disrupt our operations, be costly and time-consuming, and divert the attention of our board of directors and senior management from the pursuit of our business strategies. In addition, perceived uncertainties as to our future direction that can arise from potential changes to the composition of our board of directors sought by activists may lead to the perception of a change in the direction of the business, instability or lack of continuity which may be exploited by our competitors, may cause concern to our current or potential customers, may result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel and business partners. For example, in April 2018, we received a notification from a shareholder indicating that they intend to nominate certain individuals to serve on our Board of Directors for election at our 2018 annual meeting of stockholders. These types of actions could divert our management s attention from our

business or cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business, all of which could have a material adverse effect on our company.

Social issues around the abuse of opioids, including law enforcement and other legal concerns over diversion of opioids and regulatory efforts to combat abuse, misuse and addiction, could impact the potential market for BELBUCA®, BUNAVAIL® and any product candidates we may develop that contain opioids.

Opioid abuse in the United States is a significant healthcare issue, and our two currently marketed products (BELBUCA® and BUNAVAIL®) contain opioids as their active ingredients. Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Law enforcement and regulatory agencies have and will likely continue to apply policies and guidelines that seek to limit the availability or use of opioids. In addition, federal, state and local governments have and may enact legislation or executive orders with similar goals. State and local governments have also taken legal action against opioid manufacturers to recoup alleged damages arising out of the opioid crisis. Such efforts have challenged and could inhibit our ability to commercialize BELBUCA® and BUNAVAIL® and any product candidates we may develop that contain opioids.

Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse-resistant formulations; the ability of drug abusers to discover previously unknown ways to abuse opioid

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drugs; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our business. Additionally, there may be continued reluctance of some regulators and third-party payers to pay a premium for abuse-deterrent formulations of opioids or opioids such as BELBUCA® with less abuse and addiction potential compared to Schedule II opioids. These factors could reduce the potential size of the market for BELBUCA®, and possibly BUNAVAIL® and our product candidates and decrease the revenues we are able to generate from their sale.

Efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for BELBUCA® and BUNAVAIL®. For example, in February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA s approach to opioid medications. The plan identifies FDA s focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA s plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the REMS requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic-abuse deterrent opioid formulations, and seeking input from the FDA s Scientific Board to broaden the understanding of the public risks of opioid abuse. The FDA s Scientific Advisory Board met to address these issues on March 1, 2016. The FDA s plan is part of a broader initiative led by the HHS to address opioid-related overdose, death and dependence. The HHS initiative s focus is on improving physician s use of opioids through education and resources to address opioid over-prescribing, increasing use and development of improved delivery systems for naloxone, which can reverse overdose from both prescription opioids and heroin, to reduce overdose-related deaths, and expanding the use of Medication-Assisted Treatment, which couples counseling and behavioral therapies with medication to address substance abuse. Also, as part of this initiative, the CDC has launched a state grant program to offer state health departments resources to assist with abuse prevention efforts, including efforts to track opioid prescribing through state-run electronic databases. In March 2016, as part of the HHS initiative, the CDC released a new Guideline for Prescribing Opioids for Chronic Pain. The guideline is intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The guideline does not specifically address the use of buprenorphine for chronic pain or make treatment recommendations about the use of abuse-deterrent opioids.

In addition, at least 41 U.S. states and many cities and counties have filed civil suits or instituted other proceedings against opioid manufacturers and wholesalers of opioid drugs seeking damages under various claims for contributing to the opioid crisis. Such litigations could further damage the market for opioid products like BELBUCA® and BUNAVAIL®. To the extent our company is named in such lawsuits (such as the lawsuit in Arkansas described under Legal Proceedings), we could be required to participate in the settlement of such litigations or the payment of damages, which could divert our management s attention from our business, deplete our financial resources, and damage our reputation.

We are nearing the limit on our authorized common stock, which could impact our financing and other activities. Also, additional authorized shares of our common stock and preferred stock available for issuance may adversely affect the market for our common stock.

As of May 10, 2018, there are 58,646,522 shares of common stock issued and 58,631,031 shares of common stock outstanding and there were 2,139,000 shares issued and 2,093,155 outstanding of Series A Non-Voting Convertible Preferred Stock issued and outstanding. We also have 2,504,206 shares of common stock reserved for future issuance under our equity incentive plan, outstanding equity awards and outstanding warrants. Our certificate of incorporation currently provides for 75,000,000 authorized shares of common stock. As such, we are nearing the limit of our authorized common stock, and we will be asking our stockholders to approve an amendment to our certificate of

incorporation to increase the number of authorized shares of common stock at our next annual meeting of stockholders. Prior to such meeting, or after if such amendment in not approved, we may be unable to issue common stock for a variety of purposes, including most importantly for financing purposes. This limitation on our ability to issue common stock could have a material adverse effect on our ability to finance and operate our business.

Moreover, and even if our certificate of incorporation is amended to increase our authorized shares of common stock, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors would experience dilution, and sales of common stock by stockholders in the market could lower the price of our common stock and the value of our company.

Finally, in addition to the above referenced shares of common stock (which may be issued without stockholder approval), we have 5 million shares of authorized preferred stock, of which 2,139,000 shares have been designated as Series A Non-Voting Convertible Preferred Stock. The remaining 2,290,700 shares of preferred stock remain undesignated shares of preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.
None.

Item 3. Defaults upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
Not applicable.

Item 5. Other Information.
None.

Item 6. Exhibits.

Number	Description
31.1	Certification of Principal 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

+ Confidential treatment is being requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
* 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 10, 2018

By: /s/ Scott M. Plesha
President

(Principal Executive Officer)

Date: May 10, 2018

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

Chief Financial Officer (Principal Accounting Officer)