BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
November 08, 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 September 30, 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 every Interactive Data File required to be submitted 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 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	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 November 8, 2018, there were 70,707,109 shares of company Common Stock issued and 70,691,618 shares of company Common Stock outstanding.

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BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	$ 49,482	$ 21,195
Accounts receivable, net	12,568	8,852
Inventory, net	5,434	6,091
Prepaid expenses and other current assets	4,155	3,610
Total current assets	71,639	39,748
Property and equipment, net	3,170	3,778
Goodwill	2,715	2,715
BELBUCA® license and distribution rights, net	37,125	40,500
Other intangible assets, net	867	1,360
Total assets	$ 115,516	$ 88,101
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 23,919	$ 26,149
Total current liabilities	23,919	26,149
Notes payable, net	50,516	47,660
Other long-term liabilities	5,511	5,415
Total liabilities	79,946	79,224
Commitments and contingencies (Note 12)		
Stockholders equity:		
Preferred Stock, 5,000,000 shares authorized; Series A Non-Voting Convertible Preferred Stock. $.001 par value, 2,093,155 shares outstanding at both September 30, 2018 and December 31, 2017, respectively; Series B Non-Voting Convertible Preferred Stock, $.001 par value, 3,100 and 0 shares outstanding at September 30, 2018 and December 31, 2017, respectively.	2	2
Common Stock, $.001 par value; 125,000,000 and 75,000,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 70,598,687 and 55,904,072 shares issued;70,583,196 and 55,888,581 shares outstanding at September 30, 2018 and December 31, 2017, respectively.	71	56
Additional paid-in capital	379,824	313,922

Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(344,280)	(305,056)
Total stockholders equity	35,570	8,877
Total liabilities and stockholders equity	$ 115,516	$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales	$ 13,763	$ 8,118	$ 34,367	$ 23,798
Product royalty revenues	370	1,409	2,197	3,682
Research and development reimbursements		532		799
Contract revenues	23	1,194	1,047	21,194
Total Revenues:	14,156	11,253	37,611	49,473
Cost of sales	3,779	4,445	11,760	14,261
Expenses:				
Research and development	699	1,986	4,038	6,246
Selling, general and administrative	13,489	14,867	41,013	44,094
Total Expenses:	14,188	16,853	45,051	50,340
Loss from operations	(3,811)	(10,045)	(19,200)	(15,128)
Interest expense	(2,567)	(1,893)	(7,598)	(6,657)
Other expense, net	(2)	(13)	(8)	(28)
Bargain purchase gain				27,336
(Loss) income before income taxes	$ (6,380)	$ (11,951)	$ (26,806)	$ 5,523
Income tax (expense) benefit			(53)	15,972
Net (loss) income	$ (6,380)	$ (11,951)	$ (26,859)	$ 21,495
Beneficial conversion feature of convertible preferred stock	(12,500)		(12,500)	
Net (loss) income attributable to common stockholders	$ (18,880)	$ (11,951)	$ (39,359)	$ 21,495
Basic				
Basic (loss) income per share:	$ (0.29)	$ (0.21)	$ (0.65)	$ 0.39
Weighted average common stock shares outstanding:	64,900,007	55,604,708	60,599,456	55,170,569

Diluted				
Diluted (loss) income per share:	$ (0.29)	$ (0.21)	$ (0.65)	$ 0.38
Diluted weighted average common stock shares outstanding:	64,900,007	55,604,708	60,599,456	56,204,358

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		Preferred Stock Series B		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders
	Shares	Amount	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							4,896			4,896
Stock option exercises					285,403		528			528
Restricted stock awards					1,733,731	2	(2)			
Common stock issuance upon retirement					2,119,925	2	(2)			
Series B issuance, net of issuance costs			5,000				47,993			47,993
Series B conversion to Common Stock			(1,900)		10,555,556	11	(11)			
Series B beneficial conversion feature							12,500		(12,500)	
Cumulative effect of accounting change									135	135
Net loss									(26,859)	(26,859)
Balances, September 30, 2018	2,093,155	$ 2	3,100	$	70,598,687	$ 71	$ 379,824	$ (47)	$ (344,280)	$ 35,570

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

	Nine months ended September 30,	
	2018	**2017**
Operating activities:		
Net (loss) income	$ (26,859)	$ 21,495
Adjustments to reconcile net (loss) income to net cash flows from operating activities		
Depreciation	685	465
Accretion of debt discount and loan costs	2,953	1,941
Amortization of intangible assets	3,868	4,103
Impairment loss on equipment	78	
Provision for inventory obsolescence	396	
Stock-based compensation expense	4,896	10,223
Deferred income taxes		(15,972)
Bargain purchase gain		(27,336)
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(3,581)	(7,222)
Inventories	261	2,314
Prepaid expenses and other assets	(545)	1,826
Accounts payable and accrued liabilities	(427)	8,998
Deferred revenue		(21,716)
Net cash flows used in operating activities	(18,275)	(20,881)
Investing activities:		
BELBUCA® acquisition	(1,951)	(3,902)
Purchase of equipment	(155)	(5)
Net cash flows used in investing activities	(2,106)	(3,907)
Financing activities:		
Proceeds from issuance of Series B preferred stock	50,000	
Equity finance costs	(1,410)	
Proceeds from notes payable		45,000
Proceeds from exercise of stock options	528	313
Payment on note payable		(30,000)
Payment of deferred financing fees	(450)	(2,798)
Net cash flows provided by financing activities	48,668	12,515

Net change in cash and cash equivalents	28,287	(12,273)
Cash and cash equivalents at beginning of period	21,195	32,019
Cash and cash equivalents at end of period	**$ 49,482**	**$ 19,746**
Cash paid for interest	$ 4,645	$ 3,816

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

Non-cash Operating, Financing and Investing Activities:

The Company recorded the intrinsic value related to the beneficial conversion feature of the Series B Non-Voting Convertible Preferred Stock during the nine months ended September 30, 2018 totaling $12.5 million to retained earnings and additional paid-in capital in accordance with accounting principles generally accepted in the United States (GAAP).

The Company recorded the fair value of an accumulated total of 2,119,925 shares of common stock issued to officers who retired from the Company during the nine months ended September 30, 2018 totaling approximately $5.3 million to expense in accordance with GAAP.

The Company recorded $0.6 million of accrued financing expenses related to the Series B Non-Voting Convertible Preferred Stock offering during the nine months ended September 30, 2018. Such expense is recorded as accounts payable and accrued liabilities in the condensed consolidated balance sheet.

The Company recorded the fair value of the bargain purchase price of the BELBUCA® acquisition totaling $27.3 million to income during the nine months ended September 30, 2017 in accordance with GAAP.

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, EXCEPT PER SHARE AMOUNTS)

(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 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 and nine-month periods ended September 30, 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 $0.001 per share, is referred to as the Common Stock and the Company s preferred stock, par value $0.001 per share, is referred to as the Preferred 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 $0.6 million and $0.2 million for inventory obsolescence as of September 30, 2018 and December 31, 2017, respectively.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

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

Revenue recognition

Product sales

As discussed further below in Note 2, 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 majority of 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. The multiple performance obligations are not allocated based off of the obligations but based off of standard selling price.

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, EXCEPT PER SHARE AMOUNTS)

(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.

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 nine months ended September 30, 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

The SEC has released SEC Final Rule Release No. 33-10532 Disclosure Update and Simplification, which adopts amendments to certain disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded, in light of other SEC disclosure requirements, U.S. GAAP, or changes in the information environment. The amendments also refer certain SEC disclosure requirements that overlap with but require information incremental to U.S. GAAP to the Financial Accounting Standards Board (FASB) for potential incorporation into U.S. GAAP. The amendments are intended to facilitate the disclosure of information to investors and simplify compliance without significantly altering the total mix of information provided to investors. These amendments are part of an initiative by the Division of Corporation Finance to review disclosure requirements applicable to issuers to consider ways to improve the requirements for the benefit of investors and issuers. The amendments became effective on November 5, 2018 and did not have a material impact to the Company.

Recent accounting pronouncements-issued, not yet adopted

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

However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new ASU will require both types of leases (i.e., operating and capital leases) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases. The new standard requires a

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

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

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 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 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.

ASU 2018-07, issued in June 2018, expands the scope of Topic 718, Compensation Stock Compensation , to include share-based payment transactions for acquiring goods and services from nonemployees. The objective of the ASU is to maintain or improve the usefulness of the information provided to the users of financial statements while reducing cost and complexity by simplifying several aspects of existing guidance. The amendments are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year and early adoption is permitted. The Company is currently assessing the impact of adopting this ASU on its condensed consolidated financial statements.

2. Revenue from contracts with customers:

Effective January 1, 2018, the Company adopted Topic 606. The Company elected to apply the standard 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 $0.135 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 Topic 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 nine months ended September 30, 2018, the Company recorded financing revenue for two milestones that are not due until 2020 and 2023, respectively.

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 PAINKYL product 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, EXCEPT PER SHARE AMOUNTS)

(Unaudited)

2. Revenue from contracts with customers (continued):

The impact of adoption of Topic 606 on the Company s condensed consolidated balance sheet as of September 30, 2018 follows (in thousands):

	Condensed Consolidated Balance Sheet September 30, 2018		
	As reported	Balances without adoption of Topic 606	Effect of Adoption
Accounts receivable, net	$ 12,568	$ 12,197	$ 371
Accumulated deficit	$ (344,280)	$ (344,651)	$ 371

The impact of adoption of Topic 606 on the Company s condensed consolidated statement of operations for the three and nine months ended September 30, 2018 follows (in thousands):

	Condensed Consolidated Statement of Operations Three months ended September 30, 2018			Condensed Consolidated Statement of Operations Nine months ended September 30, 2018		
	As reported	Balances without adoption of Topic 606	Effect of Adoption	As reported	Balances without adoption of Topic 606	Effect of Adoption
Product sales	$ 13,763	$ 13,763	$	$ 34,367	$ 34,367	$
Product royalty revenues	370	393		2,197	2,195	
Contract revenues	23		23	1,047	813	236
Total revenues	$ 14,156	$ 14,133	$ 23	$ 37,611	$ 37,375	$ 236
Net loss	$ (6,380)	$ (6,403)	$ 23	$ (26,859)	$ (27,096)	$ 236

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	Nine months ended September 30, 2018	Balance at September 30, 2018
Accounts receivable with customers	$ 8,987	$ 3,581	$ 12,568

3. Liquidity and management s plans:

At September 30, 2018, the Company had cash of approximately $49.5 million. The Company used $18.3 million of cash in operations during the nine months ended September 30, 2018 and had stockholders equity of $35.6 million, versus stockholders equity of $8.9 million at December 31, 2017. The Company believes that it has sufficient current cash to manage the business as currently planned into the second quarter of 2020 which would provide sufficient capital necessary to support the continued commercialization of BELBUCA® and BUNAVAIL®.

The Company s cash on hand estimation 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. 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

4. Inventory:

The following table represents the components of inventory as of:

	September 30, 2018	December 31, 2017
Raw materials & supplies	$ 651	$ 1,338
Work-in-process	2,552	3,135
Finished goods	2,870	1,861
Obsolescence reserve	(639)	(243)
Total inventories	$ 5,434	$ 6,091

5. Accounts payable and accrued liabilities:

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

	September 30, 2018	December 31, 2017
Accounts payable	$ 8,508	$ 12,236
Accrued rebates	9,296	5,648
Accrued compensation and benefits	2,770	3,472
Accrued acquisition costs	1,427	2,311
Accrued returns	658	915
Accrued royalties	562	488
Accrued clinical trial costs	348	234
Accrued legal	72	216
Accrued other	278	629
Total accounts payable and accrued liabilities	$ 23,919	$ 26,149

6. Property and equipment:

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

	September 30, 2018	December 31, 2017
Machinery & equipment	$ 5,623	$ 5,428
Computer equipment & software	446	399
Office furniture & equipment	169	169
Leasehold improvements	44	44
Idle equipment	679	766
Total	6,961	6,806
Less accumulated depreciation and amortization	(3,791)	(3,028)
Total property and equipment, net	$ 3,170	$ 3,778

Depreciation expense was $0.2 million for each of the three-month periods ended September 30, 2018 and September 30, 2017, respectively. Depreciation expense was $0.7 million and $0.5 million for the nine-month periods ended September 30, 2018 and September 30, 2017, respectively.

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(Unaudited)

7. 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 (ii) a low double digit percent royalty payable quarterly by Purdue to the Company based on Canadian net sales of BELBUCA® (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.

On January 30, 2018, the Company and Purdue announced that BELBUCA® was 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

The Company has 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 Company received cumulative payments of $0.9 million from TTY during each of the nine month periods ended September 30, 2018 and 2017, respectively, related to royalties based on product purchased in Taiwan by TTY of PAINKYL which is recorded in the accompanying condensed consolidated statement of operations.

8. Notes payable:

On February 21, 2017 (the Closing Date), 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).

Pursuant to the Term Loan Agreement, the Company borrowed $45.0 million from the Lenders as of the Closing Date, and on December 26, 2017 borrowed an additional $15.0 million (the Second Draw) that was contingently available upon achievement of certain conditions.

The original Term Loan Agreement had a six-year term with three years of interest-only payments, (from 2017-2019). On May 16, 2018, the Company entered into an amendment to its Term Loan Agreement with CRG. Pursuant to the amendment: (i) the interest only period of the Loan Agreement was extended by one year, and certain milestones previously required for the extended interest only period have been removed; (ii) the PIK period (under which a portion of the interest accrued under the Loan Agreement can be deferred to maturity) will also be extended for a year, (to 2020); (iii) amortization of the loan principal can be deferred until maturity (making the payment of the loan a balloon payment) if the Company achieves and maintains a market capitalization of $200 million prior to the conclusion of the interest only period (provided that if the Company achieves, and thereafter falls below a $200 million market capitalization, amortization of the loan principal will resume); and (iv) certain Company revenue targets, the failure of which would create an event of default under the loan, have been recalculated. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of 12.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. On each borrowing date (including the Closing Date), the Company is required to pay CRG a financing fee based on the loan drawn on that date. The Company is also required to pay the Lenders a final payment fee equivalent to 9% of the original loan amount upon repayment of the loans in full, in addition to prepayment amounts described below.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Loan Agreement at any time upon prior notice to the Lenders subject to a certain prepayment fees during the first five years of the term (which fees are lowered over time) and no prepayment fee thereafter. In certain circumstances, including a change of control and certain asset sales or licensing transactions, the Company is required to prepay all or a portion of the loan, including the applicable prepayment premium of on the amount of the outstanding principal to be prepaid.

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(Unaudited)

8. Notes payable (continued):

The following table represents future maturities of the notes payable obligation as of September 30, 2018:

Years ending December 31, 2018	$
2019	
2020	
2021	30,619
2022	30,619
Total maturities	$ 61,238
Unamortized discount and loan costs	(10,722)
Total notes payable obligation	$ 50,516

9. Net sales by product:

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

However, the following table presents net sales by product:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
BELBUCA®	$ 12,358	$ 6,437	$ 30,128	$ 17,554
BUNAVAIL®	1,405	1,681	4,239	6,244
Net product sales	$ 13,763	$ 8,118	$ 34,367	$ 23,798

10. Stockholders equity:

Stock-based compensation

During the nine months ended September 30, 2018, a total of 2,260,211 options to purchase Common Stock, with an aggregate fair market value of approximately $3.3 million, were granted to Company employees and members of the Board of Directors. Options have a term of 10 years from the grant date. Options granted to employees vest ratably over a three-year period and options granted to members of the Board of Directors vest ratably through 2022. The fair value of each option is amortized as compensation expense evenly through the vesting period.

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

	Three months ended,		Nine months ended,	
Stock-based compensation expense	**September 30, 2018**	**September 30, 2017**	**September 30, 2018**	**September 30, 2017**
Research and Development	$ 0.02	$ 0.5	$ 1.1	$ 1.3
Selling, General and Administrative	$ 0.9	$ 3.7	$ 3.8	$ 8.9

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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10. Stockholders equity (continued):

The key assumptions used in determining the fair value of options granted during the nine months ended September 30, 2018 follows:

Expected price volatility	60.34%-68.77%
Risk-free interest rate	2.05%-2.82%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the nine months ended September 30, 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:			
Officers and Directors	1,160,341	2.41	
Employees	1,099,870	2.50	
Exercised	(285,403)	1.99	
Forfeitures	(375,785)	3.57	
Outstanding at September 30, 2018	4,311,977	$ 3.17	$ 1,405

As of September 30, 2018, options exercisable totaled 1,711,966. There was approximately $6.4 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 2022.

Restricted stock units

During the nine months ended September 30, 2018, 1,824,872 RSUs were granted to the Company s executive officers, employees and directors, with a fair market value of approximately $4.2 million. The fair value of restricted

units is determined using quoted market prices of the Common Stock and the number of shares expected to vest. These RSUs were issued under the Company s 2011 Equity Incentive Plan, as amended (the EIP).

RSU grants are either time-based or performance-based, all of which generally vest over a three-year period. Performance-based RSUs vest if specified predetermined net revenue and operating income goals are achieved. 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.

Restricted stock activity during the nine months ended September 30, 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	1,038,434	2.23
Directors	469,261	2.59
Employees	317,177	2.10
Vested	(1,733,731)	2.50
Forfeitures	(442,009)	2.63
Conversions	(2,119,925)	2.72
Outstanding at September 30, 2018	2,236,102	$ 5.15

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10. Stockholders equity (continued):

Series B Preferred Stock Financing

On May 17, 2018, the Company entered into a placement agency agreement with William Blair & Company, L.L.C., as placement agent, relating to the Company s registered direct offering, issuance and sale of an aggregate of 5,000 shares of the Company s authorized preferred stock that the Board of Directors of the Company has designated as Series B Non-Voting Convertible Preferred Stock, par value $0.001 per share (the Series B Preferred Stock). All the shares were sold by the Company. The placement agency agreement contains customary representations, warranties and covenants of the Company and the Placement Agent. The closing of the offering was completed on May 21, 2018. The shares sold in the offering were issued pursuant to a shelf registration statement, as amended, that the Company filed with the SEC, which became effective on July 13, 2015.

Each share of Series B Preferred Stock is convertible into a number of shares of the Company s common stock, par value $0.001 per share determined by dividing $10,000 by a conversion price of $1.80 per share (subject to adjustment for stock splits and stock dividends as provided in the Certificate of Designation). The outstanding shares of Series B Preferred Stock are convertible into an aggregate 27,777,778 shares of Common Stock. The Series B Preferred Stock does not contain any price-based anti-dilution protection. The Series B Preferred Stock is convertible at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series B Preferred Stock into shares of Common Stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of Common Stock then issued and outstanding, which percentage may be increased or decreased on sixty-one (61) days notice from the holder of Series B Preferred Stock to the Company.

The Company has the right to deliver a notice to the holders of the Series B Preferred Stock to require conversion of the Series B Preferred Stock into Common Stock, provided that certain conditions with respect to the Common Stock are satisfied. Such forced conversion shall be subject to a holder s beneficial ownership limitation of 9.98% of the total number of shares of Common Stock then issued and outstanding. Following an initial forced conversion of the Series B Preferred Stock, every ninety (90) days thereafter, the Company has the right to require the forced conversion of the still outstanding shares of Series B Preferred Stock up to the beneficial ownership limitation of 9.98% of the total number of shares of Common Stock then issued and outstanding.

During the nine months ended September 30, 2018, a cumulative total of 1,900 shares of Series B Preferred Stock from various holders were converted into 10,555,556 shares of Common Stock. As of September 30, 2018, 3,100 shares of Series B Preferred Stock are outstanding.

The Series B Preferred Stock issued in May 2018 contained a contingent beneficial conversion feature (BCF) that was recognized during the three and nine months ending September 30, 2018 upon the August 2018 stockholder approval, which eliminated the contingency. The conversion feature is not a separate unit of account requiring bifurcation. The Company evaluated its convertible preferred stock in accordance with provisions of ASC 815, Derivatives and Hedging, including consideration of embedded derivatives requiring bifurcation. The issuance of the Series B Preferred Stock generated a BCF, which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor or in the money at inception because the conversion option has an effective strike price that is less than the market price of the underlying stock at the commitment date. As a result, $12.5 million was recorded as a reduction to additional paid-in capital, increasing net loss attributable to the Company Common stockholders.

The Company recognized the BCF of the intrinsic value of the conversion option, which is the number of shares of common stock available upon conversion multiplied by the difference between the conversion price per share and the fair value of common stock per share on the commitment date, totaling $12.5 million, as after shareholder approval the convertible preferred stock may be converted immediately. This one-time, non-cash charge impacted net loss attributable to common stockholders and net loss per share for the three and nine month periods ended September 30, 2018.

Common Stock

On August 2, 2018, in connection with the Company s 2018 Annual Meeting of Stockholders, the Company s stockholders approved, among other matters, to amend the Company s Certificate of Incorporation to increase the number of authorized shares of Common Stock from 75,000,000 to 125,000,000.

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(Unaudited)

10. 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 September 30, 2018 with a weighted average exercise price of $2.60 per share.

11. 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).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Basic:				
Net (loss) income	$ (6,380)	$ (11,951)	$ (26,859)	$ 21,495
Less deemed dividend related to beneficial conversion feature on Series B Preferred Stock	(12,500)		(12,500)	
Net (loss) income attributable to common stockholders, basic	$ (18,880)	$ (11,951)	$ (39,359)	$ 21,495
	64,900,007	55,604,708	60,599,456	55,170,569

Weighted average common shares outstanding				
Basic (loss) income per common share	**$ (0.29)**	**$ (0.21)**	**$ (0.65)**	**$ 0.39**
Diluted:				
Effect of dilutive securities:				
Net (loss) income attributable to common stockholders, diluted	$ (18,880)	$ (11,951)	$ (39,359)	$ 21,495
Weighted average common shares outstanding	64,900,007	55,604,708	60,599,456	55,170,569
Effect of dilutive options and warrants				1,033,789
Diluted weighted average common shares outstanding	64,900,007	55,604,708	60,599,456	56,204,358
Diluted (loss) income per common share	**$ (0.29)**	**$ (0.21)**	**$ (0.65)**	**$ 0.38**

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. In addition to the weighted average shares of Common Stock outstanding, common equivalent shares from stock options, RSUs, warrants and preferred shares using the treasury stock method, are included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the three months ended September 30, 2018 and 2017, outstanding stock options, RSUs, warrants and preferred shares of 25,745,108 and 9,638,211, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect. During the nine months ended September 30, 2018 and 2017, outstanding stock options, RSUs, warrants and preferred shares of 18,917,774 and 5,230,179, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect. Included in the three and nine months ended September 30, 2018 are the Series B shares as converted to common stock.

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12. 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.

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

Litigation related to BUNAVAIL®

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 United States District for the Eastern District of North Carolina (EDNC) but denying the Company s motion to dismiss the case against the Company s commercial partner as moot. The Company has also filed a Joint Motion to Stay the case in the EDNC 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 Patent *inter partes* review (IPR) in the United States Patent and Trademark Office (USPTO).

In a related matter, on October 28, 2014, the Company 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 decisions in March 2016. The Company appealed to Court of Appeals for the Federal Circuit. The USPTO intervened with respect to whether collateral estoppel applied to the PTAB. On June 19, 2018, the Company filed a motion to remand the case for further consideration by the PTAB in view of intervening authority. On July 31, 2018, the Federal Circuit vacated the decisions, and remanded the 167 Patent IPRs for further consideration on the merits.

Litigation related to BELBUCA®

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. On July 25, 2017, the New Jersey 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 was later transferred to the 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. On October 16, 2018, denying the motion to dismiss as moot, the Delaware District Court granted the Company s motion to transfer the case to the EDNC. The case is now pending in the EDNC. The Company strongly refutes as without merit Aquestive s assertion of patent infringement and will vigorously defend the lawsuit.

Teva Pharmaceuticals USA (formerly Actavis)

The Company received notices regarding Paragraph IV certifications from Teva on November 8, 2016, November 10, 2016, and December 22, 2016, seeking to find invalid two Orange Book listed patents 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 U.S. Patent No. 7,579,019 (the 019 Patent) and U.S. Patent No. 8,147,866 (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. The Company filed complaints in Delaware against Teva on December 22, 2016 and February 3, 2017, thus the Company was 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, the Company announced that it had entered into a settlement agreement with Teva that resolved the Company s BELBUCA® patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the settlement

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12. Commitments and contingencies (continued):

agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, the Company has granted Teva a non-exclusive license (for which the Company will receive no current or future payments) that permits Teva to first begin selling the generic version of the Company s 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).

Alvogen

On September 7, 2018, the Company filed a complaint for patent infringement in Delaware against Alvogen Pb Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Incorporated, and Alvogen Group, Incorporated (collectively, Alvogen), asserting that Alvogen infringes the Company s Orange Book listed patents for BELBUCA®, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539, expiring in December of 2032. This complaint follows receipt by the Company on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating that Alvogen had filed an ANDA with the FDA for a generic version of BELBUCA® Buccal Film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg). Because the Company initiated a patent infringement suit to defend the patents identified in the Paragraph IV notice within 45 days after receipt of the Paragraph IV Certification, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. Alvogen s notice letter also does not provide any information on the timing or approval status of its ANDA.

In its Paragraph IV Certification, Alvogen does not contest infringement of at least several independent claims of each of the 866, 843, and 539 patents. Rather, Alvogen advances only invalidly arguments for these independent claims. The Company believes that it will be able to prevail on its claims of infringement of these patents, particularly as Alvogen does not contest infringement of certain claims of each patent. Additionally, as the Company has done in the past, it intends to vigorously defend its intellectual property against assertions of invalidity. Each of the three patents carry a presumption of validity, which can only be overcome by clear and convincing evidence.

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. The Company was served with the complaint on April 27, 2018. The complaint

specifically alleged that the Company 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. Therefore, on June 28, 2018, the Company moved to dismiss the case against them and on July 6, 2018, the plaintiffs filed a notice to voluntarily dismiss the Company from the Arkansas case, without prejudice.

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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.

Third Quarter and Recent Highlights

- On August 2, 2018, in connection with our 2018 Annual Meeting of Stockholders, our stockholders approved, among other matters, (i) to amend our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 75,000,000 to 125,000,000; and (ii) to ratify the newly designated sale of our 5,000 shares of Series B Preferred Stock, par value $0.001 per share, and to approve the issuance of Common Stock issuable upon the conversion of the Series B Preferred Stock as required by and in accordance with NASDAQ Marketplace Rule 5635(d).

On August 15, 2018, we announced that a leading U.S. pharmacy benefit manager had added BELBUCA® to its national preferred formulary list effective August 15, 2018. Under this preferred access plan, over 20 million covered lives will now have easier access to this important treatment option for chronic pain and will no longer need to go through a step through process. The addition of this plan expands the total number of lives with preferred access for BELBUCA® to over 75 million.

On October 29, 2018, we announced the appointment of James Vollins as General Counsel and member of our Executive Leadership Team effective November 5, 2018. Mr. Vollins will also serve as our Chief Compliance Officer and Corporate Secretary. We also announced the retirement of Ernest R. DePaolantonio, Chief Financial Officer and Corporate Secretary, which is expected to occur by mid-2019. And lastly, we announced the enhanced title of Scott Plesha to President and Chief Commercial Officer of the Company.

On November 1, 2018, we announced that a leading U.S. pharmacy benefit manager had added BELBUCA® to their national preferred formulary list. More than 100 million covered lives now have preferred access to BELBUCA®.

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

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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, 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 in January 2018 and again in September to support the commercialization efforts. BELBUCA® and BUNAVAIL® are currently supported by a field force of approximately 113 sales representatives, thirteen regional sales managers and two area directors. 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® as Schedule III offers over Schedule II opioids, such as oxycodone, hydrocodone, morphine, etc., include higher safety index, lower addiction, diversion and abuse risks accompanied by a dose-ceiling effect on respiratory depression, but not on analgesia. 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 demonstrating 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 on the number of buprenorphine-treated patients per practitioner from 100 to 275 (as outlined in the final ruling under the Drug Addiction Treatment Act of 2000 (DATA 2000) and effective on October 27, 2016), and a 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 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) and South Korea. 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®. 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 commercialize ONSOLIS® 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 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. Previous efforts to extend our supply agreement with our original ONSOLIS® manufacturer Aveva, who was subsequently acquired by Apotex, were unsuccessful and the agreement expired. However, an alternate supplier was identified and data to support qualification of the new manufacturer was submitted to the FDA in June 2018. On October 22, 2018, we received notification of FDA s approval of the regulatory submission and the new ONSOLIS® manufacturer. We are currently assessing options to commercialize ONSOLIS® including partnership or introducing ONSOLIS® utilizing the company s existing pain sales force.

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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 can provide 30 days of continuous buprenorphine treatment. 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.

Results of Operations

Comparison of the three months ended September 30, 2018 and 2017

Product Sales. We recognized $13.8 million and $8.1 million in product sales during the three months ended September 30, 2018 and 2017, respectively. The increase is principally due to increased BELBUCA® product sales from the utilization of managed care wins and the expansion of our salesforce in 2018.

Product Royalty Revenues. We recognized $0.4 million and $1.4 million in product royalty revenue during the three months ended September 30, 2018 and 2017, respectively. Of the amounts, $0.4 million and $0.9 million, respectively, can be attributed to royalties on net sales of BREAKYL under our license agreement with Meda. We also recognized $0.5 million in PAINKYL royalty revenue in each of the respective three months ended September 30, 2017, under our license agreement with TTY. The revenue decrease is principally due to lower BREAKYL and PAINKYL royalty revenue during the three months ended September 30, 2018 as compared to September 30, 2017 because of delay in shipments of BREAKYL in the EU and PAINKYL in Taiwan which will occur in the fourth quarter 2018.

Research and Development Reimbursements. We recognized $0.5 million of reimbursable revenue related to our former agreement with Collegium Pharmaceutical Inc. (Collegium) during the three months ended September 30, 2017. There was no such revenue recognized during the same period ended September 30, 2018, as Collegium terminated their agreement December 2017, which was effective March 2018.

Contract Revenues. We recognized $0.015 million and $0.08 million in contract revenues during the three months ended September 30, 2018 related to our license agreements with Purdue Canada (Purdue) and TTY, respectively. We recognized $1.2 million in contract revenue during the three months ended September 30, 2017 upon execution of our license agreement with Purdue.

Cost of Sales. We incurred $3.8 million and $4.4 million in cost of sales during the three months ended September 30, 2018 and 2017, respectively. Cost of sales during the three months ended September 30, 2018 was related primarily to BELBUCA® and BUNAVAIL®, which included $3.3 million of product cost 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 September 30, 2018 also included $0.1 million related to BREAKYL and PAINKYL. Cost of sales during the three months ended September 30, 2017 was related primarily to BELBUCA® and BUNAVAIL®, which included $2.8 million of product cost, royalties paid and depreciation, and $0.7 million of fair value of the inventory

purchased related to the BELBUCA® reacquisition. Additionally, we paid a total of $0.4 million in quarterly minimum royalty payments to CDC. Cost of sales during the three months ended September 30, 2017 also included $0.5 million related to BREAKYL and PAINKYL.

Selling, General and Administrative Expenses. During the three months ended September 30, 2018 and 2017, general and administrative expenses totaled $13.5 million and $14.9 million, respectively. Selling, general and administrative costs include commercialization costs for BELBUCA® and BUNAVAIL®, legal, accounting and management wages, and consulting and professional fees, travel costs, amortization and stock compensation expenses. During the normal course of business, we accrue additional expenses for certain legal matters from time to time, including legal matters related to the protection and enforcement of our intellectual property. The amounts accrued for such legal matters are recorded within accrued expenses on the balance sheet. The decrease in selling, general and administrative expenses during 2018 can be primarily attributed to the settlement of the Teva lawsuit which reduced legal costs and the retirement of company executives which reduced stock compensation expenses.

During the three months ended September 30, 2018 and 2017, selling, general and administrative expenses included $0.9 million and $3.7 million of stock compensation expenses, respectively. This is primarily composed of restricted stock unit

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expense for our executive management and board of directors. Also included in each of the three months ended September 30, 2018 and 2017 is amortization expense of $1.1 million for the intangible related to the BELBUCA® reacquisition.

Interest expense. During the three months ended September 30, 2018, we had net interest expense of $2.6 million, consisting of $1.4 million of scheduled interest payments, $0.9 million of related amortization of discount and loan costs and $0.3 million of warrant interest expense. During the three months ended September 30, 2017, we had net interest expense of $1.9 million, consisting of $1.4 million of scheduled interest payments, $0.3 million of related amortization of discount and loan costs and $0.2 million of warrant interest expense, all related to the February 2017 CRG Term Loan Agreement.

Comparison of the nine months ended September 30, 2018 and 2017

Product Sales. We recognized $34.4 million and $23.8 million in product sales during the nine months ended September 30, 2018 and 2017, respectively. The increase is principally due to increased BELBUCA® product sales from the utilization of managed care wins and the expansion of our salesforce in 2018. Also included in the product sales during the nine months ended September 30, 2017 is $1.7 million of revenue recorded because of changing to the sell-in method as of January 1, 2017.

Product Royalty Revenues. We recognized $2.2 million and $3.7 million in product royalty revenue during the nine months ended September 30, 2018 and 2017, respectively. Of the amounts, $1.3 million and $2.1 million, respectively, can be attributed to royalty revenue from BREAKYL under our license agreement with Meda. We recognized $0.9 million in each of the nine months ended September 30, 2018 and 2017 in PAINKYL royalty revenue under our license agreement with TTY. We also recognized $0.7 million in milestones related to our agreement with Endo during the nine months ended September 30, 2017. The revenue decrease is principally due to lower BREAKYL and PAINKYL royalty revenue during the nine months ended September 30, 2018 as compared to September 30, 2017 because of delay in shipments of BREAKYL in the EU and PAINKYL in Taiwan which will occur in the fourth quarter 2018.

Research and Development Reimbursements. We recognized $0.8 million of reimbursable revenue related to our agreement with Collegium during the nine months ended September 30, 2017. There was no such revenue recognized during the same period ended September 30, 2018, as Collegium terminated their agreement December 2017, which was effective March 2018.

Contract Revenues. We recognized $1.0 million in contract revenue during the nine months ended September 30, 2018 related to our license agreement with Purdue, which was for the Canadian commercial launch and related milestones. We recognized $20.0 million of deferred revenue during the nine months ended September 30, 2017. The $20.0 million recognized in 2017 was received in November 2015 as partial payment from Endo for the BELBUCA® NDA approval. This amount was deferred upon receipt 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 and such deferred revenue was recognized. We also recognized $1.2 million in contract revenue during the nine months ended September 30, 2017 related to our license agreement with Purdue.

Cost of Sales. We incurred $11.8 million and $14.3 million in cost of sales during the nine months ended September 30, 2018 and 2017, respectively. Cost of sales during the nine months ended September 30, 2018 was $9.9 million for both BELBUCA® and BUNAVAIL®. Additionally, we paid a total of $1.1 million in quarterly minimum and royalty payments to CDC. Cost of sales during the nine months ended September 30, 2018 also

includes $0.8 million related to BREAKYL and PAINKYL. Cost of sales during the nine months ended September 30, 2017 was $9.5 million for both BELBUCA® and BUNAVAIL®. Such product costs include manufacturing, royalties and depreciation and $2.8 million of fair value of the inventory purchased related to the BELBUCA® reacquisition. Additionally, we paid a total of $1.1 million in quarterly minimum and royalty payments to CDC. Cost of sales during the nine months ended September 30, 2017 also includes $0.9 million related to BREAKYL and PAINKYL.

Selling, General and Administrative Expenses. During the nine months ended September 30, 2018 and 2017, general and administrative expenses totaled $41.0 million and $44.1 million, respectively. Selling, general and administrative costs include commercialization costs for BELBUCA® and BUNAVAIL®, management wages and stock-based compensation, legal, accounting and other professional fees, travel costs, and the amortization of our intangible assets including the license and distribution rights from the reacquisition of BELBUCA® as noted above. During the normal course of business, we accrue additional expenses for certain legal matters from time to time, including legal matters related to the protection and enforcement of our intellectual property. The amounts accrued for such legal matters are recorded within accrued expenses on the balance sheet. The decrease in selling, general and administrative expenses during 2018 can be primarily attributed to the settlement of the Teva lawsuit which reduced legal costs and the retirement of company executives which reduced stock compensation expenses.

During the nine months ended September 30, 2018 and 2017, selling, general and administrative expenses included $3.8 million and $8.9 million of stock compensation expenses, respectively. This is primarily composed of restricted stock unit expense for our

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executive management and board of directors. Also included in each of the nine months ended September 30, 2018 and 2017 is amortization expense of $3.4 million for the intangible related to the BELBUCA® reacquisition.

Interest expense. During the nine months ended September 30, 2018, we had net interest expense of $7.6 million, consisting of $4.6 million of scheduled interest payments, $2.2 million of related amortization of discount and loan costs and $0.8 million of warrant interest expense. During the nine months ended September 30, 2017, we had net interest expense of $6.7 million, consisting of $2.9 million of scheduled interest payments and $0.8 million of related amortization of discount and loan costs and $0.4 million of warrant interest expense all related to the February 2017 CRG Term Loan Agreement. In addition, we had remaining $0.9 million of scheduled interest payments and $1.4 million of related amortization of discount, loan costs and loan pay off and $0.2 million of warrant interest expense all 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 and nine-month periods ended September 30 in thousands:

	Three months ended September 30,		Nine months ended September 30,	
	2018	**2017**	**2018**	**2017**
BELBUCA®	$ 12,358	$ 6,437	$ 30,128	$ 17,554
% of net product sales	*90%*	*79%*	*88%*	*74%*
BUNAVAIL®	1,405	1,681	4,239	6,224
% of net product sales	*10%*	*21%*	*12%*	*26%*
Net product sales	$ 13,763	$ 8,118	$ 34,367	$ 23,798

Expenditures for Research and Development Programs

Our research and development expenditures for our approved products and product candidates as of September 30 are as follows in thousands:

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative through September 30,
	2018	**2017**	**2018**	**2017**	**2018**
BELBUCA®	$ 621	$ 126	$ 3,082	$ 733	$ 125,779
BUNAVAIL®	41	702	312	2,474	41,197
ONSOLIS®	62	1,118	536	1,744	3,590
Buprenorphine Depot Injection	(28)	(6)	94	1,015	9,879
Clonidine Topical Gel*	3	46	14	280	27,533

* 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.

Non-GAAP (Loss) Income and Earnings Per Common Share:

Non-GAAP (loss) income and EPS are alternative views of our performance that we are providing because management believes this information enhances investors understanding of our results as it permits investors to understand how management assesses performance. Non-GAAP (loss) income and EPS excludes certain one-time items because of the nature of the item and the impact that is has on the analysis of underlying business performance and trends. In the presentation of non-GAAP (loss) income and EPS below, we have excluded the Series B Preferred Stock beneficial conversion feature, which was approved in August 2018, as it is non-recurring. This excluded item is a significant component in understanding and assessing financial performance. Non-GAAP (loss) income and EPS is an important internal measure for our Company. Senior management receives a monthly analysis of operating results that includes non-GAAP (loss) income and EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of our Company along with other metrics. Since non-GAAP (loss) income and EPS are not measures determined in accordance with GAAP, it has no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The non-GAAP (loss) income and EPS measures should be

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considered in addition to, but not as a substitute for or superior to, (loss) income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP).

Reconciliations to most directly comparable U.S. GAAP financial measures:

The following table reconciles net (loss) income and the numerators and denominators of the basic and diluted earnings per common share computations (in thousands, except share and per share data) under GAAP to a Non-GAAP basis.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Basic:				
Net (loss) income under GAAP	$ (18,880)	$ (11,951)	$ (39,359)	$ 21,495
Adjustment to beneficial conversion feature of convertible preferred stock	12,500		12,500	
Net (loss) income attributable to common stockholders Non-GAAP	(6,380)	(11,951)	(26,859)	21,495
Weighted average common shares outstanding	64,900,007	55,604,708	60,599,456	55,170,569
Basic (loss) income per common share	**$ (0.10)**	**$ (0.21)**	**$ (0.44)**	**$ 0.39**
Diluted:				
Effect of dilutive securities:				
Net (loss) income under GAAP	$ (18,880)	$ (11,951)	$ (39,359)	$ 21,495
Adjustment to beneficial conversion feature of convertible preferred stock	12,500		12,500	
Net (loss) income attributable to common stockholders Non-GAAP	(6,380)	(11,951)	(26,859)	21,495
Weighted average common shares outstanding	64,900,007	55,604,708	60,599,456	55,170,569
Effect of dilutive options and warrants				1,033,789
Diluted weighted average common shares outstanding	64,900,007	55,604,708	60,599,456	56,204,358
Diluted (loss) income per common share	**$ (0.10)**	**$ (0.21)**	**$ (0.44)**	**$ 0.38**

The following table reconciles GAAP diluted EPS to Non-GAAP diluted EPS for the three and nine months ended September 30, 2018 and 2017 follows:

	Three months ended September 30,		Nine months ended September 30,	
	2018	**2017**	**2018**	**2017**
Diluted EPS under GAAP	$ (0.29)	$ (0.21)	$ (0.65)	$ 0.38
Diluted EPS adjustment to beneficial conversion feature of convertible preferred stock	0.19		0.21	
Diluted EPS Non-GAAP	**$ (0.10)**	**$ (0.21)**	**$ (0.44)**	**$ 0.38**

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 September 30, 2018, we had cash of approximately $49.5 million. We used $18.3 million of cash in operations during the nine months ended September 30, 2018 and had stockholders equity of $35.6 million, versus stockholders equity of $8.9 million at December 31, 2017. We believe that we have sufficient current cash to manage the business as currently planned into the second

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quarter of 2020, which would provide sufficient capital necessary to support the continued commercialization of BELBUCA® and BUNAVAIL®.

Additional capital may 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. 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. 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 September 30, 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	$ 1,386	$ 348	$ 725	$ 313	$
Secured loan facility*	66,315			66,315	
Interest on secured loan facility*	25,161	5,663	5,883	13,615	
Minimum royalty expenses**	13,125	1,125	3,000	3,000	6,000
Purchase obligations***	1,508	493	1,015		
Total contractual cash obligations	$ 107,495	$ 7,629	$ 10,623	$ 83,243	$ 6,000

* Assumes no events of default have occurred and we elect to defer 3.5% of the scheduled quarterly interest payments through December 31, 2020 as paid-in-kind interest as provided for in the amendments to the loan agreement with CRG.

** Minimum royalty expenses represent a contractual floor that we are obligated to pay CDC and NB Athyrium LLC regardless of actual sales. The minimum payment is $0.4 million per quarter or $1.5 million per year until patent expiry on July 23, 2027.

*** Purchase obligations represent an agreement for the supply of active pharmaceutical ingredient for use in production.

Off-Balance Sheet Arrangements

As of September 30, 2018, we had no off-balance sheet arrangements.

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Effects of Inflation

We do not believe that inflation has had a material effect on our financial position or results of operations. However, there can be no assurance that our business will not be affected by inflation in the future.

Critical Accounting Policies

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

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

potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

Based on this evaluation, the Certifying Officers have concluded that our disclosure controls and procedures were effective as of September 30, 2018.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our third 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,

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and results of, scheduled or additional clinical trials and the FDA s review and/or approval and commercial activities for our products and product candidates and regulatory filings related to the same or (iv) the results of our ongoing intellectual property litigations and patent office proceedings, may differ significantly from those set forth or anticipated in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1A of our 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.

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

Litigation related to BUNAVAIL®

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 January 22, 2014, Aquestive initiated an *inter partes* review (IPR) 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 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 June 6, 2016, in an unrelated case in which Indivior and Aquestive asserted the 832 Patent against other parties, the Delaware District Court entered an order invalidating other claims in the 832 Patent. Indivior and Aquestive cross-appealed all adverse findings in that decision to the Court of Appeals for the Federal Circuit in Case No. 17-2587. Our declaratory judgment action remains stayed pending the outcome of that cross-appeal by Indivior and Aquestive.

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.

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 decisions in March 2016. We appealed to Court of Appeals for the Federal Circuit. The USPTO intervened with respect to whether collateral estoppel applied to the

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PTAB. On June 19, 2018, we filed a motion to remand the case for further consideration by the PTAB in view of intervening authority. On July 31, 2018, the Federal Circuit vacated the decisions, and remanded the 167 Patent IPRs for further consideration on the merits.

Litigation related to BELBUCA®

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. On July 25, 2017, the New Jersey 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 was later transferred to the 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. On October 16, 2018, denying the motion to dismiss as moot, the Delaware District Court granted our motion to transfer the case to the EDNC. The case is now pending in the EDNC. 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 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 U.S. Patent No. 7,579,019 (the 019 Patent), U.S. Patent No. 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) relating to the BEMA® technology, 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.

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 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, 2017 in 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) relating to the BEMA® technology, 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.

Alvogen

On September 7, 2018, we filed a complaint for patent infringement in Delaware against Alvogen Pb Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Incorporated, and Alvogen Group, Incorporated (collectively, Alvogen), asserting that Alvogen infringes our Orange Book listed patents for BELBUCA®, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539, expiring in December of 2032. This complaint follows receipt by us on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating that Alvogen had filed an ANDA with the FDA for a generic version of BELBUCA® Buccal Film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg). Because we initiated a patent infringement suit to defend the patents identified in the Paragraph IV notice within 45 days after receipt of the Paragraph IV Certification, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. Alvogen s notice letter also does not provide any information on the timing or approval status of its ANDA.

In its Paragraph IV Certification, Alvogen does not contest infringement of at least several independent claims of each of the 866, 843, and 539 patents. Rather, Alvogen advances only invalidly arguments for these independent claims. We believe that we will be able to prevail on our claims of infringement of these patents, particularly as Alvogen does not contest infringement of certain claims of each patent. Additionally, as we have done in the past, we intend to vigorously defend our intellectual property against assertions of invalidity. Each of the three patents carry a presumption of validity, which can only be overcome by clear and convincing evidence.

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 alleged that we licensed our 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. Therefore, on June 28, 2018, we moved to dismiss the case against us and most recently, on July 6, 2018, the plaintiffs filed a notice to voluntarily dismiss us from the Arkansas case, without prejudice.

Item 1A. Risk Factors.
No update.

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

Item 3. Defaults upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
Not applicable.

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Item 5. Other Information.

None.

Item 6. Exhibits.

Number	Description
3.1	Certificate of Amendment to the Company s Certificate of Incorporation to declassify board of directors, clarify voting standards and increase the number of authorized shares, dated August 6, 2018 (1)
10.1	Conditional Offer of Employment, dated July 20, 2018, between the Company and Thomas Smith *
10.2	Form of Incentive Stock Option Agreement under the 2011 Equity Incentive Plan.*
10.3	Form of Nonqualified Stock Option Agreement for Company Employees under the 2011 Equity Incentive Plan*
10.4	Form of Nonqualified Stock Option Agreement for Non-Employee Directors under the 2011 Equity Incentive Plan*
10.5	Form of Restricted Stock Unit Award Agreement for Company Employees under the 2011 Equity Incentive Plan*
10.6	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under the 2011 Equity Incentive Plan*
10.7	Form of Performance Restricted Stock Unit Award Agreement for Company Employees under the 2011 Equity Incentive Plan*
31.1	Certification of Principal Executive Officer Pursuant To Sarbanes-Oxley Section 302. (*)
31.2	Certification of Principal 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.

* Filed herewith, 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.

(1) Previously filed as an exhibit to the Company s Current Report on Form 8-K filed on August 6, 2018.

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SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: November 8, 2018

By: /s/ Herm Cukier
Herm Cukier
Chief Executive Officer and Director

(Principal Executive Officer)

Date: November 8, 2018

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

(Principal Financial and Accounting Officer)