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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

☐ **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 ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001	BDSI	The Nasdaq Capital Market

As of May 6, 2019, there were 87,418,253 shares of company Common Stock issued and 87,402,762 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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From time to time, we may use our website, our Facebook page at Facebook.com/BioDeliverySI and on Twitter at @BioDeliverySI to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at **www.bdsi.com**. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website, our Facebook page and our Twitter posts are not incorporated into, and does not form a part of, this Quarterly Report.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)
(Unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash	$ 41,329	$ 43,822
Accounts receivable, net	16,008	13,627
Inventory, net	7,259	5,406
Prepaid expenses and other current assets	2,970	3,188
Total current assets	67,566	66,043
Property and equipment, net	3,952	3,072
Goodwill	2,715	2,715
BELBUCA license and distribution rights, net	34,875	36,000
Other intangible assets, net	539	703
Total assets	$ 109,647	$ 108,533
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 23,484	$ 21,539
Total current liabilities	23,484	21,539
Notes payable, net	52,286	51,652
Other long-term liabilities	6,355	5,600
Total liabilities	82,125	78,791
Commitments and contingencies (Note 11)		
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 March 31, 2019 and December 31, 2018, respectively; Series B Non-Voting Convertible Preferred Stock, $.001 par value, 2,400 and 3,100 shares outstanding at March 31, 2019 and December 31, 2018, respectively.	2	2
Common Stock, $.001 par value; 125,000,000 shares authorized at March 31, 2019 and December 31, 2018, respectively; 75,333,254 and 75,793,725 shares issued;75,317,763 and 70,778,234 shares outstanding at March 31, 2019 and December 31, 2018, respectively.	74	71
Additional paid-in capital	382,614	381,004
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(355,121)	(351,288)
Total stockholders' equity	27,522	29,742
Total liabilities and stockholders' equity	$ 109,647	$ 108,533

See notes to condensed consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Product sales	$ 19,759	$ 9,838
Product royalty revenues	2	440
Contract revenue	8	1,003
Total revenues	19,769	11,281
Cost of sales	4,052	3,415
Expenses:		
Research and development	—	2,484
Selling, general and administrative	16,989	13,505
Total expenses	16,989	15,989
Loss from operations	(1,272)	(8,123)
Interest expense, net	(2,561)	(2,505)
Other expense, net	—	(7)
Loss before income taxes	$ (3,833)	$ (10,635)
Income tax expense	—	(74)
Net loss attributable to common stockholders	$ (3,833)	$ (10,709)
Basic and diluted:		
Weighted average common stock shares outstanding	71,344,831	58,062,997
Basic and diluted loss per share	$ (0.05)	$ (0.18)

See notes to condensed consolidated financial statements

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 Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances, January 1, 2019	2,093,155	$ 2	3,100	$ —	70,793,725	$ 71	$381,004	$ (47)	$ (351,288)	$ 29,742
Stock-based compensation	—	—	—	—	—	—	1,141	—	—	1,141
Stock option exercises	—	—	—	—	150,275	—	472	—	—	472
Restricted stock awards	—	—	—	—	500,366	(1)	1	—	—	—
Series B conversion to Common Stock	—	—	(700)	—	3,888,888	4	(4)	—	—	—
Net loss	—	—	—	—	—	—	—	—	(3,833)	(3,833)
Balances, March 31, 2019	2,093,155	$ 2	2,400	$ —	75,333,254	$ 74	$382,614	$ (47)	$ (355,121)	$ 27,522

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

See notes to condensed consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. DOLLARS, IN THOUSANDS)
(Unaudited)

	Three months ended March 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (3,833)	$(10,709)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation	85	230
Accretion of debt discount and loan costs	634	625
Amortization of intangible assets	1,289	1,289
Provision (benefit) for inventory obsolescence	149	(66)
Stock-based compensation expense	1,141	2,921
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(2,381)	864
Inventories	(2,002)	716
Prepaid expenses and other assets	218	782
Accounts payable and accrued expenses	1,814	(3,413)
Net cash flows from operating activities	(2,886)	(6,761)
Investing activities:		
BELBUCA acquisition	—	(1,951)
Purchase of equipment	—	(73)
Disposal of property and equipment	(79)	—
Net cash flows from investing activities	(79)	(2,024)
Financing activities:		
Proceeds from exercise of stock options	472	130
Payment of deferred financing fees	—	(450)
Net cash flows from (used in) financing activities	472	(320)
Net change in cash and cash equivalents	(2,493)	(9,105)
Cash and cash equivalents at beginning of period	43,822	21,195
Cash and cash equivalents at end of period	**$41,329**	**$ 12,090**
Cash paid for interest	$ 1,931	$ 1,880

See notes to condensed consolidated financial statements

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 rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic pain and associated conditions. The Company has built a portfolio of products that includes utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA) drug-delivery technology to develop and commercialize new applications of proven therapies aimed at addressing important unmet medical needs. The Company commercializes in the United States using its own sales force while working in partnership with third parties to commercialize its products outside the United States.

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, 2018 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, 2018. 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 recommended 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, 2018.

Operating results for the three-month period ended March 31, 2019 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 consolidated financial statements 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 relating to 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 $0.3 million and $0.2 million for inventory obsolescence as of March 31, 2019 and December 31, 2018, respectively.

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

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 the PAINKYL product under the Company's license agreement with TTY and the BREAKYL product under the Company's license agreement with Meda AB, which was acquired by Mylan N.V. (which we refer to herein as Mylan). 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.

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. 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, vouchers 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(Unaudited)

1. Nature of business and summary of significant accounting policies (continued):

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

adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated to be in the distribution channel. 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.

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.

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

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

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

Prompt payment discounts-The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within a prescribed number of days after the invoice date depending on the customer and the products purchased.

Gross to net accruals-A significant majority of the Company's gross to net adjustments to gross product revenues are the result of accruals for its voucher program and rebates related to Medicare Part D, Part D Coverage Gap, Medicaid and commercial contracts, with most of those programs having an accrual to payment cycle of anywhere from one to three months. In addition to this relatively short accrual to payment cycle, the Company receives daily information from the wholesalers regarding their sales of the Company's products and actual on hand inventory levels of its products. This enables the Company to execute accurate provisioning procedures. Consistent with the pharmaceutical industry, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products.

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. Yield losses and batches not meeting specifications are expensed as incurred. Cost of sales is recognized when sold to the wholesaler from our distribution center.

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):

For BREAKYL and PAINKYL (the Company's out-licensed breakthrough cancer pain therapies), cost of sales includes all costs related to creating the product at the Company's contract manufacturing location in Germany. The Company's contract manufacturer bills the Company for the final product, which includes materials, direct labor costs, and certain overhead costs as outlined in applicable supply agreements.

Cost of sales also includes royalty expenses that the Company owes to third parties.

Research and development

As of January 1, 2019, the Company has focused entirely on commercialized products rather than research and development. As such, there were no expenses incurred in research and development during the three months ended March 31, 2019. Research and development expense for the three months ended March 31, 2018 was $2.5 million.

Recent accounting pronouncements-adopted

On January 1, 2019, the Company adopted Topic 842, which is intended to improve financial reporting about leasing transactions. Under the standard, organizations that lease assets, referred to as "Lessees" shall recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. In addition, the standard requires disclosures including financial statements to assess the amount, timing and uncertainty of cash flows arising from leases.

The Company elected to use the practical expedients permitted under the transition guidance within the new standard, which among other things, allows the Company to carryforward the historical lease classification. The Company made an accounting policy election to account for leases with an initial term of 12 months or less similar to existing guidance for operating leases today. The Company recognized those lease payments in the condensed Consolidated Statements of Operations on a straight-line basis over the lease term. As of March 31, 2019, the Company has approximately $1.2 million in future minimum lease commitments. Under the new standard, the Company's lease liability is based on the present value of such payments and the related right-of-use asset will generally be based on the lease liability.

Upon adoption, the Company recorded the right-of-use lease assets of $0.9 million and liabilities of $1.0 million which were recorded in the condensed consolidated balance sheet on January 1, as summarized below.

The impact of the adoption of Topic 842 on the accompanying condensed Consolidated Balance Sheet as of January 1, 2019 is as follows (in thousands):

	December 31, 2018	Adjustments Due to the Adoption of Topic 842		January 1, 2019
		Right-of-use-asset	Lease liability	
Property and equipment, net	$ 3,072	$ 939	—	$ 4,011
Current liabilities	$ 21,539	—	$ 212	$ 21,751
Other long-term liabilities	$ 5,600	—	$ 822	$ 6,422

The components of lease expense were as follows:

	Three Months Ended March 31 2019	2018
Lease Cost		
Operating lease cost		
Operating lease	$ 82	$ 81
Variable lease costs	5	1
Total lease cost	$ 87	$ 82

The additional disclosures required by ASU 2016-02 have been included in Note 2 Leases.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(Unaudited)

2. Leases:

Supplemental cash flow information related to leases were as follows:

	Three Months Ended March 31	
	2019	2018
Other Information		
Cash paid for amounts included in the measurement of lease liabilities Operating cash flows from operating leases	$ 87	$ 82

	Three Months Ended March 31	
	2019	2018
Lease Term and Discount Rate		
Weighted-average remaining lease term Operating leases	3.3 years	4.3 years
Weighted-average discount rate Operating leases	11.8%	11.8%

Maturity of Lease Liabilities

Future minimum lease payments under non-cancellable leases as of March 31, 2019 were as follows:

Maturity of Lease Liabilities	
2019	$ 264
2020	360
2021	370
2022	219
Total lease payments	$ 1,213
Less: Interest	(207)
Present value of lease liabilities	$ 1,006

Components of Lease Assets and Liabilities

	March 31, 2019
Assets	
Property and equipment, net Operating lease-right of use asset	$ 887
Liabilities	
Current liabilities Operating lease- current liability	$ 251
Other long-term liabilities Operating lease- noncurrent liability	$ 755
Total lease liabilities	$ 1,006

3. Liquidity and management's plans:

At March 31, 2019, the Company had cash of approximately $41.3 million. The Company used $2.9 million of cash in operations during the three months ended March 31, 2019 and had stockholders' equity of $27.5 million, versus stockholders' equity of $29.7 million at December 31, 2018. The Company believes that it has sufficient current cash to manage the business as currently planned.

The Company's cash on hand estimation 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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(Unaudited)

3. Liquidity and management's plans (continued):

(including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all, which could leave the Company without adequate capital resources.

4. Inventory:

The following table represents the components of inventory as of:

	March 31, 2019	December 31, 2018
Raw materials & supplies	$ 1,043	$ 645
Work-in-process	3,154	2,093
Finished goods	3,398	2,855
Obsolescence reserve	(336)	(187)
Total inventories	$ 7,259	$ 5,406

5. Accounts payable and accrued liabilities:

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

	March 31, 2019	December 31, 2018
Accounts payable	$ 2,672	$ 3,166
Accrued rebates	14,524	12,261
Accrued compensation and benefits	3,106	3,814
Accrued acquisition costs	—	318
Accrued returns	677	715
Accrued royalties	562	159
Accrued clinical trial costs	—	464
Accrued legal	382	70
Accrued regulatory expenses	537	—
Accrued other	1,024	572
Total accounts payable and accrued liabilities	$ 23,484	$ 21,539

6. Property and equipment:

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

	March 31, 2019	December 31, 2018
Machinery & equipment	$ 5,635	$ 5,635
Right of use, building lease	886	—
Computer equipment & software	406	406
Office furniture & equipment	155	155
Leasehold improvements	43	43
Idle equipment	679	679
Total	7,804	6,918
Less accumulated depreciation and amortization	(3,852)	(3,846)
Total property and equipment, net	$ 3,952	$ 3,072

Depreciation expense was $0.09 million and $0.2 million for the three-month periods ended March 31, 2019 and 2018, respectively.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(Unaudited)

7. License agreements and acquired product rights:

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 $0.4 million from TTY during the three month periods ended March 31, 2018 related to royalties based on product purchased in Taiwan by TTY of PAINKYL which is recorded in the accompanying condensed consolidated statement of operations. There were no royalties received from TTY during the three months ended March 31, 2019.

8. Notes payable:

The following table represents future maturities of the notes payable obligation as of March 31, 2019:

2019	—
2020	—
2021	30,892
2022	30,892
Total maturities	$61,784
Unamortized discount and loan costs	(9,498)
Total notes payable obligation	$52,286

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 March 31,	
	2019	**2018**
BELBUCA	$ 18,703	$ 8,024
BUNAVAIL	1,056	1,814
Net product sales	$ 19,759	$ 9,838

10. Stockholders' equity:

Stock-based compensation

During the three months ended March 31, 2019, a total of 2,031,033 options to purchase Common Stock, with an aggregate fair market value of approximately $4.1 million, were granted to employees and officers of the Company. 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 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 three months ended March 31, 2019 follows:

Expected price volatility	61.83%-62.04%
Risk-free interest rate	2.41%-2.66%
Weighted average expected life in years	6 years
Dividend yield	—

Option activity during the three months ended March 31, 2019 was as follows:

	Number of shares	Weighted average exercise price per share	Aggregate intrinsic value
Outstanding at January 1, 2019	4,406,004	$ 3.19	$ 4,172
Granted in 2019:			
Officers and Directors	1,113,516	3.88	
Employees	917,517	4.51	
Exercised	(150,275)	3.14	
Forfeitures	(10,423)	2.18	
Outstanding at March 31, 2019	6,276,399	$ 3.50	$ 12,209

During the three months ended March 31, 2019, a cumulative total of 481,898 options were granted in excess of the Company's 2011 Equity Incentive Plan, as amended (the "EIP") available number of shares under the plan. These options are subject to shareholder approval at the Company's 2019 Annual Shareholder's Meeting.

As of March 31, 2019, options exercisable totaled 1,780,405. There are approximately $10.6 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 three months ended March 31, 2019, a cumulative total of 270,250 RSUs were granted to the Company's executive officers, members of senior management and a former officer with a fair market value of approximately $1.2 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 EIP.

RSU grants are time-based, all of which generally vest over a three-year period. The RSU grant to the former officer vested on his retirement date April 30, 2019.

Restricted stock activity during the three months ended March 31, 2019 was as follows:

	Number of restricted shares	Weighted average fair market value per RSU
Outstanding at January 1, 2019	2,166,102	$ 2.59
Granted:		
Executive officers	223,250	4.44
Employees	47,000	4.67
Vested	(500,366)	4.90
Outstanding at March 31, 2019	1,935,986	$ 2.98

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10. Stockholders' equity (continued):

Preferred Stock

During the three months ended March 31, 2019, 700 shares of Series B Preferred Stock ("Series B") were converted into 3,888,888 shares of Common Stock. As of March 31, 2019, 2,400 shares of Series B are outstanding. As of March 31, 2019, 2,093,155 shares of Series A Preferred Stock ("Series A") are outstanding. There were no conversions of Series A during the three months ended March 31, 2019.

Earnings Per Share

During the three months ended March 31, 2019 and 2018, outstanding stock options, RSUs, warrants and preferred shares of 24,743,605 and 10,243,260 , respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect.

11. 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)

The following disclosure regarding the Company's ongoing litigations with Aquestive Therapeutics, Inc. (formerly MonoSol Rx, "Aquestive") and Indivior PLC (formerly RB Pharmaceuticals Limited, "Indivior") is intended to provide some background and an update on the matter as required by the rules of the SEC. Additional details regarding the past procedural history of the matter can be found in the Company's previously filed periodic filings with the SEC.

Litigation related to BUNAVAIL

On October 29, 2013, Reckitt Benckiser, Inc., Indivior, and Aquestive (collectively, the "RB Plaintiffs") filed an action against the Company relating to its BUNAVAIL product in the United States District Court for the Eastern District of North Carolina ("EDNC") for alleged patent infringement. BUNAVAIL is a drug approved for the maintenance treatment of opioid dependence. The RB Plaintiffs claim that the formulation for BUNAVAIL, which has never been disclosed publicly, infringes its US Patent No. 8,475,832 (the "'832 Patent"). On May 21, 2014, the Court granted the Company's motion to dismiss.

On January 22, 2014, Aquestive initiated an inter partes review ("IPR") on U.S. Patent No. 7,579,019, the ("'019 Patent"). The PTAB upheld all claims of the Company's '019 Patent in 2015 and this decision was not appealed by Aquestive.

On September 20, 2014, the Company proactively filed a declaratory judgment action in the United States District Court for the EDNC requesting the Court to make a determination that the Company's 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"). The Company invalidated the "'080 Patent" in its entirety in an inter partes reexamination proceeding. The Company invalidated all relevant claims of the '832 Patent in an 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. The Company's 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 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

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11. Commitments and contingencies (continued):

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.

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. On February 7, 2019, the PTAB issued three decisions on remand purporting to deny institution of the three previously instituted IPRs of the '167 patent. On March 11, 2019, the Company timely appealed the PTAB decisions on remand to U.S. Court of Appeal for the Federal Circuit. On March 20, 2019, Aquestive and Indivior moved to dismiss the appeal, and the Company opposed that motion.

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)

On February 8, 2016, the Company received a notice relating to a Paragraph IV certification from Teva Pharmaceuticals USA, or (formerly Actavis, "Teva") seeking to find invalid three Orange Book listed patents relating specifically to BUNAVAIL. The Paragraph IV certification related to an ANDA filed by Teva with the FDA for a generic formulation of BUNAVAIL. The patents subject to Teva's certification were the '019 Patent, U.S. Patent No. 8,147,866 (the "'866 Patent") and 8,703,177 (the "'177 Patent").

On March 18, 2016, the Company 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 the Company asserted in its 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, the Company 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, the Company 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, the Company announced that it had entered into a settlement agreement with Teva that resolved the Company's 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, the Company has 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.

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11. Commitments and contingencies (continued):

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 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. The Company filed complaints in Delaware against Teva on December 22, 2016 and February 3, 2017 in which it 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 the Company 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.

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

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 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). Other terms of the Agreement are confidential.

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 the Company. The Company was served with the complaint on April 27, 2018. The complaint specifically alleged that it licensed its branded fentanyl buccal soluble film ONSOLIS to Collegium, and Collegium is also named as a defendant in the lawsuit. ONSOLIS is not presently sold in the United States and the license agreement with Collegium was terminated prior to Collegium launching ONSOLIS in the United States. Therefore, on June 28, 2018, the Company moved to dismiss the case against it and most recently, on July 6, 2018, the plaintiffs filed a notice to voluntarily dismiss us from the Arkansas case, without prejudice.

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11. Commitments and contingencies (continued):

Chemo Research, S.L

On March 1, 2019, the Company filed a complaint for patent infringement in Delaware against Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. (collectively, "Defendants"), asserting that the Defendants infringe its 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 December of 2032. This complaint follows a receipt by the Company on January 31, 2019, of a Notice Letter from Chemo Research S.L. stating that it has filed with the FDA an ANDA containing a Paragraph IV Patent Certification, for a generic version of BELBUA Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg. Because the Company initiated a patent infringement suit to defend the patents identified in the Notice Letter within 45 days after receipt, 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. Chemo Research S.L.'s Notice Letter also does not provide any information on the timing or approval status of its ANDA. On March 15, 2019, the Company filed a complaint against the Defendants in New Jersey asserting the same claims for patent infringement made in the Delaware lawsuit. On April 19, 2019, Defendants filed an answer to the Delaware complaint wherein they denied infringement of the '866, '843 and '539 patents and asserted counterclaims seeking declaratory relief concerning the alleged invalidity and non-infringement of such patents. On April 25, 2019, the Company voluntarily dismissed the New Jersey lawsuit given Defendants' consent to jurisdiction in Delaware.

The Company believes that it will be able to prevail in this lawsuit. As it has done in the past, the Company intends to vigorously defend its intellectual property against assertions of invalidity.

12. Subsequent events:

License Agreement with Shionogi Inc.

On April 4, 2019 (the "Effective Date"), the Company and Shionogi Inc. ("Shionogi"), entered into an exclusive license agreement for the commercialization of Symproic® (naldemedine tosylate) in the United States including Puerto Rico (the "Territory") for opioid-induced constipation in adult patients with chronic non-cancer pain.

Pursuant to the terms of the license agreement, the Company agreed to pay Shionogi a $30 million up-front payment, payable in two installments ($20 million on the Effective Date and $10 million on the six-month anniversary of the Effective Date (or earlier if the license agreement is assigned or transferred), and quarterly, tiered royalty payments on sales of the product in the Territory that range from 8.5% to 17.5% (plus an additional 1% of net sales on a pass-through basis to a third party licensor of Shionogi) of net sales based on volume of net sales and whether the Product is being sold as an authorized generic.

The Company and Shionogi have also entered into a customary supply agreement under which Shionogi will supply the product to the Company at cost plus an agreed upon markup for an initial term of up to two years. The Company and Shionogi also entered into a customary transition services and distribution agreement under which Shionogi will continue to perform certain sales, distribution and related activities and commercialization and administrative services on the Company's behalf until June 30, 2019, or such later date as may be agreed by the parties pursuant to the transition services and distribution agreement.

Public Offering.

On April 11, 2019 the Company announced the pricing of an underwritten public offering by the Company and a selling stockholder of 12,000,000 shares of common stock at a public offering price of $5.00 per share. The gross proceeds from the Company's portion of the offering (10,000,000 shares), before deducting the underwriter discounts and commission and other offering expenses, was $50.0 million, or net $47.5 million. The gross proceeds to the selling stockholder was approximately $10.0 million. The offering subsequently closed on April 15, 2019.

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

Our strategy is evolving with the establishment of our commercial footprint in the management of chronic conditions. We seek to build a well-balanced, diversified, high-growth specialty pharmaceutical company. Through our industry-leading commercialization infrastructure, we are executing the commercialization of our existing products. As part of our corporate growth strategy, we have licensed, and will continue to explore opportunities to acquire or license additional products that meet the needs of patients living with debilitating chronic conditions and treated primarily by therapeutic specialists. As we gain access to these drugs and technologies, we intend to employ our commercialization experience to bring them to the marketplace. With a strong commitment to patient access and a focused business-development approach for transformative acquisitions or licensing opportunities, we intend to leverage our experience and apply it to developing new partnerships that enable us to commercialize novel products that can change the lives of people suffering from debilitating chronic conditions.

We intend to pursue additional therapeutic products as well as new formulations of previously approved, active therapeutics through the FDA's 505(b)(2) approval process and acquisitions of existing commercial products. Our historical clinical and regulatory development strategy has focused primarily on our ability to use the 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved, active therapeutics incorporated into our drug-delivery technology. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, we believe it has the potential to be more cost efficient and expeditious, with less regulatory approval risk than other FDA-approval approaches.

First Quarter and Recent Highlights

- On January 15, 2019, we announced the appointment of Terry Coelho as Chief Financial Officer. Ms. Coelho also serves as our principal financial officer and principal accounting officer.
- On February 4, 2019, we announced that a leading national managed care organization has moved BELBUCA into preferred status across all its commercial formularies from its previous position of not-covered effective February 1, 2019. In addition, patients will no longer require a prior authorization to receive their BELBUCA script. This significant improvement in access for more than 7 million covered lives brings the total of Americans with preferred access for BELBUCA to more than 115 million.

Our Products and Related Trends

Our product portfolio currently consists of three products that are approved by the FDA. The three approved products utilize our patented BEMA thin film drug delivery technology.

BELBUCA (buprenorphine buccal film) is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for use in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative options are inadequate. BELBUCA is differentiated from other opioids and has the potential to address some of the most critical issues facing healthcare providers treating chronic pain with prescription opioids – abuse, misuse, addiction and the risk of overdose. Compared to currently marketed products and products under development, we believe that BELBUCA is differentiated based on the following features:

- strong and durable efficacy in both opioid naïve and opioid experienced patients;
- Schedule III designation by DEA, which indicates less abuse and addiction potential compared to Schedule II opioids, which include oxycodone, hydrocodone and morphine;
- in published studies, investigators observed that respiratory depression from buprenorphine administration reached a plateau, and we believe this ceiling effect may result in a lower risk of overdose related respiratory depression;
- favorable tolerability with a low incidence of constipation and low discontinuation rate;

- flexible dosing options with seven available strengths; and
- buccal administration to optimize buprenorphine delivery.

We believe that there are long-term growth opportunities for BELBUCA and we focus our commercial efforts primarily on BELBUCA. Our sales force is focused on current BELBUCA prescribers and clinicians we believe have the greatest opportunity to be adopters of BELBUCA. As of January 2019, BELBUCA had formulary coverage for more than 88% of commercial lives.

In June 2014, BUNAVAIL (buprenorphine and naloxone buccal film) was approved by the FDA for the maintenance treatment of opioid dependence as part of a complete treatment plan to include counseling and psychosocial support. BUNAVAIL contains the partial opioid agonist buprenorphine, which binds to the same receptors as opiate drugs but has a higher affinity, and naloxone, an opioid antagonist and an abuse deterrent.

BUNAVAIL provides an alternative treatment utilizing the advanced BEMA drug delivery technology. BUNAVAIL has approximately twice the bioavailability of sublingual buprenorphine-containing products for opioid dependence, allowing for effective treatment with half the dose when compared to Suboxone film. Additionally, BUNAVAIL offers convenient and discrete buccal administration and avoids the need for patients to avoid talking and swallowing during administration. BUNAVAIL has demonstrated an excellent tolerability profile, with a 68% reduction in the incidence of constipation at the end of 12 weeks in a Phase 3 trial in patients converted from Suboxone sublingual tablets or film to BUNAVAIL.

Our BUNAVAIL efforts are focused on current BUNAVAIL prescribers and on increasing prescriptions related to current, upcoming and future managed care contracts where BUNAVAIL is placed in a favorable formulary position.

In July 2009, ONSOLIS (fentanyl buccal soluble film) was approved for the management of pain that "breaks through" the effects of other medications being used to control persistent pain, or breakthrough pain, in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. We refer to breakthrough pain in opioid tolerant patients with cancer as BTCP. ONSOLIS provides significant reduction in pain for patients suffering from BTCP in a convenient formulation with a range of doses to allow patients to titrate to an adequate level of pain control. We are assessing options for U.S. commercialization of ONSOLIS, including the use of our current sales force, or potentially out-licensing the product. Regulatory documentation to qualify an alternate manufacturer of ONSOLIS was submitted to the FDA in June 2018, and in October 2018, we received notification of the FDA's approval of Tapemark as the new ONSOLIS manufacturer.

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 Mylan and TTY and collaborative development agreements, including those with pharmaceutical companies.

Results of Operations

Comparison of the three months ended March 31, 2019 and 2018

Product Sales. We recognized $19.8 million and $9.8 million in product sales during the three months ended March 31, 2019 and 2018, respectively. The increase in 2019 over 2018 is a result of increased sales of BELBUCA, managed care wins and the expansion of our salesforce during 2018.

Product Royalty Revenues. We recognized $0.002 million in product royalty revenue during the three months ended March 31, 2019, under agreements related to previous research and development contracts. We recognized $0.4 million in PAINKYL product royalty revenue during the three months ended March 31, 2018 under our license agreement with TTY.

Contract Revenues. We recognized $0.008 million in PAINKYL contract revenue during the three months ended March 31, 2019 under our license agreement with TTY. We recognized $1.0 million as contract revenue in a milestone payment under our former license agreement from Purdue related to BELBUCA in Canada during the three months ended March 31, 2018.

Cost of Sales. We incurred $4.1 million and $3.4 million in cost of sales during the three months ended March 31, 2019 and 2018, respectively. Cost of sales during the three months ended March 31, 2019 was related primarily to BELBUCA and BUNAVAIL, which included $3.7 million of product cost, royalties paid, depreciation and yield adjustments. Additionally, we paid a total of $0.4 million in quarterly minimum royalty payments to CDC IV, LLC ("CDC"). Cost of sales during the three months ended March 31, 2018 was related primarily to BELBUCA and BUNAVAIL, which included $2.9 million of product cost, royalties paid, depreciation and yield adjustments. Additionally, we paid a total of $0.4 million in quarterly minimum royalty payments to CDC. Cost of sales during the three months ended March 31, 2018 also included $0.02 million and $0.1 million related to BREAKYL and PAINKYL, respectively.

Selling, General and Administrative Expenses. During the three months ended March 31, 2019 and 2018, selling, general and administrative expenses totaled $17.0 million and $13.5 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, stock based compensation and amortization.

Research and Development. We recognized $2.5 million of research and development expense during the three months ended March 31, 2018 related to allocated wages and compensation to approved products and product candidates. There was no such research and development expense during the three months ended March 31, 2019 due to the Company focusing entirely on commercialized products beginning in 2019.

Interest expense, net. During the three months ended March 31, 2019, we had net interest expense of $2.6 million, consisting of $1.93 million of scheduled interest payments and $0.63 million of related amortization of loan discounts and deferred finance costs related to the February 2017 term loan agreement from CRG Servicing LLC ("CRG"). During the three months ended March 31, 2018, we had net interest expense of $2.5 million, consisting of $1.9 million of scheduled interest payments and $0.6 million of related amortization of loan discounts and deferred finance costs related to the February 2017 term loan agreement from CRG.

Revenues

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

	Three months ended March 31,	
	2019	**2018**
BELBUCA	$18,703	$8,024
% of net product sales	*95%*	*82%*
BUNAVAIL	1,056	1,814
% of net product sales	*5%*	*18%*
Net product sales	$19,759	$9,838

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from borrowings, convertible notes, and notes payable, funded research arrangements, revenue generated as a result of our worldwide license and development agreements and the commercialization of our BELBUCA and BUNAVAIL products. We intend to finance our commercialization and working capital needs from existing cash, earnings from the commercialization of BELBUCA and BUNAVAIL, royalty revenue, new sources of debt and equity financing, existing and new licensing and commercial partnership agreements and, potentially, through the exercise of outstanding common stock options and warrants to purchase common stock.

At March 31, 2019, we had cash of approximately $41.3 million. We used $2.9 million of cash in operations during the three months ended March 31, 2019. We believe that we have sufficient cash to manage the business as currently planned.

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

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

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;
- sale of product royalty;
- grants and new license revenues;
- bank loans;
- equipment financing;
- public or private debt; and

- exercise of existing warrants and options.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations in 2019 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of March 31, 2019 are as follows in thousands:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Lease obligations	$ 1,213	$ 353	$ 735	$ 125	$ —
Secured loan facility	61,784	—	30,892	30,892	—
Interest on secured loan facility	28,103	7,852	13,218	7,033	—
Minimum royalty expenses*	12,375	1,500	3,000	3,000	4,875
Purchase obligations**	1,015	493	522	—	—
Total contractual cash obligations	$104,490	$10,198	$48,367	$41,050	$ 4,875

* 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 March 31, 2019, we had no off-balance sheet arrangements.

Effects of Inflation

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

Critical Accounting Policies

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, 2018 (the "2018 Annual Report").

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Foreign currency exchange risk

We currently have, and may in the future have increased, commercial, manufacturing and clinical agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar or Euro or other applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. Such amounts are currently immaterial to our financial position or results of operations. 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 (our principal executive officer) and Chief Financial Officer (our principal 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 March 31, 2019.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our first quarter of 2019 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 similar expressions. These statements are based upon the current beliefs and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) actual sales results (including the results of our continuing commercial efforts with BELBUCA and BUNAVAIL), (ii) the application and availability of corporate funds and our need for future funds, (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA's review and/or approval and commercial activities for our products and product candidates and regulatory filings related to the same or (iv) the results of our ongoing intellectual property litigations and patent office proceedings, may differ significantly from those set forth or anticipated in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1A of our 2018 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.

See Note 11, Commitments and Contingencies, to our condensed consolidated financial statements included in Part I, Item I of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

Item 1A. Risk Factors.

We are dependent on third party suppliers for key components of our delivery technologies, products and product candidates.

Key components of our drug delivery technologies, products and product candidates, including for BELBUCA, Symproic and BUNAVAIL, may be provided by sole or limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs. Certain components used in our development activities, such as the active pharmaceutical ingredients, or API, of our products, are currently purchased from a single or a limited number of outside sources. The reliance on a sole or limited number of suppliers could result in:

- delays associated with development and non-clinical and clinical trials due to an inability to timely obtain a single or limited source component;
- inability to timely obtain sufficient quantities of API and an adequate supply of required components; and
- reduced control over pricing, quality and timely delivery.

Our relationships with our manufacturers and suppliers are particularly important to us and any loss of or material diminution of their capabilities due to factors such as regulatory issues, accidents, acts of God or any other factor would have a material adverse effect on our company. Any loss of or interruption in the supply of components from our suppliers or other third-party suppliers would require us to seek alternative sources of supply or require us to manufacture these components internally, which we are currently not able to do.

If the supply of any components is lost or interrupted, API, product or components from alternative suppliers may not be available in sufficient quality or in volumes within required time frames, if at all, to meet our or our partners' needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing or cause us to lose sales, force us into breach of other agreements, incur additional costs, delay new product introductions or harm our reputation. Furthermore, product or components from a new supplier may not be identical to those provided by the original supplier. Such differences could have material effects on our overall business plan and timing, could fall outside of regulatory requirements, affect product formulations or the safety and effectiveness of our products that are being developed.

If our competitors are successful in obtaining approval for Abbreviated New Drug Applications for products that have the same active ingredients as BELBUCA, Symproic or BUNAVAIL, sales of BELBUCA, Symproic or BUNAVAIL may be adversely affected.

Our competitors may submit for approval certain Abbreviated New Drug Applications, or ANDAs, which provide for the marketing of a drug product that has the same active ingredients in the same strengths and dosage form as a drug product already listed with the FDA, and which has been shown to be bioequivalent to such FDA-listed drug. Drugs approved in this way are commonly referred to as generic versions of a listed drug and can often be substituted by pharmacists under prescriptions written for an original listed drug. Any applicant filing an ANDA is required to make patent certifications to the FDA, such as certification to the FDA that the new product subject to the ANDA will not infringe an already approved product's listed patents or that such patents are invalid (otherwise known as a Paragraph IV Certification).

In February 2016, we announced that a generic competitor, Teva Pharmaceuticals USA (formerly known as Actavis, or Teva), had filed a Paragraph IV Certification challenging certain of our BUNAVAIL-related patents and we received notices regarding Paragraph IV certifications from Teva in November and December 2016, seeking to find invalid two Orange Book listed patents relating specifically to BELBUCA. The filing of this certification required us to initiate costly litigation against Teva. In addition, a number of our competitor companies have filed Paragraph IV Certifications challenging the patent for Suboxone® film, the market leader in the field in which we are seeking to generate sales of BUNAVAIL. To the extent that any company is successful in challenging the validity of certain patents covering BUNAVAIL or Suboxone® film under a Paragraph IV Certification, it could result in FDA approval of a drug that is lower in price to BUNAVAIL or Suboxone® film. Such a new drug could make it more difficult for BUNAVAIL to gain any significant market share in an increasingly generic marketplace, which would have a material adverse effect on our results of operations, cash flow, reputation and stock price.

In October 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 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.

In February 2018, we announced that we had entered into a Settlement Agreement with Teva that resolves our previously reported BELBUCA, patent litigation against Teva pending in the United States District Court for the District of Delaware. 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

entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BELBUCA in the U.S. on January 23, 2027 or earlier under certain circumstances. Other terms of the agreement are confidential.

As such, we have been and may continue to be subject to ANDA-related litigation, which is costly and distracting and has the potential to impair the long-term value of our products.

We are presently a party to lawsuits by third parties who claim that our products, methods of manufacture or methods of use infringe on their intellectual property rights, and we may be exposed to these types of claims in the future.

We are presently, and may continue to be, exposed to litigation by third parties based on claims that our technologies, processes, formulations, methods, or products infringe the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in pharmaceutical patents is, in most instances, uncertain and highly complex. Any litigation or claims against us, whether or not valid, would result in substantial costs, could place a significant strain on our financial and human resources and could harm our reputation. Such a situation may force us to do one or more of the following:

- incur significant costs in legal expenses for defending against an intellectual property infringement suit;
- delay the launch of, or cease selling, making, importing, incorporating or using one or more or all of our technologies and/or formulations or products that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our formulations or products, which would be costly and time-consuming.

With respect to our BEMA delivery technology, the thin film drug delivery technology space is highly competitive. There is a risk that a court of law in the United States or elsewhere could determine that one or more of our BEMA based products conflicts with or covered by external patents. This risk presently exists in our litigation with Reckitt Benckiser, Inc., Indivior PLC (formerly known as RB Pharmaceuticals Limited, or Indivior) and Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC, or Aquestive) relating to our BUNAVAIL product which was filed in September 2014 and in our litigation with Aquestive relating to our BELBUCA product which was filed in January 2017. If the courts in these cases were to rule against us and our partner in these cases, we could be forced to license technology from Aquestive or be prevented from marketing BUNAVAIL or BELBUCA, or otherwise incur liability for damages, which could have a material adverse effect on our ability for us or our partners to market and sell BUNAVAIL or BELBUCA.

We have been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by LTS to market BELBUCA and ONSOLIS within the countries of the European Union. We are required to pay a low single digit royalty on sales of products that are covered by this patent in the European Union. We have not conducted freedom to operate searches and analyses for our other proposed products. Moreover, the possibility exists that a patent could issue that would cover one or more of our products, requiring us to defend a patent infringement suit or necessitating a patent validity challenge that would be costly, time consuming and possibly unsuccessful.

Our lawsuits with Aquestive and Indivior have caused us to incur significant legal costs to defend ourselves, and we would be subject to similar costs if we are a party to similar lawsuits in the future Furthermore, if a court were to determine that we infringe any other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our BEMA products. We may be unable to obtain such licenses from the patent holders, which could materially and adversely impact our business.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Number	Description
10.1	Exclusive License Agreement dated, April 4, 2019, between the Company and Shionogi, Inc. (1)+
10.2	Amendment No. 3 to Term Loan Agreement dated, April 4, 2019, between the Company and CRG Servicing LLC (1)
10.3	Amendment No. 4 to Term Loan Agreement, dated April 25, 2019, between the Company and CRG Servicing LLC (2)
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 April 10, 2019.

(2) Previously filed as an exhibit to the Company's Current Report on Form 8-K filed on April 30, 2019.

SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 6, 2019

By: /s/ Herm Cukier
Herm Cukier
Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 6, 2019

By: /s/ Mary Theresa Coelho
Mary Theresa Coelho
Treasurer and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of Principal Executive Officer
Pursuant to Rule 13a-14(a)

I, Herm Cukier, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioDelivery Sciences International, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2019

/s/ Herm Cukier
Herm Cukier
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Rule 13a-14(a)

I, Mary Theresa Coelho, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioDelivery Sciences International, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2019

/s/ Mary Theresa Coelho
Mary Theresa Coelho
Treasurer and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

BIODELIVERY SCIENCES INTERNATIONAL, INC.
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of BioDelivery Sciences International, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Herm Cukier, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Herm Cukier
Herm Cukier
Chief Executive Officer and Director
(Principal Executive Officer)
May 6, 2019

Exhibit 32.2

BIODELIVERY SCIENCES INTERNATIONAL, INC.
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of BioDelivery Sciences International, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mary Theresa Coelho, Treasurer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Mary Theresa Coelho
Mary Theresa Coelho
Treasurer and Chief Financial Officer
(Principal Financial and Accounting Officer)
May 6, 2019