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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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

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 Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, a smaller reporting company or an emerging growth company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company", or "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer	☐	Accelerated Filer	☒
Non-Accelerated Filer	☐	Smaller Reporting Company	☐
		Emerging Growth Company	☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 12, 2019, there were 89,928,219 shares of company Common Stock issued and 89,912,728 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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Certifications

We own various trademark registrations and applications, and unregistered trademarks, including BioDelivery Sciences International, Inc., BEMA, BELBUCA, BUNAVAIL, ONSOLIS and our corporate logo. We have an exclusive license to use and display the Symproic registered trademark in order to commercialize Symproic in the United States. All other trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective holders. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

From time to time, we may use our website, our Facebook page atFacebook.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)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,863	$ 43,822
Accounts receivable, net	33,422	13,627
Inventory, net	10,766	5,406
Prepaid expenses and other current assets	4,874	3,188
Total current assets	104,925	66,043
Property and equipment, net	3,713	3,072
Goodwill	2,715	2,715
License and distribution rights, net	62,044	36,000
Other intangible assets, net	211	703
Total assets	$ 173,608	$ 108,533
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 46,545	$ 21,539
Total current liabilities	46,545	21,539
Notes payable, net	58,515	51,652
Other long-term liabilities	654	5,600
Total liabilities	105,714	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 September 30, 2019 and December 31, 2018, respectively; Series B Non-Voting Convertible Preferred Stock, $.001 par value, 1,698 and 3,100 shares outstanding at September 30, 2019 and December 31, 2018, respectively.	2	2
Common Stock, $.001 par value; 175,000,000 shares authorized at September 30, 2019 and125,000,000 shares authorized at December 31, 2018, respectively; 89,796,774 and 70,793,725 shares issued;89,781,283 and 70,778,234 shares outstanding at September 30, 2019 and December 31, 2018, respectively.	90	71
Additional paid-in capital	433,746	381,004
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(365,897)	(351,288)
Total stockholders' equity	67,894	29,742
Total liabilities and stockholders' equity	$ 173,608	$ 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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product sales	$ 29,623	$ 13,763	$ 77,438	$ 34,367
Product royalty revenues	683	370	2,154	2,197
Contract revenues	—	23	160	1,047
Total Revenues:	30,306	14,156	79,752	37,611
Cost of sales	5,350	3,779	14,325	11,760
Expenses:				
Research and development	—	699	—	4,038
Selling, general and administrative	23,360	13,489	62,304	41,013
Total Expenses:	23,360	14,188	62,304	45,051
Income (loss) from operations	1,596	(3,811)	3,123	(19,200)
Interest expense	(1,234)	(2,567)	(17,732)	(7,598)
Other (expense) income, net	(3)	(2)	5	(8)
Income (loss) before income taxes	$ 359	$ (6,380)	$ (14,604)	$ (26,806)
Income tax expense	(5)	—	(5)	(53)
Net income (loss)	$ 354	$ (6,380)	$ (14,609)	$ (26,859)
Beneficial conversion feature of convertible preferred stock	—	(12,500)	—	(12,500)
Net income (loss) attributable to common stockholders	$ 354	$ (18,880)	$ (14,609)	$ (39,359)
Basic				
Weighted average common stock shares outstanding	89,649,922	64,900,007	81,612,112	60,599,456
Basic earnings (loss) per share	$ —	$ (0.29)	$ (0.18)	$ (0.65)
Diluted				
Weighted average common stock shares outstanding	105,138,894	64,900,007	81,612,112	60,599,456
Diluted earnings (loss) per share	$ —	$ (0.29)	$ (0.18)	$ (0.65)

See notes to condensed consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS 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, June 30, 2019	2,093,155	$ 2	1,716	$ —	89,535,024	$ 88	$ 432,358	$ (47)	$ (366,251)	$ 66,150
Stock-based compensation	—	—	—	—	—	—	1,267	—	—	1,267
Stock option exercises	—	—	—	—	52,121	—	123	—	—	123
Restricted stock awards	—	—	—	—	109,629	2	(2)	—	—	—
Series B conversion to common stock	—	—	(18)	—	100,000	—	—	—	—	—
Net income	—	—	—	—	—	—	—	—	354	354
Balances, September 30, 2019	2,093,155	$ 2	1,698	$ —	89,796,774	$ 90	$ 433,746	$ (47)	$ (365,897)	$ 67,894

	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, June 30, 2018	2,093,155	$ 2	5,000	$ —	59,459,446	$ 59	$ 366,123	$ (47)	$ (325,400)	$ 40,737
Stock-based compensation	—	—	—	—	—	—	892	—	—	892
Stock option exercises	—	—	—	—	116,387	—	222	—	—	222
Restricted stock awards	—	—	—	—	467,298	1	(1)	—	—	—
Series B issuance, net of issuance cost	—	—	—	—	—	—	99	—	—	99
Series B conversion to common stock	—	—	(1,900)	—	10,555,556	11	(11)	—	—	—
Series B beneficial conversion feature	—	—	—	—	—	—	12,500	—	(12,500)	—
Net loss	—	—	—	—	—	—	—	—	(6,380)	(6,380)
Balances, September 30, 2018	2,093,155	$ 2	3,100	$ —	70,598,687	$ 71	$ 379,824	$ (47)	$ (344,280)	$ 35,570

	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	—	—	—	—	—	—	3,978	—	—	3,978
Stock option exercises	—	—	—	—	412,500	—	1,193	—	—	1,193
Restricted stock awards	—	—	—	—	801,661	1	(1)	—	—	—
Series B conversion to common stock	—	—	(1,402)	—	7,788,888	8	(8)	—	—	—
Equity offering, net of finance costs	—	—	—	—	10,000,000	10	47,580	—	—	47,590
Net loss	—	—	—	—	—	—	—	—	(14,609)	(14,609)
Balances, September 30, 2019	2,093,155	$ 2	1,698	$ —	89,796,774	$ 90	$ 433,746	$ (47)	$ (365,897)	$ 67,894

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

See notes to condensed consolidated financial statements

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

	Nine months ended September 30,	
	2019	**2018**
Operating activities:		
Net loss	$ (14,609)	$ (26,859)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation and amortization	253	685
Impairment loss on equipment	—	78
Accretion of debt discount and loan costs	11,441	2,953
Amortization of intangible assets	5,084	3,868
Provision for inventory obsolescence	57	396
Stock-based compensation expense	3,978	4,896
Changes in assets and liabilities, net of effect of acquisition:		
Accounts receivable	(19,795)	(3,581)
Inventories	(5,416)	261
Prepaid expenses and other assets	(1,686)	(545)
Accounts payable and accrued liabilities	14,844	(427)
Net cash flows used in operating activities	(5,849)	(18,275)
Investing activities:		
Product acquisitions	(20,674)	(1,951)
Acquisitions of equipment	(79)	(155)
Net cash flows used in investing activities	(20,753)	(2,106)
Financing activities:		
Proceeds from issuance of common stock	48,000	—
Proceeds from issuance of Series B preferred stock	—	50,000
Equity issuance costs	(410)	(1,410)
Proceeds from notes payable	60,000	—
Proceeds from exercise of stock options	1,193	528
Payment on note payable	(67,346)	—
Loss on refinancing of former debt	(2,794)	—
Payment of deferred financing fees	—	(450)
Net cash flows provided by financing activities	38,643	48,668
Net change in cash and cash equivalents	12,041	28,287
Cash and cash equivalents at beginning of period	43,822	21,195
Cash and cash equivalents at end of period	**$ 55,863**	**$ 49,482**
Cash paid for interest	$ 5,339	$ 4,645

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 conditions. The Company is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA) drug-delivery technology and other drug delivery technologies 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.

In April 2019, the Company entered into an exclusive license agreement for the commercialization of Symproic (naldemedine tosylate) in the United States including Puerto Rico for opioid-induced constipation in adult patients with chronic non-cancer pain (Note 6).

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- and nine-month periods ended September 30, 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 made by the Company include: revenue recognition associated with 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.

Cash and cash equivalents

Cash and cash equivalents consist of operating and money market accounts. Cash equivalents are carried at cost which approximates fair value due to their short-term nature. The Company considers all highly-liquid investments with an original maturity of 90 days or less to be cash equivalents.

The Company maintains cash equivalent balances with financial institutions that management believes are of high credit quality. The Company's cash and cash equivalents accounts at times may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk from cash and cash equivalents.

Inventory

Inventories are stated at the lower of cost or net realizable value with costs determined for each batch under the first-in, first-out method and specifically allocated to remaining inventory. Inventory consists of raw materials, work in process and finished goods. Raw materials include amounts of active pharmaceutical ingredient for a product to be manufactured, work in process includes the bulk inventory of laminate (the Company's drug delivery film) prior to being packaged for sale, and finished goods include pharmaceutical products ready for commercial sale.

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales. The Company reserved $0.2 million for inventory obsolescence as of both September 30, 2019 and December 31, 2018.

Revenue recognition

The main types of revenue contracts are:

- *Product sales*-Product sales amounts relate to sales of BELBUCA, Symproic 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.

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 obligation 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.

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

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 and Medicare 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.

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. The Company has voucher programs for BELBUCA, Symproic 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 of2% 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.

Since April 2019, cost of sales has also included direct costs attributable to the production of Symproic.

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.

Fair Value of Financial Instruments

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

GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. GAAP also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company considers the carrying amount of its cash and cash equivalents to approximate fair value due to short-term nature of this instrument. GAAP describes three levels of inputs that may be used to measure fair value:

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

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

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

The following table summarizes the cash and cash equivalents measured at fair value on a recurring basis as of September 30, 2019:

	Level 1	Level 2	Level 3	Balance at September 30, 2019
Cash and cash equivalents	$ 55,863	—	—	$ 55,863

The cash and cash equivalent balance as of September 30, 2019 includes investments in various money market accounts and cash held in interest bearing accounts.

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

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 nine months ended September 30, 2019. Research and development expense for the nine months ended September 30, 2018 totaled $4.0 million.

2. Leases:

The components of lease expense were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Lease Cost				
Operating lease cost				
Operating lease	$ 82	$ 81	$ 246	$ 244
Variable lease costs	3	1	10	1
Total lease cost	$ 85	$ 82	$ 256	$ 245

	Nine months ended September 30,	
	2019	2018
Other Information		
Cash paid for amounts included in the measurement of lease liabilities Operating cash flows from operating leases	$ 261	$ 245

	Nine months ended September 30,	
	2019	2018
Lease Term and Discount Rate		
Weighted-average remaining lease term Operating leases	3.0 years	4.0 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 September 30, 2019 were as follows:

Maturity of Lease Liabilities	
2019	$ 89
2020	360
2021	370
2022	219
Total lease payments	$ 1,038
Less: Interest	(152)
Present value of lease liabilities	$ 886

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

Components of Lease Assets and Liabilities

	September 30, 2019
Assets	
Property and equipment, net Operating lease-right of use asset	$ 777
Liabilities	
Current liabilities Operating lease- current liability	$ 271
Other long-term liabilities Operating lease- noncurrent liability	615
Total lease liabilities	$ 886

3. Inventory:

The following table represents the components of inventory as of:

	September 30, 2019	December 31, 2018
Raw materials & supplies	$ 638	$ 645
Work-in-process	6,894	2,093
Finished goods	3,478	2,855
Obsolescence reserve	(244)	(187)
Total inventories	$ 10,766	$ 5,406

4. Accounts payable and accrued liabilities:

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

	September 30, 2019	December 31, 2018
Accounts payable	$ 2,175	$ 3,166
Accrued rebates	24,625	12,261
Accrued compensation and benefits	4,662	3,814
Accrued acquisition costs	9,970	318
Accrued returns	1,477	715
Accrued royalties	419	159
Accrued clinical trial costs	—	464
Accrued legal	556	70
Accrued interest expense	1,508	—
Accrued regulatory expenses	282	—
Accrued other	871	572
Total accounts payable and accrued liabilities	$ 46,545	$ 21,539

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

5. Property and equipment:

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

	September 30, 2019	December 31, 2018
Machinery & equipment	$ 5,635	$ 5,635
Right of use, building lease	777	—
Computer equipment & software	437	406
Office furniture & equipment	161	155
Leasehold improvements	43	43
Idle equipment	679	679
Total	7,732	6,918
Less accumulated depreciation and amortization	(4,019)	(3,846)
Total property and equipment, net	$ 3,713	$ 3,072

Depreciation expense for the three-month periods ended September 30, 2019 and September 30, 2018, was approximately $0.08 million and $0.2 million, respectively. Depreciation expense for the nine-month periods ended September 30, 2019 and September 30, 2018, was approximately $0.2 million and $0.7 million, respectively.

6. License agreements and acquired product rights:

Shionogi license and supply agreement

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

Pursuant to the terms of the License Agreement, the Company paid Shionogi a $20 million up-front payment on the Effective Date and paid Shionogi a $10 million payment on the six-month anniversary of the Effective Date on October 4, 2019. Furthermore, the Company will pay quarterly tiered royalty payments on potential net sales of Symproic 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 Symproic is being sold as an authorized generic. Assets acquired as part of the License Agreement include: intellectual property, inventory, trademarks and tradenames.

The Company and Shionogi also entered into a customary supply agreement under which Shionogi will supply Symproic to the Company at cost plus an agreed upon markup for an initial term of up to two years. In the event the Company elects to source Symproic from a third party supplier, Shionogi would continue to supply the Company with naldemedine tosylate for use in Symproic at cost plus such agreed upon markup for the duration of the License Agreement. The Company and Shionogi also entered into a Pharmacovigilance agreement that required ongoing cooperation on adverse event reporting for the duration of License Agreement.

The Company accounted for the Symproic purchase as an asset acquisition under ASC 805-10-55-5b, which provides guidance for asset acquisitions. Under the guidance, if substantially all the acquisition is made up of one asset or several similar assets, then the acquisition is an asset acquisition. The Company believes that the licensing agreement and other assets acquired from Shionogi are similar and consider them all to be intangible assets.

The total purchase price was allocated to the acquired asset based on their relative estimated fair values, as follows:

Symproic license	$ 30,000
Transaction expenses	636
Total value	$ 30,636

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

Additionally, the Company also purchased from Shionogi $0.4 million of Symproic samples, which have been recorded in selling, general and administrative expenses in the accompanying condensed consolidated statement of operations for the nine months ended September 30, 2019.

The Company is amortizing the Symproic license over the life of the underlying patent, which the earliest date of generic entry for Symproic is November 2031 based on the expiration date of US patent # 9,108,975.

7. Other intangible assets:

Other intangible assets, net, consisting of product rights and licenses are summarized as follows:

September 30, 2019	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net
Product rights	$ 6,050	$ (5,864)	$ 186
BELBUCA license and distribution rights	45,000	(12,374)	32,626
Symproic license and distribution rights	30,636	(1,218)	29,418
Licenses	1,900	(1,875)	25
Total intangible assets	$ 83,586	$ (21,331)	$ 62,255

December 31, 2018	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net
Product rights	$ 6,050	$ (5,442)	$ 608
BELBUCA license and distribution rights	45,000	(9,000)	36,000
Licenses	1,900	(1,805)	95
Total intangible assets	$ 52,950	$ (16,247)	$ 36,703

8. Notes payable:

On May 23, 2019, the Company entered into a Loan Agreement (the "Loan Agreement") with Biopharma Credit plc ("Pharmakon"), for a senior secured credit facility consisting of a term loan of $60.0 million (the "Term Loan"), with the ability to draw an additional $20.0 million within twelve months of the closing date. The Loan Agreement replaced the Company's previous Term Loan Agreement (the "Original Loan Agreement") with CRG Servicing LLC ("CRG").

The Company utilized $60.0 million of the initial loan proceeds under the Loan Agreement, plus an additional $1.8 million to repay all of the outstanding loan balance owed by the Company under the Original Loan Agreement. The Company also used existing cash on hand to pay a $5.6 million backend facility fee to CRG. Upon the repayment of all amounts owed by the Company under the CRG Original Loan Agreement, all commitments to CRG were terminated and all security interests granted by the Company and its subsidiary guarantors under the CRG Original Loan Agreement were released.

During the nine months ended September 30, 2019, the Company expensed one-time events of $5.2 million in unamortized deferred loan fees, $3.9 million in unamortized warrant discount costs and $2.8 million in loan prepayment fees and realized losses arising out of the CRG Term Loan and recorded as interest expense in the accompanying consolidated statement of operations.

The new facility carries a 72-month term with interest only payments on the term loan for the first 36 months. The Term Loan will mature in May 2025 and bears an interest rate of 7.5% plus the LIBOR rate on the first day for the quarter (LIBOR effective rate as of July 1, 2019 was 2.33%.) The Term Loan is subject to mandatory prepayment provisions that require prepayment upon change of control.

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

The following table represents future maturities of the notes payable obligation as of September 30, 2019:

2019	—
2020	—
2021	—
2022	13,846
2023	18,462
2024	18,462
2025	9,230
Total maturities	$ 60,000
Unamortized discount and loan costs	(1,485)
Total notes payable obligation	$ 58,515

9. Net sales by product:

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

However, the following table presents net sales by product:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
BELBUCA	$ 26,514	$ 12,358	$ 69,277	$ 30,128
Symproic	2,172	—	5,348	—
BUNAVAIL	937	1,405	2,813	4,239
Net product sales	$ 29,623	$ 13,763	$ 77,438	$ 34,367

10. Stockholders' equity:

Public Offering

On April 15, 2019 the Company completed an underwritten public offering by the Company and a selling stockholder of12,000,000 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. The net proceeds were $47.6 million. The gross proceeds to the selling stockholder were approximately $19.0 million, which includes shares sold pursuant to the underwriters' exercise of their option to purchase an additional1,800,000 shares of common stock at the public offering price.

Common Stock

On July 25, 2019, in connection with the Company's 2019 Annual Meeting of Stockholders ("the Annual Meeting"), the Company's stockholders approved, among other matters, an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of Common Stock from 125,000,000 to 175,000,000. Shareholders also approved the Company's 2019 Stock Option and Incentive Plan (the "2019 Plan"), which reserves14,000,000 shares of stock for issuance under the 2019 Plan.

Stock-based compensation

During the nine months ended September 30, 2019, a total of2,267,904 options to purchase Common Stock, with an aggregate fair market value of approximately $9.5 million, were granted to employees, officers and directors of the Company. Options have a term of10 years from the grant date. Options granted to employees vest ratably over a three-year period and options

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granted to members of the Board of Directors vest ratably through2022. 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.

The key assumptions used in determining the fair value of options granted during the nine months ended September 30, 2019 follows:

Expected price volatility	61.80%-64.10%
Risk-free interest rate	1.36%-2.66%
Weighted average expected life in years	6 years
Dividend yield	—

Option activity during the nine months ended September 30, 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	1,132,109	3.93	
Employees	1,135,795	4.46	
Exercised	(412,500)	4.60	
Forfeitures	(490,342)	3.97	
Outstanding at September 30, 2019	5,771,066	$ 3.53	$ 5,627

As of September 30, 2019, options exercisable totaled1,903,370. There are approximately $5.6 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 nine months ended September 30, 2019, a cumulative total of360,250 RSUs were granted to the Company's executive officers, members of senior management, a former officer and directors with a fair market value of approximately $1.6 million. The fair value of restricted units is determined using quoted market prices of the Common Stock and the number of shares expected to vest.

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

Restricted stock activity during the nine months ended September 30, 2019 was as follows:

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(Unaudited)

	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
Directors	90,000	4.85
Employees	47,000	4.67
Vested	(801,661)	4.80
Forfeitures	(87,132)	2.30
Outstanding at September 30, 2019	1,637,559	$ 3.23

Preferred Stock

During the nine months ended September 30, 2019,1,402 shares of Series B Preferred Stock ("Series B") were converted into7,788,888 shares of Common Stock. As of September 30, 2019, 1,698 shares of Series B are outstanding. As of September 30, 2019,2,093,155 shares of Series A Preferred Stock ("Series A") are outstanding. There were no conversions of Series A during the nine months ended September 30, 2019.

Earnings Per Share

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Basic:				
Net income (loss)	$ 354	$ (6,380)	$ (14,609)	$ (26,859)
Less deemed dividend related to beneficial conversion feature on Series B Preferred Stock	—	(12,500)	—	(12,500)
Net earnings (loss) attributable to common stockholders	$ 354	$ (18,880)	$ (14,609)	$ (39,359)
Weighted average common shares outstanding	89,649,922	64,900,007	81,612,112	60,599,456
Basic earnings (loss) per common share	**$ —**	**$ (0.29)**	**$ (0.18)**	**$ (0.65)**
Diluted:				
Effect of dilutive securities:				
Net income (loss) attributable to common stockholders, diluted	$ 354	$ (18,880)	$ (14,609)	$ (39,359)
Weighted average common shares outstanding	89,649,922	64,900,007	81,612,112	60,599,456
Effect of dilutive options and warrants	15,488,972	—	—	—
Dilutive weighted average common shares outstanding	105,138,894	64,900,007	81,612,112	60,599,456
Diluted earnings (loss) per common share	**$—**	**$(0.29)**	**$(0.18)**	**$(0.65)**

During the three months ended September 30, 2019, outstanding stock options, RSUs, warrants and preferred shares of15,488,972 were included in the computation of diluted earnings per common share. During the three months ended September 30, 2018, outstanding stock options, RSUs, warrants and preferred shares of 25,745,108 were not included in the computation

of diluted earnings per common share, because to do so would have had an antidilutive effect. During the nine months ended September 30, 2019 and 2018, outstanding stock options, RSUs, warrants and preferred shares of 15,260,949 and 18,917,774, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect. Included in the three and nine months ended September 30, 2019 and 2018 are the Series B shares as converted to common stock.

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 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. On August 29, 2019, a three-judge panel of the Court of Appeals for the Federal Circuit granted the motion and dismissed the Company's appeal. On September 30, 2019, the Company filed a petition for an *en banc* rehearing of the order dismissing the Company's appeal by the full Federal Circuit Court of Appeals.

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. On November 20, 2018, the Company moved the EDNC to dismiss the complaint for patent infringement for failure to state a claim for relief. On August 6, 2019, the EDNC granted the Company's motion to dismiss, and dismissed the complaint without prejudice. On or about November 11, 2019, Aquestive refiled a complaint in the EDNC against the Company alleging that BELBUCA infringes the '167 Patent. 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.

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.

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 BELBUCA 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.

Derivative Litigation

On July 2, 2018, the Company filed a Schedule 14A Proxy Statement (the "Proxy") with the U.S. Securities and Exchange Commission (the "SEC") in connection with its 2018 Annual Meeting. Proposals 1 and 2 of the Proxy sought stockholder approval to amend the Company's Certificate of Incorporation by deleting Article TWELFTH of the Company's Certificate of Incorporation in its entirety and replacing it with a new Article TWELFTH that, among other things (i) provided for the declassification of the Company's Board in phases, with the full declassification to be achieved in 2020 (the "Declassification Amendment") and (ii) changed the voting standard for the uncontested election of directors to the Board from a plurality standard to the majority of votes cast standard as set forth in the bylaws of the Company (the "Election Amendment" and together with the "Declassification Amendment", the "Amendments").

On August 2, 2018, the Company held the 2018 Annual Meeting, at which time the stockholders voted on the Amendments. Following the 2018 Annual Meeting, based on consultation with the Company's advisors, the Company determined that the Amendments had been adopted by the requisite vote of stockholders and effected the Amendments by filing a Certificate of Amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware on August 6, 2018.

On September 11, 2019, two purported stockholders of the Company filed a putative class action against the Company and our directors in the Court of Chancery of the State of Delaware, captioned Drachman v. BioDelivery Sciences International, Inc., et al., C.A. No. 2019-0728-AGB (Del. Ch.) (the "Complaint"). The Complaint alleges that the Amendments did not receive the requisite vote of stockholders at the 2018 Annual Meeting and asserts claims for violation of the Delaware General Corporation Law, breach of fiduciary duties, and declaratory judgment. The Complaint seeks, inter alia, a declaration that the Amendments were not validly approved and invalidation of the Amendments, including altering the one-year terms of all directors duly elected at the 2018 and 2019 Annual Meetings to three-year terms. The Complaint also seeks costs and disbursements, including attorneys' fees. The Company will respond to the complaint by the December 6, 2019 deadline set by the Court and defend against it vigorously.

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

On November 5, 2019, the Board determined that ratifying the declassification of the Board and the change in the voting standard as set forth in the Amendments, as well as ratifying the filing and effectiveness of the Amendments, is in the best interests of the Company and its stockholders. The Board thus approved resolutions ratifying such acts and the filing and effectiveness of the Amendments under Section 204 of the Delaware General Corporation Law. The Company will submit the ratification to its stockholders for their adoption in accordance with Section 204 at its 2020 Annual Meeting.

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.

Third Quarter and Recent Highlights

- On July 1, 2019, we were added to the broad-market Russell 3000® Index as well as the Russell 2000® Index at the conclusion of the 2019 Russell indexes annual reconstitution.
- On July 9, 2019, we announced that several regional health care plans improved patient access to BELBUCA during the second quarter of this year. The regional U.S. insurance plans enhance BELBUCA's coverage to preferred status or initiated coverage for BELBUCA, which means that an additional six million covered lives now have access to BELBUCA. These six million covered lives brings the total number of commercial lives with access to BELBUCA to more than 165 million, representing more than 90% of the U.S. commercial insurance market.
- On August. 28, 2019, we reported the acceptance of five scientific abstracts highlighting data supporting our portfolio of products that address the unmet need of chronic conditions at the PAINWeek® 2019 National Conference on Pain for Frontline Practitioners which took place in September in Las Vegas, NV.
- On October 1, 2019, we announced that a major pharmacy benefits manager ("PBM") begin providing improved patient access to BELBUCA and Symproic starting October 1, 2019, with full plan adoption expected by January 1, 2020. The addition of this large national PBM will increase the number of covered lives to approximately 14 million covered lives within both commercial and health exchange plans that have access to BELBUCA as either the preferred or preferred exclusive buprenorphine product within their respective plans and Symproic as the preferred exclusive product within its class. Further, this addition brings the total number of covered lives with preferred access to BELBUCA to more than 104 million (out of more than 165 million with coverage) and the total number of covered lives with access to Symproic to more than 76 million.

Our Products and Related Trends

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

BELBUCA

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 92% of commercial lives.

The risks to our company associated with BELBUCA include: (i) inability to manufacture adequate supplies for commercial use; (ii) unexpected product safety issues; (iii) failure of our sales force to effectively sell the product and, (iv) inadequate reimbursement. A technical or commercial failure of BELBUCA would have a material adverse effect on our future revenue potential and would negatively affect investor confidence in our company and our public stock price.

SYMPROIC

Symproic is a peripherally acting mu-opioid receptor antagonist, or PAMORA, and was approved by the FDA on March 23, 2017 for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. OIC occurs primarily via activation of enteric mu-receptors in the small intestine and proximal colon, which results in harder stool and less frequent and less effective defecation. Because OIC results from the specific effects of opioids, it differs mechanistically from other forms of constipation, and deserves dedicated medical management. Compared to currently marketed products and products under development for OIC, we believe that Symproic is differentiated based on the following features:

- strong and durable efficacy observed in randomized, double-blind, placebo controlled clinical trials of 12 week and 52 week duration in OIC patients;
- OIC relief that was more frequent, more complete, with less straining than patients taking placebo
- recommended by the American Gastroenterological Association for patients with laxative refractory OIC;
- adverse event profile comparable to placebo, with low rates of abdominal pain observed across the phase III program; and
- the only prescription OIC medication with the convenience of once daily dosing, with only a tablet strength, and that can be taken with or without food and with or without laxatives.

Because of the durable efficacy, tolerability and convenience benefits, we believe that Symproic is a best-in-class PAMORA that reliably provides durable relief of OIC, which frees both the patient and the healthcare provider to focus on treating the patient's chronic pain.

We believe that there are long-term growth opportunities for Symproic. In 2018, according to data from Symphony Health, the market for PAMORAs included over 550,000 prescriptions dispensed. This represents a 1% growth in prescription volume from 2017. The growth rate of the PAMORAs has slowed since 2017, driven by a decline in opioid prescription rates.

The risks to our company associated with Symproic include: (i) unexpected product safety issues; (ii) inability to continue to supply product in adequate quantities to meet the commercial demand; (iii) inability to manufacture adequate supplies for commercial use; (iv) failure of our sales force to effectively sell the product and, (v) inadequate reimbursement.

BUNAVAIL

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. The impact of a growing generic Suboxone market has resulted in declining market conditions, and as such, BUNAVAIL is no longer a core strategic asset for our Company.

ONSOLIS

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 not currently assessing options for U.S. commercialization of ONSOLIS. Given current declining market conditions, we have no plans to introduce the product in the US at this time. The product is no longer strategic for the Company.

We will continue to seek additional license agreements. We anticipate that funding for the next several years will come primarily from earnings from sales of BELBUCA and Symproic, and milestone payments and royalties from Mylan and TTY.

Results of Operations

Comparison of the three months ended September 30, 2019 and 2018

Product Sales. We recognized $29.6 million and $13.8 million in product sales during the three months ended September 30, 2019 and 2018, respectively. The increase in 2019 is principally due to increased BELBUCA product sales from the utilization of managed care wins and the acquisition of Symproic, offset by lower BUNAVAIL product sales.

Product Royalty Revenues. We recognized $0.7 million in PAINKYL product royalty revenue during the three months ended September 30, 2019 under our license agreement with TTY. We recognized $0.4 million in BREAKYL product royalty revenue during the three months ended September 30, 2018, under our license agreement with Meda.

Contract Revenues. We recognized $0.02 million in contract revenues during the three months ended September 30, 2018 related to our license agreements with Purdue Canada ("Purdue") and TTY. There was no such contract revenues during the same period of 2019.

Cost of Sales. We incurred $5.4 million and $3.8 million in cost of sales during the three months ended September 30, 2019 and 2018, respectively. Cost of sales includes product cost, royalties paid, depreciation, yield adjustments and quarterly minimum royalty payments to CDC IV, LLC ("CDC").

Selling, General and Administrative Expenses. During the three months ended September 30, 2019 and 2018, selling, general and administrative expenses totaled $23.4 million and $13.5 million, respectively. Selling, general and administrative costs include commercialization costs for BELBUCA, BUNAVAIL and Symproic, legal, accounting and management wages, consulting and professional fees, travel costs, stock based compensation and amortization. The increase in selling, general and administrative expenses during the three months ended September 30, 2019 is due to the increase in compensation expense related to our expansion efforts, increased marketing efforts and expenses related to the acquisition of Symproic.

Research and Development. We recognized $0.7 million of research and development expense during the three months ended September 30, 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 September 30, 2019 due to the Company focusing entirely on commercialization of products beginning in 2019.

Interest expense, net. During the three months ended September 30, 2019, we had net interest expense of $1.2 million, which includes interest expense of $1.5 million and $0.06 million of amortization of discount and loan costs, both related to the new debt arrangement.

During the three months ended September 30, 2019, we also had interest income of $0.3 million.

During the three months ended September 30, 2018, we had net interest expense of $2.6 million, consisting of $1.4 million of scheduled interest payments, $0.9 million of related amortization of discount and loan costs and $0.3 million of warrant interest expense, all related to the former debt arrangement.

Comparison of the nine months ended September 30, 2019 and 2018

Product Sales. We recognized $77.4 million and $34.4 million in product sales during the nine months ended September 30, 2019 and 2018, respectively. The increase in 2019 is principally due to increased BELBUCA product sales from the utilization of managed care wins and the acquisition of Symproic, offset by lower BUNAVAIL product sales.

Product Royalty Revenues. We recognized $2.2 million in product royalty revenue during each of the nine months ended September 30, 2019 and 2018, respectively. Of the aforementioned amounts, $1.0 million and $1.3 million, respectively, can be attributed to royalty revenue from BREAKYL under our license agreement with Meda. We recognized $1.2 million and $0.9 million during the nine months ended September 30, 2019 and 2018, respectively, in PAINKYL royalty revenue under our license agreement with TTY.

Contract Revenues. We recognized $0.2 million in PAINKYL contract revenue during the nine months ended September 30, 2019 under our license agreement with TTY. We recognized $1.0 million in contract revenue during the nine months ended September 30, 2018 related to our former license agreement with Purdue, which was for the Canadian commercial launch and related milestones.

Cost of Sales. We incurred $14.3 million and $11.8 million in cost of sales during the nine months ended September 30, 2019 and 2018, respectively. Cost of sales includes product cost, royalties paid, depreciation, yield adjustments and quarterly minimum royalty payments to CDC.

Selling, General and Administrative Expenses. During the nine months ended September 30, 2019 and 2018, selling, general and administrative expenses totaled $62.3 million and $41.0 million, respectively. Selling, general and administrative costs include commercialization costs for BELBUCA, BUNAVAIL and Symproic, management wages and stock-based compensation, legal, accounting and other professional fees, travel costs, and the amortization of our intangible assets including the license and distribution rights from the reacquisition of BELBUCA and the acquisition of Symproic. During the normal course of business, we accrue additional expenses for certain legal matters from time to time, including legal matters related to the protection and enforcement of our intellectual property. The amounts accrued for such legal matters are recorded within accrued expenses on the balance sheet. The increase in selling, general and administrative expenses during 2019 is due to the increase in compensation expense related to our expansion efforts, increased marketing efforts and expenses related to the acquisition of Symproic.

Research and Development. We recognized $4.0 million of research and development expense during the nine months ended September 30, 2018 related to allocated wages and compensation to approved products and product candidates. There was no such research and development expense during the nine months ended September 30, 2019 due to the Company focusing entirely on commercialization of products beginning in 2019.

Interest expense, net. During the nine months ended September 30, 2019, we had net interest expense of $17.7 million, consisting of $11.9 million of one-time costs associated with the refinancing of our debt, $5.3 million of scheduled interest payments relating to both loans, $0.1 million of related amortization of discount and loan costs for both the old and new debt arrangements, and $0.4 million of warrant interest expense associated with the former CRG loan.

The one-time expenses related to the payoff of the CRG loan consisted of $5.2 million in unamortized deferred loan fees, $3.9 million in unamortized warrant discount costs and $2.8 million in loan prepayment fees and realized losses, for a cumulative total of $11.9 million in one-time costs.

During the nine months ended September 30, 2019, we also had interest income of $0.6 million.

During the nine months ended September 30, 2018, we had net interest expense of $7.6 million, consisting of $4.6 million of scheduled interest payments, $2.2 million of related amortization of discount and loan costs and $0.8 million of warrant interest expense, all related to the former debt arrangement.

Revenues

The following table summarizes net product sales for the three and nine month periods ended September 30 in thousands:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
BELBUCA	$ 26,514	$ 12,358	$ 69,277	$ 30,128
% of net product sales	*90 %*	*90 %*	*89 %*	*88 %*
Symproic	2,172	—	5,348	—
% of net product sales	*7 %*	*— %*	*7 %*	*— %*
BUNAVAIL	937	1,405	2,813	4,239
% of net product sales	*3 %*	*10 %*	*4 %*	*12 %*
Net product sales	$ 29,623	$ 13,763	$ 77,438	$ 34,367

Non-GAAP Financial Information:

We report our condensed consolidated financial results in accordance with GAAP; however, we believe that earnings before interest, taxes, depreciation and amortization ("EBITDA") and other non-GAAP results should not be considered in isolation of or as an alternative for, earnings measures prepared in accordance with GAAP. Management uses these non-GAAP measures internally to measure the ongoing operating performance of our Company along with other metrics, and for planning and forecasting purposes. In addition, when evaluating non-GAAP results, we exclude certain items that are considered to be non-cash and if applicable, non-recurring, in nature.

EBITDA and Non-GAAP Income/(Loss):

We have presented EBITDA because it is a key measure used by our management and board of directors to understand and evaluate our operating performance and to develop operational goals for managing our business. We believe this financial measure helps identify underlying trends in our business that could otherwise be masked by the effect of the expenses that we exclude. In particular, we believe that the exclusion of the expenses eliminated in calculating EBITDA can provide a useful measure for period-to-period comparisons of our core operating performance. Accordingly, we believe that EBITDA provides useful information to investors and others in understanding and evaluating our operating results, enhancing the overall understanding of our past performance and future prospects, and allowing for greater transparency with respect to key financial metrics used by our management in its financial and operational decision-making.

EBITDA is not prepared in accordance with GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. There are a number of limitations related to the use of adjusted EBITDA rather than net income/(loss), which is the nearest GAAP equivalent. Some of these limitations are:

- EBITDA excludes depreciation and amortization and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in EBITDA;
- EBITDA does not reflect provision for (benefit from) income taxes or the cash requirements to pay taxes; and
- EBITDA excludes net interest, including both interest expense and interest income.

Non-GAAP net income/(loss) is an alternative view of our performance that we are providing because management believes this information enhances investors' understanding of our results as it permits investors to better understand the ongoing operations of the business, the impact of any non-recurring one-time events, the cash results of the organization and is an additional measure used by management to assess performance.

Non-GAAP net income/(loss) is not prepared in accordance with GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. There are a number of limitations related to the use of non-GAAP net income/(loss) rather than net income/(loss), which is the nearest GAAP equivalent. Some of these limitations are:

- Non-GAAP income/(loss) excludes certain one-time items because of the nature of the items and the impact that those have on the analysis of underlying business performance and trends. Specifically, in the presentation of non-GAAP income/(loss) for the nine months periods September 30, 2019, we have excluded the financial impact of our debt refinancing which closed in May 2019, as it is non-recurring. This excluded item is a significant component in understanding and assessing ongoing financial performance. The one-time expenses related to the payoff of the CRG loan consisted of $5.2 million in unamortized deferred loan fees, $3.9 million in unamortized warrant discount costs and $2.8 million in loan prepayment fees and realized losses, for a cumulative total of $11.9 million in one-time costs;
- The expenses and other items that we exclude in our calculation of non-GAAP net income/(loss) may differ from the expenses and other items, if any, that other companies may exclude from non-GAAP net income/(loss) when they report their operating results since non-GAAP income/(loss) is not a measure determined in accordance with GAAP, and it has no standardized meaning prescribed by GAAP;
- We exclude stock-based compensation expense from non-GAAP net income/(loss) although (a) it has been, and will likely continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy and (b) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would likely be higher, which would affect our cash position;
- We exclude amortization of intangible assets from non-GAAP net income/(loss) due to the non-cash nature of this expense and although it has been and will continue to be for the foreseeable future a recurring expense for our business, these expenses do not affect our cash position; and
- Amortization of warrant discount costs associated with the CRG loan which was dissolved in May 2019 are excluded given these expenses did not affect our cash position;

Reconciliations of non-GAAP metrics to most directly comparable U.S. GAAP financial measures:

The following tables reconcile net income/(loss)earnings and computations (in thousands) under GAAP to a Non-GAAP basis.

	Three Months Ended September 30,		Nine Months Ended September 30,	
Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)	**2019**	**2018**	**2019**	**2018**
GAAP net income/(loss)	$ 354	$ (6,380)	$ (14,609)	$ (26,859)
Add back:				
Provision for income taxes	4	—	4	53
Net interest expense	1,237	2,569	17,727	7,606
Depreciation and amortization	1,904	1,519	5,259	4,718
EBITDA	**$ 3,499**	**$ (2,292)**	**$ 8,381**	**$ (14,482)**
Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)				
GAAP net income/(loss)	354	(6,380)	(14,609)	(26,859)
Non-GAAP adjustments:				
Stock-based compensation expense	1,267	892	3,978	4,896
Amortization of intangible assets	1,898	1,289	5,084	3,868
Amortization of warrant discount	—	269	448	807
Non-recurring financial impact of debt refinance	—	—	11,866	—
Non-GAAP net income/(loss)	**$ 3,519**	**$ (3,930)**	**$ 6,767**	**$ (17,288)**

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, Symproic and BUNAVAIL products. We

intend to finance our commercialization and working capital needs from existing cash, earnings from the commercialization of BELBUCA, Symproic 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 September 30, 2019, we had cash and cash equivalents of approximately $55.9 million. We used $5.8 million of cash in operations during the nine months ended September 30, 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, Symproic 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 September 30, 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	$ 1,038	$ 267	$ 740	$ 31	$ —
Secured loan facility	60,000	—	4,615	55,385	—
Interest on secured loan facility	25,440	5,997	11,846	7,597	—
Minimum royalty expenses*	11,625	1,500	3,000	3,000	4,125
Purchase obligations**	1,885	1,363	522	—	—
Total contractual cash obligations	$ 99,988	$ 9,127	$ 20,723	$ 66,013	$ 4,125

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

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

Off-Balance Sheet Arrangements

As of September 30, 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.

Market Risk

We do not engage in speculative transactions nor do we hold or issue financial instruments for trading purposes. In connection with the recapitalization of our business, we have entered into a secured credit facility consisting of a term loan. Our term loan note bears interest which includes fluctuating interest rates based on LIBOR.

There is currently uncertainty around whether LIBOR will continue to exist after 2021. If LIBOR ceases to exist, we may need to renegotiate our loan documents and we cannot predict what alternative index would be negotiated with our lenders. As a result, our interest expense could increase, in which event we may have difficulties making interest payments and funding our other fixed costs, and our available cash flow for general corporate requirements may be adversely affected.

Our fixed rate debt exposes our Company to changes in market interest rates reflected in the fair value of the debt and to the risk that we may need to refinance maturing debt with new debt at a higher rate.

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 September 30, 2019.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our third 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, Symproic 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 a 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 Pharmaceutical Industries Ltd., 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., RB Pharmaceuticals Limited, 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 RB Pharmaceuticals 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
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.
#This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: November 12, 2019

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

Date: November 12, 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: November 12, 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: November 12, 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 September 30, 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)
November 12, 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 September 30, 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)
November 12, 2019