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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, 2020

☐ **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 5, 2020, there were 101,126,462 shares of company Common Stock issued and 101,110,971 shares of company Common Stock outstanding.

BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

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From time to time, we may use our website, our Facebook page at Facebook.com/BioDeliverySI, on Twitter at @BioDeliverySI and on LinkedIn at linkedin.com/company/biodeliverysciencesinternational 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, our LinkedIn page and our Twitter posts are not incorporated into, and does not form a part of, this Quarterly Report.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 100,177	$ 63,888
Accounts receivable, net	43,830	38,790
Inventory, net	18,887	11,312
Prepaid expenses and other current assets	5,754	3,769
Total current assets	168,648	117,759
Property and equipment, net	1,485	2,075
Goodwill	2,715	2,715
License and distribution rights, net	55,109	60,309
Other intangible assets, net	—	47
Total assets	$ 227,957	$ 182,905
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 53,409	$ 53,993
Total current liabilities	53,409	53,993
Notes payable, net	78,363	58,568
Other long-term liabilities	300	580
Total liabilities	132,072	113,141
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; Series A Non-Voting Convertible Preferred Stock. $0.001 par value, 0 and 2,093,155 shares outstanding at September 30, 2020 and December 31, 2019, respectively; Series B Non-Voting Convertible Preferred Stock, $0.001 par value, 443 and 618 shares outstanding at September 30, 2020 and December 31, 2019, respectively.	—	2
Common Stock, $0.001 par value; 235,000,000 and 175,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 101,126,452 and 96,189,074 shares issued; 101,110,961 and 96,173,583 shares outstanding at September 30, 2020 and December 31, 2019, respectively.	100	96
Additional paid-in capital	446,910	436,306
Treasury stock, at cost, 15,491 shares, as of September 30, 2020 and December 31, 2019.	(47)	(47)
Accumulated deficit	(351,078)	(366,593)
Total stockholders' equity	95,885	69,764
Total liabilities and stockholders' equity	$ 227,957	$ 182,905

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,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	$ 38,785	$ 29,623	$ 112,946	$ 77,438
Product royalty revenues	658	683	1,358	2,154
Contract revenues	—	—	—	160
Total Revenues:	39,443	30,306	114,304	79,752
Cost of sales	5,376	5,350	16,371	14,325
Expenses:				
Selling, general and administrative	22,461	23,360	77,408	62,304
Total Expenses:	22,461	23,360	77,408	62,304
Income from operations	11,606	1,596	20,525	3,123
Interest expense, net	(2,010)	(1,234)	(4,997)	(17,732)
Other (expense)/income, net	(2)	(3)	6	5
Income/(loss) before income taxes	$ 9,594	$ 359	$ 15,534	$ (14,604)
Income tax provision	(211)	(5)	(19)	(5)
Net income/(loss) attributable to common stockholders	$ 9,383	$ 354	$ 15,515	$ (14,609)
Basic				
Weighted average common stock shares outstanding	101,031,317	89,649,922	99,377,748	81,612,112
Basic earnings/(loss) per share	$ 0.09	$ —	$ 0.16	$ (0.18)
Diluted				
Weighted average common stock shares outstanding	105,783,568	105,138,894	104,836,493	81,612,112
Diluted earnings/(loss) per share	$ 0.09	$ —	$ 0.15	$ (0.18)

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, 2020	—	$ —	443	$ —	100,916,511	$ 99	$ 445,180	$ (47)	$ (360,462)	$ 84,770
Stock-based compensation	—	—	—	—	—	—	1,539	—	—	1,539
Stock option exercises	—	—	—	—	68,623	1	191	—	—	192
Restricted stock awards	—	—	—	—	141,318	—	—	—	—	—
Net income	—	—	—	—	—	—	—	—	9,384	9,384
Balances, September 30, 2020	—	$ —	443	$ —	101,126,452	$ 100	$ 446,910	$ (47)	$ (351,078)	$ 95,885

	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 loss	—	—	—	—	—	—	—	—	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, January 1, 2020	2,093,155	$ 2	618	$ —	96,189,074	$ 96	$ 436,306	$ (47)	$ (366,593)	$ 69,764
Stock-based compensation	—	—	—	—	—	—	7,845	—	—	7,845
Stock option exercises	—	—	—	—	1,159,347	1	2,760	—	—	2,761
Restricted stock awards	—	—	—	—	712,654	—	—	—	—	—
Series A conversion to common stock	(2,093,155)	(2)	—	—	2,093,155	2	—	—	—	—
Series B conversion to common stock	—	—	(175)	—	972,222	1	(1)	—	—	—
Net loss	—	—	—	—	—	—	—	—	15,515	15,515
Balances, September 30, 2020	—	$ —	443	$ —	101,126,452	$ 100	$ 446,910	$ (47)	$ (351,078)	$ 95,885

	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

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,	
	2020	**2019**
Operating activities:		
Net income/(loss)	$ 15,515	$ (14,609)
Adjustments to reconcile net income/(loss) to net cash flows from operating activities		
Depreciation	467	253
Accretion of debt discount and loan costs	231	11,441
Amortization of intangible assets	5,248	5,084
Provision for inventory obsolescence	(297)	57
Stock-based compensation expense	7,845	3,978
Changes in assets and liabilities:		
Accounts receivable	(5,040)	(19,795)
Inventories	(7,278)	(5,416)
Prepaid expenses and other assets	(1,985)	(1,686)
Accounts payable and accrued liabilities	(701)	14,844
Taxes payable	(40)	—
Net cash flows provided by/(used in) operating activities	13,965	(5,849)
Investing activities:		
Product acquisitions	—	(20,674)
Acquisitions of equipment	—	(79)
Net cash flows used in investing activities	—	(20,753)
Financing activities:		
Proceeds from issuance of common stock	—	48,000
Equity issuance costs	—	(410)
Proceeds from notes payable	20,000	60,000
Proceeds from exercise of stock options	2,761	1,193
Payment on note payable	—	(67,346)
Loss on refinancing of former debt	—	(2,794)
Payment on deferred financing fees	(437)	—
Net cash flows provided by financing activities	22,324	38,643
Net change in cash and cash equivalents	36,289	12,041
Cash and cash equivalents at beginning of period	63,888	43,822
Cash and cash equivalents at end of period	**$ 100,177**	**$ 55,863**
Cash paid for interest	$ 5,037	$ 3,831

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

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, 2019 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, 2019. 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, 2019.

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. and Arius Two, Inc. All significant inter-company balances and transactions have been eliminated.

Use of estimates in financial statements

The preparation of the accompanying condensed consolidated financial statements 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 condensed 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 condensed 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 government program rebates, customer voucher redemptions, commercial contracts, rebates and chargebacks; sales returns reserves; sales bonuses; stock-based compensation; 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. Inventory obsolescence reserves at September 30, 2020 and December 31, 2019 were $0.1 million and $0.4 million, respectively.

Revenue recognition

The main types of revenue contracts are:

- *Product sales*-Product sales amounts relate to sales of BELBUCA, Symproic and BUNAVAIL. The Company discontinued marketing of BUNAVAIL in August 2020. 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.
- *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.

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.

Transaction price, including variable consideration

Revenue from product sales is recorded at the net sales price, which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, government chargebacks, discounts and rebates, and other incentives, such as voucher programs, and other fee for service amounts that are detailed within contracts between the Company and its customers relating to the Company's sale of its products.

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

- 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 third-party prescription data providers;
- the impact of changes in state and federal regulations; and
- the estimated remaining shelf life of products.

Revenue from product sales is recorded after considering the impact of the following variable consideration amounts at the time of revenue recognition:

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.

Government rebates and chargebacks-Government rebates and chargebacks include mandated discounts under Medicaid, Medicare, U.S. Department of Veterans Affairs and other government agencies ("Government Payors"). The Company estimates the rebates and chargebacks to Government Payors based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. In addition, the pricing of covered products under Medicaid is subject to complex calculations and involves interpretation of government rules, regulations and policies as well as adjustments based on current trends in utilization. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company estimates the rebates and chargebacks that it will provide to Government Payors based upon (i) the government-mandated discounts applicable to government-funded programs, (ii) information obtained from its customers and (iii) information obtained from other third parties regarding the payor mix for its products. The Company’s liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made for product shipments that have been recognized as revenue, but remain in the distribution channel inventories at the end of each reporting period.

Commercial Contracts-The Company’s estimates of rebates arising from commercial contracts are based on its estimated mix of various third-party payers, which are contractually entitled to discounts from the Company’s listed prices of its products. If the mix across 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.

Voucher program-The Company, from time to time, offers certain promotional product-related incentives to eligible patients. The Company has voucher programs for BELBUCA and Symproic 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.

Trade discounts and distribution fees-Trade discounts relate to prompt settlement discounts provided to customers. In addition, the Company compensates its customers for distribution of its products and the provision of data. The Company has determined that such services received to date are not distinct from its sale of products and may not reasonably represent fair value for these services. Therefore, estimates of these payments are recorded as a reduction of revenue based on contractual terms.

Cost of sales

Cost of sales includes the direct costs attributable to the production of BELBUCA, Symproic and BUNAVAIL. It includes raw materials, production costs at the Company’s contract manufacturing sites, quality testing directly related to the products, and depreciation on equipment that the Company has purchased to produce BELBUCA, Symproic and BUNAVAIL. It also includes the costs for 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.

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.

Recent accounting pronouncements-adopted

Measurement of Credit Losses of Financial Instruments

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments; in November 2018 the FASB issued a subsequent amendment ASU No. 2018-19, Codification Improvements to Topic 326, Financial Instruments—Credit Losses; in April 2019 the FASB issued ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments—Credit Losses. In May 2019 the FASB issued ASU No. 2019-05, Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief; and in November 2019 the FASB issued ASU No. 2019-11, Codification Improvements to Topic 326, Financial Instruments—Credit Losses. The new guidance changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. In November 2019 the FASB issued ASU No. 2019-10, Financial Instruments—Credit Losses (Topic 326). The Company adopted Topic 326 during the nine months ended September 30, 2020 and determined that the new guidance has no material impact on its condensed consolidated financial statements.

The Company is exposed to credit losses primarily through its product sales. The Company assesses each counterparty’s ability to pay for the products it sells by conducting a credit review. The credit review considers the Company's expected billing exposure and timing for payment and the counterparty’s established credit rating or the Company's assessment of the counterparty’s creditworthiness based on the Company's analysis of their financial statements when a credit rating is not available. The Company also considers contract terms and conditions, and business strategy in its evaluation. A credit limit is established for each counterparty based on the outcome of this review.

The Company monitors its ongoing credit exposure through active review of counterparty balances against contract terms and due dates. The Company's activities include timely account reconciliations, dispute resolution and payment confirmations. The Company may employ collection agencies and legal counsel to pursue recovery of defaulted receivables.

As of September 30, 2020, the Company reported $43.8 million of trade receivables within accounts receivable. Based on an aging analysis at September 30, 2020, 98% of the Company's accounts receivable were outstanding less than 30 days. There was no change to the allowance for doubtful accounts and credit losses between September 30, 2020 or December 31, 2019. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 and early adoption is permitted. The new guidance does not have a material impact on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606, which amends ASC 808 to clarify ASC 606 should apply in entirety to certain transactions between collaborative arrangement participants. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company has determined that the new guidance does not have a material impact on its consolidated financial statements.

Recent accounting pronouncements-not yet adopted

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes, which is intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. The Company is currently evaluating but does not expect the new guidance to have a material impact on its consolidated financial statements.

Fair Value of Financial Instruments

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

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 financial instruments measured at fair value on a recurring basis as of September 30, 2020:

	Level 1	Level 2	Level 3	Balance at September 30, 2020
Cash and cash equivalents	$ 100,177	$ —	—	$ 100,177

The cash and cash equivalent balance as of September 30, 2020 includes investments in various money market accounts and cash held in interest bearing accounts.

2. Inventory:

The following table represents the components of inventory as of:

	September 30, 2020	December 31, 2019
Raw materials	$ 3,497	$ 624
Work-in-process	10,025	6,198
Finished goods	5,452	4,874
Obsolescence reserve	(87)	(384)
Total inventories	$ 18,887	$ 11,312

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

3. Accounts payable and accrued liabilities:

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

	September 30, 2020	December 31, 2019
Accounts payable	$ 8,244	$ 11,704
Accrued rebates	28,156	28,528
Accrued compensation and benefits	5,603	5,545
Accrued returns	6,947	4,438
Accrued royalties	684	535
Accrued legal	1,564	1,484
Accrued regulatory expenses	1,252	331
Accrued other	959	1,428
Total accounts payable and accrued liabilities	$ 53,409	$ 53,993

4. Property and equipment:

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

	September 30, 2020	December 31, 2019
Machinery & equipment	$ 4,683	$ 5,635
Right of use, building lease	536	720
Computer equipment & software	259	437
Office furniture & equipment	174	174
Leasehold improvements	43	43
Idle equipment	679	679
Construction in progress	61	—
Total	6,435	7,688
Less accumulated depreciation and amortization	(4,950)	(5,613)
Total property and equipment, net	$ 1,485	$ 2,075

Depreciation expense for the three-month periods ended September 30, 2020 and September 30, 2019, was approximately $0.02 million and $0.08 million, respectively. Depreciation expense for the nine-month periods ended September 30, 2020 and September 30, 2019, was approximately $0.5 million and $0.2 million, respectively. Depreciation expense for the nine-month period ended September 30, 2020 includes a $0.3 million one-time charge due to BUNAVAIL equipment write-off.

5. Intangible assets:

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

September 30, 2020	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net
Product rights	$ 6,050	$ (6,050)	$ —
BELBUCA license and distribution rights	45,000	(16,875)	28,125
Symproic license and distribution rights	30,636	(3,652)	26,984
Total intangible assets	$ 81,686	$ (26,577)	$ 55,109

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

December 31, 2019	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net
Product rights	$ 6,050	$ (6,003)	$ 47
BELBUCA license and distribution rights	45,000	(13,500)	31,500
Symproic license and distribution rights	30,636	(1,827)	28,809
Total intangible assets	$ 81,686	$ (21,330)	$ 60,356

6. Notes payable:

On May 23, 2019, the Company entered into a Loan Agreement with BPCR LIMITED PARTNERSHIP (the successor-in-interest to Biopharma Credit plc), 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 million within twelve months of the closing date, which the Company drew down on May 22, 2020.

The loan 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, with a floor of 2% plus the LIBOR rate. (LIBOR effective rate as of July 1, 2020 was 0.30%.) The Term Loan is subject to mandatory prepayment provisions that require prepayment upon change of control.

The debt balance has been categorized within Level 2 of the fair value hierarchy. The notes payable debt balance as of September 30, 2020 approximates its fair value based on prevailing interest rates as of the balance sheet date.

The following table represents future maturities of the notes payable obligation as of September 30, 2020:

2020	—
2021	—
2022	18,462
2023	24,615
2024	24,615
2025	12,308
Total maturities	$ 80,000
Unamortized discount and loan costs	(1,637)
Total notes payable obligation	$ 78,363

7. 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,	
	2020	2019	2020	2019
BELBUCA	$ 34,758	$ 26,514	$ 100,572	$ 69,277
% of net product sales	90 %	90 %	89 %	89 %
Symproic	3,453	2,172	11,046	5,348
% of net product sales	9 %	7 %	10 %	7 %
BUNAVAIL	574	937	1,328	2,813
% of net product sales	1 %	3 %	1 %	4 %
Net product sales	$ 38,785	$ 29,623	$ 112,946	$ 77,438

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

In June 2020, we discontinued distribution of BUNAVAIL in the U.S. The revenue reflected in the three months ended September 30, 2020 for BUNAVAIL reflects the release of certain reserves taken at the time the discontinuation was announced.

8. Stockholders' equity:

Common Stock

On July 23, 2020, in connection with the Company's 2020 Annual Meeting of Stockholders, 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 175,000,000 to 235,000,000.

On November 4, 2020, the Board of Directors authorized the repurchase of up to $25 million of the Company's shares of Common Stock. The timing and amount of any shares purchased on the open market will be determined based on the Company's evaluation of market conditions, share price and other factors. The Company plans to utilize existing cash on hand to fund the share repurchase program.

Stock-based compensation

During the nine months ended September 30, 2020, a total of 2,639,978 options to purchase Common Stock, with an aggregate fair market value of approximately $6.8 million, were granted to employees, officers, a director and the Interim Chief Executive Officer of the Company. Options have a term of 10 years from the grant date. Options granted to employees, officers and the director will vest ratably over a three-year period. Of the aforementioned option grants, 160,000 options, estimated to be valued at approximately $0.3 million, offered to the Chief Executive Officer ("CEO") in connection with his role as Interim Chief Executive Officer fully vested on November 4, 2020 upon his appointment to permanent CEO on that date. In addition, 840,000 options, estimated to be valued at approximately $1.7 million, were granted to the CEO on November 4, 2020 in connection with his appointment to the role, and vest ratably over three years. Options previously granted to the former Chief Executive Officer vested upon his termination as Chief Executive Officer, and will be exercisable for a period of three years. 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, expected rate of forfeiture 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, 2020 follows:

Expected price volatility	59.00%-61.76%
Risk-free interest rate	0.25%-1.68%
Weighted average expected life in years	6 years
Dividend yield	—

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

Option activity during the nine months ended September 30, 2020 was as follows:

	Number of shares	Weighted average exercise price per share	Aggregate intrinsic value
Outstanding at January 1, 2020	5,496,971	$ 3.64	$ 15,455
Granted in 2020:			
Officers and Directors	1,430,801	$ 5.64	
Employees	1,209,177	$ 5.65	
Exercised	(1,159,347)	$ 2.38	
Forfeitures	(365,188)	$ 4.37	
Outstanding at September 30, 2020	6,612,414	$ 4.62	$ 1,620

As of September 30, 2020, options exercisable totaled 3,008,632. There are approximately $7.6 million of unrecognized compensation costs related to non-vested share-based compensation awards, including options and restricted stock units (“RSUs”) granted. These costs will be expensed through 2023.

Restricted stock units

During the nine months ended September 30, 2020, a cumulative total of 302,404 RSUs were granted to the Company’s executive officers, a member of senior management, directors and the Interim Chief Executive Officer in connection with his role as Interim Chief Executive Officer with a fair market value of approximately $1.5 million. Of the aforementioned RSU grants, 40,000 RSUs, estimated to be valued at approximately $0.2 million, granted to the Chief Executive Officer ("CEO") in connection with his role as Interim Chief Executive Officer fully vested on November 4, 2020 upon his appointment to permanent CEO on that date. In addition, 160,000 RSUs, valued at approximately $0.6 million, were granted to the CEO upon his appointment on November 4, 2020, and vest ratably over three years. 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.

Restricted stock activity during the nine months ended September 30, 2020 was as follows:

	Number of restricted shares	Weighted average fair market value per RSU
Outstanding at January 1, 2020	1,648,559	$ 3.86
Granted in 2020:		
Officers and Directors	289,949	$ 5.17
Employees	12,455	$ 5.50
Vested	(712,654)	$ 2.72
Forfeitures	(407,217)	$ 4.31
Outstanding at September 30, 2020	831,092	$ 3.82

Warrants

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. There were no warrants issued during the nine months ended September 30, 2020 and as of September 30, 2020, a cumulative of 2,136,019 warrants remain outstanding.

Preferred Stock

During the nine months ended September 30, 2020, 175 shares of Series B Preferred Stock (“Series B”) were converted into 972,222 shares of Common Stock. As of September 30, 2020, 443 shares of Series B are outstanding.

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

During the nine months ended September 30, 2020, 2,093,155 shares of Series A Preferred Stock ("Series A") were converted on a one-for-one basis into shares of Common Stock. There are no remaining outstanding shares of Series A as of September 30, 2020.

Earnings Per Share

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Basic:				
Net income (loss) attributable to common stockholders, basic	$ 9,383	$ 354	$ 15,515	$ (14,609)
Weighted average common shares outstanding	101,031,317	89,649,922	99,377,748	81,612,112
Basic earnings (loss) per common share	**$ 0.09**	**$ —**	**$ 0.16**	**$ (0.18)**
Diluted:				
Effect of dilutive securities:				
Net income (loss) attributable to common stockholders, diluted	$ 9,383	$ 354	$ 15,515	$ (14,609)
Weighted average common shares outstanding	101,031,317	89,649,922	99,377,748	81,612,112
Effect of dilutive options and warrants	4,752,251	15,488,972	5,458,745	—
Dilutive weighted average common shares outstanding	105,783,568	105,138,894	104,836,493	81,612,112
Diluted earnings (loss) per common share	**$0.09**	**$—**	**$0.15**	**$(0.18)**

During the three months ended September 30, 2020 and the nine months ended September 30, 2020, outstanding stock options, RSUs, warrants and preferred shares of 4,752,251 and 5,458,745, respectively, were included in the computation of diluted earnings per common share.

During the three months ended September 30, 2019, outstanding stock options, RSUs, warrants and preferred shares of 15,488,972 were included in the computation of diluted earnings per common share. During the nine months ended September 30, 2019, outstanding stock options, RSUs, warrants and preferred shares of 15,260,949 were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect.

9. 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 per disclosure requirements 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.

On January 13, 2020, by the Court of Appeals for the Federal Circuit denied BDSI's petition for en banc rehearing of the dismissal of BDSI's appeal relating to inter partes review proceedings on the '167 patent. On June 11, 2020, BDSI filed a petition for certiorari seeking U.S. Supreme Court review of the Federal Circuit's decision. On October 5, 2020, the U.S. Supreme Court denied the Company's petition for certiorari.

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.

The Court has scheduled a bench trial to commence on November 9, 2020 to adjudicate issues concerning the validity of the Orange Book patents listed for BELBUCA. On October 6, 2020, the Court rescheduled the bench trial with Alvogen to commence on March 1, 2021.

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, the "Chemo Defendants"), asserting that the Chemo 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 Court has scheduled a bench trial to commence on November 9, 2020 (jointly with Alvogen) to adjudicate issues concerning the validity of the Orange Book patents listed for BELBUCA. On October 6, 2020, the Court rescheduled the bench trial with Chemo and Alvogen to adjudicate issues concerning the validity of the Orange Book patents listed for BELBUCA to commence on March 1, 2021. The Court has scheduled a bench trial to commence on May 3, 2021 to adjudicate issues concerning the Chemo Defendants' infringement of the Orange Book patents.

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. On July 1, 2020, the Company filed its response to the Complaint and denied the claims asserted therein.

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. On July 23, 2020, the stockholders of the Company approved the ratification of the declassification of the Board and the change in the voting standard as set forth in the Amendments as well as the filing and effectiveness of the Amendments. On July 23, 2020, the Company filed a Certificate of Validation with the Delaware Secretary of State.

On October 8, 2020, the Court entered an agreed-to order dismissing the plaintiffs' claims for violation of the Delaware General Corporation Law. On October 13, 2020, plaintiffs filed an amended complaint, asserting individual, class and derivative claims for breach of fiduciary duties against our directors. On October 26, 2020, the Company and our directors filed a motion to dismiss the amended complaint. The Company intends to continue to defend against the litigation vigorously.

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 continue 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 plan 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 plan 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.

Our commercial strategy for BELBUCA is to further drive continued adoption in the large long-acting opioid market based on its unique profile coupled with growing physician interest, policy tailwinds, and expanding payer access. We aim to leverage the specialized commercial infrastructure we established for BELBUCA as a vehicle to enable commercial growth in Symproic, which is increasingly seen as a complementary asset.

Our Products

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

BELBUCA

BELBUCA® (buprenorphine buccal film), CIII is a buccal film that contains the Schedule III opioid buprenorphine, which 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 death related to 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 drug bioavailability.

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, chronic pain management specialists, and clinicians we believe have the greatest opportunity to be adopters of BELBUCA. As of October 2020, BELBUCA had formulary coverage for more than 94% of commercial lives.

Additionally, we recently completed a Phase I placebo-controlled study to compare the effects of BELBUCA and oral oxycodone hydrochloride (a full μ-opioid receptor agonist) on respiratory drive, as measured by the ventilatory response to hypercapnia (VRH) after drug administration. While analyses of the data is currently ongoing, our primary endpoint showed

that there was no significant change in respiratory drive compared to placebo for any dose of BELBUCA (300, 600, or 900 mcg) and there was a dose-dependent worsening of respiratory drive compared to placebo for oxycodone, and it was statistically significant at the 60mg dose.

The risks to our company associated with BELBUCA include: (i) inability to continue 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 ("PAMORA"), and was approved by the FDA on March 23, 2017 for the treatment of opioid-induced constipation ("OIC") 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-weeks and 52-weeks duration in OIC patients;
- OIC relief that was more frequent, more complete, and 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 one 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 allows both the patient and the healthcare provider to focus on managing the issue of chronic pain.

We believe that there are long-term growth opportunities for Symproic. According to data from Symphony Health, in 2019 Symproic prescription volume grew over 60%, capturing 10% of the PAMORA market. In 2019 the PAMORA market declined by 3%, with over 585,000 PAMORA prescriptions dispensed. The growth rate of the PAMORAs has slowed, driven by a decline in opioid prescription rates. As of January 2020, Symproic had formulary coverage for more than 95% of commercial lives.

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, (v) inadequate reimbursement, and (vi) a possible decrease in the OIC market.

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. The Company discontinued all marketing of BUNAVAIL in August 2020.

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 cancer pain in opioid tolerant patients 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 the current declining market

conditions, we have no plans to introduce the product in the U.S. at this time. The product is no longer a strategic asset 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, 2020 and 2019

Product Sales. We recognized $38.8 million and $29.6 million in product sales during the three months ended September 30, 2020 and 2019, respectively. The increase in 2020 is principally due to BELBUCA and Symproic product sales which have been driven by increased paid prescriptions from the utilization of managed care wins, along with growth in the Medicare channel, and offset by lower BUNAVAIL product sales resulting from our discontinuation of marketing activities. While BELBUCA gross to net deductions did increase in the third quarter as anticipated, based primarily on typical increases seen for coverage gap along with increased Medicaid costs, those increases were favorably impacted by updates to our channel estimates reflected in the third quarter of 2020. BUNAVAIL net revenue in the quarter reflects the release of a portion of the returns reserves taken at the time discontinuation was announced.

Product Royalty Revenues. We recognized $0.7 million in product royalty revenue during each of the three months ended September 30, 2020 and 2019, respectively, related to PAINKYL royalty revenue under our license agreement with TTY.

Cost of Sales. We incurred $5.4 million in cost of sales during each of the three months ended September 30, 2020 and 2019, 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, 2020 and 2019, selling, general and administrative expenses totaled $22.5 million and $23.4 million, respectively. Selling, general and administrative costs include all costs not related to the manufacturing of product. The decrease in selling, general and administrative expenses during the three months ended September 30, 2020 as compared to the same period in the prior year is primarily due to lower spend associated with cost management measures that have been put in place in response to Covid-19, particularly over select marketing programs. In addition, we have continued to see a reduction in travel expenses due to elimination of live presence at conferences and restrictions in visiting doctor's offices.

Interest expense, net . During the three months ended September 30, 2020, we had net interest expense of $2.0 million, which consisted of $1.9 million of scheduled interest payments, and $0.1 million of amortization of discount and loan costs.

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

Comparison of the nine months ended September 30, 2020 and 2019

Product Sales. We recognized $112.9 million and $77.4 million in product sales during the nine months ended September 30, 2020 and 2019, respectively. The increase in 2020 is principally due to increased BELBUCA and Symproic product sales from higher patient utilization, the impact of managed care wins, the impact of our price increase on January 1, 2020, and the full period impact of Symproic, partially offset by lower BUNAVAIL product sales.

Product Royalty Revenues. During the nine months ended September 30, 2020 and 2019, we recognized $1.4 million and $2.2 million in PAINKYL and BREAKYL product royalty revenue under our license agreements with TTY and Mylan, respectively. Product royalty revenue related to PAINKYL and BREAKYL is primarily via government demand in the Ex-U.S. countries where the products are sold by TTY and Mylan, respectively.

Contract Revenues. We recognized $0.2 million in contract revenues during the nine months ended September 30, 2019 related to our license agreements TTY. There were no such contract revenues during the same period of 2020.

Cost of Sales. We incurred $16.4 million and $14.3 million in cost of sales during the nine months ended September 30, 2020 and 2019, respectively. Cost of sales includes product cost, royalties paid, depreciation, yield adjustments and quarterly minimum royalty payments to CDC. Cost of sales for the nine months ended September 30, 2020 includes a $0.3 million one-time depreciation charge due to BUNAVAIL equipment write-off.

Selling, General and Administrative Expenses. During the nine months ended September 30, 2020 and 2019, selling, general and administrative expenses totaled $77.4 million and $62.3 million, respectively. Selling, general and administrative

costs include all other costs not connected to the manufacturing of product. The increase in selling, general and administrative expenses during the nine months ended September 30, 2020 is due primarily to increased marketing efforts during the first quarter 2020, higher legal costs, and severance costs associated with the termination of the former CEO. These increased costs have been partially offset by cost management measures that were put in place during the second quarter of 2020 in response to the pandemic, such as reductions in select marketing programs as well as a significant reduction in travel expenses resulting from the various "stay at home" orders across the country.

Interest expense, net. During the nine months ended September 30, 2020, we had net interest expense of $5.0 million, which includes interest expense of $5.0 million and $0.2 million of amortization of discount and loan costs. During the nine months ended September 30, 2020, we also had interest income of $0.2 million.

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

The one-time expenses related to the payoff of the CRG loan in May 2019 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.

Trends and Uncertainties

Potential Impact of the COVID-19 Pandemic

The recent COVID-19 pandemic is understood to have originated in Wuhan, China in December 2019 and has since spread globally, including to the United States and European countries. The continued spread of COVID-19 has adversely impacted our operations, including our efforts to market BELBUCA and Symproic. Any decrease in sales or interruption in supply of any of our products could increase our operating expenses and have a material adverse effect on our business and financial results.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all home-office employees to work remotely. We have suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

In addition, a recurrence or "second wave" of COVID-19 cases could cause other widespread or more severe impacts depending on where infection rates are highest. The extent to which COVID-19 will continue to impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers and contract manufacturers or contract research organizations operate. If we or any of the third parties with whom we engage experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

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 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:

- 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
- We exclude the financial impact of debt refinancing, the CEO termination costs and the BUNAVAIL equipment write-off, because they are each non-recurring in nature.

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.

Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
GAAP net income/(loss)	**$ 9,383**	**$ 354**	**$ 15,515**	**$ (14,609)**
Add back/(subtract):				
Income tax provision	211	4	19	4
Net interest expense	2,012	1,237	4,991	17,727
Depreciation and amortization	1,754	1,904	5,715	5,259
EBITDA	**$ 13,360**	**$ 3,499**	**$ 26,240**	**$ 8,381**
Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)				
GAAP net income/(loss)	**$ 9,383**	**$ 354**	**$ 15,515**	**$ (14,609)**
Non-GAAP adjustments:				
Stock-based compensation expense	1,473	1,267	4,424	3,978
Amortization of intangible assets	1,734	1,898	5,248	5,084
Amortization of warrant discount	—	—	—	448
Non-recurring financial impact of debt refinance	—	—	—	11,866
Non-recurring financial impact of CEO transition	67	—	5,078	—
Non-recurring financial impact of BUNAVAIL discontinuation	—	—	295	—
Non-GAAP net income/(loss)	**$ 12,657**	**$ 3,519**	**$ 30,560**	**$ 6,767**

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 and Symproic, 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, 2020, we had cash and cash equivalents of approximately $100.2 million. We generated $14.0 million of cash in operations during the nine months ended September 30, 2020 . We believe that we have sufficient cash to manage the business as currently planned.

Additional capital may be required to support the continued commercialization of our BELBUCA and Symproic products, or other products which may be acquired or licensed by us, and for general working capital requirements. Based on 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.

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 2020 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, 2020 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	$ 681	$ 368	$ 313	$ —	$ —
Secured loan facility	80,000	—	36,923	43,077	—
Interest on secured loan facility	25,049	7,706	13,186	4,157	—
Minimum royalty expenses*	10,125	1,500	3,000	3,000	2,625
Purchase obligations**	958	804	154	—	—
Total contractual cash obligations	$ 116,813	$ 10,378	$ 53,576	$ 50,234	$ 2,625

* 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, 2020, 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, 2019.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

Our cash includes all highly liquid investments with an original maturity of three months or less. Because of the short-term maturities of our cash, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash on deposit with financial institutions in the U.S. The Federal Deposit Insurance Corporation covers $0.25 million for substantially all depository accounts. As of September 30, 2020, we had approximately $100.3 million, which exceeded these insured limits.

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. However, if LIBOR ceases to exist, we will not be required to renegotiate our loan documents with our current lender.

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 Interim 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, 2020.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our third quarter of 2020 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 Reform 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," "will," "potential," "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 U.S. Securities and Exchange Commission. Actual results, including, without limitation: (i) actual sales results (including the results of our continuing commercial efforts with BELBUCA and Symproic), (ii) the application and availability of corporate funds and our need for future funds, (iii) the FDA's review of our products and any regulatory filings related thereto, or (iv) the results of our ongoing intellectual property litigations and patent office proceedings, may differ materially from those set forth or implied 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, the impact of the COVID-19 pandemic on our business and results of operations, those listed under Item 1A of our most recent Annual Report on Form 10-K filed with the SEC on March 12, 2020 and under Item 1A of this Quarterly Report on Form 10-Q and other factors detailed from time to time in our other filings with the U.S. Securities and Exchange Commission. 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 9, 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.

COVID-19 may materially and adversely affect our business and our financial results.

The recent COVID-19 pandemic is understood to have originated in Wuhan, China in December 2019 and has since spread globally, including to the United States and European countries. The continued spread of COVID-19 has adversely impacted our operations, including our efforts to market BELBUCA and Symproic. Any decrease in sales or interruption in supply of any of our products could increase our operating expenses and have a material adverse effect on our business and financial results.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all home-office employees to work remotely. We have suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

In addition, a recurrence or "second wave" of COVID-19 cases could cause other widespread or more sever impacts depending on where infection rates are highest. The extent to which COVID-19 will continue to impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers and contract manufacturers or contract research organizations operate. If we or any of the third parties with whom we engage experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

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

On November 4, 2020, the Board of Directors authorized the repurchase of up to $25 million of the Company's shares of Common Stock. The timing and amount of any shares purchased on the open market will be determined based on the Company's evaluation of market conditions, share price and other factors. The Company plans to utilize existing cash on hand to fund the share repurchase program.

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.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document contained in Exhibit 101).*

*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 5, 2020

By: /s/ Jeffrey Bailey
Jeffrey Bailey
Director and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2020

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, Jeffrey Bailey, 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 5, 2020

/s/ Jeffrey Bailey
Jeffrey Bailey
Director and Chief Executive Officer
(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 5, 2020

/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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey Bailey, 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/ Jeffrey Bailey
Jeffrey Bailey
Director and Chief Executive Officer
(Principal Executive Officer)
November 5, 2020

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, 2020, 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 5, 2020