
**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 June 30, 2021

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
(State or other jurisdiction of
incorporation or organization)

4131 ParkLake Ave., Suite 225, Raleigh, NC
(Address of principal executive offices)

35-2089858
(I.R.S. Employer
Identification No.)

27612
(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	<input type="checkbox"/>	Accelerated Filer	<input checked="" type="checkbox"/>
Non-Accelerated Filer	<input type="checkbox"/>	Smaller Reporting Company	<input type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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 August 4, 2021, there were 101,863,230 shares of company Common Stock issued and 98,597,546 shares of company Common Stock outstanding.

BioDelivery Sciences International, Inc. and Subsidiaries**Quarterly Report on Form 10-Q****TABLE OF CONTENTS**

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

From time to time, we may use our website, our Facebook page at [Facebook.com/BioDeliverySI](https://www.facebook.com/BioDeliverySI), our Twitter at [@BioDeliverySI](https://twitter.com/BioDeliverySI) and our LinkedIn at [linkedin.com/company/biodeliverysciencesinternational](https://www.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)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 119,853	\$ 111,584
Accounts receivable, net	52,872	48,150
Inventory, net	18,659	17,443
Prepaid expenses and other current assets	4,680	5,208
Total current assets	196,064	182,385
Property and equipment, net	1,640	1,418
Goodwill	2,715	2,715
License and distribution rights, net	49,908	53,376
Total assets	\$ 250,327	\$ 239,894
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 57,752	\$ 52,995
Notes payable, current	6,154	—
Total current liabilities	63,906	52,995
Notes payable, less current maturities	72,472	78,452
Other long-term liabilities	31	213
Total liabilities	136,409	131,660
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; Series B Non-Voting Convertible Preferred Stock, \$0.001 par value, 443 shares outstanding at June 30, 2021 and December 31, 2020, respectively.	—	—
Common Stock, \$0.001 par value; 235,000,000 shares authorized at June 30, 2021 and December 31, 2020, respectively; 101,794,730 and 101,417,441 shares issued; 98,529,046 and 101,354,447 shares outstanding at June 30, 2021 and December 31, 2020, respectively.	104	104
Additional paid-in capital	452,550	449,264
Treasury stock, at cost, 3,265,684 and 62,994 shares, as of June 30, 2021 and December 31, 2020, respectively.	(12,155)	(252)
Accumulated deficit	(326,581)	(340,882)
Total stockholders' equity	113,918	108,234
Total liabilities and stockholders' equity	\$ 250,327	\$ 239,894

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 June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	\$ 40,523	\$ 36,445	\$ 81,326	\$ 74,161
Product royalty revenues	916	137	1,132	700
Total revenues:	41,439	36,582	82,458	74,861
Cost of sales	4,284	5,435	10,105	10,995
Expenses:				
Selling, general and administrative	25,779	28,211	53,540	54,948
Total expenses:	25,779	28,211	53,540	54,948
Income from operations	11,376	2,936	18,813	8,918
Interest expense, net	(1,999)	(1,693)	(3,977)	(2,987)
Other (expense)/income, net	(1)	8	(1)	8
Income before income taxes	\$ 9,376	\$ 1,251	\$ 14,835	\$ 5,939
Income tax (provision)/recovery	(312)	(86)	(534)	192
Net income attributable to common stockholders	\$ 9,064	\$ 1,165	\$ 14,301	\$ 6,131
Basic				
Weighted average common stock shares outstanding	98,793,242	100,136,893	99,884,680	98,541,877
Basic earnings per share	\$ 0.09	\$ 0.01	\$ 0.14	\$ 0.06
Diluted				
Weighted average common stock shares outstanding	102,508,512	108,111,201	104,009,410	107,062,161
Diluted earnings per share	\$ 0.09	\$ 0.01	\$ 0.14	\$ 0.06

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, January 1, 2020	2,093,155	\$ 2	618	\$ —	96,189,074	\$ 96	\$ 436,306	\$ (47)	\$ (366,593)	\$ 69,764
Stock-based compensation	—	—	—	—	—	—	1,520	—	—	1,520
Stock option exercises	—	—	—	—	107,287	—	338	—	—	338
Restricted stock awards	—	—	—	—	459,670	—	—	—	—	—
Series A conversion to common stock	(2,093,155)	(2)	—	—	2,093,155	2	(1)	—	—	(1)
Series B conversion to common stock	—	—	(175)	—	972,222	1	—	—	—	1
Net income	—	—	—	—	—	—	—	—	4,966	4,966
Balances, March 31, 2020	—	—	443	\$ —	99,821,408	99	438,163	(47)	(361,627)	76,588
Stock-based compensation	—	—	—	—	—	—	4,786	—	—	4,786
Stock option exercises	—	—	—	—	983,437	—	2,231	—	—	2,231
Restricted stock awards	—	—	—	—	111,666	—	—	—	—	—
Net income	—	—	—	—	—	—	—	—	1,165	1,165
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
Stock-based compensation	—	—	—	—	—	—	1,750	—	—	1,750
Stock option exercises	—	—	—	—	240,656	1	608	—	—	609
Restricted stock awards	—	—	—	—	50,333	3	(4)	—	—	(1)
Share repurchase	—	—	—	—	—	—	—	(205)	—	(205)
Net income	—	—	—	—	—	—	—	—	10,196	10,196
Balances, December 31, 2020	—	—	443	—	101,417,441	104	449,264	(252)	(340,882)	108,234
Stock-based compensation	—	—	—	—	—	—	1,490	—	—	1,490
Stock option exercises	—	—	—	—	16,619	—	40	—	—	40
Restricted stock awards	—	—	—	—	268,174	—	—	—	—	—
Share repurchase	—	—	—	—	—	—	—	(6,147)	—	(6,147)
Net income	—	—	—	—	—	—	—	—	5,237	5,237
Balances, March 31, 2021	—	—	443	—	101,702,234	104	450,794	(6,399)	(335,645)	108,854
Stock-based compensation	—	—	—	—	—	—	1,697	—	—	1,697
Stock option exercises	—	—	—	—	25,828	—	59	—	—	59
Restricted stock awards	—	—	—	—	66,668	—	—	—	—	—
Share repurchase	—	—	—	—	—	—	—	(5,756)	—	(5,756)
Net income	—	—	—	—	—	—	—	—	9,064	9,064
Balances, June 30, 2021	—	—	443	—	101,794,730	\$104	\$452,550	\$(12,155)	\$(326,581)	\$113,918

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)

	Six months ended June 30,	
	2021	2020
Operating activities:		
Net income	\$ 14,301	\$ 6,131
Adjustments to reconcile net income to net cash flows from operating activities		
Depreciation	54	446
Accretion of debt discount and loan costs	174	142
Amortization of intangible assets	3,469	3,515
Provision for inventory obsolescence	699	72
Stock-based compensation expense	3,187	6,306
Net change in operating lease assets and liabilities	(19)	—
Changes in assets and liabilities:		
Accounts receivable	(4,722)	(9,336)
Inventories	(1,915)	(6,534)
Prepaid expenses and other assets	368	1,670
Accounts payable and accrued liabilities	4,731	2,617
Taxes payable	—	(40)
Net cash flows provided by operating activities	20,327	4,989
Investing activities:		
Acquisitions of equipment	(415)	—
Net cash flows used in investing activities	(415)	—
Financing activities:		
Proceeds from notes payable	—	20,000
Proceeds from exercise of stock options	260	2,569
Payment on share repurchase	(11,903)	—
Payment on deferred financing fees	—	(437)
Net cash flows provided by financing activities	(11,643)	22,132
Net change in cash and cash equivalents	8,269	27,121
Cash and cash equivalents at beginning of period	111,584	63,888
Cash and cash equivalents at end of period	\$ 119,853	\$ 91,009
Cash paid for interest	\$ 3,821	\$ 3,095

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, 2020 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, 2020. 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, 2020.

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.

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

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 June 30, 2021 and December 31, 2020 were \$3.0 million and \$2.3 million, respectively.

Revenue recognition

Product sales

Product sales amounts relate to sales of BELBUCA and Symproic. Product sales for the three and six months ended June 30, 2020 also included sales of BUNAVAIL. 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 Biopharm Co., Ltd., ("TTY") and the BREAKYL™ product under the Company's license agreement with Meda AB, which was acquired by Mylan N.V. and later acquired by Viatris, Inc. (which we refer to herein as Viatris). 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.

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. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with its customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component.

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;

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

- 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.

In its analyses, the Company uses prescription data purchased from a third-party data provider to develop estimates of historical inventory channel sell-through. The Company utilizes an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, management develops an estimate of the quantity of product in the channel which may be subject to various rebate and chargeback exposures. To estimate months of ending inventory in the Company's distribution channel, the Company divides estimated ending inventory in the distribution channel by the Company's recent prescription data, not considering any future anticipated demand growth beyond the succeeding quarter. Monthly for each product line, the Company prepares an internal estimate of ending inventory units in the distribution channel by adding estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. This is done for each product line by applying a rate of historical activity for rebates and chargebacks, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated, net of reserved return units, to be in the distribution channel. In addition, the Company receives daily information from the major wholesalers regarding their sales and actual on hand inventory levels of the Company's products. This enables the Company to execute accurate provisioning procedures.

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. The Company estimates product returns reserves based upon historical return rates adjusted for qualitative factors and are applied to open product batches that are currently eligible for returns, or will be eligible in the future, within company policy. Other factors considered include expected marketplace changes and the remaining shelf life of product batches. Product returns reserves for newly launched products are based on historical rates of similar products or pre-determined percentage.

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 combination of historical experience, product pricing, estimated payor mix, product growth, and the mix of contract and agreement terms. 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 estimates the rebates to commercial contracts based upon a combination of historical experience, product pricing, estimated payor mix, product growth, and the mix of contract and agreement terms. 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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(Unaudited)

Patient Assistance 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.

There can be a significant lag between the Company's establishment of an estimate and the timing of the invoicing or claim. The Company believes it has made reasonable estimates for future rebates and claims, however, these estimates involve assumptions pertaining to contractual utilization and performance, and payor mix. If the performance or mix across third-party payors 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.

Cost of sales

Cost of sales includes the direct costs attributable to the production of BELBUCA and Symproic. It includes raw materials, production costs at the Company's contract manufacturing sites, quality testing directly related to the products, inventory reserves, and depreciation on equipment that the Company has purchased to produce BELBUCA, Symproic and formerly BUNAVAIL. It also includes any batches not meeting specifications and raw material yield losses. Yield losses and the costs related to 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.

Measurement of credit losses of financial instruments

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 June 30, 2021, the Company reported \$52.9 million of trade receivables within accounts receivable. Based on an aging analysis at June 30, 2021, 93% 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 June 30, 2021 and December 31, 2020. 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.

New Accounting Pronouncements, 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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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(Unaudited)

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 adopted Topic 740 during the six months ended June 30, 2021 and determined that the new guidance did not have a material impact on its consolidated financial statements.

The Company has reviewed other new accounting pronouncements that were issued as of June 30, 2021 and does not believe that these pronouncements are applicable to the Company, or that they will have a material impact on its financial position or results of operations.

Fair Value of Financial Instruments

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

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

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

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

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

The following table summarizes the financial instruments measured at fair value on a recurring basis as of June 30, 2021:

	Level 1	Level 2	Level 3	Balance at June 30, 2021
Cash and cash equivalents	\$ 119,853	\$ —	\$ —	\$ 119,853

The cash and cash equivalent balance as of June 30, 2021 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:

	June 30, 2021	December 31, 2020
Raw materials	\$ 3,127	\$ 3,389
Work-in-process	6,828	9,949
Finished goods	11,657	6,359
Obsolescence reserve	(2,953)	(2,254)
Total inventories	<u>\$ 18,659</u>	<u>\$ 17,443</u>

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3. Accounts payable and accrued liabilities:

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

	June 30, 2021	December 31, 2020
Accounts payable	\$ 4,073	\$ 4,213
Accrued rebates	35,644	34,247
Accrued compensation and benefits	6,115	5,488
Accrued returns	6,535	5,128
Accrued royalties	1,123	704
Taxes payable	(22)	1,026
Accrued legal	2,113	515
Accrued regulatory expenses	511	397
Accrued other	1,660	1,277
Total accounts payable and accrued liabilities	\$ 57,752	\$ 52,995

4. Property and equipment:

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

	June 30, 2021	December 31, 2020
Machinery & equipment	\$ 4,848	\$ 4,683
Right of use, building lease	333	471
Computer equipment & software	640	272
Office furniture & equipment	174	174
Leasehold improvements	43	43
Idle equipment	679	679
Construction in progress	—	119
Total	6,717	6,441
Less accumulated depreciation and amortization	(5,077)	(5,023)
Total property and equipment, net	\$ 1,640	\$ 1,418

Depreciation expense for the three-month periods ended June 30, 2021 and June 30, 2020, was approximately \$0.03 million and \$0.4 million, respectively. Depreciation expense for the six-month periods ended June 30, 2021 and June 30, 2020, was approximately \$0.1 million and \$0.4 million, respectively. Depreciation expense for the three- and six-month periods ended June 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:

June 30, 2021	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net	Weighted Average Useful Life
BELBUCA license and distribution rights	45,000	(20,250)	24,750	5.5
Symproic license and distribution rights	30,636	(5,478)	25,158	10.5
Total intangible assets	\$ 75,636	\$ (25,728)	\$ 49,908	7.5

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December 31, 2020	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net	Weighted Average Useful Life
Product rights	\$ 6,050	\$ (6,050)	\$ —	
BELBUCA license and distribution rights	45,000	(18,000)	27,000	6.0
Symproic license and distribution rights	30,636	(4,260)	26,376	10.8
Total intangible assets	<u>\$ 81,686</u>	<u>\$ (28,310)</u>	<u>\$ 53,376</u>	7.9

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 \$20.0 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% for the LIBOR rate (LIBOR effective rate as of April 1, 2021 was 0.20%.) 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 June 30, 2021 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 June 30, 2021:

2021	—
2022	18,462
2023	24,615
2024	24,615
2025	12,308
Total maturities	\$ 80,000
Unamortized discount and loan costs	(1,374)
Total notes payable obligation	<u>\$ 78,626</u>

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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 June 30,		Six months ended June 30,	
	2021	2020	2021	2020
BELBUCA	\$ 36,504	\$ 32,344	\$ 72,906	\$ 65,813
% of net product sales	90 %	89 %	90 %	89 %
Symploc	4,019	3,413	8,420	7,593
% of net product sales	10 %	9 %	10 %	10 %
BUNAVAIL	—	688	—	755
% of net product sales	— %	2 %	— %	1 %
Net product sales	<u>\$ 40,523</u>	<u>\$ 36,445</u>	<u>\$ 81,326</u>	<u>\$ 74,161</u>

8. Stockholders' equity:

Common Stock

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.

During the six months ended June 30, 2021, a cumulative total of 3,202,690 shares, with a weighted average price of \$3.72 for a value of \$11.9 million were repurchased and recorded as Treasury Stock in the condensed consolidated balance sheet.

Stock-based compensation

During the six months ended June 30, 2021, a total of 2,893,682 options to purchase Common Stock, with an aggregate fair market value of approximately \$11.8 million, were granted to employees and the Company's executive officers of the Company. Options have a term of 10 years from the grant date. Options granted to employees and officers will vest ratably over a three-year 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 six months ended June 30, 2021 follows:

Expected price volatility	58.57%-59.87%
Risk-free interest rate	0.50%-1.13%
Weighted average expected life in years	6 years
Dividend yield	—

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Option activity during the six months ended June 30, 2021 was as follows:

	Number of shares	Weighted average exercise price per share	Aggregate intrinsic value
Outstanding at January 1, 2021	7,060,966	\$ 4.55	\$ 2,831
Granted in 2021:			
Officers and Directors	1,249,292	3.84	
Employees	1,644,390	4.25	
Exercised	(42,447)	2.35	
Forfeitures	(295,071)	4.79	
Outstanding at June 30, 2021	9,617,130	\$ 4.41	\$ 1,061

During the six months ended June 30, 2021 and 2020, Company employees and directors exercised approximately 42,447 and 1,090,724 stock options, respectively, with net proceeds to the Company of approximately \$0.1 million and \$2.6 million, respectively. The intrinsic value of options exercised during the six months ended June 30, 2021 and 2020 was approximately \$0.1 million and \$3.0 million, respectively.

As of June 30, 2021, options exercisable totaled 4,007,289. There are approximately \$10.7 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 2024.

Restricted stock units

During the six months ended June 30, 2021, a cumulative total of 262,369 RSUs were granted to the Company’s executive officers and members of senior management, with a fair market value of approximately \$1.0 million. The fair value of restricted units is determined using quoted market prices of the Common Stock and the number of shares expected to vest. RSU grants are time-based, all of which generally vest from a one to three-year period.

Restricted stock activity during the six months ended June 30, 2021 was as follows:

	Number of restricted shares	Weighted average fair market value per RSU
Outstanding at January 1, 2021	940,759	\$ 3.71
Granted:		
Officers and Directors	226,562	3.84
Employees	35,807	3.84
Vested	(334,842)	3.88
Forfeitures	—	—
Outstanding at June 30, 2021	868,286	\$ 3.87

Warrants

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements.

As of June 30, 2021, a cumulative total of 2,051,033 warrants, with exercise prices ranging from \$2.38 to \$3.42, remain exercisable and outstanding. The warrants were valued using the Black-Scholes Model, which a cumulative fair value of approximately \$4.5 million. There were no warrants granted or exercised during the six months ended June 30, 2021.

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Preferred Stock

As of June 30, 2021, 443 shares of Series B Preferred Stock (“Series B”) are outstanding. There were no conversions of Series B during the six months ended June 30, 2021.

Earnings Per Share

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Basic:				
Net income attributable to common stockholders, basic	\$ 9,064	\$ 1,165	\$ 14,301	\$ 6,131
Weighted average common shares outstanding	98,793,242	100,136,893	99,884,680	98,541,877
Basic earnings per common share	\$ 0.09	\$ 0.01	\$ 0.14	\$ 0.06
Diluted:				
Effect of dilutive securities:				
Net income attributable to common stockholders, diluted	\$ 9,064	\$ 1,165	\$ 14,301	\$ 6,131
Weighted average common shares outstanding	98,793,242	100,136,893	99,884,680	98,541,877
Effect of dilutive options and warrants	3,715,270	7,974,308	4,124,730	8,520,284
Dilutive weighted average common shares outstanding	102,508,512	108,111,201	104,009,410	107,062,161
Diluted earnings per common share	\$ 0.09	\$ 0.01	\$ 0.14	\$ 0.06

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

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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 did not appeal the Delaware Court's holding that other claims of the '832 Patent are invalid. On February 10, 2021, the parties in our EDNC declaratory judgment action filed a covenant by Indivior and Aquestive not to sue us for infringement of the '832 Patent. In view of that covenant and the prior invalidation of the '080 patent, we filed a notice of voluntary dismissal of the Company's EDNC declaratory judgment action.

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.

The Company strongly refutes as without merit the Plaintiffs' assertion of patent infringement and will vigorously defend the lawsuit.

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. On January 13, 2020, in lieu of answering the complaint, we filed a motion to dismiss the complaint. After the two motions were denied, on April 16, 2020, we answered the complaint. Aquestive moved to dismiss our counter-claim of

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unenforceability, but the court denied that motion. 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.

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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 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. A three day bench trial against Alvogen was conducted commencing on March 1, 2021. At the conclusion of trial, the Court ordered the parties to submit post-trial briefs. Post-trial briefing was completed on May 26, 2021. The Company subsequently moved the Court to strike (i.e., remove from the Court’s consideration) three patent invalidity defenses raised for the first time in Alvogen’s post-trial briefs and two documents improperly cited in Alvogen’s post-trial briefs. On June 28, 2021, the Court granted the Company’s motion to strike in its entirety. In addition, on June 28, 2021, the Court enjoined Alvogen from launching its generic product until the Court issues its final decision on the merits. The Company remains confident in the validity of its Orange Book patents listed for BELBUCA.

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

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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 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. Chemo did not participate in the bench trial that commenced on March 1, 2021. Instead, on February 26, 2021, Chemo agreed to be bound by the decision of the Court with respect to the validity of the BEMA patents from the March 1, 2021 trial with Alvogen. The Court had scheduled a bench trial to commence on May 3, 2021 to adjudicate issues concerning the Chemo Defendants' infringement of the Orange Book patents. On December 1, 2020, the Court rescheduled the bench trial to adjudicate issues concerning the Chemo Defendants' infringement of the Orange Book patents to commence on November 15, 2021. On July 15, 2021, the Court rescheduled the bench trial to adjudicate issues concerning the Chemo Defendants' infringement of the Orange Book patents to commence on April 25, 2022.

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 alleged that the Amendments did not receive the requisite vote of stockholders at the 2018 Annual Meeting and asserted claims for violation of the Delaware General Corporation Law, breach of fiduciary duties, and declaratory judgment. The Complaint sought, 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 sought costs and disbursements, including attorneys' fees. On July 1, 2020, the Company filed their 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.

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

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 defendants filed a motion to dismiss the amended complaint. On February 19, 2021, plaintiffs filed their opposition to the motion to dismiss. On March 8, 2021, the defendants filed a reply in further support of the motion to dismiss. The oral argument on defendants' motion to dismiss took place on June 10, 2021 and, pursuant to a request from the Court, the parties are in the process of filing supplemental briefing. The defendants intend 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. We seek to continue to build a well-balanced, diversified, high-growth specialty pharmaceutical company focused on delivering innovative therapies for individuals living with serious and debilitating chronic conditions. 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. As we gain access to these drugs and technologies, we will 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 will 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 (buprenorphine buccal film) 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 payor access. We aim to leverage the specialized commercial infrastructure we established for BELBUCA as a vehicle to enable commercial growth in Symproic, a peripherally acting mu-opioid receptor antagonist, which we view as a complementary asset.

Results of Operations

Comparison of the three months ended June 30, 2021 and 2020

Product Sales. We recognized \$40.5 million and \$36.4 million in product sales during the three months ended June 30, 2021 and 2020, respectively. The increase in 2021 is principally due to BELBUCA and Symproic product sales which have been driven by increased paid prescriptions across all channels of business.

Product Royalty Revenues. During the three months ended June 30, 2021 and 2020, we recognized \$0.9 million and \$0.1 million in PAINKYL and BREAKYL product royalty revenue under our license agreements with TTY and Mylan, respectively.

Cost of Sales. We incurred \$4.3 million and \$5.4 million in cost of sales during the three months ended June 30, 2021 and 2020, respectively. Cost of sales includes product cost, royalties paid, depreciation, yield adjustments and quarterly minimum royalty payments to CDC IV, LLC ("CDC"). Cost of sales for the three months ended June 30, 2021 includes \$1.4 million for the recovery of certain costs associated with previously reserved inventory. Cost of sales for the three months ended June 30, 2020 includes a \$0.3 million one-time depreciation charge due to BUNAVAIL equipment write-off.

Selling, General and Administrative Expenses. During the three months ended June 30, 2021 and 2020, selling, general and administrative expenses totaled \$25.8 million and \$28.2 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 June 30, 2021 as compared to the same period in the prior year is primarily due to accelerated stock compensation and severance expense related to the departure of the Company's previous Chief Executive Officer in the second quarter of 2020.

Interest expense, net. During the three months ended June 30, 2021, 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 June 30, 2020, we had net interest expense of \$1.7 million, which includes interest expense of \$1.6 million and \$0.1 million of amortization of discount and loan costs.

Comparison of the six months ended June 30, 2021 and 2020

Product Sales. We recognized \$81.3 million and \$74.2 million in product sales during the six months ended June 30, 2021 and 2020, respectively. The increase in 2021 is principally due to increased BELBUCA and Symproic product sales from higher patient utilization, the impact of managed care wins, and the impact of price increases.

Product Royalty Revenues. During the six months ended June 30, 2021 and 2020, we recognized \$1.1 million and \$0.7 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.

Cost of Sales. We incurred \$10.1 million and \$11.0 million in cost of sales during the six months ended June 30, 2021 and 2020, respectively. Cost of sales includes product cost, royalties paid, depreciation, yield adjustments and quarterly minimum royalty payments to CDC. Cost of sales for the six months ended June 30, 2021 includes \$1.4 million for the recovery of certain costs associated with previously reserved inventory. Cost of sales for the six months ended June 30, 2020 includes a \$0.3 million one-time depreciation charge due to BUNAVAIL equipment write-off.

Selling, General and Administrative Expenses. During the six months ended June 30, 2021 and 2020, selling, general and administrative expenses totaled \$53.5 million and \$54.9 million, respectively. Selling, general and administrative costs include commercialization costs for BELBUCA and Symproic, legal, accounting and wages, consulting and professional fees, travel costs, stock based compensation and amortization. The decrease in selling, general and administrative expenses during the six months ended June 30, 2021 as compared to the same period in the prior year is primarily due to accelerated stock compensation and severance expense related to the departure of the Company's Chief Executive Officer in 2020, partially offset by increased legal spend in 2021.

Interest expense, net. During the six months ended June 30, 2021, we had net interest expense of \$4.0 million, which includes interest expense of \$3.8 million and \$0.2 million of amortization of discount and loan costs. During the six months ended June 30, 2021, we also had interest income of \$0.02 million.

During the six months ended June 30, 2020, we had net interest expense of \$3.0 million, which includes interest expense of \$3.1 million and \$0.1 million of amortization of discount and loan costs. During the six months ended June 30, 2020, we also had interest income of \$0.1 million.

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:

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, 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 income taxes or the cash requirements to pay taxes; and
- EBITDA excludes the impact of currency translation and net interest, including both interest expense and interest income.

Non-GAAP net income 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 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 rather than net income, 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 may differ from the expenses and other items, if any, that other companies may exclude from non-GAAP net income when they report their operating results since non-GAAP income 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 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; and
- We exclude amortization of intangible assets from non-GAAP net income 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.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Reconciliation of GAAP net income to EBITDA (non-GAAP)				
GAAP net income	\$ 9,064	\$ 1,165	\$ 14,301	\$ 6,131
back/(subtract):				
Income tax recovery/(provision)	312	86	534	(192)
Net interest expense	1,999	1,685	3,977	2,979
Depreciation and amortization	1,769	2,159	3,523	3,960
EBITDA	\$ 13,144	\$ 5,095	\$ 22,335	\$ 12,878
Reconciliation of GAAP net income to Non-GAAP net income				
GAAP net income	\$ 9,064	\$ 1,165	\$ 14,301	\$ 6,131
adjustments:				
Stock-based compensation expense	1,697	1,364	3,187	2,884
Amortization of intangible assets	1,735	1,734	3,469	3,515
Non-recurring financial impact of CEO transition	—	5,078	—	5,078
Non-recurring financial impact of BUNAVAIL discontinuation	—	295	—	295
Non-GAAP net income	\$ 12,496	\$ 9,636	\$ 20,957	\$ 17,903

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.

As of June 30, 2021, we had cash and cash equivalents of approximately \$119.9 million. We generated \$20.3 million of cash in operations during the six months ended June 30, 2021. We believe that we have sufficient cash, along with expected proceeds from sales of BELBUCA and Symproic, 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;
- 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 2021 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.

Off-Balance Sheet Arrangements

As of June 30, 2021, 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, 2020.

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.

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.

Additionally, LIBOR is to be phased out by June 23, 2023 and replaced. However, 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 Chief Executive Officer (our principal executive officer) and Executive Vice President, Treasurer 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 June 30, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our second quarter of 2021 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 11, 2021 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.

To our knowledge and except to the extent additional factual information disclosed in this Quarterly Report on Form 10-Q relates to such risk factors, there have been no material changes in the risk factors described in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 11, 2021.

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

Issuer Purchases of Equity Securities

In millions, except share and per share data)	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of the publicly announced plan ^(a)	Maximum approximate dollar value of shares that may yet be purchased under the plan ^(b)
30, 2021	\$ 1,526,841	3.51	\$ 1,526,841	13,333
May 1-31, 2021	\$ 97,705	3.52	\$ 97,705	12,989
June 1-30, 2021	\$ —	—	\$ —	12,989
Total	1,624,546		1,624,546	

^(a) The repurchase plan was authorized on November 4, 2020

^(b) The repurchase plan approved repurchase of up to \$25 million of our Company's shares

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

During the six months ended June 30, 2021, a cumulative total of 3,202,690 shares, with a weighted average price of \$3.72 for a value of \$11.9 million were repurchased and recorded as Treasury Stock in the 2021 condensed consolidated balance sheet.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Number	Description
31	Certification of Principal Executive Officer Pursuant To Sarbanes-Oxley Section 302. *
31	Certification of Principal Financial Officer Pursuant To Sarbanes-Oxley Section 302. *
32	Certification Pursuant To 18 U.S.C. Section 1350. #
32	Certification Pursuant To 18 U.S.C. Section 1350. #
101	X BRL Instance Document.
101	X BRL Taxonomy Extension Schema Document.
101	X BRL Taxonomy Calculation Linkbase Document.
101	X BRL Taxonomy Definition Linkbase Document.
101	X BRL Taxonomy Label Linkbase Document.
101	X BRL Taxonomy Presentation Linkbase Document.
101	Cover Page Interactive Data File (embedded within the Inline XBRL document contained in Exhibit 101).*

Item 6. Exhibits.

*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: August 4, 2021

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

Date: August 4, 2021

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

**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: August 4, 2021

/s/ Jeffrey Bailey

Jeffrey Bailey

Chief Executive Officer and Director
(Principal Executive Officer)

**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: August 4, 2021

/s/ Mary Theresa Coelho

Mary Theresa Coelho

Executive Vice President, Treasurer and Chief Financial Officer
(Principal Financial and Accounting Officer)

**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 June 30, 2021, 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
Chief Executive Officer and Director
(Principal Executive Officer)
August 4, 2021

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**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 June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mary Theresa Coelho, Executive Vice President, 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
Executive Vice President, Treasurer and Chief Financial Officer
(Principal Financial and Accounting Officer)
August 4, 2021

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