

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or Section 15(d)
of the Securities Exchange Act of 1934**

Date of Report: November 3, 2021

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-31361 (Commission File Number)	35-2089858 (IRS Employer Identification No.)
4131 ParkLake Ave., Suite 225 Raleigh, NC. (Address of principal executive offices)		27612 (Zip Code)

Registrant's telephone number, including area code: 919-582-9050

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to 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.

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2021, BioDelivery Sciences International, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) is intended to be furnished and shall 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 liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on November 3, 2021, furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document contained in Exhibit 104)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

November 3, 2021

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: _____ /s/ Mary Theresa Coelho
Name: Mary Theresa Coelho
Title: Executive Vice President, Chief Financial Officer and Treasurer



BioDelivery Sciences Reports Solid Third Quarter 2021 Results

Total Net Revenue of \$41.1 Million, an Increase of 4% versus Prior Year

*Strong profitability with GAAP EPS of \$0.07, EBITDA Margin of 27% and \$7.0 million Operating Cash Flow
Closed acquisition of ELYXYB, the first FDA-approved, ready-to-use oral solution for acute migraine with potential long-term peak sales opportunity of \$350 - \$400 million*

Conference Call and Webcast Scheduled for 8:30 AM EST Today

RALEIGH, N.C., November 3, 2021 - BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions, today reported solid financial results for the third quarter ended September 30, 2021, including the following operational and performance highlights.

Key Business Highlights

- Net sales of BELBUCA® and Symproic® combined grew 7.5% year-over-year. This growth was driven by record BELBUCA net sales of \$36.9 million, which increased 6.3%, and Symproic net sales of \$4.1 million, which increased 20%.
- BELBUCA delivered an all-time high quarterly market share of 4.9%, despite the situation with Alvogen which was described in our 8K filing on September 21, 2021.
- Total BELBUCA prescriptions were over 121,000 during the third quarter, a new record high and representing year-over-year prescription volume growth of 7.7%.
- Total Symproic prescriptions were over 19,200 in the third quarter, delivering 7.6% year-over-year growth and reflecting record high TRx volume, record high NRx volume of over 11,100 leading to a record NRx share of 14.3%.
- Continued to achieve strong profitability, delivering \$6.7 million of GAAP Net Income, an attractive 27% EBITDA margin in the third quarter of 2021, GAAP EPS of \$0.07, as well as generating \$7.0 million in operating cash.
- Acquisition of ELYXYB for the treatment of acute migraine closed on September 9, 2021.

“Sales of BELBUCA and Symproic remain solid as we prepare for additional revenue growth associated with the launch of ELYXYB in the first quarter of 2022. ELYXYB, with patent protection to 2036, diversifies our portfolio, takes advantage of the synergies between pain and neurology, and leverages our current commercial infrastructure to manage ELYXYB in a very efficient way,” stated Jeff Bailey, CEO of BDSI. “Moreover, we continue our business development activities for product acquisitions and licensing opportunities, especially in the Neurology space.”



Third Quarter 2021 Financial Results

Total Company Net Revenue for the third quarter of 2021 was \$41.1 million, an increase of 4.2% compared to \$39.4 million in the third quarter of 2020. Net sales of BELBUCA and Symproic combined grew 7.5% year over year.

BELBUCA Net Sales for the third quarter of 2021 were \$36.9 million, an increase of 6.3% compared to \$34.8 million in the third quarter of 2020. Third quarter 2020 net sales were positively impacted by the gross to net channel refresh.

Symproic Net Sales for the third quarter were \$4.1 million, an increase of 20% compared to \$3.5 million in the third quarter of 2020.

Other Revenue for the third quarter totaled \$20 thousand of royalty revenue, compared to \$1.2 million in the third quarter of 2020, which included royalty revenue of approximately \$0.7 million and approximately \$0.6 million of Bunavail net sales.

Total Operating Expenses for the third quarter of 2021 were \$25.5 million, compared to \$22.5 million in the third quarter of 2020.

GAAP Net Income for the third quarter of 2021 was \$6.7 million, or \$0.07 per share, compared to GAAP net income of \$9.4 million, or \$0.09 per share, in the third quarter of 2020.

EBITDA for the third quarter of 2021 was \$11.1 million, or 27% of net sales, compared to \$13.4 million or 34% of net sales, in the third quarter of 2020.

Non-GAAP Net Income for the third quarter of 2021 was \$10.3 million and reflects GAAP net income excluding stock-based compensation and non-cash amortization of intangible assets as compared to non-GAAP net income of \$12.7 million in the third quarter of 2020, excluding the same items.

Cash Position: As of September 30, 2021, cash and cash equivalents were approximately \$100.7 million, compared to \$111.6 million as of December 31, 2020. The change in year-to-date cash of (\$10.9) million reflects operating cash flow generation of \$27.3 million, \$11.9 million in share buybacks, the prepayment of \$20.0 million of debt, as well as the \$6.0 million upfront payment for ELYXYB and \$0.4 million in transaction related costs. For the third quarter, total cash on hand decreased by \$19.1 million versus June 30, 2021, with operating cash flow generation of \$7.0 million being partially offset by \$20.0 million used towards an early, penalty-free debt repayment of our term loan and a \$6.0 million upfront payment to Dr. Reddy's for ELYXYB, along with \$0.4 million in transaction related costs. The \$20.0 million pre-payment will result in approximately \$4.4 million of interest savings over the course of the remaining loan period.

Financial Guidance

For 2021 financial guidance, the Company is lowering its full year 2021 total net revenue guidance range to \$162 - \$167 million from \$170 - \$180 million previously communicated. The situation with Alvogen is a factor contributing to our amended guidance. BDSI now expects BELBUCA net sales for 2021 to be in the range of \$144 - \$148 million dollars. The Company continues to estimate total operating expenses for the ongoing business to be in the range of \$115 - \$120 million, including pre-launch investments to support the first quarter 2022 launch of ELYXYB. EBITDA for the ongoing business, excluding ELYXYB, is projected to be at the lower end of the \$40 - \$50 million range in 2021. Following the acquisition of ELYXYB, total EBITDA is expected to be less than \$40 million in 2021 due to the Company's investments to prepare for the first quarter 2022 launch.



“We are investing in our future by entering into the attractive acute migraine space while driving the growth of our robust pain franchise,” stated Jeff Bailey. “We expect ELYXYB to be financially accretive within 24 months after its launch, and to be a differentiated and exciting new treatment option for both prescribers and patients. Our balance sheet remains strong and we will continue to invest to grow our current products and, through the establishment of a dedicated neurology sales force, we will be able to leverage our current infrastructure to manage the addition of ELYXYB in a very efficient way.”

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, November 3, 2021, at 8:30 a.m. ET to present third quarter 2021 results and to provide a business update. Dial-in details are as follows:

Date:	Wednesday, November 3, 2021
Time:	8:30 AM Eastern Time
Domestic:	877-407-0789
International:	201-689-8562
Conference ID:	13723637
Webcast:	http://public.viavid.com/index.php?id=146730

ABOUT BIODELIVERY SCIENCES INTERNATIONAL, INC.

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a commercial-stage specialty pharmaceutical company dedicated to patients living with chronic conditions. BDSI has built a portfolio of differentiated pain and neurology products and leverages its experienced sales and marketing organization to educate prescribers on their unique features. BDSI's products address serious and debilitating conditions, including chronic pain, acute migraine and opioid-induced constipation.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This press release and any statements of employees, representatives, and partners of BioDelivery Sciences International, Inc. (“BDSI”) related thereto contain, or may contain, among other things, certain “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 BDSI's plans, objectives, projections, expectations and intentions and other statements identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential” or similar expressions. These statements are based upon the current beliefs and expectations of BDSI's management and are subject to significant risks and uncertainties, including those detailed in BDSI's filings with the Securities and Exchange Commission. Actual results including, without limitation, the expectations for: net revenue, BELBUCA net sales, operating expenses, EBITDA and operating cash flows for 2021, the planned launch of ELYXYB, including net sales of ELYXYB and potential expansion opportunities for ELYXYB, may differ materially from those set forth or implied in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors



(many of which are beyond BDSI's control) including the risk that the current COVID-19 pandemic impacts on our supply chain, commercial partners, patients and their physicians and the healthcare facilities in which they work, and our personnel are greater than we anticipate, as well as those set forth in our 2020 annual report on Form 10-K filed with the US Securities and Exchange Commission and subsequent filings. BDSI undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future presentations or otherwise, except as required by applicable law.

Non-GAAP Financial Measures

This press release includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principles in the United States, or GAAP, including non-GAAP net income and EBITDA. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Non-GAAP net income adjusts for one-time and non-cash charges by excluding the following from GAAP net income: stock-based compensation expense, non-cash amortization of intangible assets, and the financial impact of certain one-time items that are non-recurring, including the discontinuation of Bunavail, and costs associated with the CEO transition in Q2 2020.

EBITDA excludes net interest, including both interest expense and interest income, provision for (benefit from) income taxes, depreciation, and amortization.

The Company's management and board of directors utilize these non-GAAP financial measures to evaluate the Company's performance. The Company provides these non-GAAP measures of the Company's performance to investors because management believes that these non-GAAP financial measures, when viewed with the Company's results under GAAP and the accompanying reconciliations, are useful in identifying underlying trends in ongoing operations. However, non-GAAP net income and EBITDA are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance. Further, non-GAAP net income and EBITDA should not be considered measures of our liquidity.

A reconciliation of certain GAAP to non-GAAP financial measures has been provided in the tables included in this press release.

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 100,710	\$ 111,584
Accounts receivable, net	57,572	48,150
Inventory, net	23,075	17,443
Prepaid expenses and other current assets	6,904	5,208
Total current assets	188,261	182,385
Property and equipment, net	1,525	1,418
Goodwill	2,715	2,715
License and distribution rights, net	63,569	53,376
Total assets	\$ 256,070	\$ 239,894
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 74,580	\$ 52,995
Notes payable, current	3,077	—
Total current liabilities	77,657	52,995
Notes payable, less current maturities	55,638	78,452
Other long-term liabilities	—	213
Total liabilities	133,295	131,660
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; Series B Non-Voting Convertible Preferred Stock, \$0.001 par value, 443 shares outstanding at September 30, 2021 and December 31, 2020, respectively.	—	—
Common Stock, \$0.001 par value; 235,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 102,057,290 and 101,417,441 shares issued; 98,791,606 and 101,354,447 shares outstanding at September 30, 2021 and December 31, 2020, respectively.	104	104
Additional paid-in capital	454,738	449,264
Treasury stock, at cost, 3,265,684 and 62,994 shares, as of September 30, 2021 and December 31, 2020, respectively.	(12,155)	(252)
Accumulated deficit	(319,912)	(340,882)
Total stockholders' equity	122,775	108,234
Total liabilities and stockholders' equity	\$ 256,070	\$ 239,894



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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product sales	\$ 41,072	\$ 38,785	\$ 122,398	\$ 112,946
Product royalty revenues	20	658	1,151	1,358
Total Revenues:	41,092	39,443	123,549	114,304
Cost of sales	6,365	5,376	16,470	16,371
Expenses:				
Selling, general and administrative	25,468	22,461	79,007	77,408
Total Expenses:	25,468	22,461	79,007	77,408
Income from operations	9,259	11,606	28,072	20,525
Interest expense, net	(1,984)	(2,010)	(5,962)	(4,997)
Other (expense)/income, net	—	(2)	(1)	6
Income before income taxes	\$ 7,275	\$ 9,594	\$ 22,109	\$ 15,534
Income tax provision	(606)	(211)	(1,139)	(19)
Net income attributable to common stockholders	\$ 6,669	\$ 9,383	\$ 20,970	\$ 15,515
Basic				
Weighted average common stock shares outstanding	98,699,857	101,031,317	99,485,399	99,377,748
Basic earnings per share	\$ 0.07	\$ 0.09	\$ 0.21	\$ 0.16
Diluted				
Weighted average common stock shares outstanding	102,430,883	105,783,568	103,473,967	104,836,493
Diluted earnings per share	\$ 0.07	\$ 0.09	\$ 0.20	\$ 0.15



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

	Nine months ended September 30,	
	2021	2020
Operating activities:		
Net income	\$ 20,970	\$ 15,515
Adjustments to reconcile net income to net cash flows from operating activities		
Depreciation and amortization	97	467
Accretion of debt discount and loan costs	264	231
Amortization of intangible assets	5,262	5,248
Provision for/(release of) inventory obsolescence	1,100	(297)
Stock-based compensation expense	5,024	7,845
Net change in operating lease assets and liabilities	(30)	—
Changes in assets and liabilities:		
Accounts receivable	(9,422)	(5,040)
Inventories	(6,731)	(7,278)
Prepaid expenses and other assets	(1,856)	(1,985)
Accounts payable and accrued liabilities	12,005	(701)
Taxes payable	606	(40)
Net cash flows provided by operating activities	27,289	13,965
Investing activities:		
Product acquisitions	(6,456)	—
Acquisitions of property, plant and equipment	(415)	—
Net cash flows used in investing activities	(6,871)	—
Financing activities:		
Payment on notes payable	(20,000)	—
Proceeds from notes payable	—	20,000
Proceeds from exercise of stock options	611	2,761
Payment on share repurchase	(11,903)	—
Payment on deferred financing fees	—	(437)
Net cash flows (used in)/provided by financing activities	(31,292)	22,324
Net change in cash and cash equivalents	(10,874)	36,289
Cash and cash equivalents at beginning of period	111,584	63,888
Cash and cash equivalents at end of period	\$ 100,710	\$ 100,177



BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
RECONCILIATION OF NON-GAAP METRICS
(U.S. DOLLARS, IN THOUSANDS)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Reconciliation of GAAP net income to EBITDA (non-GAAP)				
GAAP net income	\$ 6,669	\$ 9,383	\$ 20,970	\$ 15,515
Add back/(subtract):				
Income tax provision	606	211	1,139	19
Net interest expense	1,984	2,012	5,962	4,991
Depreciation and amortization	1,837	1,754	5,359	5,715
EBITDA	\$ 11,096	\$ 13,360	\$ 33,430	\$ 26,240
Reconciliation of GAAP net income to Non-GAAP net income				
GAAP net income	\$6,669	\$9,383	\$20,970	\$15,515
Non-GAAP adjustments:				
Stock-based compensation expense	1,837	1,473	5,024	4,424
Amortization of intangible assets	1,795	1,734	5,262	5,248
Non-recurring financial impact of CEO transition	—	67	—	5,078
Non-recurring financial impact of BUNAVAIL discontinuation	—	—	—	295
Non-GAAP net income	\$ 10,301	\$ 12,657	\$ 31,256	\$ 30,560