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: August 4, 2021

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

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

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

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 August 4, 2021, BioDelivery Sciences International, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 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 August 4, 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.

August 4, 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 Second Quarter 2021 Results

Total Company Net Revenue of $41.4 Million Driven by BELBUCA® All-Time High TRx Market Share

Strong Profitability with GAAP Net Income of $9.1 Million, or $0.09 per share, EBITDA Margin of 32%, and Non-GAAP Net Income of $12.5 Million, or $0.12 per Share, Drives Operating Cash Generation of $9.2 Million

Announces Agreement to Acquire ELYXYB ™ for the Acute Treatment of Migraine

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

RALEIGH, N.C., August 4, 2021 - BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions, today reported strong financial results for the second quarter ended June 30, 2021, including the following operational and performance highlights.

“BELBUCA continued its strong double-digit revenue growth trajectory in spite of a slower-than-expected rebound in the pain market, however, we are starting to see gradual signs of market normalization.” stated Jeff Bailey, CEO of BDSI. “I am proud of the team and our ability to effectively manage the overall business, delivering an attractive 32% EBITDA margin in the quarter.”

“We are also very pleased to be adding ELYXYB to our portfolio of valuable and differentiated products, as the only ready-to-use oral solution approved for acute migraine with or without aura in adults,” Bailey added. “This differentiated drug represents a highly attractive opportunity to diversify our product portfolio, deepening our presence in neurology, a logical adjacency to our chronic pain franchise. We see this acquisition as establishing a great growth platform in neurology.”

Key Business Highlights

- Total Company net revenue for the second quarter increased by 13% versus the prior year period to $41.4 million. This growth was driven by all-time high BELBUCA net sales of $36.5 million, which increased 13% year over year, and Symproic® net sales of $4.0 million, which increased 18% year over year.
- BELBUCA achieved an all-time high quarterly market share of 4.7% as well as an all- time high in unique BELBUCA prescribers of 8,345 which is an increase of 11% year over year. Total BELBUCA prescriptions were approximately 119,000 during the second quarter, representing year-over-year prescription volume growth of 11%.
- Total Symproic prescriptions were approximately 18,000 in the second quarter, up 3% versus the prior year period.
- Strong gross margin of 89.7%, coupled with prudent management and prioritization of operating expenses, contributed to continued strong profitability, with $9.1 million of GAAP Net Income, an attractive 32% EBITDA margin, and non-GAAP Net Income of $12.5 million or $0.12 cents per share in the second quarter of 2021. Year-to-date through June 30, 2021, non-GAAP Net Income is $21.0 million or $0.20 cents per share. Both GAAP and non-GAAP net income were impacted by higher litigation spend year to date through June 30, 2021.

- On August 3, 2021, the Company entered into an agreement to acquire the U.S. and Canadian rights to ELYXYB (celecoxib oral solution), from Dr. Reddy's Laboratories. ELYXYB is the only ready-to-use oral solution approved by the FDA for the acute treatment of migraine, with or without aura, in adults. When launched in the US, ELYXYB will participate in a substantial and growing market, and is expected to drive the Company's revenue growth and shareholder value while leveraging much of its existing infrastructure.
- The Company repurchased 1.6 million shares in the quarter under its existing share buyback program, at an average price of $3.51 per share, bringing the total shares purchased to date under the program to 3.3 million shares, at an average price of $3.70.

Second Quarter 2021 Financial Results

Total Company Net Revenue for the second quarter of 2021 was $41.4 million, an increase of 13% compared to $36.6 million in the second quarter of 2020. Total product net revenue, including sales of BELBUCA and Symproic, grew 11% year over year.

BELBUCA Net Sales for the second quarter of 2021 were an all-time high of $36.5 million, an increase of 13% compared to $32.3 million in the second quarter of 2020.

Symproic Net Sales for the second quarter were $4.0 million, an increase of 18% compared to $3.4 million in the second quarter of 2020.

Total Operating Expenses for the second quarter of 2021 were $25.8 million, compared to $28.2 million in the second quarter of 2020.

GAAP Net Income for the second quarter of 2021 was $9.1 million, or $0.09 per share, compared to GAAP net income of $1.2 million, or $0.01 per share, in the second quarter of 2020.

EBITDA for the second quarter of 2021 was $13.1 million, or 32% of net sales, compared to $5.1 million or 14% of net sales, in the second quarter of 2020.

Non-GAAP Net Income for the second quarter of 2021 was $12.5 million, or $0.12 cents per share, and reflects GAAP net income excluding stock-based compensation and non-cash amortization of intangible assets, as compared to non-GAAP net income of $9.6 million, or $0.10 cents per share, in the second quarter of 2020, excluding the same items as well as the one-time costs associated with the CEO transition in that period.

Cash Position: As of June 30, 2021, cash and cash equivalents were approximately $119.9 million, compared to $111.6 million as of December 31, 2020. The total cash flow generation year to date of $8.3 million includes continued strong operating cash generation of $20.3 million, partially offset by $11.9 million used to repurchase shares.

Financial Guidance

The Company reiterates its 2021 financial guidance, with full year 2021 total Company net sales of $170 - $180 million, including full year 2021 BELBUCA net sales of $155 - $165 million. However, due to a slower than anticipated rebound in the chronic pain selling environment associated with the COVID-19 pandemic, the Company expects BELBUCA net sales to be at the lower end of its prior guidance range. Total operating

expenses are expected to be in the range of $115 - $120 million for the ongoing business, as the Company continues to invest to support the growth of its existing brands. Additionally, EBITDA remains on track to be in the $40 - $50 million range 2021 for the ongoing business. The Company continues to expect to deliver positive operating cash flow in 2021. The Company will share any updates to its guidance as a result of the ELYXYB acquisition at a future date.

“We continue to invest behind our growing brands and infrastructure to drive future growth. The persistent efforts of our commercial team permit us to continue growing our market share for BELBUCA within the long-acting opioid market. Our focus remains on helping patients with unmet needs and driving long-term shareholder value through our pain and now neurology franchises,” stated Jeff Bailey.

Please see Important Safety Information about ELYXYB below.

Conference Call & Webcast Details

BioDelivery Sciences will host a conference call and webcast today, August 4, 2021, at 8:30 a.m. ET to present second quarter 2021 results and to provide a business update. Dial-in details are as follows:

Date:	Wednesday, August 4, 2021
Time:	8:30 AM Eastern Time
Domestic:	877-407-0789
International:	201-689-8562
Conference ID:	13720500
Webcast:	http://public.viavid.com/index.php?id=145242

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 products that includes utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology to develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important unmet medical needs. BDSI's marketed products address serious and debilitating conditions, including chronic pain 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 total company net sales, BELBUCA net sales, operating expenses, EBITDA and operating cash flows in 2021, the acquisition and launch of ELYXYB and growth in neurology 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 coronavirus 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 and non-cash amortization of intangible assets, as well as one-time costs associated with the CEO transition in the second quarter of 2020 and the non-recurring impact of the discontinuation of BUNAVAIL.

EBITDA excludes net interest, including both interest expenses 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.

ELYXYB INDICATION AND USAGE

ELYXYB is indicated in adults for the acute treatment of migraine with or without aura.

Limitations of Use: ELYXYB is not indicated for the preventive treatment of migraine.

ELYXYB IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use *[see Warnings and Precautions (5.1)].*
- ELYXYB is contraindicated in the setting of coronary artery bypass graft (CABG) surgery *[see Contraindications (4) and Warnings and Precautions (5.1)].*

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious (GI) events *[see Warnings and Precautions (5.2)].*

ELYXB is contraindicated in patients with:

- Known hypersensitivity to celecoxib, any components of the drug product, or sulfonamides (4)
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs (4)
- In the setting of CABG surgery (4)

To minimize the potential risk for an adverse cardiovascular (CV) event in NSAID-treated patients, use ELYXYB for the fewest number of days per month as needed, based on individual treatment goals. Physicians and patients should remain alert for the development of such events, throughout the entire treatment course, even in the absence of previous CV symptoms. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

Avoid the use of ELYXYB in patients with a recent myocardial infarction (MI) unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ELYXYB is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.

NSAIDs, including ELYXYB, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with celecoxib. Only one in five patients who develop a serious upper GI adverse event on NSAID therapy is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occurred in approximately 1% of patients treated for 3 to 6 months, and in about 2% to 4% of patients treated for one year. However, even short-term NSAID therapy is not without risk.

Avoid the use of ELYXYB in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If ELYXYB is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Elevations of ALT or AST (less than three times ULN) may occur in up to 15% of patients treated with NSAIDs, including ELYXYB.

Long-term administration of NSAIDs, including celecoxib, the active ingredient in ELYXYB, has resulted in renal papillary necrosis and other renal injury.

No information is available from controlled clinical studies regarding the use of celecoxib in patients with severe renal impairment. The renal effects of celecoxib may hasten the progression of renal dysfunction in patients with preexisting renal disease.

Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, nonsteroidal anti-inflammatory drugs or combination of these drugs for 10 or more days per month), including ELYXYB, may lead to exacerbation of headache (medication

overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

NSAIDs, including ELYXYB, may increase the risk of bleeding events. Co-morbid conditions such as coagulation disorders or concomitant use of warfarin, other anticoagulants, antiplatelet drugs (e.g., aspirin), SSRIs, and serotonin norepinephrine reuptake inhibitors (SNRIs) may increase this risk.

Most common adverse reaction (at least 3% and greater than placebo) is dysgeusia.

These are not all the side effects associated with ELYXYB.

Please see Patient Information, Instructions For Use, Medication Guide and Full Prescribing Information for ELYXYB (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212157s000lbl.pdf)

Contact:

Bob Yedid
LifeSci Advisors
646-597-6989
Bob@LifeSciAdvisors.com

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		
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**

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	$ 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**

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 and amortization	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 (used in)/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**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Reconciliation of GAAP net income to EBITDA (non-GAAP)	**2021**	**2020**	**2021**	**2020**
GAAP net income	**$ 9,064**	**$ 1,165**	**$ 14,301**	**$ 6,131**
Add 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**	**$6,131**
Non-GAAP adjustments:				
Stock-based compensation expense	1,697	1,364	3,187	2,884
Amortization of intangible assets	1,735	1,734	3,469	3,515
Non-recurring financial impact of CEO transition	—	5,078	—	5,078
Non-recurring financial impact of BUNAVAIL discontinuation	—	295	—	295
Non-GAAP net income	**$ 12,496**	**$ 9,636**	**$ 20,957**	**$ 17,903**