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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): November 9, 2020

NEUROCRINE BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**0-22705**	**33-0525145**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
12780 El Camino Real, San Diego, California		**92130**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 617-7600

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	NBIX	Nasdaq Global Select Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ 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))

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 9, 2020, Neurocrine Biosciences, Inc. announced its financial results for the third quarter ended September 30, 2020. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, 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 liability 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.

Exhibit	Description
99.1	Press Release dated November 9, 2020
104	Cover Page Interactive Data File

SIGNATURES

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

NEUROCRINE BIOSCIENCES, INC.

Dated: November 9, 2020

/s/ Matthew C. Abernethy

Matthew C. Abernethy

Chief Financial Officer
(Duly authorized officer and Principle Financial Officer)

Exhibit 99.1

Neurocrine Biosciences Reports Third Quarter 2020 Financial Results

INGREZZA® (valbenazine) Third Quarter Net Product Sales of $254 million with Approximately 45,100 TRx

ONGENTYS® (opicapone) Now Available in the U.S. as an Add-On Treatment for Patients with Parkinson's Disease Experiencing "Off" Episodes

Initiating Phase II Study of NBI-827104, a Clinical Stage Selective T-type Calcium Channel Blocker, Licensed from Idorsia, for the Treatment of Continuous Spikes and Waves During Sleep (CSWS) Epilepsy

SAN DIEGO, Nov. 9, 2020 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the third quarter ended September 30, 2020 and provided revised full-year 2020 financial expense guidance.

"Our focus remains on helping as many patients with tardive dyskinesia as possible and we are adapting to the challenges posed by the pandemic, including the slow recovery of in-person visits with psychiatrists. We are encouraged by recent trends and remain confident in the intermediate and long-term opportunity of INGREZZA to help many more patients with tardive dyskinesia," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We are pleased to expand our reach with neurologists with the addition of ONGENTYS to our movement disorder portfolio and continue to advance our development programs focused on neurological, endocrine and psychiatric disorders."

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
(unaudited, in millions, except per share data)	2020	2019	2020	2019
Revenues:				
Product sales, net	$ 254.1	$ 198.1	$ 752.8	$ 515.0
Collaboration revenue	4.4	24.0	45.2	29.0
Total revenues	$ 258.5	$ 222.1	$ 798.0	$ 544.0
GAAP Research and Development (R&D)	$ 69.1	$ 45.3	$ 208.3	$ 144.7
Non-GAAP R&D	$ 60.3	$ 38.3	$ 161.9	$ 116.3
GAAP Selling, General and Administrative (SG&A)	$ 112.5	$ 84.5	$ 326.8	$ 252.8
Non-GAAP SG&A	$ 94.6	$ 71.2	$ 274.2	$ 217.2
GAAP net (loss) income	$ (57.6)	$ 53.8	$ 59.4	$ 3.0
GAAP net (loss) income per share – diluted	$ (0.62)	$ 0.56	$ 0.61	$ 0.03
Non-GAAP net income	$ 96.0	$ 86.7	$ 314.2	$ 181.6
Non-GAAP net income per share – diluted	$ 0.97	$ 0.90	$ 3.21	$ 1.91

(unaudited, in millions)	September 30, 2020	December 31, 2019
Total cash and cash equivalents and debt securities available-for-sale	$ 1,126.1	$ 970.2

Net Product Sales Highlights:

- INGREZZA net product sales for the third quarter of 2020 were $254 million, representing a year-over-year increase of 28%. Inventory adjusted net sales for the third quarter of 2020 were approximately $248 million.
- New prescriptions increased slightly in the third quarter of 2020 vs. the second quarter of 2020.
- Refill and persistency rates for existing INGREZZA patients in the third quarter 2020 moderated slightly vs. the second quarter of 2020 and remained at the higher end of historical averages.
- ONGENTYS launched in the United States in late September 2020 and net product sales for the third quarter of 2020 were approximately $0.1 million.

Financial Highlights:

- Third quarter 2020 GAAP net loss and loss per share were approximately $58 million and $0.62, respectively, compared with net income and diluted earnings per share of approximately $54 million and $0.56, respectively, in the third quarter of 2019, primarily driven by higher In-Process Research and Development (IPR&D) costs and operating expenses, offset by higher INGREZZA sales.
- Third quarter 2020 non-GAAP net income and diluted earnings per share were approximately $96 million and $0.97, respectively, compared with approximately $87 million and $0.90, respectively, in the third quarter of 2019 driven by higher INGREZZA sales.
- Research and Development (R&D) expense increased in the third quarter of 2020 versus the third quarter of 2019, primarily due to increased investment across our expanded pipeline programs and higher headcount costs.
- Selling, General and Administrative (SG&A) expense increased in the third quarter of 2020 versus the third quarter of 2019, primarily due to increased investment in marketing initiatives and higher headcount costs.
- At September 30, 2020, the Company had cash, cash equivalents and debt securities available-for-sale of $1.1 billion.

A reconciliation of GAAP to non-GAAP quarterly financial results can be found in Table 3 at the end of this earnings release.

Recent Events

- In September 2020, the Company launched ONGENTYS® (opicapone), the first and only once-daily COMT inhibitor, as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes - periods of time when motor symptoms such as tremor, slowed movement and difficulty walking occur. ONGENTYS also increases "on" time without troublesome dyskinesia, the time when the motor symptoms of a patient with Parkinson's disease are better controlled.
- In October 2020, the U.S. Food and Drug Administration (FDA) provided feedback on an Investigational New Drug (IND) application submitted by Neurocrine Biosciences in support of a Phase II clinical trial of NBI-921352 in pediatric SCN8A developmental and epileptic encephalopathy syndrome patients. As part of its review of the IND, the FDA is requesting additional non-clinical data to support dose justification in this pediatric study. Together with Xenon, the Company will engage with the FDA to address the feedback received with the goal of initiating a Phase II clinical trial in 2021. In parallel, the Company is advancing clinical plans to develop NBI-921352 for the treatment of adult focal epilepsy.
- In November 2020, the Company announced the initiation of a Phase II study of NBI-827104 (formerly ACT-709478) in CSWS, a rare pediatric epilepsy. NBI-827104 was licensed from Idorsia and is a potent, selective, orally-active and brain penetrating T-type calcium channel blocker.
- In November 2020, the Data Safety Monitoring Board (DSMB) for the RESTORE-1 Phase II clinical trial reviewed patient imaging data from the ongoing trial. The DSMB requested additional data and recommended the Company pause dosing of subjects in RESTORE-1 until the DSMB can review these additional data, which is expected by year-end. The DSMB informed the Company and Voyager Therapeutics that they could continue screening patients for potential enrollment into the trial. However, as previously announced, trial sites participating in RESTORE-1 are not currently screening and enrolling patients as a result of the COVID-19 pandemic. In response to the DSMB's recommendation, the Company and Voyager Therapeutics have decided to delay the planned resumption this quarter of patient screening in the RESTORE-1 trial until the DSMB is able to complete its evaluation. The Company is preparing an expedited safety report that will be submitted to the FDA within the 15-day reporting window.

Full-Year 2020 Expense Guidance

(in millions)	Range	
	Low	High
Combined GAAP R&D and SG&A expenses	$ 880	$ 900
Combined Non-GAAP R&D and SG&A expenses	$ 590	$ 610

- Previously, the Company expected combined GAAP R&D and SG&A expenses in the range of $850 million to $900 million and combined non-GAAP R&D and SG&A expenses in the range of $570 million to $610 million.

Conference Call and Webcast Today at 4:30 PM Eastern Time

Neurocrine Biosciences will hold a live conference call and webcast today at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time). Participants can access the live conference call by dialing 877-830-2596 (US) or 785-424-1744 (International) using the conference ID: NBIX. The webcast can also be accessed on Neurocrine Biosciences' website under Investors at www.neurocrine.com. A replay of the webcast will be available on the website approximately one hour after the conclusion of the event and will be archived for approximately one month.

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, Neurocrine Biosciences has specialized in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit neurocrine.com, and follow the company on LinkedIn. *(*in collaboration with AbbVie)*

Non-GAAP Financial Measures

In addition to the financial results and financial guidance that are provided in accordance with accounting principles generally accepted in the United States (GAAP), this press release also contains certain non-GAAP financial measures. When preparing these supplemental non-GAAP financial results and guidance, the Company excludes certain GAAP items that management does not consider to be normal, including recurring cash operating expenses that might not meet the definition of unusual or non-recurring items. In particular, the non-GAAP measures exclude: milestones received from licenses and collaborations, milestones paid related to licenses and collaborations, non-cash collaboration revenue, acquired in-process research and development, share-based compensation expense, non-cash interest expense related to convertible debt, changes in fair value of equity security investments and certain adjustments to income tax expense. These non-GAAP measures are provided as a complement to results provided in accordance with GAAP as management believes these non-GAAP financial measures help indicate underlying trends in the Company's business, are important in comparing current results with prior period results and provide additional information regarding the Company's financial position. Management also uses these non-GAAP financial measures to establish budgets and operational goals that are communicated internally and externally and to manage the Company's business and evaluate its performance. The Company provides guidance regarding combined research and development and sales, general, and administrative expenses on both a GAAP and a non-GAAP basis. The guidance regarding GAAP research and development expenses and sales, general and administrative expenses does not include estimates for expenses associated with any potential future business development activities. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the attached financial information.

Forward-Looking Statements

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements related to: the benefits to be derived from our products and product candidates; the value our products and/or our product candidates may bring to patients; the continued success of INGREZZA; our launch of ONGENTYS; our financial and operating performance, including our future expenses; our collaborative partnerships; expectations regarding the impact of COVID-19 on our business; expectations regarding our ability to adapt our business to the evolving COVID-19 pandemic, mitigate its impact on our business and maintain business continuity, including our ability to protect the safety and well-being of our employees, to continue to support uninterrupted supply of INGREZZA, including patient and healthcare provider access to INGREZZA, to continue our ongoing clinical trials and other development activities, and to otherwise advance our business objectives; and the timing of completion of our clinical, regulatory, and other development activities and those of our collaboration partners. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: our future financial and

operating performance; risks associated with the commercialization of INGREZZA and ONGENTYS; the impact of the COVID-19 pandemic on our business and the business operations of our customers; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risk and uncertainties related to any COVID-19 quarantines, shelter-in-place, social distancing and other government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our business operations and the business operations of the third parties on which we rely; risks related to the development of our product candidates; risks associated with our dependence on third parties for development and manufacturing activities related to INGREZZA and our product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks associated with our dependence on AbbVie for the commercialization of ORILISSA and ORIAHNN, as well as the continued development of elagolix; risks associated with our dependence on BIAL for manufacturing activities for ONGENTYS, and our ability to manage BIAL; risks that clinical development activities may not be completed on time or at all, or may be delayed for regulatory, manufacturing, COVID-19 or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that the potential benefits of the agreements with our collaboration partners may never be realized; risks that our products, and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks described in our periodic reports filed with the SEC, including without limitation our quarterly report on Form 10-Q for the quarter ended September 30, 2020. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

This press release refers to certain non-GAAP financial measures. These non-GAAP financial measures should not be considered replacements for, and should be read together with, the most comparable GAAP financial measures. Reconciliations of non-GAAP financial results to the most directly comparable GAAP financial results are included at the end of this press release, which has been filed with the SEC in a Current Report on Form-8-K dated as of event date herewith. In addition, Neurocrine provides guidance regarding combined research and development and sales, general and administrative expenses on both a GAAP and non-GAAP basis.

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Contact: Neurocrine Biosciences, Inc.

Navjot Rai (Media)
858-617-7623
media@neurocrine.com

Todd Tushla (Investors)
858-617-7143
ir@neurocrine.com

TABLE 1

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions, except per share data)	**2020**	**2019**	**2020**	**2019**
Revenues:				
Product sales, net	$ 254.1	$ 198.1	$ 752.8	$ 515.0
Collaboration revenue	4.4	24.0	45.2	29.0
Total revenues	258.5	222.1	798.0	544.0
Operating expenses:				
Cost of sales	2.7	2.2	7.2	4.9
Research and development	69.1	45.3	208.3	144.7
Acquired in-process research and development	118.5	—	164.5	118.1
Selling, general and administrative	112.5	84.5	326.8	252.8
Total operating expenses	302.8	132.0	706.8	520.5
Operating (loss) income	(44.3)	90.1	91.2	23.5
Other (expense) income:				
Interest expense	(8.5)	(8.0)	(25.0)	(23.8)
Unrealized loss on equity securities	(7.0)	(28.5)	(12.2)	(5.8)
Investment income and other, net	2.7	4.8	11.0	14.0
Total other expense, net	(12.8)	(31.7)	(26.2)	(15.6)
(Loss) income before provision for income taxes	(57.1)	58.4	65.0	7.9
Provision for income taxes	0.5	4.6	5.6	4.9
Net (loss) income	$ (57.6)	$ 53.8	$ 59.4	$ 3.0
Net (loss) income per share, basic	$ (0.62)	$ 0.59	$ 0.64	$ 0.03
Net (loss) income per share, diluted	$ (0.62)	$ 0.56	$ 0.61	$ 0.03
Weighted average common shares outstanding, basic	93.3	91.9	93.0	91.4
Weighted average common shares outstanding, diluted	93.3	96.1	98.0	95.2

TABLE 2

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

(in millions)	September 30, 2020	December 31, 2019
Cash and cash equivalents and debt securities available-for-sale	$ 944.7	$ 670.5
Other current assets	212.2	160.5
Total current assets	1,156.9	831.0
Debt securities available-for-sale	181.4	299.7
Right-of-use assets	71.0	74.3
Equity securities	43.7	55.9
Property and equipment, net	43.0	41.9
Restricted cash and other long-term assets	6.6	3.2
Total assets	$ 1,502.6	$ 1,306.0
Convertible senior notes	$ 425.0	$ 408.8
Other current liabilities	186.0	156.5
Total current liabilities	611.0	565.3
Operating lease liabilities	83.0	86.7
Other long-term liabilities	4.3	17.1
Stockholders' equity	804.3	636.9
Total liabilities and stockholders' equity	$ 1,502.6	$ 1,306.0

TABLE 3

NEUROCRINE BIOSCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions, except per share data)	2020	2019	2020	2019
GAAP net (loss) income	$ (57.6)	$ 53.8	$ 59.4	$ 3.0
Adjustments:				
Milestones received from licenses and collaborations [A]	—	(20.0)	(30.0)	(20.0)
Non-cash collaboration revenue [B]	(0.5)	—	(1.8)	—
Acquired in-process research and development (IPR&D) [C]	118.5	—	164.5	118.1
Milestones paid related to licenses and collaborations - R&D	—	—	20.0	10.0
Share-based compensation expense - R&D	8.8	7.0	26.4	18.4
Share-based compensation expense - SG&A	17.9	13.3	52.6	35.6
Non-cash interest related to convertible debt	5.5	5.1	16.2	15.1
Changes in fair value of equity security investments [D]	7.0	28.5	12.2	5.8
Income tax effect related to reconciling items [E]	(3.6)	(1.0)	(5.3)	(4.4)
Non-GAAP net income	$ 96.0	$ 86.7	$ 314.2	$ 181.6
Net (loss) income per diluted common share:				
GAAP	$ (0.62)	$ 0.56	$ 0.61	$ 0.03
Non-GAAP [F]	$ 0.97	$ 0.90	$ 3.21	$ 1.91

[A] During the nine months ended September 30, 2020, the Company recognized a $30.0 million event-based milestone as revenue upon FDA approval for ORIAHNN for uterine fibroids. During the nine months ended September 30, 2019, the Company recognized a $20.0 million event-based milestone as revenue upon FDA acceptance of the New Drug Application for elagolix for uterine fibroids.

[B] During the nine months ended September 30, 2020, the Company recognized non-cash collaboration revenue from Mitsubishi Tanabe Pharma Corporation under the collaboration and license agreement entered into in 2015.

[C] The Company incurred IPR&D expenses of $118.5 million and $164.5 million during the three and nine months ended September 30, 2020, respectively, in association with the exclusive license agreement entered into with Takeda and the collaboration and license agreement entered into with Idorsia, and $118.1 million during the nine months ended September 30, 2019, in association with the collaboration and license agreement entered into with Voyager Therapeutics in 2019.

[D] The Company recognized an unrealized loss of $7.0 million and $28.5 million for the three months ended September 30, 2020 and 2019, respectively, and $12.2 million and $5.8 million for the nine months ended September 30, 2020 and 2019, respectively, to adjust its equity security investments to fair value.

[E] Estimated income tax effect of non-GAAP reconciling items are calculated using applicable statutory tax rates, taking into consideration any valuation allowance.

[F] Non-GAAP net income per diluted common share for the three months ended September 30, 2020, reflects diluted shares of 98.9 million, which were calculated in accordance with the guidance on earnings per share in ASC 260.