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 1, 2021

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 1, 2021, Neurocrine Biosciences, Inc. announced its financial results for the third quarter ended September 30, 2021. 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 1, 2021
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 1, 2021

/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 2021 Financial Results

INGREZZA® (valbenazine) Third Quarter 2021 Net Product Sales of $287 Million with Approximately 52,000 Total Prescriptions

SAN DIEGO, Nov. 1, 2021 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the third quarter ended September 30, 2021.

“Our third quarter results reflect INGREZZA’s continued growth. With this momentum and increased investment to expand our commercial footprint, we can better serve patients and our customers, and significantly improve diagnosis and treatment rates for people living with tardive dyskinesia,” said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. “We are prudently investing in our advancing and growing R&D pipeline. With important clinical data read-outs expected over the next two years, we are executing well on our strategy to become a leading neuroscience-focused company.”

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
(unaudited, in millions, except per share data)	**2021**	**2020**	**2021**	**2020**
Revenues:				
Product sales, net	$ 288.8	$ 254.1	$ 786.6	$ 752.8
Collaboration revenue	7.2	4.4	34.9	45.2
Total revenues	$ 296.0	$ 258.5	$ 821.5	$ 798.0
GAAP Research and Development (R&D)	$ 92.7	$ 69.1	$ 240.7	$ 208.3
Non-GAAP R&D	$ 80.7	$ 60.3	$ 204.5	$ 181.9
GAAP Selling, General and Administrative (SG&A)	$ 154.6	$ 112.5	$ 426.8	$ 326.8
Non-GAAP SG&A	$ 129.5	$ 94.6	$ 364.4	$ 274.2
GAAP net income (loss)	$ 22.5	$ (57.6)	$ 96.9	$ 59.4
GAAP net income (loss) per share – diluted	$ 0.23	$ (0.62)	$ 0.99	$ 0.61
Non-GAAP net income (loss)	$ 62.6	$ (16.9)	$ 181.5	$ 163.1
Non-GAAP net income (loss) per share – diluted	$ 0.64	$ (0.18)	$ 1.85	$ 1.66

(unaudited, in millions)	**September 30, 2021**	**December 31, 2020**
Total cash, cash equivalents and debt securities available-for-sale	$ 1,279.6	$ 1,028.1

Third Quarter INGREZZA Net Product Sales and Commercial Highlights:

- Net product sales for the third quarter of 2021 were $287 million and $285 million on an inventory adjusted basis
- Record total prescriptions achieved during the third quarter 2021 reflecting higher customer demand and increased commercial activities
- New prescriptions increased throughout the third quarter, reaching their highest levels since March 2020
- Expanding commercial organization in 2022 to establish dedicated field teams to better meet the needs of healthcare professionals across diverse sites of care and help more patients access effective treatment more quickly

Financial Highlights:

- Third quarter 2021 GAAP net income and diluted earnings per share were approximately $23 million and $0.23, respectively, compared with a net loss and net loss per share of approximately $58 million and $0.62, respectively, in the third quarter of 2020
- Third quarter 2021 non-GAAP net income and diluted earnings per share were approximately $63 million and $0.64, respectively, compared with a net loss and net loss per share of approximately $17 million and $0.18, respectively, in the third quarter of 2020
- Difference between third quarter 2021 GAAP and non-GAAP net income and diluted earnings per share compared with the third quarter of 2020 were driven by:
    - Prior year In-Process Research and Development (IPR&D) associated with $118.5 million of upfront fees paid pursuant to our exclusive license agreement with Takeda Pharmaceutical Company Limited (Takeda)
    - Increased R&D expense primarily due to increased investment to support advancing our pipeline programs, including our psychiatry programs in-licensed in mid-2020 and advancement of our in-licensed epilepsy programs which began at the end of 2019
    - Increased SG&A expense primarily due to increased investment in commercial initiatives including the launch of our INGREZZA direct-to-consumer advertising campaign, “TD Spotlight”
- Third quarter 2021 provision for income taxes was approximately $8 million, compared with approximately $1 million in the third quarter of 2020. In the first quarter of 2021, the Company began recording a provision for income taxes using an effective tax rate approximating federal and state statutory rates. Due to the Company’s ability to offset its pre-tax income against previously benefited federal net operating losses, no federal cash tax is expected in 2021
- At September 30, 2021, the Company had cash, cash equivalents and debt securities available-for-sale of approximately $1.3 billion

A reconciliation of GAAP to non-GAAP financial results can be found in Table 3 and Table 4 at the end of this earnings release.

Recent Events

- In August 2021, the Company announced plans to initiate registrational studies in the second half of 2021 with valbenazine for adjunctive treatment in schizophrenia and for dyskinesia due to cerebral palsy
- In September 2021, the Company received approval of a clinical trial application (CTA) submitted in the European Union for NBI-921352 for the treatment of focal-onset seizures in adults. In connection with the approval, the Company paid Xenon a $10 million milestone, of which the Company expensed $5.4 million as R&D in the third quarter of 2021, and purchased an additional $4.6 million of Xenon's common stock

Full-Year 2021 Expense Guidance

	Range	
(in millions)	**Low**	**High**
Combined GAAP R&D and SG&A expenses	$ 895	$ 915
Combined Non-GAAP R&D and SG&A expenses	$ 760	$ 780

- Previously, the Company expected combined GAAP R&D and SG&A expenses in the range of $855 million to $905 million and Non-GAAP R&D and SG&A expenses in the range of $720 million to $770 million.
- GAAP expense guidance range includes $10 million of IPR&D and milestone expenses, and approximately $135 million of share-based compensation, including increased share-based compensation for an equity grant to full-time employees other than executive officers in September 2021.

Expected Milestones and Key Activities

Program	Indication	2021 Milestones / Key Activities
Valbenazine	Chorea in Huntington Disease	Registrational Top-Line Data Expected in December
	Tardive Dyskinesia	Mitsubishi Tanabe Pharma Corporation Submitted Marketing Authorization with Ministry of Health and Welfare in Japan
	Dyskinesia Due to Cerebral Palsy (Neurological Indication)	Initiating Registrational Study in Q4
	Adjunctive Treatment in Schizophrenia (Psychiatric Indication)	Initiating Registrational Study in November
Crinecerfont	Congenital Adrenal Hyperplasia (Adult)	Enrolling Registrational Study
	Congenital Adrenal Hyperplasia (Pediatric)	Enrolling Registrational Study
Luvadaxistat (NBI-1065844)	Cognitive Impairment Associated with Schizophrenia (CIAS)	Initiating Phase 2 Study in Q4
NBI-1065845	Inadequate Response to Treatment in Major Depressive Disorder (MDD)	Initiating Phase 2 Study in Q4
NBI-1065846	Anhedonia in Depression	Initiating Phase 2 Study in Q4
NBI-827104	Rare Pediatric Epilepsy: Epileptic Encephalopathy with Continuous Spike and Wave During Sleep (CSWS)	Enrolling Phase 2 Study
	Essential Tremor	Enrolling Phase 2 Study
NBI-921352	Focal-Onset Seizure in Adults	Initiating Phase 2 Study in Q4
	Rare Pediatric Epilepsy: SCN8A Developmental Epileptic Encephalopathy (SCN8A-DEE)	Initiated Phase 2 Study

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 800-895-3361 (US) or 785-424-1062 (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 the following non-GAAP financial measures: non-GAAP R&D expense, non-GAAP SG&A expense, and non-GAAP net income and net income per share. When preparing the 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, these non-GAAP financial measures exclude: 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 financial 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 R&D and SG&A expenses on both a GAAP and a non-GAAP basis. A reconciliation of these GAAP financial results to non-GAAP financial results is included in the attached financial information. In addition, INGREZZA net sales are presented in accordance with GAAP and as inventory-adjusted net sales, which is a non-GAAP financial measure. The difference between INGREZZA net sales and inventory-adjusted net sales reflects changes in channel inventory that are not representative of the underlying prescription demand. Management uses inventory-adjusted net sales to manage the Company’s business and evaluate its performance.

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 financial and operating performance, including our future revenues, expenses, or profits; our collaborative partnerships; expectations regarding our ability to adapt our business to the evolving COVID-19 pandemic, mitigate its impact on our business, including our ability to continue conducting our ongoing clinical trials and other development activities, to protect the safety and well-being of our employees, to continue to support uninterrupted supply of INGREZZA, and to otherwise advance our business objectives; and the timing of the initiation and/or 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 evolving 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 quarantine, social distancing and other requirements put in place by governments, customers, or clinical trial sites, including the impact of such requirements on the ability of patients to have in-person visits with their health care provider; risks related to the development of our product candidates; risks associated with our dependence on third parties for development and manufacturing activities for our products and 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 that clinical development activities may not be initiated or 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; risks associated with potential generic entrants for our products; 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, 2021. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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TABLE 1

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

(in millions, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 288.8	$ 254.1	$ 786.6	$ 752.8
Collaboration revenue	7.2	4.4	34.9	45.2
Total revenues	296.0	258.5	821.5	798.0
Operating expenses:				
Cost of sales	4.2	2.7	10.2	7.2
Research and development	92.7	69.1	240.7	208.3
Acquired in-process research and development	—	118.5	5.0	164.5
Selling, general and administrative	154.6	112.5	426.8	326.8
Total operating expenses	251.5	302.8	682.7	706.8
Operating income (loss)	44.5	(44.3)	138.8	91.2
Other (expense) income:				
Interest expense	(6.6)	(8.5)	(19.2)	(25.0)
Unrealized loss on equity securities	(8.2)	(7.0)	(7.5)	(12.2)
Investment income and other, net	0.8	2.7	3.1	11.0
Total other expense, net	(14.0)	(12.8)	(23.6)	(26.2)
Income (loss) before provision for income taxes	30.5	(57.1)	115.2	65.0
Provision for income taxes	8.0	0.5	18.3	5.6
Net income (loss)	$ 22.5	$ (57.6)	$ 96.9	$ 59.4
Net income (loss) per share, basic	$ 0.24	$ (0.62)	$ 1.03	$ 0.64
Net income (loss) per share, diluted	$ 0.23	$ (0.62)	$ 0.99	$ 0.61
Weighted average common shares outstanding, basic	94.7	93.3	94.5	93.0
Weighted average common shares outstanding, diluted	97.7	93.3	97.9	98.0

TABLE 2

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

(in millions)	September 30, 2021	December 31, 2020
Cash, cash equivalents and debt securities available-for-sale	$ 765.9	$ 801.0
Other current assets	239.8	215.2
Total current assets	1,005.7	1,016.2
Deferred tax assets	310.4	319.4
Debt securities available-for-sale	513.7	227.1
Right-of-use assets	97.9	82.8
Equity securities	35.3	38.2
Property and equipment, net	51.1	44.6
Other assets	3.2	6.4
Total assets	$ 2,017.3	$ 1,734.7
Total current liabilities	$ 225.9	$ 186.5
Convertible senior notes	330.7	317.9
Operating lease liabilities	106.4	94.4
Other long-term liabilities	8.3	9.7
Stockholders’ equity	1,346.0	1,126.2
Total liabilities and stockholders’ equity	$ 2,017.3	$ 1,734.7

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)	**2021**	**2020**	**2021**	**2020**
GAAP net income (loss) [A]	$ 22.5	$ (57.6)	$ 96.9	$ 59.4
Adjustments:				
Share-based compensation expense - R&D	12.0	8.8	36.2	26.4
Share-based compensation expense - SG&A	25.1	17.9	62.4	52.6
Non-cash interest related to convertible senior notes	4.4	5.5	12.9	16.2
Changes in fair value of equity security investments [B]	8.2	7.0	7.5	12.2
Income tax effect related to reconciling items [C]	(9.6)	1.5	(34.4)	(3.7)
Non-GAAP net income (loss) [A]	$ 62.6	$ (16.9)	$ 181.5	$ 163.1
Net income (loss) per diluted common share:				
GAAP	$ 0.23	$ (0.62)	$ 0.99	$ 0.61
Non-GAAP	$ 0.64	$ (0.18)	$ 1.85	$ 1.66

[A] GAAP net income (loss) includes IPR&D expense. During the nine months ended September 30, 2021, the Company recognized IPR&D expenses of $5.0 million associated with upfront fees paid. During the three and nine months ended September 30, 2020, the Company recognized IPR&D expenses of $118.5 million and $164.5 million, respectively, in association with the exclusive license agreement entered into with Takeda and the collaboration and license agreement entered into with Idorsia.

[B] The Company recognized an unrealized loss to adjust its equity security investments to fair value.

[C] Estimated income tax effect of non-GAAP reconciling items are calculated using applicable statutory tax rates, taking into consideration any valuation allowance and adjustments to exclude excess tax benefits associated with share-based compensation. On December 31, 2020, the Company released substantially all of its valuation allowance against its net operating losses and other deferred tax assets.

Note: Beginning in the third quarter of 2021, milestone payments received from licenses and collaborations, milestones paid related to licenses and collaborations, non-cash collaboration revenue, and acquired in-process research and development are no longer excluded from non-GAAP financial results. Non-GAAP financial results for 2020 have been updated for comparability to current year periods.

TABLE 4

NEUROCRINE BIOSCIENCES, INC.

RECONCILIATION OF GAAP TO NON-GAAP EXPENSES
(unaudited)

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
GAAP R&D	$ 92.7	$ 69.1	$ 240.7	$ 208.3
Adjustments:				
Share-based compensation expense	12.0	8.8	36.2	26.4
Non-GAAP R&D	$ 80.7	$ 60.3	$ 204.5	$ 181.9
GAAP SG&A	$ 154.6	$ 112.5	$ 426.8	$ 326.8
Adjustments:				
Share-based compensation expense	25.1	17.9	62.4	52.6
Non-GAAP SG&A	$ 129.5	$ 94.6	$ 364.4	$ 274.2