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, 2022**

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, CA** (Address of principal executive offices)	**92130** (Zip Code)

(858) 617-7600
(Registrant's telephone number, including area code)

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))

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

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, 2022, Neurocrine Biosciences, Inc. announced its financial results for the third quarter ended September 30, 2022. 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, 2022
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 hereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

Dated: November 1, 2022

/s/ Matthew C. Abernethy

Matthew C. Abernethy

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

Neurocrine Biosciences Reports Third Quarter 2022 Financial Results and Raises 2022 INGREZZA Sales Guidance

INGREZZA® (valbenazine) Third Quarter Net Product Sales of $376 Million

INGREZZA® (valbenazine) 2022 Net Product Sales Guidance Raised to $1.4 - $1.425 Billion

Supplemental New Drug Application (sNDA) of Valbenazine For the Treatment of Chorea in Patients with Huntington Disease Submitted to the U.S. Food and Drug Administration

SAN DIEGO, Nov. 1, 2022 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the third quarter ended September 30, 2022 and raised net sales guidance for INGREZZA in 2022.

“INGREZZA continues to help more and more patients who suffer from tardive dyskinesia. With the submission of the sNDA of valbenazine for the treatment of chorea associated with Huntington Disease, we have the potential to help even more patients with our valbenazine franchise,” said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. “Our clinical programs continue to progress with multiple data readouts in 2023 including for crinecerfont in congenital adrenal hyperplasia and for NBI-’352 in adult focal onset seizures. Additionally, we recently dosed our first patient in our lead muscarinic program for the treatment of schizophrenia. With a strong commercial and R&D presence, and an attractive financial profile, Neurocrine Biosciences is well positioned to be a leading neuroscience-focused company.”

Financial Highlights

(unaudited, in millions, except per share data)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Revenues:				
Product sales, net	$ 379.3	$ 288.8	$ 1,036.3	$ 786.6
Collaboration revenue	8.6	7.2	40.4	34.9
Total revenues	$ 387.9	$ 296.0	$ 1,076.7	$ 821.5
GAAP Research and Development (R&D)	$ 107.7	$ 92.7	$ 345.8	$ 240.7
Non-GAAP R&D	$ 92.8	$ 80.7	$ 302.2	$ 204.5
GAAP Selling, General and Administrative (SG&A)	$ 186.3	$ 154.6	$ 569.8	$ 426.8
Non-GAAP SG&A	$ 158.1	$ 129.5	$ 483.8	$ 364.4
GAAP net income	$ 68.5	$ 22.5	$ 65.5	$ 96.9
GAAP earnings per share – diluted	$ 0.69	$ 0.23	$ 0.67	$ 0.99
Non-GAAP net income	$ 106.7	$ 62.6	$ 218.5	$ 181.5
Non-GAAP earnings per share – diluted	$ 1.08	$ 0.64	$ 2.22	$ 1.85

(unaudited, in millions)	September 30, 2022	December 31, 2021
Total cash, cash equivalents and marketable securities	$ 1,162.0	$ 1,272.0

Third Quarter INGREZZA Net Product Sales and Commercial Highlights:

- Net product sales were $376 million with total prescriptions (TRx) of approximately 68,600
- Net product sales and TRx grew 31% and 32%, respectively, vs. third quarter of 2021
- Sequential growth driven by record new patients and continued strength in existing patients' refill rates

Financial Highlights:

- Third quarter 2022 GAAP net income and diluted earnings per share of $69 million and $0.69, respectively, compared with $23 million and $0.23, respectively, for third quarter 2021.
- Third quarter 2022 non-GAAP net income and diluted earnings per share of $107 million and $1.08, respectively, compared with $63 million and $0.64, respectively, for third quarter 2021.
- Differences in third quarter 2022 GAAP and non-GAAP operating expenses compared with third quarter 2021 driven by:
  - Increased R&D expense in support of an expanded and advancing clinical portfolio
  - Increased SG&A expense primarily due to ongoing commercial initiatives, including the deployment of the expanded salesforce in April 2022
- At September 30, 2022, the Company had cash, cash equivalents and marketable securities of approximately $1.2 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:

- On November 1, 2022, we acquired Diurnal Group plc, or Diurnal, in an all-cash transaction, for an aggregate value of approximately £48.3 million GBP, or approximately $56 million USD. We believe the transaction presents an opportunity to accelerate the establishment of our clinical development and commercial capabilities in the United Kingdom to the benefit of patient communities and other stakeholders.

Updated 2022 INGREZZA Sales and Reaffirmed Operating Expense Guidance:

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales [1]	$ 1,400	$ 1,425
GAAP R&D expense [2]	$ 415	$ 450
Non-GAAP R&D expense [3]	$ 360	$ 395
GAAP SG&A expense	$ 720	$ 735
Non-GAAP SG&A expense [3]	$ 605	$ 620

1. INGREZZA sales guidance for fiscal 2022 is based on recent trends and the anticipated benefit from our recently completed salesforce expansion. If new COVID-19 related disruptions emerge, the Company's ability to meet these expectations could be negatively impacted.
2. GAAP R&D guidance includes (i) amounts for milestones that are probable of achievement or have been achieved and (ii) amounts for in-process research and development once significant collaboration and licensing arrangements have been completed. GAAP R&D guidance includes approximately $40 million of milestone expenses in connection with collaborations.

3. Non-GAAP guidance adjusted to exclude estimated non-cash stock-based compensation expense of $60 million in R&D and $110 million in SG&A.

Based upon available Federal net operating losses and tax credits, the Company expects to begin making cash payments for Federal income tax beginning in the fourth quarter of 2022.

Expected Future Pipeline Milestones and Key Activities

Program	Indication	Expected Milestones / Key Activities
Valbenazine* (Selective VMAT2 Inhibitor)	Chorea in Huntington Disease	Submitted Supplemental New Drug Application
	Adjunctive Treatment of Schizophrenia	Top-Line Data from 1st Registrational Study in 2024
	Dyskinetic Cerebral Palsy	Top-Line Registrational Data in 2024
NBI-1117568† (Selective M4 Agonist)	Treatment of Schizophrenia	Initiated Phase 2 Study
NBI-827104** (Selective T-Type Ca_V Channel Blocker)	Rare Pediatric Epilepsy: CSWS	Top-Line Phase 2 Data in Q4 2022
Crinecerfont (CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Adult)	Top-Line Registrational Data in 2023
	Congenital Adrenal Hyperplasia (Pediatric)	Top-Line Registrational Data in 2023
NBI-921352∞ (Selective $Na_V1.6$ Channel Blocker)	Focal Onset Seizure in Adults	Phase 2 Data in 2023
NBI-1065846‡ (GPR-139 Agonist)	Anhedonia in Major Depressive Disorder	Phase 2 Data in 2023
NBI-1065845‡ (AMPA Potentiator)	Inadequate Response to Treatment in Major Depressive Disorder	Phase 2 Data in 2024
NBI-1070770‡	Major Depressive Disorder	Initiated Phase 1 Study

Key: VMAT2 = Vesicular Monoamine Transporter 2; Ca_V = Calcium Channel, Voltage-Gated; CSWS = Epileptic Encephalopathy with Continuous Spike and Wave During Sleep; M4= M4 Muscarinic Receptor; CFR1 = Corticotropin-Releasing Factor Type 1; $Na_V1.6$ = Sodium Channel, Voltage-Gated; GPR = Orphan G Protein Coupled Receptor; AMPA = Alpha-Amino-3-Hydroxy-5-Methyl-4-Isoxazole Propionic Acid

*Neurocrine Bioscience Partners: * Mitsubishi Tanabe Pharma Corporation has commercialization rights in East Asia;*
*** In-Licensed from Idorsia Pharmaceuticals; † In-Licensed from Sosei Group Corporation; ∞ In-Licensed from Xenon Pharmaceuticals; ‡ Partnered with Takeda Pharmaceutical Company Limited;*

Conference Call and Webcast Today at 8:00 AM Eastern Time

Neurocrine Biosciences will hold a live conference call and webcast today at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time). Participants can access the live conference call by dialing 866-952-8559 (US) or 785-424-1881 (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 with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis* and uterine fibroids*, as well as over a dozen mid-to-late-stage clinical programs in multiple therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. 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: non-cash stock-based compensation expense, non-cash interest expense related to convertible debt, loss on extinguishment of convertible senior notes, changes in fair value of equity security investments, changes in foreign currency exchange rates 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.

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; expected future clinical and regulatory milestones; expectations regarding our ability to adapt our business to the evolving COVID-19 pandemic globally, 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 globally on our business and the business operations of our customers, collaborators, vendors, and clinical trial sites including the impact 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, manufacturing, and commercialization 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 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 U.S. federal or state legislative or regulatory and/or policy efforts which may result in, among other things, an adverse impact on our revenues or potential revenue; risks associated with potential generic entrants for our products; and other risks described in our periodic reports filed with the SEC, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022. 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
(unaudited)

(in millions, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product sales, net	$ 379.3	$ 288.8	$ 1,036.3	$ 786.6
Collaboration revenue	8.6	7.2	40.4	34.9
Total revenues	387.9	296.0	1,076.7	821.5
Operating expenses:				
Cost of revenues	6.1	4.2	15.5	10.2
Research and development	107.7	92.7	345.8	240.7
Acquired in-process research and development	—	—	—	5.0
Selling, general and administrative	186.3	154.6	569.8	426.8
Total operating expenses	300.1	251.5	931.1	682.7
Operating income	87.8	44.5	145.6	138.8
Other income (expense):				
Interest expense	(1.2)	(6.6)	(6.0)	(19.2)
Unrealized gain (loss) on equity securities	11.1	(8.2)	23.6	(7.5)
Loss on extinguishment of convertible senior notes	—	—	(70.0)	—
Investment income and other, net	0.2	0.8	2.8	3.1
Total other income (expense), net	10.1	(14.0)	(49.6)	(23.6)
Income before provision for income taxes	97.9	30.5	96.0	115.2
Provision for income taxes	29.4	8.0	30.5	18.3
Net income	$ 68.5	$ 22.5	$ 65.5	$ 96.9
Earnings per share, basic	$ 0.72	$ 0.24	$ 0.69	$ 1.03
Earnings per share, diluted	$ 0.69	$ 0.23	$ 0.67	$ 0.99
Weighted average common shares outstanding, basic	95.8	94.7	95.6	94.5
Weighted average common shares outstanding, diluted	99.0	97.7	98.3	97.9

TABLE 2

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

(in millions)	September 30, 2022	December 31, 2021
Cash, cash equivalents and debt securities available-for-sale	$ 799.4	$ 711.3
Other current assets	406.1	261.5
Total current assets	1,205.5	972.8
Deferred tax assets	319.4	315.1
Debt securities available-for-sale	362.6	560.7
Right-of-use assets	89.6	97.2
Equity securities	94.9	63.7
Property and equipment, net	60.9	58.6
Other assets	10.5	4.4
Total assets	$ 2,143.4	$ 2,072.5
Convertible senior notes	$ 169.2	$ —
Other current liabilities	315.9	245.8
Total current liabilities	$ 485.1	$ 245.8
Convertible senior notes	—	335.1
Operating lease liabilities	96.6	105.3
Other long-term liabilities	17.1	12.3
Stockholders' equity	1,544.6	1,374.0
Total liabilities and stockholders' equity	$ 2,143.4	$ 2,072.5

TABLE 3

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

(in millions, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP net income	$ 68.5	$ 22.5	$ 65.5	$ 96.9
Adjustments:				
Stock-based compensation expense - R&D	14.9	12.0	43.6	36.2
Stock-based compensation expense - SG&A	28.2	25.1	86.0	62.4
Loss on extinguishment of convertible senior notes [1]	—	—	70.0	—
Non-cash interest related to convertible senior notes	0.2	4.4	1.0	12.9
Changes in fair value of equity security investments [2]	(11.1)	8.2	(23.6)	7.5
Changes in foreign currency exchange rates	3.4	—	3.4	—
Income tax effect related to reconciling items [3]	2.6	(9.6)	(27.4)	(34.4)
Non-GAAP net income	$ 106.7	$ 62.6	$ 218.5	$ 181.5
Diluted earnings per share:				
GAAP	$ 0.69	$ 0.23	$ 0.67	$ 0.99
Non-GAAP	$ 1.08	$ 0.64	$ 2.22	$ 1.85

1. The Company recognized a loss on extinguishment of $70.0 million related to the partial repurchase of its convertible senior notes in the second quarter of 2022.
2. Reflects periodic fluctuations in the fair values of the Company's equity security investments.
3. 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 tax benefits or expenses associated with non-cash stock-based compensation and premium paid on repurchase of its convertible senior notes.

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. 2021 non-GAAP financial results have been updated for comparability to current year periods.

TABLE 4

NEUROCRINE BIOSCIENCES, INC.

RECONCILIATION OF GAAP TO NON-GAAP EXPENSES

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
GAAP R&D	$ 107.7	$ 92.7	$ 345.8	$ 240.7
Adjustments:				
Stock-based compensation expense	14.9	12.0	43.6	36.2
Non-GAAP R&D	$ 92.8	$ 80.7	$ 302.2	$ 204.5
GAAP SG&A	$ 186.3	$ 154.6	$ 569.8	$ 426.8
Adjustments:				
Stock-based compensation expense	28.2	25.1	86.0	62.4
Non-GAAP SG&A	$ 158.1	$ 129.5	$ 483.8	$ 364.4