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): **August 1, 2023**

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 August 1, 2023, Neurocrine Biosciences, Inc. announced its financial results for the second quarter ended June 30, 2023. 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 August 1, 2023
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: August 1, 2023

/s/ Matthew C. Abernethy

Matthew C. Abernethy

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

Exhibit 99.1

Neurocrine Biosciences Reports Second Quarter 2023 Financial Results and Raises 2023 INGREZZA Sales Guidance

INGREZZA® (valbenazine) Second Quarter Net Product Sales of $440 Million Representing 26% Year-Over-Year Growth

INGREZZA® (valbenazine) 2023 Net Product Sales Guidance Raised to $1.77 - $1.82 Billion

SAN DIEGO, Aug. 1, 2023 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the second quarter ended June 30, 2023 and raised net sales guidance for INGREZZA in 2023.

“INGREZZA’s performance reflects the significant benefit the medicine is providing to patients with tardive dyskinesia enabling us to raise guidance once again,” said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. “Operationally, we are set up well in the second half of 2023 with growing INGREZZA sales, a PDUFA for valbenazine to treat chorea associated with Huntington’s disease, and meaningful progress with our muscarinic programs. Importantly, we remain on-track for four pipeline read-outs in the fourth quarter, including the Phase 3 studies of crinecerfont for the treatment of pediatric and adult congenital adrenal hyperplasia.”

	Three Months Ended June 30,		Six Months Ended June 30,	
(unaudited, in millions, except per share data)	**2023**	**2022**	**2023**	**2022**
Revenues:				
Net Product Sales	$ 446.3	$ 352.0	$ 861.6	$ 657.0
Collaboration Revenue	6.4	26.2	11.5	31.8
Total Revenues	$ 452.7	$ 378.2	$ 873.1	$ 688.8
GAAP Research and Development (R&D)	$ 145.8	$ 135.9	$ 285.3	$ 238.1
Non-GAAP R&D	$ 122.0	$ 119.7	$ 247.7	$ 209.4
GAAP Selling, General and Administrative (SG&A)	$ 221.8	$ 182.8	$ 464.5	$ 383.5
Non-GAAP SG&A	$ 177.1	$ 149.5	$ 393.7	$ 325.7
GAAP Net Income (Loss)	$ 95.5	$ (16.9)	$ 18.9	$ (3.0)
GAAP Earnings (Loss) Per Share – Diluted	$ 0.95	$ (0.18)	$ 0.19	$ (0.03)
Non-GAAP Net Income	$ 125.7	$ 82.1	$ 76.2	$ 111.8
Non-GAAP Earnings Per Share – Diluted	$ 1.25	$ 0.84	$ 0.76	$ 1.14

(unaudited, in millions)	**June 30, 2023**	**December 31, 2022**
Total Cash, Cash Equivalents and Marketable Securities	$ 1,319.3	$ 1,288.7

Second Quarter INGREZZA Net Product Sales Highlights:

- INGREZZA second quarter 2023 net product sales were $440 million and grew 26% vs. the second quarter 2022 driven by prescription demand
- Record number of new patients received therapy during the second quarter of 2023

Second Quarter Financial Highlights:

- Second quarter 2023 GAAP net income and earnings per share of $96 million and $0.95, respectively, compared with second quarter 2022 GAAP net loss and loss per share of $17 million and $0.18, respectively, primarily driven by $70 million loss on extinguishment of debt in the second quarter of 2022
- Second quarter 2023 non-GAAP net income and earnings per share of $126 million and $1.25, respectively, compared with second quarter 2022 non-GAAP net income and earnings per share of $82 million and $0.84, respectively
- Differences in second quarter 2023 GAAP and non-GAAP operating expenses compared with second quarter 2022 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
- At June 30, 2023, the Company had cash, cash equivalents and marketable securities 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.

Updated 2023 INGREZZA Sales Guidance and Reaffirmed Operating Expense Guidance:

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales [1]	$ 1,770	$ 1,820
GAAP R&D Expense [2]	$ 550	$ 580
Non-GAAP R&D Expense [3]	$ 495	$ 525
GAAP and Non-GAAP IPR&D [4]	$ 144	$ 144
GAAP SG&A Expense	$ 850	$ 870
Non-GAAP SG&A Expense [3]	$ 730	$ 750

1. INGREZZA sales guidance for fiscal 2023 reflects expected sales of INGREZZA in tardive dyskinesia only.
2. GAAP R&D guidance includes amounts for milestones that are probable of achievement or have been achieved.
3. Non-GAAP guidance adjusted to exclude estimated non-cash stock-based compensation expense of $65 million in R&D and $135 million in SG&A.
4. IPR&D guidance reflects acquired in-process research and development once significant collaboration and licensing arrangements have been completed. IPR&D guidance includes $143.9 million associated with the new strategic collaboration with Voyager.

2023 Expected Pipeline Milestones and Key Activities

Program	Indication	2023 Milestones / Key Activities
Valbenazine* (Selective VMAT2 Inhibitor)	Chorea in Huntington's Disease	PDUFA Date = August 20, 2023
Crinecerfont (CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Adult)	Top-Line Registrational Data in Early Q4 2023
	Congenital Adrenal Hyperplasia (Pediatric)	Top-Line Registrational Data in Early Q4 2023
NBI-921352** (Selective $Na_V1.6$ Channel Blocker)	Focal Onset Seizure in Adults	Top-Line Phase 2 Data in Q4 2023
NBI-1065846† (GPR-139 Agonist)	Anhedonia in Major Depressive Disorder	Top-Line Phase 2 Data in Q4 2023
NBI-1117570‡ (Dual M1/ M4 Agonist)	Treatment of Schizophrenia	Clinical Trial Application Accepted; Initiating Phase 1 Study in Q3
New Chemical Entity or Entities	Indication(s) TBD	Initiate at Least One Phase 1 Study

Key: VMAT2 = Vesicular Monoamine Transporter 2; CFR1 = Corticotropin-Releasing Factor Type 1; $Na_V1.6$ = Sodium Channel, Voltage-Gated; M1 / M4 = M1 / M4 Muscarinic Receptor; GPR = Orphan G Protein Coupled Receptor

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

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 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 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 a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core 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, Twitter and Facebook. (**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, loss on extinguishment of convertible senior notes, non-cash interest expense related to convertible debt, non-cash amortization expense related to acquired intangible assets, acquisition-related transaction costs, 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; 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 and uncertainties associated with the commercialization of INGREZZA; 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, 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, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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Contact: Neurocrine Biosciences, Inc.

Tony Jewell (Media)
858-617-7578
media@neurocrine.com

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

TABLE 1

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

(in millions, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Net product sales	$ 446.3	$ 352.0	$ 861.6	$ 657.0
Collaboration revenue	6.4	26.2	11.5	31.8
Total revenues	452.7	378.2	873.1	688.8
Operating expenses:				
Cost of revenues	11.5	4.8	20.0	9.4
Research and development	145.8	135.9	285.3	238.1
Acquired in-process research and development	—	—	143.9	—
Selling, general and administrative	221.8	182.8	464.5	383.5
Total operating expenses	379.1	323.5	913.7	631.0
Operating income (loss)	73.6	54.7	(40.6)	57.8
Other income (expense):				
Interest expense	(1.3)	(2.2)	(2.4)	(4.8)
Unrealized gain (loss) on equity security investments	37.3	(7.4)	39.5	12.5
Loss on extinguishment of convertible senior notes	—	(70.0)	—	(70.0)
Investment income and other, net	12.0	1.6	21.8	2.6
Total other income (expense), net	48.0	(78.0)	58.9	(59.7)
Income (loss) before provision for (benefit from) income taxes	121.6	(23.3)	18.3	(1.9)
Provision for (benefit from) income taxes	26.1	(6.4)	(0.6)	1.1
Net income (loss)	$ 95.5	$ (16.9)	$ 18.9	$ (3.0)
Earnings (loss) per share, basic	$ 0.98	$ (0.18)	$ 0.19	$ (0.03)
Earnings (loss) per share, diluted	$ 0.95	$ (0.18)	$ 0.19	$ (0.03)
Weighted average common shares outstanding, basic	97.6	95.6	97.4	95.4
Weighted average common shares outstanding, diluted	100.2	95.6	100.3	95.4

TABLE 2

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

(in millions)	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 976.7	$ 989.3
Other current assets	519.9	464.2
Total current assets	1,496.6	1,453.5
Deferred tax assets	379.0	305.9
Debt securities available-for-sale	342.6	299.4
Right-of-use assets	83.5	87.0
Equity security investments	173.0	102.1
Property and equipment, net	65.6	58.6
Intangible assets, net	36.9	37.2
Other assets	35.9	25.0
Total assets	$ 2,613.1	$ 2,368.7
Convertible senior notes	$ 169.7	$ 169.4
Other current liabilities	412.8	368.3
Total current liabilities	582.5	537.7
Operating lease liabilities	89.1	93.5
Other long-term liabilities	88.5	29.7
Stockholders' equity	1,853.0	1,707.8
Total liabilities and stockholders' equity	$ 2,613.1	$ 2,368.7

TABLE 3

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions, except per share data)	**2023**	**2022**	**2023**	**2022**
GAAP net income (loss)	$ 95.5	$ (16.9)	$ 18.9	$ (3.0)
Adjustments:				
Stock-based compensation expense - R&D	23.8	16.2	37.6	28.7
Stock-based compensation expense - SG&A	44.7	33.3	70.8	57.8
Loss on extinguishment of convertible senior notes [1]	—	70.0	—	70.0
Non-cash interest related to convertible senior notes	0.2	0.4	0.4	0.8
Non-cash amortization related to acquired intangible assets	0.9	—	1.8	—
Changes in fair value of equity security investments [2]	(37.3)	7.4	(39.5)	(12.5)
Income tax effect related to reconciling items [3]	(2.1)	(28.3)	(13.8)	(30.0)
Non-GAAP net income	$ 125.7	$ 82.1	$ 76.2	$ 111.8
Diluted earnings (loss) per share:				
GAAP	$ 0.95	$ (0.18)	$ 0.19	$ (0.03)
Non-GAAP [4]	$ 1.25	$ 0.84	$ 0.76	$ 1.14

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.
4. Non-GAAP diluted earnings per share for the three and six months ended June 30, 2022, reflect diluted shares of 98.2 million and 97.9 million, respectively, which were calculated in accordance with the guidance on earnings per share in ASC 260.

TABLE 4

NEUROCRINE BIOSCIENCES, INC.

RECONCILIATION OF GAAP TO NON-GAAP EXPENSES
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	**2023**	**2022**	**2023**	**2022**
GAAP cost of revenues	$ 11.5	$ 4.8	$ 20.0	$ 9.4
Adjustments:				
Non-cash amortization related to acquired intangible assets	0.9	—	1.8	—
Non-GAAP cost of revenues	$ 10.6	$ 4.8	$ 18.2	$ 9.4

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	**2023**	**2022**	**2023**	**2022**
GAAP R&D	$ 145.8	$ 135.9	$ 285.3	$ 238.1
Adjustments:				
Stock-based compensation expense	23.8	16.2	37.6	28.7
Non-GAAP R&D	$ 122.0	$ 119.7	$ 247.7	$ 209.4

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	**2023**	**2022**	**2023**	**2022**
GAAP SG&A	$ 221.8	$ 182.8	$ 464.5	$ 383.5
Adjustments:				
Stock-based compensation expense	44.7	33.3	70.8	57.8
Non-GAAP SG&A	$ 177.1	$ 149.5	$ 393.7	$ 325.7

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	**2023**	**2022**	**2023**	**2022**
GAAP other income, net	$ 48.0	$ (78.0)	$ 58.9	$ (59.7)
Adjustments:				
Loss on extinguishment of convertible senior notes	—	70.0	—	70.0
Non-cash interest related to convertible senior notes	0.2	0.4	0.4	0.8
Changes in fair value of equity security investments	(37.3)	7.4	(39.5)	(12.5)
Non-GAAP other income (expense), net	$ 10.9	$ (0.2)	$ 19.8	$ (1.4)