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): February 11, 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, 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 February 11, 2022, Neurocrine Biosciences, Inc. announced its financial results for the fourth quarter and fiscal year ended December 31, 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 February 11, 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: February 11, 2022

/s/ Matthew C. Abernethy

Matthew C. Abernethy

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

Neurocrine Biosciences Reports Fourth Quarter and Fiscal 2021 Financial Results and Provides Financial Expectations for Fiscal 2022

INGREZZA® (valbenazine) 2021 Net Product Sales of $1.1 Billion with 200,000 TRx

INGREZZA® (valbenazine) 2022 Net Product Sales Guidance of $1.25 - $1.35 Billion

Expanded Pipeline Expected to Deliver Multiple Registrational and Phase 2 Study Data Readouts Over the Next Two Years

SAN DIEGO, Feb. 11, 2022 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the fourth quarter and fiscal year ended December 31, 2021 and provided financial guidance for 2022.

“As we exited last year with restored growth for INGREZZA, investments we are making this year will further accelerate our ability to help many more patients with tardive dyskinesia who remain undiagnosed and untreated. Additionally, we now have 12 clinical programs in mid-to-late-stage studies, many which will generate important data readouts over the next two years,” said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. “With a blockbuster product in INGREZZA, a novel and diverse pipeline, and a strong balance sheet, Neurocrine Biosciences is uniquely positioned to be a leading neuroscience-focused company.”

Financial Highlights

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(unaudited, in millions, except per share data)	**2021**	**2020**	**2021**	**2020**
Revenues:				
Product sales, net	$ 303.5	$ 241.3	$ 1,090.1	$ 994.1
Collaboration revenue	8.5	6.6	43.4	51.8
Total revenues	$ 312.0	$ 247.9	$ 1,133.5	$ 1,045.9
GAAP Research and Development (R&D)	$ 87.4	$ 66.7	$ 328.1	$ 275.0
Non-GAAP R&D	$ 75.2	$ 59.4	$ 279.7	$ 241.3
GAAP Selling, General and Administrative (SG&A)	$ 156.5	$ 106.5	$ 583.3	$ 433.3
Non-GAAP SG&A	$ 133.1	$ 92.8	$ 497.5	$ 367.0
GAAP net (loss) income	$ (7.3)	$ 347.9	$ 89.6	$ 407.3
GAAP (loss) earnings per share – diluted	$ (0.08)	$ 3.58	$ 0.92	$ 4.16
Non-GAAP net income	$ 4.3	$ 86.9	$ 185.8	$ 250.0
Non-GAAP earnings per share – diluted	$ 0.04	$ 0.89	$ 1.90	$ 2.56

	December 31,	
(unaudited, in millions)	**2021**	**2020**
Total cash, cash equivalents and marketable securities	$ 1,272.0	$ 1,028.1

Fourth Quarter and Fiscal 2021 INGREZZA Net Product Sales and Commercial Highlights:

- INGREZZA fourth quarter and fiscal 2021 net product sales of $301 million and $1.1 billion, respectively
- Fourth quarter 2021 INGREZZA net sales and total prescriptions grew 25% and 32%, respectively, vs. fourth quarter of 2020
- Quarterly growth driven by record number of patients on therapy exiting 2021
- Commercial expansion to better meet the needs of healthcare professionals across diverse sites of care on track for completion by the end of Q1 2022

Financial Highlights:

- Fourth quarter 2021 GAAP net loss and loss per share of $7 million and $0.08, respectively, compared with fourth quarter 2020 GAAP net income and diluted earnings per share of $348 million and $3.58, respectively, primarily driven by a non-cash tax benefit of $296 million related to the release of substantially all of the Company's valuation allowance against its deferred tax assets on December 31, 2020
- Fourth quarter 2021 non-GAAP net income and diluted earnings per share of $4 million and $0.04, respectively, compared with $87 million and $0.89, respectively, for fourth quarter 2020
- Differences in fourth quarter 2021 GAAP and non-GAAP financial results compared with fourth quarter 2020 driven by:
    - In-Process Research and Development (IPR&D) associated with a $100 million upfront fee paid to Sosei Heptares pursuant to our exclusive license agreement
    - Increased R&D expense in support of our expanded and advancing portfolio, including investment in in-licensed programs in epilepsy and psychiatry commencing at the end of 2019 and in mid-2020, respectively
    - 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"
- No cash payments for federal income tax were made in 2021 as the Company offset pre-tax income against previously benefited Federal net operating losses (NOLs)
- At December 31, 2021, the Company had cash, cash equivalents and marketable securities of $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 December 2021, the Company completed a strategic partnership with Sosei Heptares to expand its clinical psychiatry pipeline. The $100 million upfront fee paid to Sosei Heptares pursuant to our exclusive license agreement was expensed as IPR&D in fiscal 2021.
- In the fourth quarter of 2021, the Company announced positive top-line data from the Phase III KINECT-HD study evaluating the efficacy, safety and tolerability of valbenazine in 120 adult patients with chorea in Huntington disease, also known as Huntington chorea. The study met the primary endpoint of reduction in severity of chorea. The Company plans to submit a supplemental new drug

application for valbenazine for the treatment of Huntington chorea with the FDA in the second half of 2022.

- In February 2022, the Company entered into a lease agreement for a four-building campus facility to be constructed in San Diego, California, pursuant to which a 6-year option for the construction of a fifth building and an option to purchase the entire campus facility in the future were also secured. Upon completion of construction, the Company expects to utilize the campus facility as its new corporate headquarters, which will consist of office space and R&D laboratories. The Company expects to begin subleasing its existing leased facilities beginning in 2023.

Fiscal 2022 INGREZZA and Expense Guidance:

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales[1]	$ 1,250	$ 1,350
GAAP R&D expense[2]	$ 410	$ 430
Non-GAAP R&D expense[3]	$ 350	$ 370
GAAP SG&A expense[4]	$ 690	$ 720
Non-GAAP SG&A expense[3]	$ 580	$ 610

1. INGREZZA sales guidance for fiscal 2022 reflects approximately 20% year-over-year growth, at the mid-point of the range, and is based on recent trends and an anticipated improving environment throughout the year and benefit from our previously announced sales force expansion during the second half of 2022. If new COVID-19 related disruptions emerge, the Company's ability to meet these expectations could be negatively impacted.
2. GAAP R&D guidance reflects the progression of the Company's pipeline including 12 mid-to-late-stage clinical studies and meaningful investment in the Company's recent Sosei Heptares collaboration programs. GAAP R&D guidance includes 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 $7 million of milestone expense for the Xenon collaboration which was achieved in January 2022.
3. Non-GAAP guidance adjusted to exclude estimated non-cash stock compensation expense of $60 million in R&D and $110 million in SG&A.
4. GAAP SG&A guidance reflects the increased investment in INGREZZA commercial initiatives including the continuation of the Company's direct-to-consumer advertising campaign, "TD Spotlight" and sales force expansion expected to be completed in the end of the first quarter

Based upon Federal NOL's and tax credits, the Company expects to make minimal cash payments for Federal income tax beginning in the fourth quarter of 2022.

Expected Future Milestones and Key Activities

Program	Indication	Expected Milestones / Key Activities
Valbenazine* (VMAT2 Inhibitor)	Chorea in Huntington Disease	File Supplemental New Drug Application in Second Half (2H) 2022
	Adjunctive Treatment of Schizophrenia	Initiate 2nd Registrational Study in 2022; Top-Line Data from 1st Registrational Study in 2023
	Dyskinetic Cerebral Palsy	Top-Line Registrational Data in 2023
NBI-827104** (Selective T-Type Ca_V Channel Blocker)	Essential Tremor	Top-Line Phase 2 Data in Mid-2022
	Rare Pediatric Epilepsy: CSWS	Top-Line Phase 2 Data in 2H 2022
NBI-1117568† (Selective M4 Agonist)	Treatment of Schizophrenia	Initiate Phase 2 Study in 2022
New Chemical Entity	Neurological or Psychiatric Indication	Initiate Phase 1 Study in 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-1065845‡ (AMPA Potentiator)	Inadequate Response to Treatment in Major Depressive Disorder	Phase 2 Data in 2023
NBI-1065846‡ (GPR-139 Agonist)	Anhedonia in Major Depressive Disorder	Phase 2 Data in 2023
NBI-921352∞ (Selective $Na_V1.6$ Channel Blocker)	Focal Onset Seizure in Adults	Phase 2 Data in 2023

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; AMPA = Alpha-Amino-3-Hydroxy-5-Methyl-4-Isoxazole Propionic Acid; GPR = Orphan G Protein Coupled Receptor; $Na_V1.6$ = Sodium Channel, Voltage-Gated

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

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 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: 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.

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 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 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 (LOSS) INCOME
(unaudited)

(in millions, except per share data)	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 303.5	$ 241.3	$ 1,090.1	$ 994.1
Collaboration revenue	8.5	6.6	43.4	51.8
Total revenues	312.0	247.9	1,133.5	1,045.9
Operating expenses:				
Cost of sales	4.1	2.9	14.3	10.1
Research and development	87.4	66.7	328.1	275.0
Acquired in-process research and development	100.3	—	105.3	164.5
Selling, general and administrative	156.5	106.5	583.3	433.3
Total operating expenses	348.3	176.1	1,031.0	882.9
Operating (loss) income	(36.3)	71.8	102.5	163.0
Other income (expense):				
Interest expense	(6.6)	(7.8)	(25.8)	(32.8)
Unrealized gain (loss) on equity securities	28.4	(5.5)	20.9	(17.7)
Loss on extinguishment of convertible senior notes	—	(18.4)	—	(18.4)
Investment income and other, net	0.7	1.6	3.8	12.6
Total other income (expense), net	22.5	(30.1)	(1.1)	(56.3)
(Loss) income before (benefit from) provision for income taxes	(13.8)	41.7	101.4	106.7
(Benefit from) provision for income taxes	(6.5)	(306.2)	11.8	(300.6)
Net (loss) income	$ (7.3)	$ 347.9	$ 89.6	$ 407.3
(Loss) earnings per share, basic	$ (0.08)	$ 3.72	$ 0.95	$ 4.38
(Loss) earnings per share, diluted	$ (0.08)	$ 3.58	$ 0.92	$ 4.16
Weighted average common shares outstanding, basic	94.9	93.5	94.6	93.1
Weighted average common shares outstanding, diluted	94.9	97.2	97.9	97.8

TABLE 2

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

(in millions)	December 31, 2021	December 31, 2020
Cash, cash equivalents and debt securities available-for-sale	$ 711.3	$ 801.0
Other current assets	261.5	215.2
Total current assets	972.8	1,016.2
Deferred tax assets	315.1	319.4
Debt securities available-for-sale	560.7	227.1
Right-of-use assets	97.2	82.8
Equity securities	63.7	38.2
Property and equipment, net	58.6	44.6
Other assets	4.4	6.4
Total assets	$ 2,072.5	$ 1,734.7
Total current liabilities	$ 245.8	$ 186.5
Convertible senior notes	335.1	317.9
Operating lease liabilities	105.3	94.4
Other long-term liabilities	12.3	9.7
Stockholders’ equity	1,374.0	1,126.2
Total liabilities and stockholders’ equity	$ 2,072.5	$ 1,734.7

TABLE 3

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

(in millions, except per share data)	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Twelve Months Ended December 31, 2021	Twelve Months Ended December 31, 2020
GAAP net (loss) income [A]	$ (7.3)	$ 347.9	$ 89.6	$ 407.3
Adjustments:				
Share-based compensation expense - R&D	12.2	7.3	48.4	33.7
Share-based compensation expense - SG&A	23.4	13.7	85.8	66.3
Loss on extinguishment of convertible senior notes [B]	—	18.4	—	18.4
Non-cash interest related to convertible senior notes	4.4	5.2	17.3	21.4
Changes in fair value of equity security investments [C]	(28.4)	5.5	(20.9)	17.7
Income tax effect related to reconciling items [D]	—	(311.1)	(34.4)	(314.8)
Non-GAAP net income [A]	$ 4.3	$ 86.9	$ 185.8	$ 250.0
(Loss) earnings per diluted common share:				
GAAP	$ (0.08)	$ 3.58	$ 0.92	$ 4.16
Non-GAAP [E]	$ 0.04	$ 0.89	$ 1.90	$ 2.56

[A] Fourth quarter and fiscal 2021 include IPR&D expense of $100.3 million and $105.3 million, respectively, and $164.5 million for fiscal 2020 related to upfront payments for asset acquisitions.

[B] Reflects loss recognized on the partial repurchase of outstanding convertible debt in November 2020.

[C] Reflects unrealized (gain) loss recognized to adjust equity security investments to fair value.

[D] 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. In the fourth quarter of 2020, the Company recognized a non-cash tax benefit of approximately $296 million related to the release of substantially all of its valuation against deferred tax assets on December 31, 2020. The fourth quarter 2020 benefit associated with the valuation allowance release has been excluded from non-GAAP net income.

[E] Fourth quarter 2021 non-GAAP net income per diluted common share reflects diluted shares of 97.8 million, which were calculated in accordance with the guidance on earnings per share in ASC 260.

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. Fiscal 2020 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)

(in millions)	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
GAAP R&D	$ 87.4	$ 66.7	$ 328.1	$ 275.0
Adjustments:				
Share-based compensation expense	12.2	7.3	48.4	33.7
Non-GAAP R&D	$ 75.2	$ 59.4	$ 279.7	$ 241.3
GAAP SG&A	$ 156.5	$ 106.5	$ 583.3	$ 433.3
Adjustments:				
Share-based compensation expense	23.4	13.7	85.8	66.3
Non-GAAP SG&A	$ 133.1	$ 92.8	$ 497.5	$ 367.0