Neurocrine Biosciences Reports Fourth Quarter and Fiscal 2022 Financial Results and Provides Financial Expectations for 2023

February 6, 2023

INGREZZA® (valbenazine) Fourth Quarter Net Product Sales of $399 Million

INGREZZA® (valbenazine) 2023 Net Product Sales Guidance of $1.67 - $1.77 Billion

Enrollment Complete in Adult and Pediatric Registrational Studies of Crinecerfont for the Treatment of Congenital Adrenal Hyperplasia

Top-Line Data for Clinical Programs in Congenital Adrenal Hyperplasia, Focal Onset Seizure and Anhedonia in Major Depressive Disorder Expected in the Second Half of 2023

SAN DIEGO, Feb. 6, 2023 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the fourth quarter and fiscal year ended December 31, 2022 and provided financial guidance for 2023.

"We enter this year with tremendous momentum aiming to help the 7 out of 10 patients living with tardive dyskinesia in the U.S. who have not received a proper diagnosis for their uncontrollable movement disorder," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "Our capital allocation priorities remain: Invest in INGREZZA and in our pipeline. Enrollment is now complete in both the adult and pediatric registrational studies of crinecerfont for the treatment of congenital adrenal hyperplasia and we look forward to sharing the top-line data this year. With INGREZZA growing and our pipeline advancing, the fundamentals of our business are strong as we advance on our mission to be a leading neuroscience company."

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(unaudited, in millions, except per share data)	**2022**	**2021**	**2022**	**2021**
Revenues:				
Product sales, net	$ 404.6	$ 303.5	$ 1,440.9	$ 1,090.1
Collaboration revenue	7.4	8.5	47.8	43.4
Total revenues	$ 412.0	$ 312.0	$ 1,488.7	$ 1,133.5
GAAP Research and Development (R&D)	$ 118.0	$ 87.4	$ 463.8	$ 328.1
Non-GAAP R&D	$ 103.9	$ 75.2	$ 406.1	$ 279.7
GAAP Selling, General and Administrative (SG&A)	$ 182.9	$ 156.5	$ 752.7	$ 583.3
Non-GAAP SG&A	$ 151.8	$ 133.1	$ 635.6	$ 497.5
GAAP net income (loss)	$ 89.0	$ (7.3)	$ 154.5	$ 89.6
GAAP earnings (loss) per share – diluted	$ 0.88	$ (0.08)	$ 1.56	$ 0.92
Non-GAAP net income	$ 124.7	$ 4.3	$ 343.2	$ 185.8
Non-GAAP earnings per share – diluted	$ 0.88	$ 0.04	$ 3.47	$ 1.90

(unaudited, in millions)	December 31, 2022	December 31, 2021
Total cash, cash equivalents and marketable securities	$ 1,288.7	$ 1,272.0

Fourth Quarter and Fiscal 2022 INGREZZA Net Product Sales and Commercial Highlights:

- INGREZZA fourth quarter and fiscal 2022 net product sales were $399 million and $1.43 billion, respectively
- INGREZZA fourth quarter net product sales and total prescriptions grew 33% and 29%, respectively, vs. fourth quarter of 2021
- Sequential growth driven by record new patients and continued strength in existing patients' refill rates

Fourth Quarter Financial Highlights:

- Fourth quarter 2022 GAAP net income and diluted earnings per share of $89 million and $0.88, respectively, compared with GAAP net loss and earnings per share of $7 million and $0.08, respectively, for fourth quarter 2021.
- Fourth quarter 2022 non-GAAP net income and diluted earnings per share of $125 million and $1.24, respectively, compared with $4 million and $0.04, respectively, for fourth quarter 2021.
- Differences in fourth quarter 2022 GAAP and non-GAAP operating expenses compared with fourth quarter 2021 driven by:
    - In-Process Research and Development (IPR&D) in fourth quarter 2021 associated with a $100 million upfront fee paid to Sosei Heptares pursuant to our exclusive license agreement
    - 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 December 31, 2022, 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.

Recent Events:

- On November 1, 2022, we acquired Diurnal Group plc in an all-cash transaction, for an aggregate value of approximately $55 million. 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.
- On December 22, 2022, we announced that the U.S. Food and Drug Administration accepted the supplemental New Drug Application for valbenazine as a treatment for chorea associated with Huntington Disease. The agency set a Prescription Drug User Fee Act target action date of August 20, 2023.
- On January 8, 2023, we entered into a new strategic collaboration with Voyager Therapeutics, Inc., or Voyager, to acquire the worldwide rights to Voyager's GBA1 gene therapy program for Parkinson's disease and other GBA1-mediated diseases and three gene therapy programs directed to rare central nervous system targets. This transaction is anticipated to close in the first quarter subject to certain conditions including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions.
- On February 6, 2023, we announced enrollment is complete in both the Adult and Pediatric Registrational Studies of crinecerfont for Congenital Adrenal Hyperplasia. We anticipate top-line data for both studies to read-out in the second half of 2023.

Fiscal 2023 INGREZZA Sales and Operating Expense Guidance:

	Range	
(in millions)	**Low**	**High**
INGREZZA (Tardive Dyskinesia Only) Net Product Sales [1]	$ 1,670	$ 1,770
GAAP R&D expense [2]	$ 550	$ 580
Non-GAAP R&D expense [3]	$ 495	$ 525
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. The guidance range is based upon recent trends and underlying business initiatives underway to help advance the development of the tardive dyskinesia market.
2. GAAP R&D guidance reflects the progression of the Company's pipeline including 12 mid-to-late-stage clinical studies, meaningful investments in the muscarinic portfolio and expanded pre-clinical research efforts. 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.
3. GAAP SG&A guidance reflects the continued investment in the expanded commercial organization to support INGREZZA as well as the Company's direct-to-consumer advertising campaign. In addition, guidance includes an investment to support the anticipated approval for valbenazine to treat patients with chorea associated with Huntington disease. Non-GAAP guidance adjusted to exclude estimated non-cash stock-based compensation expense of $55 million in R&D and $120 million in SG&A.

2023 Expected Pipeline Milestones and Key Activities

Program	Indication	2023 Milestones / Key Activities
Valbenazine* (Selective VMAT2 Inhibitor)	Chorea in Huntington Disease	PDUFA Aug. 20, 2023
Crinecerfont	Congenital Adrenal Hyperplasia (Adult)	Top-Line Registrational Data in Second Half of 2023

(CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Pediatric)	Top-Line Registrational Data in Second Half of 2023
NBI-921352** (Selective $Na_V1.6$ Channel Blocker)	Focal Onset Seizure in Adults	Top-Line Phase 2 Data in Second Half of 2023
NBI-1065846† (GPR-139 Agonist)	Anhedonia in Major Depressive Disorder	Top-Line Phase 2 Data in Second Half of 2023
NBI-1117570‡ (Dual M1/ M4 Agonist)	Treatment of Schizophrenia	Initiate Phase 1 Study
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 866-952-8559 (US) or 785-424-1743 (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*, and 12 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, 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; 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 September 30, 2022. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

TABLE 1
NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions, except per share data)	**2022**	**2021**	**2022**	**2021**
Revenues:				
Product sales, net	$ 404.6	$ 303.5	$ 1,440.9	$ 1,090.1
Collaboration revenue	7.4	8.5	47.8	43.4
Total revenues	412.0	312.0	1,488.7	1,133.5
Operating expenses:				
Cost of revenues	7.7	4.1	23.2	14.3
Research and development	118.0	87.4	463.8	328.1
Acquired in-process research and development	—	100.3	—	105.3
Selling, general and administrative	182.9	156.5	752.7	583.3
Total operating expenses	308.6	348.3	1,239.7	1,031.0
Operating income (loss)	103.4	(36.3)	249.0	102.5
Other income (expense):				
Interest expense	(1.1)	(6.6)	(7.1)	(25.8)
Unrealized gain on equity securities	7.2	28.4	30.8	20.9
Loss on extinguishment of convertible senior notes	—	—	(70.0)	—
Investment income and other, net	8.4	0.7	11.2	3.8
Total other income (expense), net	14.5	22.5	(35.1)	(1.1)
Income (loss) before provision for income taxes	117.9	(13.8)	213.9	101.4
Provision for (benefit from) income taxes	28.9	(6.5)	59.4	11.8
Net income (loss)	$ 89.0	$ (7.3)	$ 154.5	$ 89.6
Earnings (loss) per share, basic	$ 0.92	$ (0.08)	$ 1.61	$ 0.95
Earnings (loss) per share, diluted	$ 0.88	$ (0.08)	$ 1.56	$ 0.92
Weighted average common shares outstanding, basic	96.3	94.9	95.8	94.6
Weighted average common shares outstanding, diluted	100.8	94.9	98.9	97.9

TABLE 2
NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

(in millions)	December 31, 2022	December 31, 2021
Cash, cash equivalents and debt securities available-for-sale	$ 989.3	$ 711.3
Other current assets	464.2	261.5
Total current assets	1,453.5	972.8
Deferred tax assets	305.9	315.1
Debt securities available-for-sale	299.4	560.7
Right-of-use assets	87.0	97.2
Equity securities	102.1	63.7
Property and equipment, net	58.6	58.6
Intangible assets, net	37.2	—
Other assets	25.0	4.4
Total assets	$ 2,368.7	$ 2,072.5
Convertible senior notes	$ 169.4	$ —
Other current liabilities	368.3	245.8
Total current liabilities	537.7	245.8
Convertible senior notes	—	335.1
Operating lease liabilities	93.5	105.3
Other long-term liabilities	29.7	12.3
Stockholders' equity	1,707.8	1,374.0
Total liabilities and stockholders' equity	$ 2,368.7	$ 2,072.5

TABLE 3
NEUROCRINE BIOSCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions, except per share data)	**2022**	**2021**	**2022**	**2021**
GAAP net income (loss)	$ 89.0	$ (7.3)	$ 154.5	$ 89.6
Adjustments:				
Stock-based compensation expense - R&D	14.1	12.2	57.7	48.4
Stock-based compensation expense - SG&A	29.4	23.4	115.4	85.8
Loss on extinguishment of convertible senior notes [1]	—	—	70.0	—
Non-cash interest related to convertible senior notes	0.2	4.4	1.2	17.3
Non-cash amortization related to acquired intangible assets	0.5	—	0.5	—
Acquisition-related transaction costs - SG&A [2]	1.7	—	1.7	—
Changes in fair value of equity security investments [3]	(7.2)	(28.4)	(30.8)	(20.9)
Changes in foreign currency exchange rates	(1.5)	—	1.9	—
Income tax effect related to reconciling items [4]	(1.5)	—	(28.9)	(34.4)
Non-GAAP net income	$ 124.7	$ 4.3	$ 343.2	$ 185.8
Diluted earnings (loss) per share:				
GAAP	$ 0.88	$ (0.08)	$ 1.56	$ 0.92
Non-GAAP[5]	$ 1.24	$ 0.04	$ 3.47	$ 1.90

1. The Company recognized a loss on extinguishment of $70.0 million in connection with the partial repurchase of its convertible senior notes in the second quarter of 2022.
2. The Company recognized transaction costs of $1.7 million in connection with its acquisition of Diurnal Group plc in November 2022.
3. Reflects periodic fluctuations in the fair values of the Company's equity security investments.
4. 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.
5. 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.

TABLE 4
NEUROCRINE BIOSCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP EXPENSES
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2022**	**2021**	**2022**	**2021**
GAAP cost of revenues	$ 7.7	$ 4.1	$ 23.2	$ 14.3
Adjustments:				
Non-cash amortization related to acquired intangible assets	0.5	—	0.5	—
Non-GAAP cost of revenues	$ 7.2	$ 4.1	$ 22.7	$ 14.3

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2022**	**2021**	**2022**	**2021**
GAAP R&D	$ 118.0	$ 87.4	$ 463.8	$ 328.1
Adjustments:				
Stock-based compensation expense	14.1	12.2	57.7	48.4
Non-GAAP R&D	$ 103.9	$ 75.2	$ 406.1	$ 279.7

(in millions)	Three Months Ended December 31, 2022	Three Months Ended December 31, 2021	Twelve Months Ended December 31, 2022	Twelve Months Ended December 31, 2021
GAAP SG&A	$ 182.9	$ 156.5	$ 752.7	$ 583.3
Adjustments:				
Stock-based compensation expense	29.4	23.4	115.4	85.8
Acquisition-related transaction costs	1.7	—	1.7	—
Non-GAAP SG&A	$ 151.8	$ 133.1	$ 635.6	$ 497.5

(in millions)	Three Months Ended December 31, 2022	Three Months Ended December 31, 2021	Twelve Months Ended December 31, 2022	Twelve Months Ended December 31, 2021
GAAP other income (expense), net	$ 14.5	$ 22.5	$ (35.1)	$ (1.1)
Adjustments:				
Loss on extinguishment of convertible senior notes	—	—	70.0	—
Non-cash interest related to convertible senior notes	0.2	4.4	1.2	17.3
Changes in fair value of equity security investments	(7.2)	(28.4)	(30.8)	(20.9)
Changes in foreign currency exchange rates	(1.5)	—	1.9	—
Non-GAAP other income (expense), net	$ 6.0	$ (1.5)	$ 7.2	$ (4.7)

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