Neurocrine Biosciences Reports Fourth Quarter and Fiscal 2023 Financial Results and Provides Financial Expectations for 2024

February 7, 2024

INGREZZA® (valbenazine) Fourth Quarter and Full Year 2023 Net Product Sales of $500 Million and $1.84 Billion, Representing Year-over-Year Growth of 25% and 29% Respectively

INGREZZA® (valbenazine) Full Year 2024 Net Product Sales Guidance of $2.1 - $2.2 Billion

Crinecerfont FDA Regulatory Submission Anticipated in the Second Quarter for the Treatment of Congenital Adrenal Hyperplasia in Adults and Pediatrics

SAN DIEGO, Feb. 7, 2024 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the fourth quarter and full year ended December 31, 2023 and provided financial guidance for 2024.

"I'm exceptionally proud of the progress we made with INGREZZA last year, helping more patients than ever before treat their tardive dyskinesia. In addition, the positive Phase 3 crinecerfont results for the treatment of congenital adrenal hyperplasia opens the door for us to help patients living with a disabling neuroendocrine disorder," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "With a strong foundation in INGREZZA, a potential second important growth driver in crinecerfont, and an advancing pipeline, Neurocrine Biosciences is making significant progress towards becoming a leading neuroscience focused company."

Financial Highlights

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(unaudited, in millions, except per share data)	**2023**	**2022**	**2023**	**2022**
Revenues:				
Net Product Sales	$ 507.2	$ 404.6	$ 1,860.6	$ 1,440.9
Collaboration Revenue	8.0	7.4	26.5	47.8
Total Revenues	$ 515.2	$ 412.0	$ 1,887.1	$ 1,488.7
GAAP Research and Development (R&D)	$ 137.5	$ 118.0	$ 565.0	$ 463.8
Non-GAAP R&D	$ 124.3	$ 103.9	$ 497.0	$ 406.1
GAAP Selling, General and Administrative (SG&A)	$ 218.9	$ 182.9	$ 887.6	$ 752.7
Non-GAAP SG&A	$ 194.0	$ 151.8	$ 757.4	$ 635.6
GAAP Net Income	$ 147.7	$ 89.0	$ 249.7	$ 154.5
GAAP Earnings Per Share – Diluted	$ 1.44	$ 0.88	$ 2.47	$ 1.56
Non-GAAP Net Income	$ 157.7	$ 124.7	$ 390.0	$ 343.2
Non-GAAP Earnings Per Share – Diluted	$ 1.54	$ 1.24	$ 3.86	$ 3.47

(unaudited, in millions)	December 31, 2023	December 31, 2022
Total Cash, Cash Equivalents and Marketable Securities	$ 1,719.1	$ 1,288.7

INGREZZA Net Product Sales Highlights

- INGREZZA fourth quarter and fiscal 2023 net product sales were $500 million and $1.84 billion, respectively
- INGREZZA fourth quarter net product sales grew 25% compared with fourth quarter 2022, driven by strong underlying patient demand offset slightly by seasonal gross-to-net dynamics

Other Key Financial Highlights

- Differences in fourth quarter 2023 GAAP and non-GAAP operating expenses compared with fourth quarter 2022 were driven by:
  - Increased R&D expense in support of an expanded and advancing clinical portfolio including preclinical investments in muscarinic compounds, gene therapy programs and second generation VMAT2 inhibitors
  - Increased SG&A expense primarily due to ongoing commercial initiatives supporting INGREZZA growth including the expanded indication to treat chorea associated with Huntington's disease
- Fourth quarter 2023 GAAP net income and earnings per share were $148 million and $1.44, respectively, compared with $89 million and $0.88, respectively, for fourth quarter 2022
- Fourth quarter 2023 non-GAAP net income and earnings per share were $158 million and $1.54, respectively, compared with $125 million and $1.24, respectively, for fourth quarter 2022
- At December 31, 2023, the Company had cash, cash equivalents and marketable securities totaling approximately $1.7 billion

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

Recent Developments

- In November 2023, the Company announced that all patent litigation brought by Neurocrine Biosciences against the companies that filed Abbreviated New Drug Applications (ANDA) to the FDA seeking approval to market generic versions of INGREZZA prior to the expiration of the Orange Book listed patents have been resolved. Accordingly, such companies have the right to sell generic versions of INGREZZA in the U.S. beginning March 2038, or earlier under certain circumstances.
- In December 2023, the Company announced crinecerfont received Breakthrough Therapy designation from the FDA for the treatment of Congenital Adrenal Hyperplasia in adults and pediatrics.

Full Year 2024 Financial Guidance

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales [1]	$ 2,100	$ 2,200
GAAP R&D Expense [2]	$ 645	$ 675
Non-GAAP R&D Expense [3]	$ 570	$ 600
GAAP SG&A Expense [4]	$ 930	$ 950
Non-GAAP SG&A Expense [3, 4]	$ 830	$ 850

1. INGREZZA sales guidance reflects expected net product sales of INGREZZA in tardive dyskinesia and chorea associated with Huntington's disease.
2. GAAP R&D guidance includes expense for development milestones once determined achievement is deemed probable. Acquired in-process research and development expense is included in guidance once significant collaboration and licensing arrangements have been completed.
3. Non-GAAP guidance adjusted primarily to exclude estimated non-cash stock-based compensation expense of $75 million in R&D and $100 million in SG&A.
4. SG&A guidance range reflects expense for ongoing commercial initiatives supporting INGREZZA growth including the expanded indication to treat chorea associated with Huntington's disease and pre-launch commercial activities for crinecerfont.

2024 Expected Pipeline Milestones and Key Activities

Program	Indication	Expected Milestones / Key Activities
Valbenazine* (Selective VMAT2 Inhibitor)	Sprinkle Formulation for Tardive Dyskinesia / Chorea in Huntington's Disease	PDUFA April 30, 2024
Crinecerfont (CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Pediatric and Adult)	Submitting New Drug Application to the FDA in Q2'24

Efmody (Hydrocortisone Modified Release Hard Capsules)	Adrenal Insufficiency	Top-Line Phase 2 Data in 1H'24
Efmody (Hydrocortisone Modified Release Hard Capsules)	Congenital Adrenal Hyperplasia	Top-Line Phase 2 Data in 1H'24
NBI-1065845** (AMPA Potentiator)	Inadequate Response in Major Depressive Disorder	Top-Line Phase 2 Data in 1H'24
NBI-1117568† (M4 Agonist)	Schizophrenia	Top-Line Phase 2 Data in 2H'24
Luvadaxistat** (DAAO Inhibitor)	Cognitive Impairment Associated with Schizophrenia	Top-Line Phase 2 Data in 2H'24
NBI-1070770** (NMDA NR2B NAM)	Major Depressive Disorder	Initiating Phase 2 Study
NBI-1117567† (M1 Agonist)	CNS Indications	Initiating Phase 1 Study
NBI-1076986 (M4 Antagonist)	Movement Disorders	Initiating Phase 1 Study
NBI-1065890 (Selective VMAT2 Inhibitor)	CNS Indications	Initiating Phase 1 Study

Key: VMAT2 = Vesicular Monoamine Transporter 2; CFR1 = Corticotropin-Releasing Factor Type 1; AMPA = alpha-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid; M4 = M4 Muscarinic Receptor; DAAO = d-amino acid oxidase; NMDA NR2B NAM = n-methyl-d-aspartate Receptor Subtype 2B Negative Allosteric Modulator; M1 = M1 Muscarinic Receptor

*Neurocrine Biosciences Partners: * Mitsubishi Tanabe Pharma Corporation has commercialization rights in East Asia; ** 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 800-225-9448 (US) or 203-518-9708 (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, chorea associated with Huntington'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, X (Formerly 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 and integration 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 government and third-party regulatory and/or policy efforts which may, among other things, impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products; risks associated with competition from other therapies or products, including 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, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than as required by law.

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)	**2023**	**2022**	**2023**	**2022**
Revenues:				
Net product sales	$ 507.2	$ 404.6	$ 1,860.6	$ 1,440.9
Collaboration revenue	8.0	7.4	26.5	47.8
Total revenues	515.2	412.0	1,887.1	1,488.7
Operating expenses:				
Cost of revenues	8.5	7.7	39.7	23.2
Research and development	137.5	118.0	565.0	463.8
Acquired in-process research and development	—	—	143.9	—
Selling, general and administrative	218.9	182.9	887.6	752.7
Total operating expenses	364.9	308.6	1,636.2	1,239.7
Operating income	150.3	103.4	250.9	249.0
Other income (expense):				
Interest expense	(1.1)	(1.1)	(4.6)	(7.1)
Unrealized gain on equity security investments	29.0	7.2	28.4	30.8
Loss on extinguishment of convertible senior notes	—	—	—	(70.0)
Investment income and other, net	20.0	8.4	57.4	11.2
Total other income (expense), net	47.9	14.5	81.2	(35.1)
Income before provision for income taxes	198.2	117.9	332.1	213.9
Provision for income taxes	50.5	28.9	82.4	59.4
Net income	$ 147.7	$ 89.0	$ 249.7	$ 154.5
Earnings per share, basic	$ 1.50	$ 0.92	$ 2.56	$ 1.61
Earnings per share, diluted	$ 1.44	$ 0.88	$ 2.47	$ 1.56

Weighted average common shares outstanding, basic	98.4	96.3	97.7	95.8
Weighted average common shares outstanding, diluted	102.3	100.8	101.0	98.9

TABLE 2

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

(in millions)	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 1,031.6	$ 989.3
Other current assets	575.4	464.2
Total current assets	1,607.0	1,453.5
Deferred tax assets	362.6	305.9
Debt securities available-for-sale	687.5	299.4
Right-of-use assets	276.5	87.0
Equity security investments	161.9	102.1
Property and equipment, net	70.8	58.6
Intangible assets, net	35.5	37.2
Other assets	49.6	25.0
Total assets	$ 3,251.4	$ 2,368.7
Convertible senior notes	$ 170.1	$ 169.4
Other current liabilities	484.7	368.3
Total current liabilities	654.8	537.7
Operating lease liabilities	258.3	93.5
Other long-term liabilities	106.3	29.7
Stockholders' equity	2,232.0	1,707.8
Total liabilities and stockholders' equity	$ 3,251.4	$ 2,368.7

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)	2023	2022	2023	2022
GAAP net income	$ 147.7	$ 89.0	$ 249.7	$ 154.5
Adjustments:				
Stock-based compensation expense - R&D	13.2	14.1	68.0	57.7
Stock-based compensation expense - SG&A	24.9	29.4	126.3	115.4
Loss on extinguishment of convertible senior notes [1]	—	—	—	70.0
Non-cash interest related to convertible senior notes	0.1	0.2	0.7	1.2
Non-cash amortization related to acquired intangible assets	0.8	0.5	3.5	0.5
Acquisition and integration costs - SG&A [2]	—	1.7	3.9	1.7
Changes in fair value of equity security investments [3]	(29.0)	(7.2)	(28.4)	(30.8)
Changes in foreign currency exchange rates	—	(1.5)	—	1.9
Income tax effect related to reconciling items [4]	—	(1.5)	(33.7)	(28.9)
Non-GAAP net income	$ 157.7	$ 124.7	$ 390.0	$ 343.2

Diluted earnings per share:				
GAAP	$ 1.44	$ 0.88	$ 2.47	$ 1.56
Non-GAAP	$ 1.54	$ 1.24	$ 3.86	$ 3.47

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 transaction and integration costs for contract terminations related to the Diurnal Group plc acquisition.
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.

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)	**2023**	**2022**	**2023**	**2022**
GAAP cost of revenues	$ 8.5	$ 7.7	$ 39.7	$ 23.2
Adjustments:				
Non-cash amortization related to acquired intangible assets	0.8	0.5	3.5	0.5
Non-GAAP cost of revenues	$ 7.7	$ 7.2	$ 36.2	$ 22.7

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2023**	**2022**	**2023**	**2022**
GAAP R&D	$ 137.5	$ 118.0	$ 565.0	$ 463.8
Adjustments:				
Stock-based compensation expense	13.2	14.1	68.0	57.7
Non-GAAP R&D	$ 124.3	$ 103.9	$ 497.0	$ 406.1

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2023**	**2022**	**2023**	**2022**
GAAP SG&A	$ 218.9	$ 182.9	$ 887.6	$ 752.7
Adjustments:				
Stock-based compensation expense	24.9	29.4	126.3	115.4
Acquisition and integration costs	—	1.7	3.9	1.7
Non-GAAP SG&A	$ 194.0	$ 151.8	$ 757.4	$ 635.6

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2023**	**2022**	**2023**	**2022**
GAAP other income (expense), net	$ 47.9	$ 14.5	$ 81.2	$ (35.1)
Adjustments:				
Loss on extinguishment of convertible senior notes	—	—	—	70.0
Non-cash interest related to convertible senior notes	0.1	0.2	0.7	1.2
Changes in fair value of equity security investments	(29.0)	(7.2)	(28.4)	(30.8)
Changes in foreign currency exchange rates	—	(1.5)	—	1.9

Non-GAAP other income, net	$ 19.0	$ 6.0	$ 53.5	$ 7.2

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SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc.: Tony Jewell (Media), 858-617-7578, media@neurocrine.com; Todd Tushla (Investors), 858-617-7143, ir@neurocrine.com