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

October 31, 2023

INGREZZA® (valbenazine) Third Quarter Net Product Sales of $486 Million Representing 29% Year-Over-Year Growth

INGREZZA® (valbenazine) 2023 Net Product Sales Guidance Raised to $1.82 - $1.84 Billion

Crinecerfont Adult and Pediatric CAHtalyst™ Studies Met Primary Endpoint and Key Secondary Endpoints for the Treatment of Congenital Adrenal Hyperplasia

Analyst Day on December 5th Focused on R&D Portfolio and Strategy

SAN DIEGO, Oct. 31, 2023 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the third quarter ended September 30, 2023, raised 2023 net sales guidance for INGREZZA, and announced an Analyst Day to be held in New York City on December 5th.

"With INGREZZA sales continuing to grow, an expanded indication to treat chorea associated with Huntington's disease, and positive Phase 3 results in congenital adrenal hyperplasia, Neurocrine remains well positioned to build a leading neuroscience-focused company," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We look forward to sharing more insight into our R&D portfolio and strategy at our December Analyst Day."

	Three Months Ended September 30,		Nine Months Ended September 30,	
(unaudited, in millions, except per share data)	**2023**	**2022**	**2023**	**2022**
Revenues:				
Net Product Sales	$ 491.8	$ 379.3	$ 1,353.4	$ 1,036.3
Collaboration Revenue	7.0	8.6	18.5	40.4
Total Revenues	$ 498.8	$ 387.9	$ 1,371.9	$ 1,076.7
GAAP Research and Development (R&D)	$ 142.2	$ 107.7	$ 427.5	$ 345.8
Non-GAAP R&D	$ 125.0	$ 92.8	$ 372.7	$ 302.2
GAAP Selling, General and Administrative (SG&A)	$ 204.2	$ 186.3	$ 668.7	$ 569.8
Non-GAAP SG&A	$ 169.7	$ 158.1	$ 563.4	$ 483.8
GAAP Net Income	$ 83.1	$ 68.5	$ 102.0	$ 65.5
GAAP Earnings Per Share – Diluted	$ 0.82	$ 0.69	$ 1.01	$ 0.67
Non-GAAP Net Income	$ 156.1	$ 106.7	$ 232.3	$ 218.5
Non-GAAP Earnings Per Share – Diluted	$ 1.54	$ 1.08	$ 2.31	$ 2.22

(unaudited, in millions)	September 30, 2023	December 31, 2022
Total Cash, Cash Equivalents and Marketable Securities	$ 1,549.8	$ 1,288.7

Third Quarter INGREZZA Net Product Sales Highlights:

- INGREZZA third quarter 2023 net product sales were $486 million and grew 29% vs. the third quarter 2022 driven by prescription demand
- Continued high level of new patient scripts generated in the third quarter of 2023

Third Quarter Financial Highlights:

- Third quarter 2023 GAAP net income and earnings per share of $83 million and $0.82, respectively, compared with $69 million and $0.69, respectively, for third quarter 2022
- Third quarter 2023 non-GAAP net income and earnings per share of $156 million and $1.54, respectively, compared with $107 million and $1.08, respectively, for third quarter 2022
- Differences in third quarter 2023 GAAP and non-GAAP operating expenses compared with third quarter 2022 driven by:
    - Increased R&D expense in support of an expanded and advancing clinical portfolio including preclinical investments in VMAT2, crinecerfont, and our muscarinic compounds
    - 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
- At September 30, 2023, the Company had cash, cash equivalents and marketable securities of approximately $1.5 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 August 2023, the FDA approved INGREZZA for the treatment of adults with chorea associated with Huntington's disease.
- In September 2023, the Company announced the FDA accepted its New Drug Application (NDA) for INGREZZA oral granules, a new sprinkle formulation of INGREZZA capsules for oral administration. The agency set a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2024.
- In September 2023, the Company announced positive top-line data from the Phase 3 CAHtalyst™ clinical study of crinecerfont in adults with classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency (21-OHD). The study met its primary as well as important key secondary endpoints.
- In October 2023, the Company announced positive top-line data from the Phase 3 CAHtalyst clinical study of crinecerfont in pediatrics with CAH due to 21-hydroxylase deficiency (21-OHD). The study met both its primary and key secondary endpoint.

Updated 2023 INGREZZA Sales Guidance and Operating Expense Guidance:

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales [1]	$ 1,820	$ 1,840
GAAP R&D Expense [2]	$ 560	$ 570
Non-GAAP R&D Expense [3]	$ 490	$ 500
GAAP and Non-GAAP IPR&D [4]	$ 144	$ 144
GAAP SG&A Expense [5]	$ 870	$ 890
Non-GAAP SG&A Expense [3]	$ 740	$ 760

1. INGREZZA sales guidance for fiscal 2023 reflects expected sales of INGREZZA.
2. GAAP R&D guidance includes amounts for milestones that are probable of achievement or have been achieved.
3. Non-GAAP guidance adjusted primarily to exclude estimated non-cash stock-based compensation expense of $70 million in R&D and $125 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.
5. SG&A guidance range reflects increased spend following INGREZZA expanded indication to treat chorea associated with Huntington's disease and positive Phase 3 results in CAH.

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.

Neurocrine Biosciences' Analyst Day and Webcast on Tuesday, December 5, 2023

Neurocrine Biosciences will hold an Analyst Day in New York City on Tuesday, December 5, 2023. A live video webcast will begin at 1:00 p.m. Eastern Time and can 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, 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 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 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, 2023. 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 September 30,	Nine Months Ended September 30,

(in millions, except per share data)	2023	2022	2023	2022
Revenues:				
Net product sales	$ 491.8	$ 379.3	$ 1,353.4	$ 1,036.3
Collaboration revenue	7.0	8.6	18.5	40.4
Total revenues	498.8	387.9	1,371.9	1,076.7
Operating expenses:				
Cost of revenues	11.2	6.1	31.2	15.5
Research and development	142.2	107.7	427.5	345.8
Acquired in-process research and development	—	—	143.9	—
Selling, general and administrative	204.2	186.3	668.7	569.8
Total operating expenses	357.6	300.1	1,271.3	931.1
Operating income	141.2	87.8	100.6	145.6
Other income (expense):				
Interest expense	(1.1)	(1.2)	(3.5)	(6.0)
Unrealized (loss) gain on equity security investments	(40.1)	11.1	(0.6)	23.6
Loss on extinguishment of convertible senior notes	—	—	—	(70.0)
Investment income and other, net	15.6	0.2	37.4	2.8
Total other (expense) income, net	(25.6)	10.1	33.3	(49.6)
Income before provision for income taxes	115.6	97.9	133.9	96.0
Provision for income taxes	32.5	29.4	31.9	30.5
Net income	$ 83.1	$ 68.5	$ 102.0	$ 65.5
Earnings per share, basic	$ 0.85	$ 0.72	$ 1.05	$ 0.69
Earnings per share, diluted	$ 0.82	$ 0.69	$ 1.01	$ 0.67
Weighted average common shares outstanding, basic	97.9	95.8	97.5	95.6
Weighted average common shares outstanding, diluted	101.1	99.0	100.6	98.3

TABLE 2

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

(in millions)	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 1,095.1	$ 989.3
Other current assets	554.8	464.2
Total current assets	1,649.9	1,453.5
Deferred tax assets	383.2	305.9
Debt securities available-for-sale	454.7	299.4
Right-of-use assets	80.8	87.0
Equity security investments	132.8	102.1
Property and equipment, net	68.8	58.6
Intangible assets, net	34.9	37.2
Other assets	43.1	25.0
Total assets	$ 2,848.2	$ 2,368.7
Convertible senior notes	$ 169.9	$ 169.4
Other current liabilities	521.7	368.3
Total current liabilities	691.6	537.7
Operating lease liabilities	85.9	93.5
Other long-term liabilities	68.6	29.7
Stockholders' equity	2,002.1	1,707.8

Total liabilities and stockholders' equity	$ 2,848.2	$ 2,368.7

TABLE 3

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions, except per share data)	**2023**	**2022**	**2023**	**2022**
GAAP net income	$ 83.1	$ 68.5	$ 102.0	$ 65.5
Adjustments:				
Stock-based compensation expense - R&D	17.2	14.9	54.8	43.6
Stock-based compensation expense - SG&A	30.6	28.2	101.4	86.0
Loss on extinguishment of convertible senior notes [1]	—	—	—	70.0
Non-cash interest related to convertible senior notes	0.2	0.2	0.6	1.0
Non-cash amortization related to acquired intangible assets	0.9	—	2.7	—
Acquisition and integration costs - SG&A [2]	3.9	—	3.9	—
Changes in fair value of equity security investments [3]	40.1	(11.1)	0.6	(23.6)
Changes in foreign currency exchange rates	—	3.4	—	3.4
Income tax effect related to reconciling items [4]	(19.9)	2.6	(33.7)	(27.4)
Non-GAAP net income	$ 156.1	$ 106.7	$ 232.3	$ 218.5
Diluted earnings per share:				
GAAP	$ 0.82	$ 0.69	$ 1.01	$ 0.67
Non-GAAP	$ 1.54	$ 1.08	$ 2.31	$ 2.22

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 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 September 30,		Nine Months Ended September 30,	
(in millions)	**2023**	**2022**	**2023**	**2022**
GAAP cost of revenues	$ 11.2	$ 6.1	$ 31.2	$ 15.5
Adjustments:				
Non-cash amortization related to acquired intangible assets	0.9	—	2.7	—
Non-GAAP cost of revenues	$ 10.3	$ 6.1	$ 28.5	$ 15.5

	Three Months Ended September 30,	Nine Months Ended September 30,

(in millions)	2023	2022	2023	2022
GAAP R&D	$ 142.2	$ 107.7	$ 427.5	$ 345.8
Adjustments:				
Stock-based compensation expense	17.2	14.9	54.8	43.6
Non-GAAP R&D	$ 125.0	$ 92.8	$ 372.7	$ 302.2

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2023	2022	2023	2022
GAAP SG&A	$ 204.2	$ 186.3	$ 668.7	$ 569.8
Adjustments:				
Stock-based compensation expense	30.6	28.2	101.4	86.0
Acquisition and integration costs	3.9	—	3.9	—
Non-GAAP SG&A	$ 169.7	$ 158.1	$ 563.4	$ 483.8

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2023	2022	2023	2022
GAAP other (expense) income, net	$ (25.6)	$ 10.1	$ 33.3	$ (49.6)
Adjustments:				
Loss on extinguishment of convertible senior notes	—	—	—	70.0
Non-cash interest related to convertible senior notes	0.2	0.2	0.6	1.0
Changes in fair value of equity security investments	40.1	(11.1)	0.6	(23.6)
Changes in foreign currency exchange rates	—	3.4	—	3.4
Non-GAAP other income, net	$ 14.7	$ 2.6	$ 34.5	$ 1.2

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SOURCE Neurocrine Biosciences, Inc.

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