Neurocrine Biosciences Reports Fourth Quarter and Fiscal 2024 Financial Results and Provides Financial Expectations for 2025

February 6, 2025

INGREZZA® (valbenazine) Fourth Quarter and Full Year 2024 Net Product Sales of $615 Million and $2.3 Billion, Representing Year-Over-Year* Growth of 23% *and* 26% *Respectively

INGREZZA® (valbenazine) Full Year 2025 Net Product Sales Guidance of $2.5 - $2.6 Billion

CRENESSITY™ (crinecerfont), a First-in-Class Treatment for Children and Adults with Classic Congenital Adrenal Hyperplasia, Approved and Launched in the United States

Phase 3 Programs for Osavampator in Major Depressive Disorder and NBI-'568 in Schizophrenia Initiating in the First Half of 2025

SAN DIEGO, Feb. 6, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the fourth quarter and full year ended December 31, 2024 and provided financial guidance for 2025.

"I'm proud of the tremendous progress we made last year with the continued growth of INGREZZA for patients living with tardive dyskinesia or Huntington disease chorea. With the approval and launch of CRENESSITY, we look forward to delivering the first new treatment for the congenital adrenal hyperplasia community in over 70 years, transforming the standard of care for patients," said Kyle W. Gano, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "With a rapidly advancing and growing pipeline and a strong financial profile, we are well positioned to build a leading neuroscience company."

Financial Highlights

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(unaudited, in millions, except per share data)	2024	2023	2024	2023
Revenues:				
Net Product Sales	$ 621.2	$ 507.2	$ 2,330.6	$ 1,860.6
Collaboration Revenue	6.5	8.0	24.7	26.5
Total Revenues	$ 627.7	$ 515.2	$ 2,355.3	$ 1,887.1
GAAP Research and Development (R&D)	$ 185.6	$ 137.5	$ 731.1	$ 565.0
Non-GAAP R&D	$ 164.4	$ 124.3	$ 662.3	$ 497.0
GAAP Selling, General, and Administrative (SG&A)	$ 287.8	$ 218.9	$ 1,007.2	$ 887.6
Non-GAAP SG&A	$ 241.6	$ 194.0	$ 862.5	$ 757.4
GAAP Net Income	$ 103.1	$ 147.7	$ 341.3	$ 249.7
GAAP Earnings Per Share – Diluted	$ 1.00	$ 1.44	$ 3.29	$ 2.47
Non-GAAP Net Income	$ 173.4	$ 157.7	$ 656.3	$ 390.0
Non-GAAP Earnings Per Share – Diluted	$ 1.69	$ 1.54	$ 6.33	$ 3.86

(unaudited, in millions)	December 31, 2024	December 31, 2023
Total Cash, Cash Equivalents, and Marketable Securities	$ 1,815.6	$ 1,719.1

Net Product Sales Highlights

- INGREZZA fourth quarter and fiscal 2024 net product sales were $615 million and $2.3 billion, respectively
- INGREZZA fourth quarter net product sales grew 23% compared to fourth quarter 2023, driven by strong underlying patient demand and improvement in gross-to-net dynamics
- CRENESSITY fourth quarter and fiscal 2024 net product sales were $2 million reflecting initial pharmacy orders following approval by the U.S. Food and Drug Administration (FDA) in December 2024

Other Key Financial Highlights

- Differences in fourth quarter 2024 GAAP and Non-GAAP operating expenses compared with fourth quarter 2023 were driven by:
    - Increased R&D expense in support of an expanded and advancing portfolio including investments in osavampator in major depressive disorder, our muscarinic franchise and preclinical research and discovery activities.
    - Increased SG&A expense includes incremental investment in CRENESSITY-related headcount, CRENESSITY-related pre-launch activities, and continued investment in INGREZZA, including the recent expansion of our psychiatry and long-term care sales teams in September 2024.
    - Increased stock-based compensation expense (GAAP) of $28 million primarily related to performance-based awards achievement associated with CRENESSITY FDA approval and a charge associated with the retirement of our CEO in October 2024.
- Fourth quarter 2024 GAAP net income and earnings per share were $103 million and $1.00, respectively, compared with $148 million and $1.44, respectively, for fourth quarter 2023
- Fourth quarter 2024 Non-GAAP net income and earnings per share were $173 million and $1.69, respectively, compared with $158 million and $1.54, respectively, for fourth quarter 2023
- Differences in fourth quarter 2024 GAAP and Non-GAAP net income compared with fourth quarter 2023 driven by:
    - Higher INGREZZA net sales
    - Increased operating expenses to support expanding and advancing R&D portfolio, incremental investments for CRENESSITY pre-launch activities and INGREZZA recent sales force expansion
    - Fourth quarter 2024 includes $66 million of stock-based compensation expense compared with $38 million for fourth quarter 2023 (Non-GAAP adjustment)
    - Fourth quarter 2024 includes a $2 million loss from changes in fair values of equity investments compared with a $29 million gain for fourth quarter 2023 (Non-GAAP adjustment)
- As of December 31, 2024, repurchased and retired approximately 2.0 million shares of the Company's common stock valued at approximately $240.5 million pursuant to a previously announced $300 million accelerated share repurchase (ASR) program. The $300 million program was completed in early February 2025 repurchasing and retiring approximately 2.3 million shares.
- At December 31, 2024, the Company had cash, cash equivalents and marketable securities totaling approximately $1.8 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

- CRENESSITY was approved in December 2024 by the FDA as an adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients four years of age and older with classic congenital adrenal hyperplasia (CAH).
- Announced the initiation of the Phase 3 program for osavampator (formerly NBI-1065845 / TAK-653), a potential first-in-class AMPA positive allosteric modulator in development for patients with inadequate response to treatment of major depressive disorder (MDD).
- Announced amendment to strategic collaboration with Takeda to develop and commercialize osavampator. Under the amended agreement, Neurocrine will obtain exclusive rights for all indications to develop and commercialize osavampator in all territories worldwide except Japan, where Takeda will acquire exclusive rights. Under the terms of the updated agreement, each company is responsible for development costs in their respective region, and both companies are eligible to receive royalty payments.
- Received Centers for Medicare and Medicaid Services (CMS) notification in January that INGREZZA qualifies for the small biotech exemption under the Medicare Drug Price Negotiation Program.
- Announced the initiation of its Phase 1 clinical study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of investigational compound NBI-921355 in healthy adult participants. NBI-921355 is an investigational, selective inhibitor of voltage-gated sodium channels Nav1.2 and Nav1.6 and in development for the potential treatment of certain types of epilepsy.
- Presented subgroup analyses and data from the KINECT®-HD study showing the impact of INGREZZA capsules on emotional health and psychiatric stability in patients with chorea associated with Huntington's disease. The subgroup analysis showed consistent efficacy in reducing chorea compared to placebo across all identified subgroups, categorized

by demographics and baseline assessment scores. A separate data analysis showed improvements in some aspects of emotional health with no worsening of psychiatric symptoms.
- Presented data from more than 300 patients diagnosed with tardive dyskinesia and treated with INGREZZA capsules. These data showed significant improvements in functional, social, emotional and health-related quality of life measures in Phase 3 and 4 studies and improvements in functional, social, independence, emotional and physical aspects of patients' lives and antipsychotic adherence in real-world practice.

Full Year 2025 Financial Guidance

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales [1]	$ 2,500	$ 2,600
GAAP R&D Expense [2]	$ 960	$ 1,010
Non-GAAP R&D Expense [2, 3]	$ 890	$ 940
GAAP SG&A Expense [4]	$ 1,110	$ 1,130
Non-GAAP SG&A Expense [3, 4]	$ 955	$ 975

1. INGREZZA sales guidance reflects expected net product sales of INGREZZA in tardive dyskinesia and chorea associated with Huntington's disease.
2. R&D guidance reflects the continued advancement of our pre-clinical and clinical portfolio including the initiation of our Phase 3 programs for osavampator in MDD and NBI-568 in schizophrenia. R&D guidance includes $60 million of expense for development milestones primarily in connection with our collaborations with Takeda and Nxera achieved or deemed probable to achieve. 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 to exclude estimated non-cash stock-based compensation expense of $70 million in R&D and $130 million in SG&A and vacated legacy campus facility costs.
4. SG&A guidance range reflects expense for ongoing commercial initiatives supporting INGREZZA growth and the launch of CRENESSITY.

Conference Call and Webcast Today at 4:30 PM Eastern Time

Neurocrine Biosciences will hold a live conference call and webcast today at 4:30 p.m. Eastern Time (1:30 p.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 and accompanying slides can also be accessed at approximately 4:30 p.m. Eastern Time 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. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neuropsychiatric, neurological, and neuroendocrine disorders. The company's diverse portfolio includes U.S. FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, classic congenital adrenal hyperplasia, 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, charges associated with convertible senior notes, vacated legacy campus facility costs, net of sublease income, non-cash amortization expense related to acquired intangible assets, acquisition and integration costs, changes in fair value of equity 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; successfully launching CRENESSITY; 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. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements, include but are not limited to the following: risks and uncertainties associated with Neurocrine Biosciences' business and finances in general; risks and uncertainties associated with the commercialization of INGREZZA and CRENESSITY; 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 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 Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024. 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 INCOME
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions, except per share data)	**2024**	**2023**	**2024**	**2023**
Revenues:				
Net product sales	$ 621.2	$ 507.2	$ 2,330.6	$ 1,860.6
Collaboration revenue	6.5	8.0	24.7	26.5
Total revenues	627.7	515.2	2,355.3	1,887.1
Operating expenses:				
Cost of revenues	9.3	8.5	34.0	39.7
Research and development	185.6	137.5	731.1	565.0
Acquired in-process research and development	3.0	—	12.5	143.9
Selling, general, and administrative	287.8	218.9	1,007.2	887.6
Total operating expenses	485.7	364.9	1,784.8	1,636.2
Operating income	142.0	150.3	570.5	250.9
Other income (expense):				
Unrealized (loss) gain on equity investments	(1.9)	29.0	(37.1)	28.4
Charges associated with convertible senior notes	—	—	(138.4)	—
Investment income and other, net	22.5	18.9	91.0	52.8
Total other income (expense), net	20.6	47.9	(84.5)	81.2
Income before provision for income taxes	162.6	198.2	486.0	332.1
Provision for income taxes	59.5	50.5	144.7	82.4
Net income	$ 103.1	$ 147.7	$ 341.3	$ 249.7
Earnings per share, basic	$ 1.03	$ 1.50	$ 3.40	$ 2.56

Earnings per share, diluted	$ 1.00	$ 1.44	$ 3.29	$ 2.47
Weighted average common shares outstanding, basic	100.0	98.4	100.4	97.7
Weighted average common shares outstanding, diluted	102.9	102.3	103.7	101.0

TABLE 2

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

(in millions)	December 31, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 1,076.1	$ 1,031.6
Other current assets	648.6	575.4
Total current assets	1,724.7	1,607.0
Deferred tax assets	485.7	362.6
Marketable securities	739.5	687.5
Right-of-use assets	509.4	276.5
Equity investments	124.8	161.9
Property and equipment, net	82.6	70.8
Intangible assets, net	36.5	35.5
Other noncurrent assets	15.5	49.6
Total assets	$ 3,718.7	$ 3,251.4
Convertible senior notes	$ —	$ 170.1
Other current liabilities	507.7	484.7
Total current liabilities	507.7	654.8
Noncurrent operating lease liabilities	455.1	258.3
Other noncurrent liabilities	166.2	106.3
Stockholders' equity	2,589.7	2,232.0
Total liabilities and stockholders' equity	$ 3,718.7	$ 3,251.4

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)	2024	2023	2024	2023
GAAP net income [1]	$ 103.1	$ 147.7	$ 341.3	$ 249.7
Adjustments:				
Stock-based compensation expense - R&D	21.2	13.2	68.8	68.0
Stock-based compensation expense - SG&A	45.2	24.9	126.7	126.3
Charges associated with convertible senior notes [2]	—	—	138.4	—
Vacated legacy campus facility costs, net of sublease income [3]	1.0	—	18.0	—
Non-cash amortization related to acquired intangible assets	0.9	0.8	3.6	3.5
Changes in fair values of equity investments [4]	1.9	(29.0)	37.1	(28.4)
Other	—	0.1	0.3	4.6
Income tax effect related to reconciling items [5]	0.1	—	(77.9)	(33.7)
Non-GAAP net income [1]	$ 173.4	$ 157.7	$ 656.3	$ 390.0

Diluted earnings per share:

GAAP	$ 1.00	$ 1.44	$ 3.29	$ 2.47
Non-GAAP	$ 1.69	$ 1.54	$ 6.33	$ 3.86

1. Twelve months ended December 31, 2024 reflect $71.7 million of expense for development milestones achieved under collaborations and $12.5 million of IPR&D expense for payments of upfront fees. Twelve months ended December 31, 2023 reflect $143.9 million of IPR&D expense related to expansion of strategic partnership with Voyager Therapeutics, Inc.
2. Reflects charges associated with the settlement of convertible senior notes conversions.
3. Reflects impairment charges and other costs associated with our vacated legacy campus facilities, net of sublease income, as we transition to occupy our new campus facility.
4. Reflects periodic fluctuations in the fair values of equity investments.
5. 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 charges associated with convertible senior notes and 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)	**2024**	**2023**	**2024**	**2023**
GAAP cost of revenues	$ 9.3	$ 8.5	$ 34.0	$ 39.7
Adjustments:				
Non-cash amortization related to acquired intangible assets	0.9	0.8	3.6	3.5
Non-GAAP cost of revenues	$ 8.4	$ 7.7	$ 30.4	$ 36.2

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2024**	**2023**	**2024**	**2023**
GAAP R&D	$ 185.6	$ 137.5	$ 731.1	$ 565.0
Adjustments:				
Stock-based compensation expense	21.2	13.2	68.8	68.0
Non-GAAP R&D	$ 164.4	$ 124.3	$ 662.3	$ 497.0

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2024**	**2023**	**2024**	**2023**
GAAP SG&A	$ 287.8	$ 218.9	$ 1,007.2	$ 887.6
Adjustments:				
Stock-based compensation expense	45.2	24.9	126.7	126.3
Vacated legacy campus facility costs, net of sublease income	1.0	—	18.0	—
Other	—	—	—	3.9
Non-GAAP SG&A	$ 241.6	$ 194.0	$ 862.5	$ 757.4

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2024**	**2023**	**2024**	**2023**
GAAP other income (expense), net	$ 20.6	$ 47.9	$ (84.5)	$ 81.2
Adjustments:				
Charges associated with convertible senior notes	—	—	138.4	—
Changes in fair values of equity investments	1.9	(29.0)	37.1	(28.4)
Other	—	0.1	0.3	0.7
Non-GAAP other income, net	$ 22.5	$ 19.0	$ 91.3	$ 53.5

View original content to download multimedia:https://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-fourth-quarter-and-fiscal-2024-financial-results-and-provides-financial-expectations-for-2025-302370642.html

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