Neurocrine Biosciences Reports Third Quarter 2024 Financial Results and Raises 2024 INGREZZA Sales Guidance

October 30, 2024

INGREZZA® (valbenazine) Third Quarter Net Product Sales of $613 Million Representing 26% Year-Over-Year Growth

INGREZZA® (valbenazine) 2024 Net Product Sales Guidance Raised to $2.30 - $2.32 Billion

Board Authorizes $300 Million Share Repurchase Plan

SAN DIEGO, Oct. 30, 2024 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the third quarter ended September 30, 2024 and provided an update on its 2024 financial guidance.

"With continued INGREZZA growth across the tardive dyskinesia and Huntington's disease chorea indications, FDA Priority Review for crinecerfont in congenital adrenal hyperplasia, a deep neuroscience focused pipeline and a strong balance sheet, we are confident in our ability to help more patients than ever before," said Kyle W. Gano, Ph.D., Chief Executive Officer of Neurocrine Biosciences.

William Rastetter, Chairman of the Board of Directors of Neurocrine Biosciences, said, "The share repurchase authorization reflects the Board's confidence in Neurocrine's significant value creation potential. Importantly, the new share repurchase authorization preserves our flexibility to drive sustained growth through investments in INGREZZA and the anticipated launch of crinecerfont, while also advancing our diverse pipeline and maintaining our strong balance sheet."

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
(unaudited, in millions, except per share data)	**2024**	**2023**	**2024**	**2023**
Revenues:				
Net Product Sales	$ 616.6	$ 491.8	$ 1,709.4	$ 1,353.4
Collaboration Revenue	5.5	7.0	18.2	18.5
Total Revenues	$ 622.1	$ 498.8	$ 1,727.6	$ 1,371.9
GAAP Research and Development (R&D)	$ 195.0	$ 142.2	$ 545.5	$ 427.5
Non-GAAP R&D	$ 180.2	$ 125.0	$ 497.9	$ 372.7
GAAP Selling, General, and Administrative (SG&A)	$ 234.3	$ 204.2	$ 719.4	$ 668.7
Non-GAAP SG&A	$ 204.6	$ 169.7	$ 620.9	$ 563.4
GAAP Net Income	$ 129.8	$ 83.1	$ 238.2	$ 102.0
GAAP Earnings Per Share – Diluted	$ 1.24	$ 0.82	$ 2.29	$ 1.01
Non-GAAP Net Income	$ 189.2	$ 156.1	$ 482.9	$ 232.3
Non-GAAP Earnings Per Share – Diluted	$ 1.81	$ 1.54	$ 4.64	$ 2.31

(unaudited, in millions)	**September 30, 2024**	**December 31, 2023**

Total Cash, Cash Equivalents, and Marketable Securities	$ 1,871.9	$ 1,719.1

INGREZZA Net Product Sales Highlights

- INGREZZA third quarter 2024 net product sales were $613 million and grew 26% compared to the third quarter 2023
- Year-over-year growth driven by strong underlying patient demand and improvement in gross-to-net dynamics

Other Key Financial Highlights

- Differences in third quarter 2024 GAAP and Non-GAAP operating expenses compared with third quarter 2023 were driven by:
  - Increased R&D expense in support of an expanded and advancing portfolio including investments in muscarinic compounds, gene therapy programs, and second generation VMAT2 inhibitors. Third quarter 2024 R&D expense includes $39 million for development milestones achieved under collaborations with Nxera Pharma UK Limited (Nxera, formerly known as Sosei Heptares) and Voyager Therapeutics, Inc. (Voyager).
  - Increased SG&A expense includes incremental investment in crinecerfont-related headcount, crinecerfont-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.
- Third quarter 2024 GAAP net income and earnings per share were $130 million and $1.24, respectively, compared with $83 million and $0.82, respectively, for third quarter 2023
- Third quarter 2024 Non-GAAP net income and earnings per share were $189 million and $1.81, respectively, compared with $156 million and $1.54, respectively, for third quarter 2023
- Differences in third quarter 2024 GAAP and Non-GAAP net income compared with third quarter 2023 driven by:
  - Higher INGREZZA net sales and improved operating margin
  - Third quarter 2024 includes $17 million loss from changes in fair values of equity investments compared with $40 million loss for third quarter 2023 (Non-GAAP adjustment)
  - Third quarter 2024 includes $39 million of expense for development milestones achieved under collaborations with Nxera and Voyager
- At September 30, 2024, the Company had cash, cash equivalents and marketable securities totaling approximately $1.9 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

- Kyle W. Gano, Ph.D. appointed Chief Executive Officer effective October 11, 2024.
- Announced the Company's Board of Directors has authorized a $300 million share repurchase plan. The Company subsequently intends to enter into a $300 million accelerated share repurchase transaction in the coming days, subject to market conditions, which will constitute the entirety of the authorized share repurchase plan.
- Announced positive topline data for the Phase 2 study of NBI-1117568, a first-in-class, orally active, highly selective investigational M4 agonist, in development as a potential treatment for schizophrenia. The successful completion of the Phase 2 study triggered a $35 million milestone payment to Nxera in the third quarter of 2024. We expect to advance NBI-1117568 into Phase 3 development in the first half of 2025, which would trigger an additional $15 million milestone payment to Nxera upon initiation of the Phase 3 study.
- Presented KINECT®-HD2 interim data at the 2024 MDS International Congress of Parkinson's Disease and Movement Disorders demonstrating robust and sustained improvements in chorea associated with Huntington's Disease through week 104 irrespective of antipsychotic use.
- Announced the ERUDITE™ Phase 2 study of luvadaxistat (NBI-1065844) in cognitive impairment associated with schizophrenia (CIAS) did not meet its primary endpoint. In addition, we provided Takeda Pharmaceutical Company Limited with written notice of termination of the license agreement to develop and commercialize luvadaxistat and NBI-1065846. The termination is anticipated to be effective in April 2025.
- Provided Idorsia Pharmaceuticals Ltd. with written notice of termination of the license agreement to develop and commercialize NBI-827104 in epileptic encephalopathy with continuous spike and wave during sleep. The termination is anticipated to be effective in January 2025.

Raised 2024 Net Sales Guidance and Updated Expense Guidance

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales [1]	$ 2,300	$ 2,320
GAAP R&D Expense [2]	$ 700	$ 720
Non-GAAP R&D Expense [3]	$ 635	$ 655
GAAP and Non-GAAP IPR&D [4]	$ 10	$ 10

GAAP SG&A Expense [5]	$	970	$	990
Non-GAAP SG&A Expense [3, 5]	$	825	$	845

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 $71 million of expense for development milestones achieved or deemed probable to achieve under collaborations (Nxera Pharma UK Limited, Takeda Pharmaceutical Company Limited, Voyager Therapeutics, Inc.) of which $39 million was recognized in the third quarter 2024. These milestone expenses are associated with our advancing pre-clinical and clinical pipeline.
3. Non-GAAP guidance adjusted to exclude estimated non-cash stock-based compensation expense of $65 million in R&D and $125 million in SG&A and vacated legacy campus facility costs, including office space impairment charges of approximately $20 million in SG&A. SG&A stock-based compensation includes an approximate $15 million charge to be recognized in the fourth quarter associated with the retirement of our CEO in October 2024.
4. Acquired in-process R&D (IPR&D) is included in guidance once significant collaboration and licensing arrangements have been completed.
5. SG&A guidance range reflects expense for ongoing commercial initiatives supporting INGREZZA growth including the expansion of the psychiatry and long-term care sales teams in September and pre-launch commercial activities for crinecerfont.

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 and accompanying slides can also be accessed at approximately 8:00 a.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, 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, 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 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; the timing of the initiation and/or completion of our clinical, regulatory, and other development activities and those of our collaboration partners; and our intention to enter into an accelerated share repurchase transaction, including the expected dollar amounts and the timing of the transaction. 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 that the crinecerfont

New Drug Applications (NDAs) may not obtain regulatory approval, such approval may be delayed, or may not receive the benefits associated with priority review; 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; constraints, volatility, or disruptions in the capital markets or other factors affecting our ability to enter into or complete an accelerated share repurchase transaction; 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, 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 September 30,		Nine Months Ended September 30,	
(in millions, except per share data)	**2024**	**2023**	**2024**	**2023**
Revenues:				
Net product sales	$ 616.6	$ 491.8	$ 1,709.4	$ 1,353.4
Collaboration revenue	5.5	7.0	18.2	18.5
Total revenues	622.1	498.8	1,727.6	1,371.9
Operating expenses:				
Cost of revenues	8.0	11.2	24.7	31.2
Research and development	195.0	142.2	545.5	427.5
Acquired in-process research and development	1.0	—	9.5	143.9
Selling, general, and administrative	234.3	204.2	719.4	668.7
Total operating expenses	438.3	357.6	1,299.1	1,271.3
Operating income	183.8	141.2	428.5	100.6
Other income (expense):				
Unrealized loss on equity investments	(16.9)	(40.1)	(35.2)	(0.6)
Charges associated with convertible senior notes	—	—	(138.4)	—
Investment income and other, net	23.4	14.5	68.5	33.9
Total other income (expense), net	6.5	(25.6)	(105.1)	33.3
Income before provision for income taxes	190.3	115.6	323.4	133.9
Provision for income taxes	60.5	32.5	85.2	31.9
Net income	$ 129.8	$ 83.1	$ 238.2	$ 102.0
Earnings per share, basic	$ 1.28	$ 0.85	$ 2.37	$ 1.05
Earnings per share, diluted	$ 1.24	$ 0.82	$ 2.29	$ 1.01
Weighted average common shares outstanding, basic	101.1	97.9	100.6	97.5
Weighted average common shares outstanding, diluted	104.3	101.1	104.0	100.6

TABLE 2

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

(in millions)	September 30, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 1,228.0	$ 1,031.6
Other current assets	648.6	575.4
Total current assets	1,876.6	1,607.0
Deferred tax assets	454.4	362.6
Marketable securities	643.9	687.5
Right-of-use assets	257.3	276.5
Equity investments	126.7	161.9
Property and equipment, net	80.0	70.8
Intangible assets, net	34.5	35.5
Other noncurrent assets	61.6	49.6
Total assets	$ 3,535.0	$ 3,251.4
Convertible senior notes	$ —	$ 170.1
Other current liabilities	429.7	484.7
Total current liabilities	429.7	654.8
Noncurrent operating lease liabilities	251.4	258.3
Other noncurrent liabilities	135.0	106.3
Stockholders' equity	2,718.9	2,232.0
Total liabilities and stockholders' equity	$ 3,535.0	$ 3,251.4

TABLE 3

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

(in millions, except per share data)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
GAAP net income [1]	$ 129.8	$ 83.1	$ 238.2	$ 102.0
Adjustments:				
Stock-based compensation expense - R&D	14.8	17.2	47.6	54.8
Stock-based compensation expense - SG&A	26.7	30.6	81.5	101.4
Charges associated with convertible senior notes [2]	—	—	138.4	—
Vacated legacy campus facility costs, net of sublease income [3]	3.0	—	17.0	—
Non-cash amortization related to acquired intangible assets	0.9	0.9	2.7	2.7
Changes in fair values of equity investments [4]	16.9	40.1	35.2	0.6
Other	—	4.1	0.3	4.5
Income tax effect related to reconciling items [5]	(2.9)	(19.9)	(78.0)	(33.7)
Non-GAAP net income [1]	$ 189.2	$ 156.1	$ 482.9	$ 232.3
Diluted earnings per share:				
GAAP	$ 1.24	$ 0.82	$ 2.29	$ 1.01
Non-GAAP	$ 1.81	$ 1.54	$ 4.64	$ 2.31

1. Three and nine months ended September 30, 2024 reflect $38.8 million and $71.4 million, respectively, of expense for development milestones achieved under collaborations. Nine months ended September 30, 2024 reflects IPR&D expense of $9.5 million. Nine months ended September 30, 2023 reflects IPR&D expense of $143.9 million 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 September 30,		Nine Months Ended September 30,	
(in millions)	**2024**	**2023**	**2024**	**2023**
GAAP cost of revenues	$ 8.0	$ 11.2	$ 24.7	$ 31.2
Adjustments:				
Non-cash amortization related to acquired intangible assets	0.9	0.9	2.7	2.7
Non-GAAP cost of revenues	$ 7.1	$ 10.3	$ 22.0	$ 28.5

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2024**	**2023**	**2024**	**2023**
GAAP R&D	$ 195.0	$ 142.2	$ 545.5	$ 427.5
Adjustments:				
Stock-based compensation expense	14.8	17.2	47.6	54.8
Non-GAAP R&D	$ 180.2	$ 125.0	$ 497.9	$ 372.7

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2024**	**2023**	**2024**	**2023**
GAAP SG&A	$ 234.3	$ 204.2	$ 719.4	$ 668.7
Adjustments:				
Stock-based compensation expense	26.7	30.6	81.5	101.4
Vacated legacy campus facility costs, net of sublease income	3.0	—	17.0	—
Other	—	3.9	—	3.9
Non-GAAP SG&A	$ 204.6	$ 169.7	$ 620.9	$ 563.4

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2024**	**2023**	**2024**	**2023**
GAAP other income (expense), net	$ 6.5	$ (25.6)	$ (105.1)	$ 33.3
Adjustments:				
Charges associated with convertible senior notes	—	—	138.4	—
Changes in fair values of equity investments	16.9	40.1	35.2	0.6
Other	—	0.2	0.3	0.6
Non-GAAP other income, net	$ 23.4	$ 14.7	$ 68.8	$ 34.5

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SOURCE Neurocrine Biosciences, Inc.

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