



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

August 1, 2024

INGREZZA® (valbenazine) Second Quarter Net Product Sales of \$580 Million Representing 32% Year-Over-Year Growth

INGREZZA® (valbenazine) 2024 Net Product Sales Guidance Raised to \$2.25 - \$2.3 Billion

Top-Line Phase 2 Data Readouts for NBI-568 and Luvadaxistat Remain On Track in Q3

SAN DIEGO, Aug. 1, 2024 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the second quarter ended June 30, 2024 and provided an update on its 2024 financial guidance.



"At Neurocrine, we are energized by the tremendous opportunity we see to help many more patients, and we are encouraged by our recent progress, including INGREZZA's continued success in treating tardive dyskinesia and Huntington's disease chorea and the FDA's decision to grant Priority Review for crinecerfont to treat congenital adrenal hyperplasia," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We are in the process of building our endocrinology team and expanding the INGREZZA salesforce, positioning our company for continued strong growth in the years ahead."

Kevin Gorman added, "As I look ahead to my planned retirement in October, I have never been more confident in Neurocrine's future. I am incredibly proud of all that we have achieved together and excited to see what this team will continue to accomplish for patients under Kyle Gano's leadership."

Financial Highlights

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
<i>(unaudited, in millions, except per share data)</i>	2024	2023	2024	2023
Revenues:				
Net Product Sales	\$ 583.8	\$ 446.3	\$ 1,092.8	\$ 861.6
Collaboration Revenue	6.4	6.4	12.7	11.5
Total Revenues	\$ 590.2	\$ 452.7	\$ 1,105.5	\$ 873.1
GAAP Research and Development (R&D)	\$ 191.1	\$ 145.8	\$ 350.5	\$ 285.3
Non-GAAP R&D	\$ 175.3	\$ 122.0	\$ 317.7	\$ 247.7
GAAP Selling, General and Administrative (SG&A)	\$ 242.0	\$ 221.8	\$ 485.1	\$ 464.5
Non-GAAP SG&A	\$ 200.7	\$ 177.1	\$ 416.3	\$ 393.7
GAAP Net Income	\$ 65.0	\$ 95.5	\$ 108.4	\$ 18.9
GAAP Earnings Per Share – Diluted	\$ 0.63	\$ 0.95	\$ 1.04	\$ 0.19
Non-GAAP Net Income	\$ 168.9	\$ 125.7	\$ 293.7	\$ 76.2
Non-GAAP Earnings Per Share – Diluted	\$ 1.63	\$ 1.25	\$ 2.83	\$ 0.76
			June 30,	December 31,
<i>(unaudited, in millions)</i>			2024	2023

INGREZZA Net Product Sales Highlights

- INGREZZA second quarter 2024 net product sales were \$580 million and grew 32% compared to the second 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 second quarter 2024 GAAP and Non-GAAP operating expenses compared with second quarter 2023 were driven by:
 - Increased R&D expense in support of an expanded and advancing clinical portfolio including investments in muscarinic compounds, gene therapy programs and second generation VMAT2 inhibitors. R&D expense for the second quarter 2024 includes \$27 million for development milestones achieved under our collaborations with Nxera Pharma UK Limited (Nxera, formerly known as Sosei Heptares), Takeda Pharmaceutical Company Limited (Takeda) 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. GAAP SG&A expense also includes impairment charges of \$14 million associated with leased office space that has been vacated as we continue to occupy our new campus facility
- Second quarter 2024 GAAP net income and earnings per share were \$65 million and \$0.63, respectively, compared with \$96 million and \$0.95, respectively, for second quarter 2023
- Second quarter 2024 Non-GAAP net income and earnings per share were \$169 million and \$1.63, respectively, compared with \$126 million and \$1.25, respectively, for second quarter 2023
- Differences in second quarter 2024 GAAP and Non-GAAP net income compared with second quarter 2023 driven by:
 - Higher INGREZZA net sales and improved operating margin
 - Second quarter 2024 includes \$50 million charge associated with the settlement of convertible senior notes conversions (Non-GAAP adjustment)
 - Second quarter 2024 includes \$20 million loss from changes in fair value of equity security investments compared to \$37 million gain the second quarter 2023 (Non-GAAP adjustment)
 - Second quarter 2024 includes \$27 million of development milestones expense achieved under collaborations
 - Second quarter 2024 includes \$14 million leased office space impairment charge (Non-GAAP adjustment)
- At June 30, 2024, the Company had cash, cash equivalents and marketable securities totaling approximately \$1.7 billion which reflects the \$309 million payment to fully retire our convertible senior notes

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

- Announced Kevin Gorman, Ph.D., will retire as Chief Executive Officer on October 11, 2024. Kyle Gano, Ph.D., currently Neurocrine's Chief Business Development and Strategy Officer, will succeed him in the CEO role. Dr. Gano will also join the Company's Board of Directors at that time, and Dr. Gorman will continue to serve on the Company's Board.
- Announced positive topline data for the Phase 2 SAVITRI™ study. This randomized, double-blind, placebo-controlled dose-finding study assessed the efficacy and safety of NBI-1065845 in adult subjects with major depressive disorder (MDD). NBI-1065845 is an investigational alpha-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid (AMPA) positive allosteric modulator (PAM) in development as a potential treatment for patients with MDD who have not benefited from treatment with at least one antidepressant in their current episode of depression.
- Announced FDA accepted New Drug Applications (NDAs) and granted Priority Review for crinecerfont for adult and pediatric patients with congenital adrenal hyperplasia (CAH). The agency set Prescription Drug User Fee (PDUFA) target actions dates of December 29, 2024 for the capsule formulation and December 30, 2024 for the oral solution formulation.
- At the Endocrine Society Annual Meeting (ENDO 2024), presented new Phase 3 clinical study data from the CAHtalyst™ registrational studies of crinecerfont in pediatric and adult patients with classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency. In parallel, announced that the primary study results from the CAHtalyst™ registrational studies of crinecerfont in pediatric and adult patients with classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency have been published in The New England Journal of Medicine.
- Initiated Phase 2 study of NBI-1070770 in adults with major depressive disorder. NBI-1070770 is a novel, selective and orally active, negative allosteric modulator (NAM) of the NR2B subunit-containing N-methyl-D-aspartate (NMDA NR2B) receptor.
- Initiated Phase 1 study of NBI-1117567 in healthy adult participants. NBI-1117567 is an investigational, oral, M1/M4 (M1 preferring) selective muscarinic agonist for the potential treatment of neurological and neuropsychiatric conditions.
- Initiated Phase 1 study of NBI-1076968 in healthy adult participants. NBI-1076968 is an investigational, oral, M4 subtype-selective muscarinic antagonist for the potential treatment of movement disorders.
- Received notification from the Centers for Medicare and Medicaid Services that INGREZZA qualified for the Specified Small Manufacturer Exception pertaining to the Part D redesign of the Inflation Reduction Act.
- Settled the convertible senior notes due May 15, 2024 in full in cash upon maturity.
- Announced planned expansion of the INGREZZA psychiatry and long-term care sales teams to better serve patients by accelerating the number of people who are diagnosed and treated for tardive dyskinesia and chorea associated with

Huntington's disease.

- Launched new sprinkle formulation of INGREZZA® (valbenazine) capsules for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease.

Raised 2024 Net Sales Guidance and Updated Expense Guidance

<i>(in millions)</i>	Range	
	Low	High
INGREZZA Net Product Sales ¹	\$ 2,250	\$ 2,300
GAAP R&D Expense ²	\$ 665	\$ 695
Non-GAAP R&D Expense ³	\$ 600	\$ 630
GAAP and Non-GAAP IPR&D ⁴	\$ 9	\$ 9
GAAP SG&A Expense ⁵	\$ 955	\$ 975
Non-GAAP SG&A Expense ^{3, 5}	\$ 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 \$33 million of expense for development milestones in connection with our collaborations (Nxera, Voyager and Takeda) achieved or deemed probable to achieve. 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 approximately \$65 million in R&D and \$110 million in SG&A and \$14 million leased office space impairment charge in SG&A.
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 announced planned expansion of the psychiatry and long-term care sales teams and pre-launch commercial activities for crinecerfont.

2024 Pipeline Milestones and Key Activities

Program	Indication	Milestones / Key Activities
NBI-1065845* (AMPA Potentiator)	Inadequate Response in Major Depressive Disorder	Reported Positive Top-Line Phase 2 Data; Conducting End of Phase 2 Meeting with FDA; Initiating Phase 3 Studies in 2025
Crinecerfont (CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Pediatric and Adult)	Priority Review with PDUFA Dates Set for December 29 and 30, 2024
NBI-1117568** (M4 Agonist)	Schizophrenia	Top-Line Phase 2 Data in Q3'24
Luvadaxistat* (DAAO Inhibitor)	Cognitive Impairment Associated with Schizophrenia	Top-Line Phase 2 Data in Q3'24
NBI-1070770* (NMDA NR2B NAM)	Major Depressive Disorder	Phase 2 Study Ongoing; Top-Line Data in 2025
NBI-1065890 (Selective VMAT2 Inhibitor)	CNS Indications	Phase 1 Study Ongoing
NBI-1117569** (M4-Prefering Agonist)	CNS Indications	Phase 1 Study Ongoing
NBI-1117570** (M1/M4 Dual Agonist)	CNS Indications	Phase 1 Study Ongoing
NBI-1117567** (M1 Agonist)	CNS Indications	Phase 1 Study Ongoing
NBI-1076986 (M4 Antagonist)	Movement Disorders	Phase 1 Study Ongoing

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

Neurocrine Biosciences Partners: * Partnered with Takeda Pharmaceutical Company Limited; ** In-Licensed from Nxera Pharma UK Limited (formerly Sosei Heptares)

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 800-445-7795 (US) or 785-424-1699 (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*)

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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, impairment charges associated with leased properties, 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 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; and other risks described in our periodic reports filed with the SEC, including our Quarterly Report on Form 10-Q for the quarter ended June 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.

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(unaudited)

<i>(in millions, except per share data)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Net product sales	\$ 583.8	\$ 446.3	\$ 1,092.8	\$ 861.6
Collaboration revenue	6.4	6.4	12.7	11.5
Total revenues	590.2	452.7	1,105.5	873.1
Operating expenses:				
Cost of revenues	9.2	11.5	16.7	20.0
Research and development	191.1	145.8	350.5	285.3
Acquired in-process research and development	2.5	—	8.5	143.9
Selling, general and administrative	242.0	221.8	485.1	464.5
Total operating expenses	444.8	379.1	860.8	913.7
Operating income (loss)	145.4	73.6	244.7	(40.6)
Other (expense) income:				
Unrealized (loss) gain on equity securities	(19.9)	37.3	(18.3)	39.5
Charges associated with convertible senior notes	(49.7)	—	(138.4)	—
Investment income and other, net	22.8	10.7	45.1	19.4
Total other (expense) income, net	(46.8)	48.0	(111.6)	58.9
Income before provision for income taxes	98.6	121.6	133.1	18.3
Provision for (benefit from) income taxes	33.6	26.1	24.7	(0.6)
Net income	\$ 65.0	\$ 95.5	\$ 108.4	\$ 18.9
Earnings per share, basic	\$ 0.64	\$ 0.98	\$ 1.08	\$ 0.19
Earnings per share, diluted	\$ 0.63	\$ 0.95	\$ 1.04	\$ 0.19
Weighted average common shares outstanding, basic	100.8	97.6	100.3	97.4
Weighted average common shares outstanding, diluted	103.9	100.2	103.8	100.3

TABLE 2

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

<i>(in millions)</i>	June 30,	December 31,
	2024	2023
Cash, cash equivalents and marketable securities	\$ 1,038.9	\$ 1,031.6
Other current assets	630.9	575.4
Total current assets	1,669.8	1,607.0
Deferred tax assets	419.5	362.6
Debt securities available-for-sale	637.8	687.5
Right-of-use assets	262.9	276.5
Equity security investments	143.6	161.9
Property and equipment, net	80.1	70.8
Intangible assets, net	33.5	35.5
Other noncurrent assets	57.8	49.6
Total assets	\$ 3,305.0	\$ 3,251.4
Convertible senior notes	\$ —	\$ 170.1

Other current liabilities	398.5	484.7
Total current liabilities	398.5	654.8
Noncurrent operating lease liabilities	256.2	258.3
Other noncurrent long-term liabilities	141.1	106.3
Stockholders' equity	2,509.2	2,232.0
Total liabilities and stockholders' equity	<u>\$ 3,305.0</u>	<u>\$ 3,251.4</u>

TABLE 3

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

<i>(in millions, except per share data)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
GAAP net income ¹	\$ 65.0	\$ 95.5	\$ 108.4	\$ 18.9
Adjustments:				
Stock-based compensation expense - R&D	15.8	23.8	32.8	37.6
Stock-based compensation expense - SG&A	27.3	44.7	54.8	70.8
Charges associated with convertible senior notes ²	49.7	—	138.4	—
Impairment charges associated with leased properties ³	14.0	—	14.0	—
Non-cash amortization related to acquired intangible assets	0.9	0.9	1.8	1.8
Changes in fair value of equity security investments ⁴	19.9	(37.3)	18.3	(39.5)
Other	0.1	0.2	0.3	0.4
Income tax effect related to reconciling items ⁵	(23.8)	(2.1)	(75.1)	(13.8)
Non-GAAP net income	<u>\$ 168.9</u>	<u>\$ 125.7</u>	<u>\$ 293.7</u>	<u>\$ 76.2</u>

Diluted earnings per share:

GAAP	\$ 0.63	\$ 0.95	\$ 1.04	\$ 0.19
Non-GAAP	\$ 1.63	\$ 1.25	\$ 2.83	\$ 0.76

1. Three and six months ended June 30, 2024 reflect \$26.5 million and \$32.6 million, respectively, of development milestone expense achieved under collaboration agreements. Six months ended June 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 associated with leased office space that has been vacated as the Company continues to occupy its new campus facility.
4. Reflects periodic fluctuations in the fair values of the Company's equity security 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)


<i>(in millions)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
GAAP cost of revenues	\$ 9.2	\$ 11.5	\$ 16.7	\$ 20.0
Adjustments:				

Non-cash amortization related to acquired intangible assets	0.9	0.9	1.8	1.8
Non-GAAP cost of revenues	\$ 8.3	\$ 10.6	\$ 14.9	\$ 18.2

<i>(in millions)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	GAAP R&D	\$ 191.1	\$ 145.8	\$ 350.5
Adjustments:				
Stock-based compensation expense	15.8	23.8	32.8	37.6
Non-GAAP R&D	\$ 175.3	\$ 122.0	\$ 317.7	\$ 247.7

<i>(in millions)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	GAAP SG&A	\$ 242.0	\$ 221.8	\$ 485.1
Adjustments:				
Stock-based compensation expense	27.3	44.7	54.8	70.8
Impairment charges associated with leased properties	14.0	—	14.0	—
Non-GAAP SG&A	\$ 200.7	\$ 177.1	\$ 416.3	\$ 393.7

<i>(in millions)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	GAAP other (expense) income, net	\$ (46.8)	\$ 48.0	\$ (111.6)
Adjustments:				
Charges associated with convertible senior notes	49.7	—	138.4	—
Changes in fair value of equity security investments	19.9	(37.3)	18.3	(39.5)
Other	0.1	0.2	0.3	0.4
Non-GAAP other income, net	\$ 22.9	\$ 10.9	\$ 45.4	\$ 19.8

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