



Neurocrine Biosciences Reports First Quarter 2024 Financial Results

May 1, 2024

INGREZZA® (valbenazine) First Quarter Net Product Sales of \$506 Million Representing 23% Year-Over-Year Growth

INGREZZA® SPRINKLE (valbenazine) Capsules Approved by the U.S. FDA

Crinecerfont New Drug Applications for the Treatment of Congenital Adrenal Hyperplasia Submitted to the U.S. FDA

Positive Phase 2 Top-Line Data for NBI-1065845, a Potential First-In-Class AMPA Positive Allosteric Modulator, in Adults with Major Depressive Disorder

SAN DIEGO, May 1, 2024 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the first quarter ended March 31, 2024 and provided an update on its 2024 financial guidance.



"Significant unmet need still exists for the many patients living with tardive dyskinesia as exemplified with INGREZZA's first quarter year-over-year growth of 23%," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "With the recent New Drug Application submissions for crinecerfont, positive Phase 2 results for a potential first-in-class medication in NBI-'845 for major depressive disorder, and the deepest pipeline in our company's history, Neurocrine Biosciences is well positioned to become a leader in neuroscience."

Financial Highlights

<i>(unaudited, in millions, except per share data)</i>	Three Months Ended March 31,	
	2024	2023
Revenues:		
Net Product Sales	\$ 509.0	\$ 415.3
Collaboration Revenue	6.3	5.1
Total Revenues	\$ 515.3	\$ 420.4
GAAP Research and Development (R&D)	\$ 159.4	\$ 139.5
Non-GAAP R&D	\$ 142.4	\$ 125.7
GAAP Selling, General and Administrative (SG&A)	\$ 243.1	\$ 242.7
Non-GAAP SG&A	\$ 215.6	\$ 216.6
GAAP Net Income (Loss)	\$ 43.4	\$ (76.6)
GAAP Earnings (Loss) Per Share – Diluted	\$ 0.42	\$ (0.79)
Non-GAAP Net Income (Loss)	\$ 124.8	\$ (49.5)
Non-GAAP Earnings (Loss) Per Share – Diluted	\$ 1.20	\$ (0.51)
	March 31, December 31,	
<i>(unaudited, in millions)</i>	2024	2023
Total Cash, Cash Equivalents and Marketable Securities	\$ 1,911.0	\$ 1,719.1

INGREZZA Net Product Sales Highlights

- INGREZZA first quarter 2024 net product sales were \$506 million and grew 23% compared to the first 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 first quarter 2024 GAAP and non-GAAP operating expenses compared with first quarter 2023 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
 - Flat SG&A expense includes continued investment in INGREZZA and incremental investment in crinecerfont-related headcount and pre-launch activities
- First quarter 2024 GAAP net income and earnings per share were \$43 million and \$0.42, respectively, compared with GAAP net loss and loss per share of \$77 million and \$0.79, respectively, for first quarter 2023
- First quarter 2024 non-GAAP net income and earnings per share were \$125 million and \$1.20, respectively, compared with non-GAAP net loss and loss per share of \$50 million and \$0.51, respectively, for first quarter 2023
- Differences in first quarter 2024 GAAP and non-GAAP net income compared with first quarter 2023 driven by:
 - Higher INGREZZA net sales and improved operating margin
 - First quarter 2024 includes \$89 million charge associated with convertible senior notes election to settle outstanding principal and conversion premium in cash (non-GAAP adjustment)
 - First quarter 2023 includes Acquired In-Process R&D (IPR&D) expense of \$144 million associated with expansion of strategic partnership with Voyager Therapeutics, Inc. (Voyager)
- At March 31, 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

- In January, the Company elected to settle the convertible senior notes due May 2024 in cash.
- In April, the Company reported positive Phase 2 data for its completed Phase 2 study of NBI-1065845 in adult subjects with major depressive disorder. The study met its primary and key secondary endpoints, demonstrating that once-daily, oral administration of NBI-1065845 produced a statistically significant change from baseline in Montgomery Åsberg Depression Rating Scale (MADRS) total score at both Day 28 (primary endpoint) and Day 56 (key secondary endpoint).
- In April, the Company submitted two New Drug Applications to the FDA for crinecerfont as a treatment for adult and pediatric patients with classic congenital adrenal hyperplasia.
- In April, the Company received approval from the U.S. Food and Drug Administration for INGREZZA SPRINKLE (valbenazine) capsules, a new oral granules formulation of INGREZZA (valbenazine) capsules.

Reaffirmed 2024 Net Sales Guidance and Updated Expense Guidance

<i>(in millions)</i>	Range	
	Low	High
INGREZZA Net Product Sales ¹	\$ 2,100	\$ 2,200
GAAP R&D Expense ²	\$ 665	\$ 695
Non-GAAP R&D Expense ³	\$ 600	\$ 630
GAAP and Non-GAAP IPR&D ⁴	\$ 6	\$ 6
GAAP SG&A Expense ⁵	\$ 920	\$ 940
Non-GAAP SG&A Expense ^{3, 5}	\$ 810	\$ 830

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 approximately \$34 million expense for development milestones in connection with our collaborations (Nxera, Voyager and Takeda) achieved in first quarter 2024 or achievement is deemed probable in second quarter 2024. These milestone expenses are associated with our advancing pre-clinical and clinical pipeline.
3. Non-GAAP guidance adjusted primarily to exclude estimated non-cash stock-based compensation expense of \$65 million in R&D and \$110 million 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 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
INGREZZA* (Selective VMAT2 Inhibitor)	Sprinkle Formulation for Tardive Dyskinesia / Chorea in Huntington's Disease	Approved by FDA on April 30, 2024
Crinecerfont (CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Pediatric and Adult)	Submitted New Drug Applications to the FDA
NBI-1065845** (AMPA Potentiator)	Inadequate Response in Major Depressive Disorder	Reported Positive Top-Line Phase 2 Data; Engaging with FDA on Path Forward
Efmody (Hydrocortisone Modified Release Hard Capsules)	Adrenal Insufficiency	Reported Positive Top-Line Phase 2 Data
Efmody (Hydrocortisone Modified Release Hard Capsules)	Congenital Adrenal Hyperplasia	Reported Positive Top-Line Phase 2 Data
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	Initiated Phase 2 Study
NBI-1065890 (Selective VMAT2 Inhibitor)	CNS Indications	Initiated Phase 1 Study
NBI-1117569† (M4-Prefering Agonist)	CNS Indications	Initiated Phase 1 Study
NBI-1117570† (M1/M4 Dual Agonist)	CNS Indications	Initiated Phase 1 Study
NBI-1117567† (M1 Agonist)	CNS Indications	Initiating Phase 1 Study
NBI-1076986 (M4 Antagonist)	Movement Disorders	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 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 800-343-4136 (US) or 203-518-9814 (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, loss on extinguishment of convertible senior notes, charges associated with 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 March 31, 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 OPERATIONS
(unaudited)

<i>(in millions, except per share data)</i>	Three Months Ended	
	March 31,	
	2024	2023
Revenues:		
Net product sales	\$ 509.0	\$ 415.3
Collaboration revenue	6.3	5.1
Total revenues	515.3	420.4
Operating expenses:		
Cost of revenues	7.5	8.5
Research and development	159.4	139.5
Acquired in-process research and development	6.0	143.9
Selling, general and administrative	243.1	242.7
Total operating expenses	416.0	534.6
Operating income (loss)	99.3	(114.2)
Other (expense) income:		
Interest expense	(1.1)	(1.1)
Unrealized gain on equity security investments	1.6	2.2

Charges associated with convertible senior notes	(88.7)	—
Investment income and other, net	23.4	9.8
Total other (expense) income, net	(64.8)	10.9
Income (loss) before benefit from income taxes	34.5	(103.3)
Benefit from income taxes	(8.9)	(26.7)
Net income (loss)	\$ 43.4	\$ (76.6)
Earnings (loss) per share, basic	\$ 0.43	\$ (0.79)
Earnings (loss) per share, diluted	\$ 0.42	\$ (0.79)
Weighted average common shares outstanding, basic	99.8	97.1
Weighted average common shares outstanding, diluted	103.6	97.1

TABLE 2

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

<i>(in millions)</i>	March 31, December 31,	
	2024	2023
Cash, cash equivalents and marketable securities	\$ 1,210.6	\$ 1,031.6
Other current assets	588.4	575.4
Total current assets	1,799.0	1,607.0
Deferred tax assets	378.2	362.6
Debt securities available-for-sale	700.4	687.5
Right-of-use assets	270.8	276.5
Equity security investments	163.5	161.9
Property and equipment, net	75.3	70.8
Intangible assets, net	34.3	35.5
Other assets	50.9	49.6
Total assets	\$ 3,472.4	\$ 3,251.4
Convertible senior notes, at carrying value (\$170.4 million face value)	\$ 122.8	\$ 170.1
Convertible senior notes embedded derivative liability	136.2	—
Other current liabilities	453.9	484.7
Total current liabilities	712.9	654.8
Operating lease liabilities	252.9	258.3
Other long-term liabilities	120.5	106.3
Stockholders' equity	2,386.1	2,232.0
Total liabilities and stockholders' equity	\$ 3,472.4	\$ 3,251.4

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	
	March 31,	
	2024	2023
GAAP net income (loss)	\$ 43.4	\$ (76.6)
Adjustments:		
Stock-based compensation expense - R&D	17.0	13.8
Stock-based compensation expense - SG&A	27.5	26.1

Charges associated with convertible senior notes ¹	88.7	—
Non-cash interest related to convertible senior notes	0.2	0.2
Non-cash amortization related to acquired intangible assets	0.9	0.9
Changes in fair value of equity security investments ²	(1.6)	(2.2)
Income tax effect related to reconciling items ³	(51.3)	(11.7)
Non-GAAP net income	<u>\$ 124.8</u>	<u>\$ (49.5)</u>

Diluted earnings per share:

GAAP	\$ 0.42	\$ (0.79)
Non-GAAP	\$ 1.20	\$ (0.51)

1. Reflects charges associated with election to cash settle principal and conversion premium of convertible senior notes and the requirement to bifurcate the embedded conversion option and accrete to other expense.
2. Reflects periodic fluctuations in the fair values of the Company's equity security investments.
3. 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 March 31,	
	2024	2023
GAAP cost of revenues	\$ 7.5	\$ 8.5
Adjustments:		
Non-cash amortization related to acquired intangible assets	0.9	0.9
Non-GAAP cost of revenues	<u>\$ 6.6</u>	<u>\$ 7.6</u>

<i>(in millions)</i>	Three Months Ended March 31,	
	2024	2023
GAAP R&D	\$ 159.4	\$ 139.5
Adjustments:		
Stock-based compensation expense	17.0	13.8
Non-GAAP R&D	<u>\$ 142.4</u>	<u>\$ 125.7</u>

<i>(in millions)</i>	Three Months Ended March 31,	
	2024	2023
GAAP SG&A	\$ 243.1	\$ 242.7
Adjustments:		
Stock-based compensation expense	27.5	26.1
Non-GAAP SG&A	<u>\$ 215.6</u>	<u>\$ 216.6</u>

<i>(in millions)</i>	Three Months Ended March 31,	
	2024	2023
GAAP other (expense) income, net	\$ (64.8)	\$ 10.9
Adjustments:		
Charges associated with convertible senior notes	88.7	—
Non-cash interest related to convertible senior notes	0.2	0.2
Changes in fair value of equity security investments	(1.6)	(2.2)

Non-GAAP other income, net \$ 22.5 \$ 8.9

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SOURCE Neurocrine Biosciences, Inc.

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