Neurocrine Biosciences Reports Second Quarter 2022 Financial Results and Raises 2022 INGREZZA Sales Guidance

August 4, 2022

INGREZZA® (valbenazine) Second Quarter Net Product Sales of $350 Million

INGREZZA® (valbenazine) 2022 Net Product Sales Guidance Raised to $1.35 - $1.40 Billion

Essential Tremor Signal-Seeking Study Did Not Meet Specified Endpoints

SAN DIEGO, Aug. 4, 2022 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the second quarter ended June 30, 2022 and raised net sales guidance for INGREZZA in 2022.

"Following INGREZZA's strong performance in the first half of this year, we raised full year net sales guidance. Growth continues to be driven by improving diagnosis and treatment rates for patients with tardive dyskinesia," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "Although disappointed that our essential tremor data was not what we hoped to see, we look forward to the continued advancement of our pipeline with the recent FDA approval to initiate a Phase 2 proof-of-concept study for the treatment of schizophrenia with our selective M4 agonist."

Financial Highlights

	Three Months Ended June 30,		Six Months Ended June 30,	
(unaudited, in millions, except per share data)	**2022**	**2021**	**2022**	**2021**
Revenues:				
Product sales, net	$ 352.0	$ 266.8	$ 657.0	$ 497.8
Collaboration revenue	26.2	22.1	31.8	27.7
Total revenues	$ 378.2	$ 288.9	$ 688.8	$ 525.5
GAAP Research and Development (R&D)	$ 135.9	$ 74.8	$ 238.1	$ 148.0
Non-GAAP R&D	$ 119.7	$ 65.6	$ 209.4	$ 123.8
GAAP Selling, General and Administrative (SG&A)	$ 182.8	$ 143.2	$ 383.5	$ 272.2
Non-GAAP SG&A	$ 149.5	$ 123.8	$ 325.7	$ 234.9
GAAP net (loss) income	$ (16.9)	$ 42.3	$ (3.0)	$ 74.4
GAAP (loss) earnings per share – diluted	$ (0.18)	$ 0.43	$ (0.03)	$ 0.76
Non-GAAP net income	$ 82.1	$ 70.1	$ 111.8	$ 118.9
Non-GAAP earnings per share – diluted	$ 0.84	$ 0.72	$ 1.14	$ 1.21

(unaudited, in millions)	**June 30, 2022**	**December 31, 2021**
Total cash, cash equivalents and marketable securities	$ 1,053.5	$ 1,272.0

Second Quarter INGREZZA Net Product Sales and Commercial Highlights:

- Net product sales were $350 million with total prescriptions (TRx) of approximately 64,200
- Net product sales and TRx grew 32% and 31%, respectively, vs. second quarter of 2021
- Sequential growth driven by record new patients and continued strength in existing patients' refill rates

Financial Highlights:

- Second quarter 2022 GAAP net loss and loss per share of $17 million and $0.18, respectively, compared with second quarter 2021 GAAP net income and diluted earnings per share of $42 million and $0.43, respectively, primarily driven by

$70 million loss on extinguishment of debt in the second quarter of 2022.

- Second quarter 2022 non-GAAP net income and diluted earnings per share of $82 million and $0.84, respectively, compared with $70 million and $0.72, respectively, for second quarter 2021.
- Differences in second quarter 2022 GAAP and non-GAAP operating expenses compared with second quarter 2021 driven by:
    - Increased R&D expense in support of an expanded and advancing clinical portfolio, including $30 million milestone expense incurred for our Sosei Heptares muscarinic collaboration
    - Increased SG&A expense primarily due to ongoing commercial initiatives, including the INGREZZA direct-to-consumer advertising campaign which launched in May 2021 and deployment of the expanded salesforce in March 2022
- Total debt outstanding decreased by $211 million to $170 million following our repurchase of approximately 55% of total debt outstanding in the second quarter of 2022. The total aggregate repurchase price of $279 million was paid in cash and resulted in the recognition of a $70 million loss on extinguishment in the second quarter of 2022.
- At June 30, 2022, the Company had cash, cash equivalents and marketable securities of approximately $1.1 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 June 2022, the Mitsubishi Tanabe Pharma Corporation (MTPC) launched DYSVAL® (valbenazine) in Japan for the treatment of tardive dyskinesia. In connection with MTPC's first commercial sale of DYSVAL in Japan, we received a milestone payment of $20.0 million, which was recognized as revenue in the second quarter of 2022.
- In the second quarter of 2022, the FDA accepted our submission of an investigational new drug application (IND) for NBI-1117568 for the treatment of schizophrenia, for which we anticipate initiating a Phase 2 study during the second half of 2022. Based upon this progress, a milestone of $30.0 million was expensed as R&D in the second quarter of 2022, which we expect to pay to Sosei Heptares in the third quarter of 2022.
- In August, the Phase 2a study of NBI-827104 in essential tremor did not meet specified endpoints. Based on the totality of data from the Phase 2a study, at this time, we do not plan to proceed further with the clinical development of NBI-827104 in essential tremor.

Updated 2022 INGREZZA Sales and Operating Expense Guidance:

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales[1]	$ 1,350	$ 1,400
GAAP R&D expense [2]	$ 415	$ 450
Non-GAAP R&D expense [3]	$ 360	$ 395
GAAP SG&A expense	$ 720	$ 735
Non-GAAP SG&A expense[3]	$ 605	$ 620

1. INGREZZA sales guidance for fiscal 2022 is based on recent trends and the anticipated benefit from our recently completed salesforce expansion. If new COVID-19 related disruptions emerge, the Company's ability to meet these expectations could be negatively impacted.

2. GAAP R&D guidance includes (i) amounts for milestones that are probable of achievement or have been achieved and (ii) amounts for in-process research and development once significant collaboration and licensing arrangements have been completed. GAAP R&D guidance includes approximately $40 million of milestone expenses in connection with collaborations.
3. Non-GAAP guidance adjusted to exclude estimated non-cash stock-based compensation expense of $60 million in R&D and $110 million in SG&A.

Based upon available Federal net operating losses and tax credits, the Company expects to begin making cash payments for Federal income tax beginning in the fourth quarter of 2022.

Expected Future Pipeline Milestones and Key Activities

Program	Indication	Expected Milestones / Key Activities
Valbenazine* (Selective VMAT2 Inhibitor)	Chorea in Huntington Disease	File Supplemental New Drug Application in Second Half (2H) 2022
	Adjunctive Treatment of Schizophrenia	Top-Line Data from 1st Registrational Study in 2023
	Dyskinetic Cerebral Palsy	Top-Line Registrational Data in 2024
NBI-827104** (Selective T-Type Ca_V Channel Blocker)	Rare Pediatric Epilepsy: CSWS	Top-Line Phase 2 Data in 2H 2022

NBI-1117568† (Selective M4 Agonist)	Treatment of Schizophrenia	Initiating Phase 2 Study in 2H 2022
NBI-1070770	Psychiatric Indication	Initiating Phase 1 Study in 2H 2022
Crinecerfont (CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Adult)	Top-Line Registrational Data in 2023
	Congenital Adrenal Hyperplasia (Pediatric)	Top-Line Registrational Data in 2023
NBI-1065845‡ (AMPA Potentiator)	Inadequate Response to Treatment in Major Depressive Disorder	Phase 2 Data in 2023
NBI-1065846‡ (GPR-139 Agonist)	Anhedonia in Major Depressive Disorder	Phase 2 Data in 2023
NBI-921352∞ (Selective $Na_V1.6$ Channel Blocker)	Focal Onset Seizure in Adults	Phase 2 Data in 2023

Key: VMAT2 = Vesicular Monoamine Transporter 2; Ca_V = Calcium Channel, Voltage-Gated; CSWS = Epileptic Encephalopathy with Continuous Spike and Wave During Sleep; M4= M4 Muscarinic Receptor; CFR1 = Corticotropin-Releasing Factor Type 1; AMPA = Alpha-Amino-3-Hydroxy-5-Methyl-4-Isoxazole Propionic Acid; GPR = Orphan G Protein Coupled Receptor; $Na_V1.6$ = Sodium Channel, Voltage-Gated

*Neurocrine Bioscience Partners: * Mitsubishi Tanabe Pharma Corporation has commercialization rights in East Asia; ** In-Licensed from Idorsia Pharmaceuticals; † In-Licensed from Sosei Group Corporation; ‡ Partnered with Takeda Pharmaceutical Company Limited; ∞ In-Licensed from Xenon Pharmaceuticals*

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 800-895-3361 (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.

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, Parkinson's disease, endometriosis* and uterine fibroids*, as well as over a dozen mid-to-late-stage clinical programs in multiple 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. *(*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, non-cash interest expense related to convertible debt, loss on extinguishment of convertible senior notes, changes in fair value of equity security investments 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; expectations regarding our ability to adapt our business to the evolving COVID-19 pandemic globally, mitigate its impact on our business, including our ability to continue conducting our ongoing clinical trials and other development activities, to protect the safety and well-being of our employees, to continue to support uninterrupted supply of INGREZZA, and to otherwise advance our business objectives; 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 associated with the commercialization of INGREZZA and ONGENTYS; the impact of the evolving COVID-19 pandemic globally on our business and the business operations of our customers, collaborators, vendors, and clinical trial sites including the impact on the ability of patients to have in-person visits with their health care provider; 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, COVID-19 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 June 30, 2022. 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 June 30,		Six Months Ended June 30,	
(in millions, except per share data)	**2022**	**2021**	**2022**	**2021**
Revenues:				
Product sales, net	$ 352.0	$ 266.8	$ 657.0	$ 497.8
Collaboration revenue	26.2	22.1	31.8	27.7
Total revenues	378.2	288.9	688.8	525.5
Operating expenses:				
Cost of revenues	4.8	3.1	9.4	6.0
Research and development	135.9	74.8	238.1	148.0
Acquired in-process research and development	—	5.0	—	5.0
Selling, general and administrative	182.8	143.2	383.5	272.2
Total operating expenses	323.5	226.1	631.0	431.2
Operating income	54.7	62.8	57.8	94.3
Other (expense) income:				
Interest expense	(2.2)	(6.2)	(4.8)	(12.6)
Unrealized (loss) gain on equity securities	(7.4)	—	12.5	0.7
Loss on extinguishment of convertible senior notes	(70.0)	—	(70.0)	—
Investment income and other, net	1.6	0.9	2.6	2.3
Total other expense, net	(78.0)	(5.3)	(59.7)	(9.6)
(Loss) income before (benefit from) provision for income taxes	(23.3)	57.5	(1.9)	84.7
(Benefit from) provision for income taxes	(6.4)	15.2	1.1	10.3
Net (loss) income	$ (16.9)	$ 42.3	$ (3.0)	$ 74.4
(Loss) earnings per share, basic	$ (0.18)	$ 0.45	$ (0.03)	$ 0.79
(Loss) earnings per share, diluted	$ (0.18)	$ 0.43	$ (0.03)	$ 0.76
Weighted average common shares outstanding, basic	95.6	94.6	95.4	94.4
Weighted average common shares outstanding, diluted	95.6	97.7	95.4	98.0

TABLE 2
NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

(in millions)	**June 30, 2022**	**December 31, 2021**
Cash, cash equivalents and debt securities available-for-sale	$ 648.3	$ 711.3
Other current assets	371.0	261.5
Total current assets	1,019.3	972.8
Deferred tax assets	328.4	315.1
Debt securities available-for-sale	405.2	560.7
Right-of-use assets	92.2	97.2
Equity securities	83.8	63.7
Property and equipment, net	66.8	58.6
Other assets	10.0	4.4
Total assets	$ 2,005.7	$ 2,072.5
Total current liabilities	$ 285.7	$ 245.8
Convertible senior notes	169.0	335.1
Operating lease liabilities	99.6	105.3
Other long-term liabilities	28.0	12.3
Stockholders' equity	1,423.4	1,374.0
Total liabilities and stockholders' equity	$ 2,005.7	$ 2,072.5

TABLE 3
NEUROCRINE BIOSCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS

(unaudited)

(in millions, except per share data)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
GAAP net (loss) income	$ (16.9)	$ 42.3	$ (3.0)	$ 74.4
Adjustments:				
Stock-based compensation expense - R&D	16.2	9.2	28.7	24.2
Stock-based compensation expense - SG&A	33.3	19.4	57.8	37.3
Loss on extinguishment of convertible senior notes [1]	70.0	—	70.0	—
Non-cash interest related to convertible senior notes	0.4	4.3	0.8	8.5
Changes in fair value of equity security investments [2]	7.4	—	(12.5)	(0.7)
Income tax effect related to reconciling items [3]	(28.3)	(5.1)	(30.0)	(24.8)
Non-GAAP net income	$ 82.1	$ 70.1	$ 111.8	$ 118.9
Diluted earnings per share:				
GAAP	$ (0.18)	$ 0.43	$ (0.03)	$ 0.76
Non-GAAP [4]	$ 0.84	$ 0.72	$ 1.14	$ 1.21

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 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 non-cash stock-based compensation and premium paid on repurchase of its convertible senior notes.
4. Non-GAAP diluted earnings per share for the three and six months ended June 30, 2022, reflect diluted shares of 98.2 million and 97.9 million, respectively, which were calculated in accordance with the guidance on earnings per share in ASC 260.

Note: Beginning in the third quarter of 2021, milestone payments received from licenses and collaborations, milestones paid related to licenses and collaborations, non-cash collaboration revenue, and acquired in-process research and development are no longer excluded from non-GAAP financial results. 2021 non-GAAP financial results have been updated for comparability to current year periods.

TABLE 4
NEUROCRINE BIOSCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP EXPENSES
(unaudited)

(in millions)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
GAAP R&D	$ 135.9	$ 74.8	$ 238.1	$ 148.0
Adjustments:				
Stock-based compensation expense	16.2	9.2	28.7	24.2
Non-GAAP R&D	$ 119.7	$ 65.6	$ 209.4	$ 123.8
GAAP SG&A	$ 182.8	$ 143.2	$ 383.5	$ 272.2
Adjustments:				
Stock-based compensation expense	33.3	19.4	57.8	37.3
Non-GAAP SG&A	$ 149.5	$ 123.8	$ 325.7	$ 234.9

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SOURCE Neurocrine Biosciences, Inc.

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