Neurocrine Biosciences Reports First Quarter 2022 Financial Results and Reiterates 2022 Financial Guidance

May 4, 2022

INGREZZA® (valbenazine) First Quarter Net Product Sales of $303 Million

INGREZZA® (valbenazine) 2022 Net Product Sales Guidance Reiterated at $1.25 - $1.35 Billion

SAN DIEGO, May 4, 2022 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the first quarter ended March 31, 2022 and reiterated financial guidance for 2022.

"INGREZZA's first quarter performance reflects the opportunity we have to help patients living with tardive dyskinesia (TD). We completed our salesforce expansion in April and we now have three dedicated teams across psychiatry, neurology, and long-term care who are focused on improving diagnosis and treatment rates for TD," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "With a growing product in INGREZZA, several mid-to-late-stage clinical data read-outs this year and next, and a strong financial profile, Neurocrine Biosciences continues to establish our position as a leading neuroscience-focused company."

Financial Highlights

	Three Months Ended March 31,	
(unaudited, in millions, except per share data)	**2022**	**2021**
Revenues:		
Product sales, net	$ 305.0	$ 231.0
Collaboration revenue	5.6	5.6
Total revenues	$ 310.6	$ 236.6
GAAP Research and Development (R&D)	$ 102.2	$ 73.2
Non-GAAP R&D	$ 89.7	$ 58.2
GAAP Selling, General and Administrative (SG&A)	$ 200.7	$ 129.0
Non-GAAP SG&A	$ 176.2	$ 111.1
GAAP net income	$ 13.9	$ 32.1
GAAP earnings per share – diluted	$ 0.14	$ 0.33
Non-GAAP net income	$ 29.7	$ 48.8
Non-GAAP earnings per share – diluted	$ 0.30	$ 0.50

(unaudited, in millions)	**March 31, 2022**	**December 31, 2021**
Total cash, cash equivalents and marketable securities	$ 1,205.9	$ 1,272.0

First Quarter INGREZZA Net Product Sales and Commercial Highlights:

- Net product sales were $303 million with total prescriptions (TRx) of approximately 57,600
- Net product sales and TRx grew 32% and 33%, respectively, vs. first quarter of 2021
- Improved levels of persistence and compliance for existing patients when compared to prior first quarters driven by strong commercial execution
- Record number of new patients
- In April 2022, salesforce expansion was completed establishing separate psychiatry, neurology, and long-term care teams

Financial Highlights:

- First quarter 2022 GAAP net income and diluted earnings per share of $14 million and $0.14, respectively, compared with

$32 million and $0.33, respectively, for first quarter 2021
- First quarter 2022 non-GAAP net income and diluted earnings per share of $30 million and $0.30, respectively, compared with $49 million and $0.50, respectively, for first quarter 2021
- Differences in first quarter 2022 GAAP and non-GAAP financial results compared with first quarter 2021 driven by:
    - Increased R&D expense in support of an expanded and advancing clinical portfolio
    - Increased SG&A expense primarily due to ongoing commercial initiatives, including the TD Spotlight-branded direct-to-consumer INGREZZA advertising campaign which launched in May 2021 and deployment of the expanded salesforce in March 2022
- At March 31, 2022, the Company had cash, cash equivalents and marketable securities of $1.2 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 March 2022, Mitsubishi Tanabe Pharma Corporation (MTPC) received Japanese Ministry of Health, Labour and Welfare approval for DYSVAL® (valbenazine) for the treatment of tardive dyskinesia in Japan. Under the terms of the license agreement, the Company is entitled to receive a milestone payment of $20 million upon MTPC's first commercial sale of DYSVAL in Japan, which is expected to occur in the second quarter of 2022.
- In April 2022, Neurocrine Biosciences presented Phase 3 data for the KINECT-HD study evaluating valbenazine for chorea associated with Huntington disease. In the study, valbenazine met the primary endpoint of significant ($p<0.0001$) improvement in chorea severity versus placebo as measured by the Unified Huntington's Disease Rating Scale (UHDRS®) Total Maximal Chorea (TMC) Score, with improvements beginning in week 2. Clinically meaningful results, demonstrated by greater response rates, were seen by clinicians (CGI-C) and patients (PGI-C) for valbenazine versus placebo. In addition, the safety profile was consistent with the known safety profile of valbenazine. The Company plans to submit a supplemental New Drug Application to the U.S. Food and Drug Administration in the second half of 2022.

Reiterated 2022 INGREZZA Sales and Operating Expense Guidance:

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales [1]	$ 1,250	$ 1,350
GAAP R&D expense [2]	$ 380	$ 415
Non-GAAP R&D expense [3]	$ 325	$ 360
GAAP SG&A expense	$ 720	$ 735
Non-GAAP SG&A expense [3]	$ 605	$ 620

1. INGREZZA sales guidance for fiscal 2022 reflects approximately 20% year-over-year growth, at the mid-point of the range, and is based on recent trends, an anticipated improving COVID-19 related environment throughout the year, and benefit from our recently completed salesforce expansion during the second half of 2022. 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 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 $7 million of milestone expense for the Xenon collaboration which was achieved in January 2022.
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 Federal NOL's and tax credits, the Company expects to begin making cash payments for Federal income tax beginning in the fourth quarter of 2022.

Expected Future 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)	Essential Tremor	Top-Line Phase 2 Data in Mid-2022
	Rare Pediatric Epilepsy: CSWS	Top-Line Phase 2 Data in 2H 2022
NBI-1117568† (Selective M4 Agonist)	Treatment of Schizophrenia	Initiate Phase 2 Study in 2022
New Chemical Entity	Neurological or Psychiatric Indication	Initiate Phase 1 Study in 2022
Crinecerfont	Congenital Adrenal Hyperplasia (Adult)	Top-Line Registrational Data in 2023

(CRF1 Receptor Antagonist)	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 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 800-895-3361 (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, 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 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, 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 INCOME
(unaudited)

(in millions, except per share data)	Three Months Ended March 31, 2022	2021
Revenues:		
Product sales, net	$ 305.0	$ 231.0
Collaboration revenue	5.6	5.6
Total revenues	310.6	236.6
Operating expenses:		
Cost of revenues	4.6	2.9
Research and development	102.2	73.2
Selling, general and administrative	200.7	129.0
Total operating expenses	307.5	205.1
Operating income	3.1	31.5
Other income (expense):		
Interest expense	(2.6)	(6.4)
Unrealized gain on equity securities	19.9	0.7
Investment income and other, net	1.0	1.4
Total other income (expense), net	18.3	(4.3)
Income before provision for (benefit from) income taxes	21.4	27.2
Provision for (benefit from) income taxes	7.5	(4.9)
Net income	$ 13.9	$ 32.1
Earnings per share, basic	$ 0.15	$ 0.34
Earnings per share, diluted	$ 0.14	$ 0.33
Weighted average common shares outstanding, basic	95.3	94.2
Weighted average common shares outstanding, diluted	97.6	98.2

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

(in millions)	March 31, 2022	December 31, 2021
Cash, cash equivalents and debt securities available-for-sale	$ 664.9	$ 711.3
Other current assets	353.3	261.5
Total current assets	1,018.2	972.8
Deferred tax assets	325.3	315.1
Debt securities available-for-sale	541.0	560.7
Right-of-use assets	94.7	97.2
Equity securities	91.3	63.7
Property and equipment, net	63.9	58.6
Other assets	10.1	4.4
Total assets	$ 2,144.5	$ 2,072.5
Total current liabilities	$ 253.5	$ 245.8
Convertible senior notes	377.7	335.1
Operating lease liabilities	102.5	105.3
Other long-term liabilities	19.7	12.3
Stockholders' equity	1,391.1	1,374.0
Total liabilities and stockholders' equity	$ 2,144.5	$ 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 March 31, 2022	2021
GAAP net income	$ 13.9	$ 32.1
Adjustments:		
Share-based compensation expense - R&D	12.5	15.0
Share-based compensation expense - SG&A	24.5	17.9
Non-cash interest related to convertible senior notes	0.4	4.2
Changes in fair value of equity security investments [1]	(19.9)	(0.7)
Income tax effect related to reconciling items [2]	(1.7)	(19.7)
Non-GAAP net income	$ 29.7	$ 48.8
Diluted earnings per share:		
GAAP	$ 0.14	$ 0.33
Non-GAAP	$ 0.30	$ 0.50

1. Reflects unrealized gain recognized to adjust equity security investments to fair value.
2. 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.

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. First quarter 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 March 31, 2022	2021
GAAP R&D	$ 102.2	$ 73.2
Adjustments:		
Share-based compensation expense	12.5	15.0
Non-GAAP R&D	$ 89.7	$ 58.2
GAAP SG&A	$ 200.7	$ 129.0
Adjustments:		
Share-based compensation expense	24.5	17.9
Non-GAAP SG&A	$ 176.2	$ 111.1

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