Neurocrine Biosciences Reports Second Quarter 2021 Financial Results

August 3, 2021

INGREZZA® (valbenazine) Second Quarter 2021 Net Product Sales of $265 Million with Approximately 48,900 Total Prescriptions

Phase 3 Registrational Program of Valbenazine for the Treatment of Chorea Associated with Huntington Disease Fully Enrolled with Top-Line Data Expected by Year-End

SAN DIEGO, Aug. 3, 2021 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the second quarter ended June 30, 2021.

"We helped more tardive dyskinesia patients than ever before as our second quarter results reflect sustained growth for INGREZZA. While 8 out of 10 patients still remain undiagnosed, the underlying opportunity to improve the lives of patients with TD remains strong. Therefore, we continue to invest in healthcare provider and patient-focused awareness campaigns to help improve TD diagnosis and treatment rates," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We remain committed to advancing our R&D pipeline and are making steady progress towards initiating 9 mid-to-late-stage clinical trials this year. With significant long-term commercial growth opportunities and a diverse and growing pipeline, we are well positioned to become a leading neuroscience-focused biopharmaceutical company."

Financial Highlights

	Three Months Ended June 30,		Six Months Ended June 30,	
(unaudited, in millions, except per share data)	**2021**	**2020**	**2021**	**2020**
Revenues:				
Product sales, net	$ 266.8	$ 267.6	$ 497.8	$ 498.7
Collaboration revenue	22.1	34.8	27.7	40.8
Total revenues	$ 288.9	$ 302.4	$ 525.5	$ 539.5
GAAP Research and Development (R&D)	$ 74.8	$ 80.9	$ 148.0	$ 139.2
Non-GAAP R&D	$ 65.6	$ 51.0	$ 123.8	$ 101.6
GAAP Selling, General and Administrative (SG&A)	$ 143.2	$ 96.5	$ 272.2	$ 214.3
Non-GAAP SG&A	$ 123.8	$ 76.9	$ 234.9	$ 179.6
GAAP net income	$ 42.3	$ 79.6	$ 74.4	$ 117.0
GAAP net income per share – diluted	$ 0.43	$ 0.81	$ 0.76	$ 1.20
Non-GAAP net income	$ 61.3	$ 139.1	$ 109.2	$ 218.2
Non-GAAP net income per share – diluted	$ 0.63	$ 1.42	$ 1.11	$ 2.24

	June 30, 2021	December 31, 2020
(unaudited, in millions)		
Total cash, cash equivalents and debt securities available-for-sale	$1,222.7	$ 1,028.1

Second Quarter Net Product Sales and Commercial Highlights:

- INGREZZA net product sales for the second quarter of 2021 were $265 million and $269 million on an inventory adjusted basis
- Record total prescriptions achieved during the second quarter 2021 reflecting increased commercial activities
- New prescriptions increased throughout the second quarter, reaching their highest levels since March 2020 despite continued significant use of telemedicine within psychiatry
- Second quarter refill rates per patient returned to historical normal range versus seasonally low first quarter levels

Financial Highlights:

- Second quarter 2021 GAAP net income and diluted earnings per share were approximately $42 million and $0.43, respectively, compared with approximately $80 million and $0.81, respectively, in the second quarter of 2020
- Second quarter 2021 non-GAAP net income and diluted earnings per share were approximately $61 million and $0.63, respectively, compared with approximately $139 million and $1.42, respectively, in the second quarter of 2020
- Difference between second quarter 2021 GAAP and non-GAAP net income and diluted earnings per share compared with the second quarter of 2020 were driven by:
    - Increased research and development expense primarily due to increased investment and headcount to support our expanded pipeline programs
    - Increased selling, general and administrative expense primarily due to increased investment in commercial initiatives including the launch of "TD Spotlight", our INGREZZA direct-to-consumer advertising campaign
- Second quarter 2021 provision for income taxes was $15 million, compared with $4 million in the second quarter of 2020. In the first quarter of 2021, the Company began recording a provision for income taxes using an effective tax rate approximating federal and state statutory rates. Due to the Company's ability to offset its pre-tax income against previously benefited federal net operating losses, no federal cash tax is expected in 2021.
- At June 30, 2021, the Company had cash, cash equivalents and debt securities available-for-sale 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 April 2021, Mitsubishi Tanabe Pharma Corporation (MTPC) submitted a Marketing Authorization Application, or MAA, with the Ministry of Health and Welfare in Japan for valbenazine for the treatment of tardive dyskinesia. The MTPC submission of valbenazine triggered a milestone payment of $15 million, which the Company recognized as collaboration revenue in the second quarter of 2021.
- In August 2021, the Company announced plans to initiate registrational studies in the second half of 2021 with valbenazine for adjunctive treatment in schizophrenia and for dyskinesia due to cerebral palsy.

Full-Year 2021 Expense Guidance Reaffirmed

	Range	
(in millions)	**Low**	**High**
Combined GAAP R&D and SG&A expenses	$855	$905
Combined Non-GAAP R&D and SG&A expenses	$720	$770

- GAAP-only guidance includes approximately $130 million of share-based compensation and $5 million of In-Process Research and Development (IPR&D). GAAP-only guidance does not include any potential milestones or IPR&D costs associated with current collaborations or future business development activities.

2021 Expected Milestones and Key Activities

Program	Indication	2021 Milestones / Key Activities
Valbenazine	Chorea in Huntington Disease	Study Fully Enrolled with Registrational Top-Line Data Expected by Year-End
	Tardive Dyskinesia	MTPC Submitted Marketing Authorization with Ministry of Health and Welfare in Japan
	Dyskinesia Due to Cerebral Palsy (Neurological Indication)	Initiating Registrational Study in 2H 2021
	Adjunctive Treatment in Schizophrenia (Psychiatric Indication)	Initiating Registrational Study in 2H 2021
Crinecerfont	Congenital Adrenal Hyperplasia (Adult)	Enrolling Registrational Study
	Congenital Adrenal Hyperplasia (Pediatric)	Enrolling Registrational Study
Luvadaxistat (NBI-1065844)	Cognitive Impairment Associated with Schizophrenia (CIAS)	Initiating Phase 2 Study in 2H 2021
NBI-1065845	Inadequate Response to Treatment in Major Depressive Disorder (MDD)	Initiating Phase 2 Study in 2H 2021
NBI-1065846	Anhedonia in Depression	Initiating Phase 2 Study in 2H 2021
NBI-827104	Rare Pediatric Epilepsy: Epileptic Encephalopathy with Continuous Spike and Wave During Sleep (CSWS)	Enrolling Phase 2 Study
	Essential Tremor	Enrolling Phase 2 Study
NBI-921352	Focal-Onset Seizure in Adults	Initiating Phase 2 Study in 2H 2021
	Rare Pediatric Epilepsy: SCN8A Developmental Epileptic Encephalopathy (SCN8A-DEE)	Initiating Phase 2 Study in 2H 2021

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 866-952-8559 (US) or 785-424-1743 (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 dedicated to discovering, developing and delivering life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, Neurocrine Biosciences has specialized in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. 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: milestone payments received from licenses and collaborations, milestones paid related to licenses and collaborations, non-cash collaboration revenue, acquired in-process research and development, share-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 research and development and sales, general, and administrative expenses on both a GAAP and a non-GAAP basis. The guidance regarding GAAP research and development expenses and sales, general and administrative expenses does not include estimates for expenses associated with any potential future business development activities. A reconciliation of these GAAP financial results to non-GAAP financial results is included in the attached financial information. In addition, INGREZZA net sales are presented in accordance with GAAP and as inventory-adjusted net sales, which is a non-GAAP financial measure. The difference between INGREZZA net sales and inventory-adjusted net sales reflects changes in channel inventory that are not representative of the underlying prescription demand. Management uses inventory-adjusted net sales to manage the Company's business and evaluate its performance.

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; expectations regarding the impact of COVID-19 on our business; expectations regarding our ability to adapt our business to the evolving COVID-19 pandemic, 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 on our business and the business operations of our customers; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risk and uncertainties related to any COVID-19 quarantine, social distancing and other requirements put in place by governments, customers, or clinical trial sites, including the impact of such requirements 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 and manufacturing 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 associated with our dependence on AbbVie for the commercialization of ORILISSA and ORIAHNN, as well as the continued development of elagolix; 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; and other risks described in our periodic reports filed with the SEC, including without limitation our quarterly report on Form 10-Q for the quarter ended June 30, 2021. 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions, except per share data)	**2021**	**2020**	**2021**	**2020**
Revenues:				
Product sales, net	$ 266.8	$ 267.6	$ 497.8	$ 498.7
Collaboration revenue	22.1	34.8	27.7	40.8

Total revenues	288.9	302.4	525.5	539.5
Operating expenses:				
Cost of sales	3.1	2.4	6.0	4.5
Research and development	74.8	80.9	148.0	139.2
Acquired in-process research and development	5.0	46.0	5.0	46.0
Selling, general and administrative	143.2	96.5	272.2	214.3
Total operating expenses	226.1	225.8	431.2	404.0
Operating income	62.8	76.6	94.3	135.5
Other (expense) income:				
Interest expense	(6.2)	(8.3)	(12.6)	(16.5)
Unrealized gain (loss) on equity securities	—	11.3	0.7	(5.2)
Investment income and other, net	0.9	3.6	2.3	8.3
Total other (expense) income, net	(5.3)	6.6	(9.6)	(13.4)
Income before provision for income taxes	57.5	83.2	84.7	122.1
Provision for income taxes	15.2	3.6	10.3	5.1
Net income	$ 42.3	$ 79.6	$ 74.4	$ 117.0
Net income per share, basic	$ 0.45	$ 0.86	$ 0.79	$ 1.26
Net income per share, diluted	$ 0.43	$ 0.81	$ 0.76	$ 1.20
Weighted average common shares outstanding, basic	94.6	93.0	94.4	92.8
Weighted average common shares outstanding, diluted	97.7	98.2	98.0	97.6

TABLE 2

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

(in millions)	**June 30, 2021**	**December 31, 2020**
Cash, cash equivalents and debt securities available-for-sale	$ 884.9	$ 801.0
Other current assets	225.2	215.2
Total current assets	1,110.1	1,016.2
Deferred tax assets	316.1	319.4
Debt securities available-for-sale	337.8	227.1
Right-of-use assets	100.3	82.8
Equity securities	38.9	38.2
Property and equipment, net	50.0	44.6
Other assets	3.2	6.4
Total assets	$1,956.4	$ 1,734.7
Total current liabilities	$ 212.9	$ 186.5
Convertible senior notes	326.3	317.9
Operating lease liabilities	109.0	94.4
Other long-term liabilities	29.0	9.7
Stockholders' equity	1,279.2	1,126.2
Total liabilities and stockholders' equity	$1,956.4	$ 1,734.7

TABLE 3

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

	Three Months Ended June 30,		**Six Months Ended June 30,**	
(in millions, except per share data)	**2021**	**2020**	**2021**	**2020**
GAAP net income	$ 42.3	$ 79.6	$ 74.4	$ 117.0
Adjustments:				
Milestones received from licenses and collaborations [A]	(15.0)	(30.0)	(15.0)	(30.0)
Non-cash collaboration revenue [B]	(1.3)	—	(2.4)	(1.3)
Acquired in-process research and development (IPR&D) [C]	5.0	46.0	5.0	46.0
Milestones paid related to licenses and collaborations - R&D	—	20.0	—	20.0
Share-based compensation expense - R&D	9.2	9.9	24.2	17.6
Share-based compensation expense - SG&A	19.4	19.6	37.3	34.7

Non-cash interest related to convertible senior notes	4.3	5.4	8.5	10.7
Changes in fair value of equity security investments [D]	—	(11.3)	(0.7)	5.2
Income tax effect related to reconciling items [E]	(2.6)	(0.1)	(22.1)	(1.7)
Non-GAAP net income	$ 61.3	$ 139.1	$ 109.2	$ 218.2
Net income per diluted common share:				
GAAP	$ 0.43	$ 0.81	$ 0.76	$ 1.20
Non-GAAP	$ 0.63	$ 1.42	$ 1.11	$ 2.24

[A] In the second quarter of 2021, the Company recognized a $15.0 million event-based milestone as revenue upon the Mitsubishi Tanabe Pharma Corporation (MTPC) MAA submission for valbenazine for the treatment of tardive dyskinesia in Japan. In the second quarter of 2020, the Company recognized a $30.0 million event-based milestone as revenue upon AbbVie's receipt of FDA approval for ORIAHNN for uterine fibroids.

[B] The Company recognized non-cash collaboration revenue under the collaboration and license agreement entered into with MTPC in 2015.

[C] In the second quarter of 2021, the Company recognized IPR&D expenses of $5.0 million associated with upfront fees paid. In the second quarter of 2020, the Company recognized IPR&D expenses of $46.0 million associated with collaboration and license agreement entered into with Idorsia Pharmaceuticals.

[D] The Company recognized an unrealized (gain) loss to adjust its equity security investments to fair value.

[E] 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 excess tax benefits associated with share-based compensation. On December 31, 2020, the Company released substantially all of its valuation allowance against its net operating losses and other deferred tax assets.

TABLE 4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	**2021**	**2020**	**2021**	**2020**
GAAP R&D	$ 74.8	$ 80.9	$ 148.0	$ 139.2
Adjustments:				
Milestones paid related to licenses and collaborations	—	20.0	—	20.0
Share-based compensation expense	9.2	9.9	24.2	17.6
Non-GAAP R&D	$ 65.6	$ 51.0	$ 123.8	$ 101.6
GAAP SG&A	$ 143.2	$ 96.5	$ 272.2	$ 214.3
Adjustments:				
Share-based compensation expense	19.4	19.6	37.3	34.7
Non-GAAP SG&A	$ 123.8	$ 76.9	$ 234.9	$ 179.6

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SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc., Tony Jewell (Media), 858-617-7578, media@neurocrine.com; Todd Tushla (Investors), 858-617-7143, ir@neurocrine.com