Neurocrine Biosciences Reports First Quarter 2021 Financial Results

May 5, 2021

INGREZZA® (valbenazine) First Quarter 2021 Net Product Sales of $230 Million with Approximately 43,300 TRx
Initiated Pediatric Phase III Registrational Program of Crinecerfont for the Treatment of Classic Congenital Adrenal Hyperplasia
Initiated Phase II Study of NBI-827104 in Essential Tremor

SAN DIEGO, May 5, 2021 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the first quarter ended March 31, 2021 and provided revised full-year 2021 financial expense guidance.

"Our first quarter results reflect a lower than normal refill rate per patient due to the typical seasonal payor dynamics for INGREZZA that were exacerbated by COVID. Importantly, we did not see an increase in discontinuations and exited the quarter with more patients on INGREZZA versus the prior quarter. New patient starts did pick up late in the quarter and we are focused on restoring INGREZZA growth as the impact of the pandemic wanes," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We made meaningful progress advancing our large, growing and diverse pipeline, including initiating a registrational study for the treatment of pediatric patients with congenital adrenal hyperplasia and a Phase II study in essential tremor. With important commercial products addressing patient needs and on track to initiate nine mid-to-late stage clinical studies this year, we are executing our plan to build a leading neuroscience-based company."

Financial Highlights

	Three Months Ended March 31,	
(unaudited, in millions, except per share data)	**2021**	**2020**
Revenues:		
Product sales, net	$ 231.0	$ 231.1
Collaboration revenue	5.6	6.0
Total revenues	$ 236.6	$ 237.1
GAAP Research and Development (R&D)	$ 73.2	$ 58.3
Non-GAAP R&D	$ 58.2	$ 50.6
GAAP Selling, General and Administrative (SG&A)	$ 129.0	$ 117.8
Non-GAAP SG&A	$ 111.1	$ 102.7
GAAP net income	$ 32.1	$ 37.4
GAAP net income per share – diluted	$ 0.33	$ 0.39
Non-GAAP net income	$ 47.9	$ 79.1
Non-GAAP net income per share – diluted	$ 0.49	$ 0.82

	March 31, 2021	December 31, 2020
(unaudited, in millions)		
Total cash, cash equivalents and debt securities available-for-sale	$ 1,123.3	$ 1,028.1

First Quarter Net Product Sales and Commercial Highlights:

- INGREZZA net product sales for the first quarter of 2021 were $230 million and $227 million on an inventory adjusted basis
- Annual seasonal payor dynamics resulted in lower refill rates per existing patient as compared to historical norms due to the COVID-19 pandemic and related disruption on timing of patient insurance reauthorizations
- Exiting the first quarter, commercial activity and weekly new prescriptions both achieved their highest levels since the start of the pandemic reflecting an improved environment for diagnosis of tardive dyskinesia (TD). We expect second quarter

inventory adjusted sales sequential dollar growth to be similar to 2020.
- INGREZZA direct-to-consumer advertising campaign, "TD Spotlight", to be launched in May to educate patients about tardive dyskinesia and the benefits of INGREZZA

Financial Highlights:

- First quarter 2021 GAAP net income and diluted earnings per share were approximately $32 million and $0.33, respectively, compared with approximately $37 million and $0.39, respectively, in the first quarter of 2020
- First quarter 2021 non-GAAP net income and diluted earnings per share were approximately $48 million and $0.49, respectively, compared with approximately $79 million and $0.82, respectively, in the first quarter of 2020
- Difference between first quarter 2021 GAAP and non-GAAP net income and diluted earnings per share vs. the first quarter of 2020 were driven by:
    - Increased Research and Development (R&D) expense primarily due to increased investment across our expanded pipeline programs and higher headcount costs
    - Increased Selling, General and Administrative (SG&A) expense primarily due to increased investment in commercial initiatives
- At March 31, 2021, the Company had cash, cash equivalents and debt securities available-for-sale of $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.

Provision for Income Taxes:

First quarter 2021 benefit from income taxes was $4.9 million, compared with a provision for income taxes of $1.5 million in the first quarter of 2020. Our effective tax rate for the first quarter of 2021 was lower than federal and state statutory rates primarily due to excess tax benefits related to stock compensation. On December 31, 2020, the Company released substantially all of its valuation allowance against its net operating losses and other deferred tax assets. Beginning 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 our ability to offset our pre-tax income against previously benefited federal net operating losses, no federal cash tax is expected in 2021.

Recent Events

- In February 2021, the Mitsubishi Tanabe Pharma Corporation (MTPC) reported positive top-line results from the J-KINECT Phase III Study, designed to evaluate the efficacy and safety of valbenazine in tardive dyskinesia. Detailed results from this trial will be presented at a future medical conference. In April 2021, MTPC submitted a Marketing Authorization Application (MAA) with the Ministry of Health and Welfare in Japan for valbenazine for the treatment of tardive dyskinesia. MTPC submission of valbenazine triggered a milestone payment of $15 million, to be paid by MTPC to Neurocrine Biosciences and recognized as collaboration revenue in the second quarter of 2021.
- In February 2021, the Company notified Voyager Therapeutics, Inc. (Voyager) of the Company's termination of the NBIb-1817 (VY-AADC) development program in Parkinson's disease (the Program). The Company will work to transfer the rights to the Program to Voyager by August 2, 2021.
- On March 2, 2021, the Company announced that investigational drug luvadaxistat (NBI-1065844/TAK-831) did not meet its primary endpoint in the Phase II INTERACT study in adults with negative symptoms of schizophrenia. Luvadaxistat met both secondary endpoints of cognitive assessment. The Company plans to initiate a Phase II study for the treatment of cognitive impairment associated with schizophrenia (CIAS) by the end of 2021.
- In April 2021, the U.S. Food and Drug Administration (FDA) approved a 60 mg INGREZZA capsule for the treatment of adults with tardive dyskinesia. The 60 mg capsule of INGREZZA is expected to be available to patients by late second quarter 2021.

Full-Year 2021 Revised Expense Guidance

	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

- Previously, the Company expected combined GAAP R&D and SG&A expenses in the range of $800 million to $850 million and combined non-GAAP R&D and SG&A expenses in the range of $675 million to $725 million
- Increase to GAAP and Non-GAAP expense guidance range primarily driven by investment in INGREZZA direct-to-consumer marketing campaign, "TD Spotlight"
- GAAP-only guidance includes approximately $130 million of share-based compensation. GAAP-only guidance does not include any potential milestones or in-process research and development 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	Registrational Top-Line Data Expected by Year-End
	Tardive Dyskinesia	MTPC Submitted Marketing Authorization with Ministry of Health and Welfare in Japan
	Neurological Indication	Initiate Registrational Study
	Psychiatric Indication	Initiate Registrational Study
Crinecerfont	Congenital Adrenal Hyperplasia (Adult)	Enrolling Registrational Study
	Congenital Adrenal Hyperplasia (Pediatric)	Enrolling Registrational Study
Luvadaxistat (NBI-1065844)	Cognitive Impairment Associated with Schizophrenia (CIAS)	Initiate Phase II Study
NBI-1065845	Inadequate Response to Treatment in Major Depressive Disorder (MDD)	Initiate Phase II Study
NBI-1065846	Anhedonia in Depression	Initiate Phase II Study
NBI-827104	Rare Pediatric Epilepsy: Epileptic Encephalopathy with Continuous Spike and Wave During Sleep (CSWS)	Enrolling Phase II Study
	Essential Tremor	Enrolling Phase II Study
NBI-921352	Focal-Onset Seizure in Adults	Initiate Phase II
	Rare Pediatric Epilepsy: SCN8A Developmental Epileptic Encephalopathy (SCN8A-DEE)	Initiate Phase II

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 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 launch of ONGENTYS; our financial and operating performance, including our future expenses; 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 and maintain business continuity, including our ability to protect the safety and well-being of our employees, to continue to support uninterrupted supply of INGREZZA, patient in-person access to their healthcare provider, to continue our ongoing clinical trials and other development activities, 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 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 quarantines, shelter-in-place, social distancing and other government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our and our customers' business operations and the business operations of the third parties on which we rely; 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 March 31, 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 March 31,	
(in millions, except per share data)	**2021**	**2020**
Revenues:		
Product sales, net	$ 231.0	$ 231.1
Collaboration revenue	5.6	6.0
Total revenues	236.6	237.1
Operating expenses:		
Cost of sales	2.9	2.1
Research and development	73.2	58.3
Selling, general and administrative	129.0	117.8
Total operating expenses	205.1	178.2
Operating income	31.5	58.9
Other (expense) income:		
Interest expense	(6.4)	(8.2)
Unrealized gain (loss) on equity securities	0.7	(16.5)
Investment income and other, net	1.4	4.7
Total other expense, net	(4.3)	(20.0)
Income before (benefit from) provision for income taxes	27.2	38.9
(Benefit from) provision for income taxes	(4.9)	1.5
Net income	$ 32.1	$ 37.4
Net income per share, basic	$ 0.34	$ 0.40
Net income per share, diluted	$ 0.33	$ 0.39
Weighted average common shares outstanding, basic	94.2	92.6
Weighted average common shares outstanding, diluted	98.2	97.0

TABLE 2

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

	March 31, 2021	December 31, 2020
(in millions)		
Cash, cash equivalents and debt securities available-for-sale	$ 873.7	$ 801.0
Other current assets	211.7	215.2
Total current assets	1,085.4	1,016.2
Deferred tax assets	325.6	319.4
Debt securities available-for-sale	249.6	227.1
Right-of-use assets	97.0	82.8
Equity securities	38.9	38.2
Property and equipment, net	45.3	44.6
Restricted cash and other long-term assets	4.6	6.4

Total assets	$ 1,846.4	$ 1,734.7
Total current liabilities	$ 190.0	$ 186.5
Convertible senior notes	322.0	317.9
Operating lease liabilities	107.5	94.4
Other long-term liabilities	21.3	9.7
Stockholders' equity	1,205.6	1,126.2
Total liabilities and stockholders' equity	$ 1,846.4	$ 1,734.7

TABLE 3

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

	Three Months Ended March 31,	
(in millions, except per share data)	**2021**	**2020**
GAAP net income	$ 32.1	$ 37.4
Adjustments:		
Non-cash collaboration revenue [A]	(1.1)	(1.3)
Share-based compensation expense - R&D	15.0	7.7
Share-based compensation expense - SG&A	17.9	15.1
Non-cash interest related to convertible senior notes	4.2	5.3
Changes in fair value of equity security investments [B]	(0.7)	16.5
Income tax effect related to reconciling items [C]	(19.5)	(1.6)
Non-GAAP net income	$ 47.9	$ 79.1
Net income per diluted common share:		
GAAP	$ 0.33	$ 0.39
Non-GAAP	$ 0.49	$ 0.82

[A] The Company recognized non-cash collaboration revenue under the collaboration and license agreement entered into with Mitsubishi Tanabe Pharma Corporation in 2015.

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

[C] Estimated income tax effect of non-GAAP reconciling items are calculated using applicable statutory tax rates, taking into consideration any valuation allowance. On December 31, 2020, the Company released substantially all of its valuation allowance against its net operating losses and other deferred tax assets. First quarter of 2021, also includes adjustment to exclude the excess tax benefits related to stock compensation.

TABLE 4

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

	Three Months Ended March 31,	
(in millions)	**2021**	**2020**
GAAP R&D	$ 73.2	$ 58.3
Adjustments:		
Share-based compensation expense	15.0	7.7
Non-GAAP R&D	$ 58.2	$ 50.6
GAAP SG&A	$ 129.0	$ 117.8
Adjustments:		
Share-based compensation expense	17.9	15.1

Non-GAAP SG&A	$ 111.1	$ 102.7

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SOURCE Neurocrine Biosciences, Inc.

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