Neurocrine Biosciences Reports Fourth Quarter and Full-Year 2020 Financial Results

February 4, 2021

Total Annual Revenues in 2020 Grew 33% to Over $1 Billion
INGREZZA® (valbenazine) Full Year 2020 Net Product Sales and TRx Both Grew 32% to $993 Million and Approximately 175,700 TRx, Respectively
Mitsubishi Tanabe Pharma Corporation (MTPC) Reports Successful Top-Line Results for Asia-Based J-KINECT Phase III Study to Evaluate the Efficacy and Safety of Valbenazine in Tardive Dyskinesia

SAN DIEGO, Feb. 4, 2021 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the fourth quarter and full-year ended December 31, 2020 and provided full-year 2021 financial expense guidance.

"In 2020, we served more patients with tardive dyskinesia than ever before despite the pandemic weighing on the development of the overall market. We are pleased with the recently updated guidelines from the American Psychiatric Association that now recommend first-line treatment for tardive dyskinesia with a VMAT2 inhibitor, which we hope will benefit even more patients as the vast majority of patients living with tardive dyskinesia remain undiagnosed," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "In 2021, we plan to initiate eight mid-to-late stage clinical studies and look forward to important data read-outs for NBI-1065844 in the negative symptoms of schizophrenia and valbenazine for the treatment of chorea associated with Huntington's Disease."

Financial Highlights

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(unaudited, in millions, except per share data)	**2020**	**2019**	**2020**	**2019**
Revenues:				
Product sales, net	$ 241.3	$ 237.9	$ 994.1	$ 752.9
Collaboration revenue	6.6	6.2	51.8	35.2
Total revenues	$ 247.9	$ 244.1	$ 1,045.9	$ 788.1
GAAP Research and Development (R&D)	$ 66.7	$ 55.3	$ 275.0	$ 200.0
Non-GAAP R&D	$ 59.4	$ 47.9	$ 221.3	$ 164.2
GAAP Selling, General and Administrative (SG&A)	$ 106.5	$ 101.3	$ 433.3	$ 354.1
Non-GAAP SG&A	$ 92.8	$ 87.4	$ 367.0	$ 304.6
GAAP net income	$ 347.9	$ 34.0	$ 407.3	$ 37.0
GAAP net income per share – diluted	$ 3.58	$ 0.35	$ 4.16	$ 0.39
Non-GAAP net income	$ 88.1	$ 102.2	$ 402.3	$ 283.8
Non-GAAP net income per share – diluted	$ 0.91	$ 1.05	$ 4.11	$ 2.96

(unaudited, in millions)	December 31, 2020	December 31, 2019
Total cash, cash equivalents and debt securities available-for-sale	$ 1,028.1	$ 970.2

Fourth Quarter and Full-Year Net Product Sales and Revenues Highlights:

- INGREZZA net product sales for the fourth quarter and full-year 2020 were $240 million and $993 million, respectively, representing an increase of 1% and 32% versus respective 2019 comparable periods
- INGREZZA inventory adjusted net product sales for the fourth quarter of 2020 were $258 million representing 4%

sequential growth vs. the third quarter of 2020
- INGREZZA end of fourth quarter 2020 days-on-hand channel inventory decreased by $18 million relative to the third quarter
- INGREZZA new prescriptions increased in the fourth quarter of 2020 vs. the third quarter of 2020
- Refill and persistency rates continued to be strong for existing INGREZZA patients
- ONGENTYS launched in the United States in late September 2020 and net product sales for the fourth quarter of 2020 were approximately $1 million reflecting growing uptake throughout the quarter
- Elagolix royalties received from AbbVie on combined fourth quarter 2020 net sales of ORILISSA® (elagolix tablets) and ORIAHNN™ (elagolix, estradiol and norethindrone acetate capsules and elagolix capsules) totaled $6 million

Financial Highlights:

- Fourth quarter 2020 GAAP net income and diluted earnings per share were approximately $348 million and $3.58, respectively, compared with approximately $34 million and $0.35, respectively, in the fourth quarter of 2019, primarily driven by a non-cash tax benefit of $296 million related to the release of substantially all of the Company's valuation allowance against its deferred tax assets on December 31, 2020
- Fourth quarter 2020 non-GAAP net income and diluted earnings per share were approximately $88 million and $0.91, respectively, compared with approximately $102 million and $1.05, respectively, in the fourth quarter of 2019 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 marketing initiatives and higher headcount costs
- 2020 full-year GAAP and non-GAAP net income of $407 million and $402 million, respectively, represents year-over-year growth of approximately 10 times and 41%, respectively
- Total debt outstanding decreased by $136 million to $381 million after repurchase of approximately 26% of debt outstanding during the fourth quarter of 2020. The total aggregate repurchase price of $187 million was paid in cash and the transaction resulted in an $18 million loss recognized during the fourth quarter of 2020.
- At December 31, 2020, the Company had cash, cash equivalents and debt securities available-for-sale of $1.0 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.

Income Tax Benefit:
The Company's fourth quarter financial results include the reversal of substantially all of the valuation allowance recorded against the deferred tax assets of the Company. This reversal resulted in the recognition of a non-cash income tax benefit in the fourth quarter 2020 of $296 million, or $3.05 earnings per diluted share. The Company has performed a continuing evaluation of its deferred tax asset valuation allowance on a quarterly basis. The Company has now concluded that, as of December 31, 2020, it is more likely than not that the Company will generate sufficient taxable income within the applicable net operating loss and R&D carryforward periods to realize substantially all of its deferred tax assets. This conclusion, and the resulting reversal of the deferred tax asset valuation allowance, is based upon consideration of a number of factors, including the Company's strong financial performance over the past few years and its forecast of future profitability.

After recognizing the valuation allowance reversal, the Company's net deferred tax assets totaled $319 million at December 31, 2020, net of a valuation allowance of $50 million. The ability to recognize the remaining deferred tax assets that continue to be subject to a valuation allowance will be evaluated on a quarterly basis to determine if there are significant events that would affect the Company's ability to utilize these deferred tax assets. As a result of this reversal, the Company will begin recording federal and state tax expense on its earnings beginning in the first quarter of 2021. No federal cash tax is expected in 2021 based upon a net operating loss position of approximately $500 million entering 2021.

Recent Events

- In October 2020, the U.S. Food and Drug Administration (FDA) requested additional non-clinical data to support the Investigational New Drug Application (IND) we submitted in August 2020 in support of a Phase II clinical study for NBI-921352 in patients with SCN8A Developmental Epileptic Encephalopathy (SCN8A-DEE). Based on feedback received in January 2021, we plan to initiate a Phase II clinical study in adolescent patients (aged 12 years and older) with SCN8A-DEE in the third quarter of 2021, and the study protocol will be amended to include younger pediatric patients (aged 2-11 years) with SCN8A-DEE as soon as the FDA has reviewed and approved additional non-clinical information. We are also advancing clinical plans to initiate a Phase II clinical study of NBI-921352 for the treatment of adult focal epilepsy in 2021. In addition, in October 2020, we announced the FDA granted us Rare Pediatric Disease Designation for NBI-921352 for the treatment of SCN8A-DEE.
- In November 2020, the Company announced the initiation of a Phase II study of NBI-827104 (formerly ACT-709478) in Epileptic Encephalopathy with Continuous Spike and Wave during Sleep (CSWS), a rare pediatric epilepsy. NBI-827104 was licensed from Idorsia and is a potent, selective, orally active and brain penetrating T-type calcium channel blocker.
- 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. With positive data in hand, a marketing authorization with the Ministry of Health and Welfare is planned for 2021 in Japan. In addition, MTPC submitted filings for marketing authorization in South Korea, Thailand, Singapore, Indonesia, and Malaysia in 2020.

- 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.

Full-Year 2021 Expense Guidance

	Range	
(in millions)	**Low**	**High**
Combined GAAP R&D and SG&A expenses	$800	$850
Combined Non-GAAP R&D and SG&A expenses	$675	$725

- GAAP and Non-GAAP expense guidance range reflects increased investment in:
  - R&D expense including meaningful investments in collaboration programs (specifically with Idorsia, Xenon and Takeda) and the planned initiation of eight mid-to-late-stage clinical studies
  - INGREZZA and ONGENTYS marketing costs
- GAAP-only guidance includes approximately $125 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's Disease	Phase III Top-Line Data Expected in Q4 2021
	Tardive Dyskinesia	Marketing Authorization with Ministry of Health and Welfare in Japan
	Neurological Indication	Initiate Phase III Registrational Study
	Psychiatric Indication	Initiate Registrational Study
Crinecerfont	Congenital Adrenal Hyperplasia (Adult)	Continue Phase III Registrational Study Enrollment
	Congenital Adrenal Hyperplasia (Pediatric)	Initiate Phase III Registrational Study
NBI-1065844	Negative Symptoms of Schizophrenia	Phase II Top-Line Data Expected in Q1 2021
NBI-1065845	Treatment Resistant Depression	Initiate Phase II
NBI-1065846	Anhedonia in Depression	Initiate Phase II
NBI-827104	Rare Pediatric Epilepsy: CSWS	Continue Phase II Enrollment
	Neurological Indication	Initiate Phase II
NBI-921352	Focal Onset Seizure in Adults	Initiate Phase II
	Rare Pediatric Epilepsy: 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 September 30, 2020. Neurocrine 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 December 31,		Twelve Months Ended December 31,	
(in millions, except per share data)	**2020**	**2019**	**2020**	**2019**
Revenues:				
Product sales, net	$ 241.3	$ 237.9	$ 994.1	$ 752.9
Collaboration revenue	6.6	6.2	51.8	35.2
Total revenues	247.9	244.1	1,045.9	788.1
Operating expenses:				
Cost of sales	2.9	2.5	10.1	7.4
Research and development	66.7	55.3	275.0	200.0
Acquired in-process research and development	—	36.2	164.5	154.3
Selling, general and administrative	106.5	101.3	433.3	354.1
Total operating expenses	176.1	195.3	882.9	715.8
Operating income	71.8	48.8	163.0	72.3
Other (expense) income:				
Interest expense	(7.8)	(8.2)	(32.8)	(32.0)
Unrealized loss on equity securities	(5.5)	(7.2)	(17.7)	(13.0)
Loss on extinguishment of convertible senior notes	(18.4)	—	(18.4)	—
Investment income and other, net	1.6	5.2	12.6	19.2
Total other expense, net	(30.1)	(10.2)	(56.3)	(25.8)
Income before (benefit from) provision for income taxes	41.7	38.6	106.7	46.5

(Benefit from) provision for income taxes	(306.2)	4.6	(300.6)	9.5
Net income	$ 347.9	$ 34.0	$ 407.3	$ 37.0
Net income per share, basic	$ 3.72	$ 0.37	$ 4.38	$ 0.40
Net income per share, diluted	$ 3.58	$ 0.35	$ 4.16	$ 0.39
Weighted average common shares outstanding, basic	93.5	92.2	93.1	91.6
Weighted average common shares outstanding, diluted	97.2	97.2	97.8	95.7

TABLE 2

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

(in millions)	**December 31, 2020**	**December 31, 2019**
Cash, cash equivalents and debt securities available-for-sale	$ 801.0	$ 670.5
Other current assets	215.2	160.5
Total current assets	1,016.2	831.0
Debt securities available-for-sale	227.1	299.7
Right-of-use assets	82.8	74.3
Equity securities	38.2	55.9
Property and equipment, net	44.6	41.9
Deferred tax assets	319.4	—
Restricted cash and other long-term assets	6.4	3.2
Total assets	$ 1,734.7	$ 1,306.0
Convertible senior notes	$ —	$ 408.8
Other current liabilities	186.5	156.5
Total current liabilities	186.5	565.3
Convertible senior notes	317.9	—
Operating lease liabilities	94.4	86.7
Other long-term liabilities	9.7	17.1
Stockholders' equity	1,126.2	636.9
Total liabilities and stockholders' equity	$ 1,734.7	$ 1,306.0

TABLE 3

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

	Three Months Ended December 31,		**Twelve Months Ended December 31,**	
(in millions, except per share data)	**2020**	**2019**	**2020**	**2019**
GAAP net income	$ 347.9	$ 34.0	$ 407.3	$ 37.0
Adjustments:				
Milestones received from licenses and collaborations [A]	—	—	(30.0)	(20.0)
Non-cash collaboration revenue [B]	(0.9)	(0.9)	(2.7)	(0.9)
Acquired in-process research and development (IPR&D) [C]	—	36.2	164.5	154.3
Milestones paid related to licenses and collaborations - R&D	—	—	20.0	10.0
Share-based compensation expense - R&D	7.3	7.4	33.7	25.8
Share-based compensation expense - SG&A	13.7	13.9	66.3	49.5
Loss on extinguishment of convertible senior notes [D]	18.4	—	18.4	—
Non-cash interest related to convertible senior notes	5.2	5.2	21.4	20.3
Changes in fair value of equity security investments [E]	5.5	7.2	17.7	13.0
Income tax effect related to reconciling items [F]	(309.0)	(0.8)	(314.3)	(5.2)
Non-GAAP net income	$ 88.1	$ 102.2	$ 402.3	$ 283.8
Net income per diluted common share:				
GAAP	$ 3.58	$ 0.35	$ 4.16	$ 0.39

Non-GAAP	$ 0.91	$ 1.05	$ 4.11	$ 2.96

[A] During 2020, the Company recognized a $30.0 million event-based milestone as revenue upon FDA approval for ORIAHNN for uterine fibroids. During 2019, the Company recognized a $20.0 million event-based milestone as revenue upon FDA acceptance of the New Drug Application for elagolix for uterine fibroids.

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

[C] The Company incurred IPR&D expenses of $164.5 million during 2020 in association with the exclusive license agreement entered into with Takeda Pharmaceutical and the collaboration and license agreement entered into with Idorsia Pharmaceuticals. During 2019, the Company incurred IPR&D expenses of $154.3 million in association with collaboration and license agreements entered into with Voyager Therapeutics and Xenon Pharmaceuticals.

[D] The Company recognized a loss on extinguishment of $18.4 million related to the partial repurchase of its convertible debt in the fourth quarter of 2020.

[E] The Company recognized an unrealized loss to adjust its equity security investments to fair value.

[F] Estimated income tax effect of non-GAAP reconciling items are calculated using applicable statutory tax rates, taking into consideration any valuation allowance. In the fourth quarter of 2020, the Company recognized a non-cash tax benefit of approximately $296 million related to the release of substantially all of its valuation allowance against its deferred tax assets on December 31, 2020. The fourth quarter 2020 benefit associated with the valuation allowance release has been excluded from non-GAAP net income.

TABLE 4

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions)	**2020**	**2019**	**2020**	**2019**
GAAP R&D	$ 66.7	$ 55.3	$ 275.0	$ 200.0
Adjustments:				
Milestones paid related to licenses and collaborations	—	—	20.0	10.0
Share-based compensation expense	7.3	7.4	33.7	25.8
Non-GAAP R&D	$ 59.4	$ 47.9	$ 221.3	$ 164.2
GAAP SG&A	$ 106.5	$ 101.3	$ 433.3	$ 354.1
Adjustments:				
Share-based compensation expense	13.7	13.9	66.3	49.5
Non-GAAP SG&A	$ 92.8	$ 87.4	$ 367.0	$ 304.6

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SOURCE Neurocrine Biosciences, Inc.

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