Neurocrine Biosciences Reports Fourth Quarter and Full-Year 2019 Financial Results

February 4, 2020

INGREZZA® (valbenazine) Fourth Quarter Net Product Sales of $238 Million with Approximately 42,100 TRx
INGREZZA® (valbenazine) Full-Year 2019 Net Product Sales of $753 Million with Approximately 132,700 TRx

SAN DIEGO, Feb. 4, 2020 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the fourth quarter and full-year ended December 31, 2019 and provided full-year 2020 financial expense guidance.

"I am very pleased with the accomplishments of Neurocrine Biosciences this past year, including our quarterly and full-year business results. We anticipate an exciting year ahead as we continue to build a leading global neuroscience-focused biopharmaceutical company," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "In 2020, we will continue to focus on educating healthcare providers, caregivers and patients to help even more people suffering from the debilitating movements caused by tardive dyskinesia. In addition, we look forward to helping patients with Parkinson's disease with the anticipated approval of opicapone and the potential expanded use of elagolix to help women with uterine fibroids. By mid-2020, our activities position us to have three approved treatments in four indications and three additional ongoing pivotal studies."

Fourth Quarter and Full-Year 2019 Financial Highlights

	Three Months Ended December 31,		Year Ended December 31,	
(unaudited, in millions, except per share data)	**2019**	**2018**	**2019**	**2018**
Revenues:				
INGREZZA product sales, net	$ 237.9	$ 130.3	$ 752.9	$ 409.6
Collaboration revenue	6.2	1.1	35.2	41.6
Total revenues	$ 244.1	$ 131.4	$ 788.1	$ 451.2
GAAP R&D	$ 55.3	$ 34.5	$ 200.0	$ 155.8
Non-GAAP R&D	$ 47.9	$ 29.9	$ 164.2	$ 119.6
GAAP SG&A	$ 101.3	$ 69.0	$ 354.1	$ 248.9
Non-GAAP SG&A	$ 87.4	$ 60.5	$ 304.6	$ 217.1
GAAP net income	$ 34.0	$ 18.0	$ 37.0	$ 21.1
GAAP net income per share – diluted	$ 0.35	$ 0.19	$ 0.39	$ 0.22
Non-GAAP net income	$ 102.2	$ 38.4	$ 283.8	$ 70.5
Non-GAAP net income per share – diluted	$ 1.05	$ 0.40	$ 2.96	$ 0.74

	December 31,	
(unaudited, in millions)	**2019**	**2018**
Cash, cash equivalents and marketable securities	$ 970.2	$ 866.9

Fourth Quarter and Full Year Net Product Sales Highlights:

- INGREZZA® (valbenazine) net product sales for the fourth quarter and full year 2019 were $238 million and $753 million respectively, representing an increase of over 80% versus prior period comparisons.
- Continued strength in INGREZZA new patient additions in the fourth quarter.
- End of fourth quarter 2019 days-on-hand channel inventory increased relative to the third quarter 2019 due to timing of

quarter-end purchases resulting in an approximate $11 million benefit to net product sales.

Financial Highlights:

- Research and Development (R&D) investment increased in the fourth quarter of 2019 versus the fourth quarter of 2018 primarily as a result of the Company's ongoing activities in congenital adrenal hyperplasia studies and in gene therapy partially offset by prior year spending on the Tourette syndrome program.
- Selling, General and Administrative (SG&A) investment increased in the fourth quarter of 2019 versus the fourth quarter of 2018, primarily as a result of the patient-focused disease state awareness campaign, "Talk About TD", and an increase in the Branded Pharmaceutical Drug, or BPD, fee expense.
- In-Process Research and Development (IPR&D) expense of $36 million in the fourth quarter of 2019 reflects the Company's collaboration with Xenon Pharmaceuticals specific to NBI-921352 (XEN901) for epilepsy.
- Fourth quarter of 2019 GAAP net income and diluted earnings per share (EPS) were $34 million and $0.35, respectively, compared to $18 million and $0.19, respectively, in the fourth quarter of 2018.
- Fourth quarter of 2019 non-GAAP net income and diluted earnings per share (EPS) were $102 million and $1.05, respectively, compared to $38 million and $0.40, respectively, in the fourth quarter of 2018.
- As of December 31, 2019, the Company had cash, cash equivalents and marketable securities totaling $970 million.

A reconciliation of GAAP to non-GAAP quarterly financial results can be found in Tables 3 through 5 at the end of this earnings release.

Recent Events

- In December 2019, the Company entered into a license and collaboration agreement with Xenon, a clinical-stage biopharmaceutical company. Pursuant to the terms of the agreement, the Company gained an exclusive license to NBI-921352, a clinical-stage selective Nav1.6 sodium channel inhibitor with potential in SCN8A developmental and epileptic encephalopathy (SCN8A-DEE) and other forms of epilepsy, including focal epilepsy. Upon filing of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in mid-2020, the Company intends to start a Phase II study in SCN8A-DEE patients in 2H 2020.
- In January 2020, the Company announced an option agreement that was originally signed in 2019 with Idorsia granting the Company an option to license ACT-709478, a potent, selective, orally-active, and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy. A Phase II study in a rare pediatric epilepsy is planned in 2H 2020 dependent upon IND application acceptance by the FDA in mid-2020.

Full-Year 2020 Financial Guidance

	Range	
(in millions)	**Low**	**High**
Combined GAAP R&D and SG&A expenses	$740	$770
Combined Non-GAAP R&D and SG&A expenses	$620	$650

- GAAP and Non-GAAP expense guidance range reflects increased investment in R&D programs including three registrational programs, meaningful investments across early stage programs including Voyager and Xenon collaborations, continued investment in INGREZZA and marketing costs associated with the anticipated launch of opicapone.
- GAAP-only guidance includes approximately $100 million of share-based compensation and a $20 million expected milestone payment to BIAL connected with the expected approval of opicapone by the FDA during the second quarter. GAAP-only guidance does not include any other potential milestones or in-process research and development costs associated with current collaborations or future business development activities.

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 877-876-9173 (US) or 785-424-1667 (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 INGREZZA® (valbenazine) Capsules
INGREZZA, a selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is the first FDA-approved product indicated for the treatment of adults with tardive dyskinesia, a condition associated with uncontrollable, abnormal and repetitive movements of the face, torso, and/or other body parts.

INGREZZA is thought to work by reducing the amount of dopamine released in a region of the brain that controls movement and motor function, helping to regulate nerve signaling in adults with tardive dyskinesia. VMAT2 is a protein in the brain that packages neurotransmitters, such as dopamine, for transport and release from presynaptic neurons. INGREZZA, developed in Neurocrine's

laboratories, is novel in that it selectively inhibits VMAT2 with no appreciable binding affinity for VMAT1, dopaminergic (including D2), serotonergic, adrenergic, histaminergic, or muscarinic receptors. Additionally, INGREZZA can be taken for the treatment of tardive dyskinesia as one capsule, once-daily, together with psychiatric medications such as antipsychotics or antidepressants.

Important Safety Information
Contraindications
INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

Warnings & Precautions
Somnolence
INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

QT Prolongation
INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

Parkinsonism
INGREZZA may cause Parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

Adverse Reactions
The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at **www.fda.gov/medwatch** or call 1-800-FDA-1088.

Please see INGREZZA full Prescribing Information at www.INGREZZA.com/PI.

About Neurocrine Biosciences
Neurocrine Biosciences (Nasdaq: NBIX) is a neuroscience-focused, biopharmaceutical company with more than 25 years of experience discovering and developing 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 and endometriosis* and clinical development programs in multiple therapeutic areas including Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, epilepsy, uterine fibroids* and polycystic ovary syndrome*. Headquartered in San Diego, Neurocrine Biosciences specializes 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 certain non-GAAP financial measures. When preparing these supplemental 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, the non-GAAP measures exclude: milestones 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 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 the 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: our preliminary unaudited financial information; the benefits to be derived from our products and product candidates, including INGREZZA and our partnered product, ORILISSA; the value INGREZZA, ORILISSA, and/or our product candidates may bring to patients; the continued success of the

launch of INGREZZA; AbbVie's launch of ORILISSA; the opicapone NDA; our financial and operating performance, including our future expenses; our collaborative partnerships; and the timing of 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: risks and uncertainties associated with items that may be identified during the financial statement closing process that cause adjustments to the estimates included in this press release; our future financial and operating performance; risks associated with the commercialization of INGREZZA and ORILISSA; risks that the opicapone NDA may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks related to the development of our product candidates; risks associated with our dependence on third parties for development and manufacturing activities related to INGREZZA and our 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 the continued development of elagolix; risks associated with our dependence on BIAL for development and manufacturing activities related to opicapone, and our ability to manage BIAL; risks that clinical development activities may not be completed on time or at all, or may be delayed for regulatory, manufacturing, 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, 2019. 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 INCOME
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in millions, except per share data)	**2019**	**2018**	**2019**	**2018**
Revenues:				
Product sales, net	$ 237.9	$ 130.3	$ 752.9	$ 409.6
Collaboration revenue	6.2	1.1	35.2	41.6
Total revenues	244.1	131.4	788.1	451.2
Operating expenses:				
Cost of sales	2.5	1.4	7.4	4.9
Research and development	55.3	34.5	200.0	155.8
Acquired in-process research and development	36.2	4.8	154.3	4.8
Selling, general and administrative	101.3	69.0	354.1	248.9
Total operating expenses	195.3	109.7	715.8	414.4
Operating income	48.8	21.7	72.3	36.8
Other (expense) income:				
Interest expense	(8.2)	(7.7)	(32.0)	(30.5)
Unrealized loss on restricted equity securities	(7.2)	—	(13.0)	—
Investment income and other, net	5.2	4.7	19.2	15.5
Total other expense, net	(10.2)	(3.0)	(25.8)	(15.0)
Income before provision for income taxes	38.6	18.7	46.5	21.8
Provision for income taxes	4.6	0.7	9.5	0.7
Net income	$ 34.0	$ 18.0	$ 37.0	$ 21.1
Net income per share, basic	$ 0.37	$ 0.20	$ 0.40	$ 0.23
Net income per share, diluted	$ 0.35	$ 0.19	$ 0.39	$ 0.22
Weighted average common shares outstanding, basic	92.2	90.7	91.6	90.2
Weighted average common shares outstanding, diluted	97.2	95.7	95.7	95.4

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

	December 31,	
(in millions)	**2019**	**2018**
Cash, cash equivalents and marketable securities	$ 670.5	$ 650.9
Other current assets	160.5	86.9
Total current assets	831.0	737.8

Property and equipment, net	41.9	33.9
Marketable securities	299.7	216.0
Restricted equity securities	55.9	—
Operating lease assets	74.3	—
Restricted cash	3.2	5.5
Total assets	$1,306.0	$993.2
Convertible senior notes	$ 408.8	$ —
Other current liabilities	156.5	88.2
Total current liabilities	565.3	88.2
Noncurrent operating lease liabilities	86.7	—
Convertible senior notes	—	388.5
Other long-term liabilities	17.1	35.7
Stockholders' equity	636.9	480.8
Total liabilities and stockholders' equity	$1,306.0	$993.2

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)	**2019**	**2018**	**2019**	**2018**
GAAP net income	$ 34.0	$ 18.0	$ 37.0	$ 21.1
Adjustments:				
Milestones received from licenses and collaborations [A]	—	—	(20.0)	(40.0)
Non-cash collaboration revenue [B]	(0.9)	—	(0.9)	—
Acquired in-process research and development (IPR&D) [C]	36.2	4.8	154.3	4.8
Milestones paid related to licenses and collaborations – R&D [D]	—	—	10.0	10.0
Share-based compensation expense – R&D	7.4	4.6	25.8	26.2
Share-based compensation expense – SG&A	13.9	8.5	49.5	31.8
Non-cash interest related to convertible debt	5.2	4.8	20.3	18.9
Changes in fair value of equity security investments [E]	7.2	—	13.0	—
Income tax effect related to reconciling items [F]	(0.8)	(2.3)	(5.2)	(2.3)
Non-GAAP net income	$ 102.2	$ 38.4	$ 283.8	$ 70.5
Net income per diluted common share:				
GAAP	$ 0.35	$ 0.19	$ 0.39	$ 0.22
Non-GAAP	$ 1.05	$ 0.40	$ 2.96	$ 0.74

[A] During the third quarter of 2019 and third quarter of 2018, the Company recognized event-based milestones from AbbVie of $20.0 million and $40.0 million, respectively, for regulatory milestones associated with elagolix.

[B] During the fourth quarter of 2019, the Company recognized non-cash collaboration revenue from Mitsubishi Tanabe Pharma Corporation (MTPC) under the collaboration and license agreement entered into in 2015.

[C] During 2019, the Company incurred IPR&D expenses of $118.1 million and $36.2 million, respectively, in association with collaboration and license agreements entered into with Voyager and Xenon and $4.8 million in association with a research collaboration agreement entered into with Jnana Therapeutics Inc during fourth quarter of 2018.

[D] During each of the second quarter of 2019 and first quarter of 2018, the Company incurred milestone expenses of $10.0 million related to event-based milestones for opicapone related to the Company's collaboration with BIAL.

[E] The Company's investments include equity security investments in Voyager and Xenon. The Company recognized unrealized losses of $7.2 million for the fourth quarter of 2019 and $13.0 million for full-year 2019 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.

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

	Three Months Ended	Year Ended

(in millions, except per share data)	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019	December 31, 2019
GAAP net income	$ (102.1)	$ 51.3	$ 53.8	$ 34.0	$ 37.0
Adjustments:					
Milestones received from licenses and collaborations [A]	—	—	(20.0)	—	(20.0)
Non-cash collaboration revenue [B]	—	—	—	(0.9)	(0.9)
Acquired in-process research and development (IPR&D) [C]	113.1	5.0	—	36.2	154.3
Milestones paid related to licenses and collaborations – R&D [D]	—	10.0	—	—	10.0
Share-based compensation expense – R&D	5.4	6.0	7.0	7.4	25.8
Share-based compensation expense – SG&A	10.4	11.9	13.3	13.9	49.5
Non-cash interest related to convertible debt	4.9	5.1	5.1	5.2	20.3
Changes in fair value of equity security investments [E]	(1.7)	(21.0)	28.5	7.2	13.0
Income tax effect related to reconciling items [F]	(2.3)	(1.1)	(1.0)	(0.8)	(5.2)
Non-GAAP net income	$ 27.7	$ 67.2	$ 86.7	$ 102.2	$ 283.8
Net income per diluted common share:					
GAAP	$ (1.12)	$ 0.54	$ 0.56	$ 0.35	$ 0.39
Non-GAAP	$ 0.29	$ 0.71	$ 0.90	$ 1.05	$ 2.96

[A] During the third quarter of 2019, the Company recognized a $20.0 million event-based milestone as revenue upon FDA acceptance of AbbVie's NDA submission of elagolix for the treatment of uterine fibroids.

[B] During the fourth quarter of 2019, the Company recognized non-cash collaboration revenue from MTPC under the collaboration and license agreement entered into in 2015.

[C] The Company incurred IPR&D expenses of $118.1 million and $36.2 million, respectively, in association with collaboration and license agreements entered into with Voyager and Xenon during 2019.

[D] During the second quarter of 2019, the Company incurred milestone expenses of $10.0 million related to FDA acceptance of the opicapone NDA for Parkinson's disease.

[E] The Company's investments include equity security investments in Voyager and Xenon. The Company recognized unrealized (gains) losses 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.

TABLE 5
NEUROCRINE BIOSCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(unaudited)

	Three Months Ended				Year Ended
(in millions, except per share data)	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018	December 31, 2018
GAAP net income (loss)	$ (41.8)	$ (5.9)	$ 50.8	$ 18.0	$ 21.1
Adjustments:					
Milestones received from licenses and collaborations [A]	—	—	(40.0)	—	(40.0)
Acquired in-process research and development (IPR&D) [B]	—	—	—	4.8	4.8
Milestones paid related to licenses and collaborations – R&D [C]	10.0	—	—	—	10.0
Share-based compensation expense – R&D	12.6	4.3	4.7	4.6	26.2
Share-based compensation expense – SG&A	7.3	7.6	8.4	8.5	31.8
Non-cash interest related to convertible debt	4.6	4.7	4.8	4.8	18.9
Income tax effect related to reconciling items [D]	—	—	—	(2.3)	(2.3)
Non-GAAP net income (loss)	$ (7.3)	$ 10.7	$ 28.7	$ 38.4	$ 70.5
Net income (loss) per diluted common share:					
GAAP	$ (0.47)	$ (0.07)	$ 0.52	$ 0.19	$ 0.22
Non-GAAP	$ (0.08)	$ 0.11	$ 0.30	$ 0.40	$ 0.74

[A] During the third quarter of 2018, the Company recognized a $40.0 million event-based milestone as revenue related to FDA approval of ORILISSA.

[B] During the fourth quarter of 2018, the Company made a $4.8 million upfront payment in association with a research collaboration agreement entered into with Jnana Therapeutics Inc.

[C] During the first quarter of 2018, the Company incurred milestone expenses of $10.0 million related to guidance received from the FDA in which it did not request an additional Phase III clinical trial to support an NDA submission for opicapone.

[D] Estimated income tax effect of non-GAAP reconciling items are calculated using applicable statutory tax rates, taking into consideration any valuation allowance.

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SOURCE Neurocrine Biosciences, Inc.

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