Neurocrine Biosciences Reports Third Quarter 2019 Financial Results

November 4, 2019

INGREZZA® (valbenazine) Third Quarter Net Product Sales of $198.1 Million with Approximately 34,800 TRx
Initiated KINECT-HD Phase III Study of Valbenazine to Treat Chorea in Patients with Huntington's Disease

SAN DIEGO, Nov. 4, 2019 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter ended September 30, 2019 and provided an update on the launch of INGREZZA® (valbenazine) and its clinical development programs.

"We are pleased that a record number of new patients initiated treatment with INGREZZA as healthcare providers continue to recognize and treat the involuntary movements associated with tardive dyskinesia," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "Our development programs continue to progress including engagement with regulatory agencies on the adult CAH pivotal trial design. We remain focused on providing patients with access to INGREZZA and preparing for the approval of opicapone in the U.S., while investing strategically to position the company as a leading global biopharmaceutical organization."

Financial Results

Total revenues for the three and nine months ended September 30, 2019, were $222.1 million and $544.1 million, respectively, compared to $151.8 million and $319.7 million for the same periods in 2018.

Total revenues were comprised of the following (*unaudited*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2019**	**2018**	**2019**	**2018**
INGREZZA product sales, net	$ 198,094	$ 111,291	$ 515,069	$ 279,282
Collaboration revenue	24,000	40,466	29,008	40,466
Total revenues	$ 222,094	$ 151,757	$ 544,077	$ 319,748

Collaboration revenue reflects event-based milestones and royalties earned under the Company's collaboration agreement with AbbVie. During the third quarter of 2019, the Company recognized a $20 million event-based milestone as revenue upon the U.S. Food & Drug Administration (FDA) acceptance of AbbVie's New Drug Application (NDA) submission of elagolix for the treatment of uterine fibroids. During the third quarter of 2018, the Company recognized a $40 million event-based milestone as revenue upon the FDA approval of ORILISSA® (elagolix) for the management of endometriosis with associated moderate to severe pain.

For the third quarter of 2019, the Company reported net income of $53.8 million, or $0.56 diluted earnings per share, compared to net income of $50.8 million, or $0.52 diluted earnings per share, for the same period in 2018. The increase in net income is due to increased INGREZZA net product sales partially offset by continued INGREZZA investment and a $28.5 million unrealized loss on the Company's Voyager Therapeutics equity investment. For the nine months ended September 30, 2019, the Company reported net income of $3.0 million, or $0.03 diluted earnings per share, compared to net income of $3.0 million, or $0.03 diluted earnings per share, for the same period in 2018. Net income for the first nine months of 2019 reflects increased INGREZZA net product sales offset by $118.1 million of in-process research and development (IPR&D) in connection with the strategic collaboration with Voyager.

Research and development (R&D) expenses for the three and nine months ended September 30, 2019, were $45.3 million and $144.6 million, respectively, compared to $35.5 million and $121.4 million for the same periods in 2018. The increase in R&D expenses for both periods is primarily due to funding of development activities in connection with the Voyager transaction.

In further connection with the Voyager collaboration, the Company recognized IPR&D of $118.1 million during the first nine months of 2019. In addition, the Company made an equity investment in Voyager which is required to be marked to market each quarter, resulting in an unrealized loss of $28.5 million and $5.8 million for the third quarter and first nine months of 2019, respectively, and is reflected in Other Expense.

Sales, general and administrative (SG&A) expenses for the three and nine months ended September 30, 2019, were $84.5 million and $252.9 million, respectively, compared to $60.4 million and $180.0 million for the same periods in 2018. The increase in SG&A expenses for both periods is primarily due to the sales force expansion completed in the third quarter of 2018, the national launch of a patient-focused disease state awareness campaign, Talk About TD, and an increase in the Branded Pharmaceutical Drug fee expense.

As of September 30, 2019, the Company's cash and available-for-sale investments was $875.0 million.

Updated 2019 SG&A and R&D Expense Guidance

SG&A, IPR&D, and R&D expenses for 2019 are expected to be $658 million to $668 million. Ongoing SG&A and R&D expenses for 2019, excluding IPR&D, are now expected to approximate $540 million to $550 million, which compares to the prior SG&A and R&D expense guidance of $540 million to $570 million.

Pipeline Highlights

Valbenazine Update - Chorea Associated with Huntington's Disease

In September 2019, the Company initiated KINECT-HD, a Phase III study of valbenazine for the treatment of chorea associated with Huntington's disease. This is a multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety and tolerability of once-daily valbenazine in up to 120 adult patients over 12 weeks of treatment. The primary endpoint of this study is the comparison of the change from baseline of the Total Maximal Chorea sub-score of the Unified Huntington's Disease Rating Scale between placebo and active treatment groups using the average of week 10 and week 12 scoring. Top-line data are expected in 2021.

Opicapone Update

In February 2017, the Company entered into an exclusive licensing agreement with BIAL – Portela & CA, S.A. (BIAL) for the development and commercialization of opicapone in the United States and Canada. Opicapone is a once-daily, oral, selective catechol-O-methyltransferase inhibitor, being developed as an adjunctive therapy to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes. The Company met with the FDA in January 2018 and based upon the BIPARK-1 and BIPARK-2 pivotal Phase III studies conducted by BIAL, the FDA did not require additional Phase III trials to form an NDA submission. The NDA for opicapone was submitted to the FDA during the second quarter of 2019. The NDA was accepted by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of April 26, 2020.

Elagolix Update

On July 24, 2018, AbbVie, in collaboration with Neurocrine Biosciences, announced FDA approval and in October 2018 Health Canada approval for ORILISSA for the management of endometriosis with associated moderate to severe pain.

AbbVie provided positive top-line efficacy data from two Phase III studies in women with uterine fibroids in the first quarter of 2018 and from the associated six-month safety extension study during the third quarter of 2018. The ELARIS UF-I and UF-II studies of elagolix met all primary and ranked secondary endpoints at month six. The NDA for uterine fibroids was submitted to the FDA and accepted during the third quarter of 2019 with a PDUFA target action date in the second quarter of 2020. With the FDA acceptance of the NDA, a $20 million event-based milestone was recognized as revenue in the third quarter with a payment to be made by AbbVie during the fourth quarter of 2019.

AbbVie initiated a Phase II study of elagolix in women with polycystic ovary syndrome (PCOS) during the third quarter of 2019.

Congenital Adrenal Hyperplasia (CAH) Program (NBI-74788) Update

The Company began an adaptive, Phase II proof-of-concept study examining the pharmacokinetics, pharmacodynamics, and safety of NBI-74788 in adults with classic 21-hydroxylase deficiency congenital adrenal hyperplasia (CAH) in November 2017. This study evaluates the safety and tolerability of NBI-74788 in patients with CAH together with the relationship between exposure and specific steroid hormone levels in these patients. In March 2019, positive interim results from this ongoing study demonstrated a clinically meaningful reduction in key biomarkers associated with the management of CAH. NBI-74788 was shown to be well tolerated with no serious adverse events reported to date.

In July 2019, the Company initiated an adaptive, Phase II proof-of-concept study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of NBI-74788 in pediatric patients with classic CAH. In Q3 2019, the Company engaged with the FDA and the European Medicines Agency (EMA) to discuss the registrational trial design for the adult program.

Voyager Collaboration and VY-AADC Program

During the first quarter of 2019, Neurocrine Biosciences formed a strategic collaboration with Voyager Therapeutics focused on the development and commercialization of Voyager's gene therapy programs, VY-AADC for Parkinson's disease and VY-FXN01 for Friedreich's ataxia, as well as rights to two programs to be determined. This collaboration combines Neurocrine Biosciences' expertise in neuroscience, drug development and commercialization with Voyager's innovative gene therapy programs targeting severe neurological diseases.

Based on the results from the VY-AADC Phase I programs in Parkinson's disease, RESTORE-1, a Phase II, randomized, placebo-surgery controlled, double-blinded, multi-center, clinical trial was initiated to evaluate the safety and efficacy of VY-AADC in patients who have been diagnosed with Parkinson's disease for at least four years, are not responding adequately to oral medications, and have at least three hours of OFF time during the day as measured by a validated self-reported patient diary.

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 800-894-5910 (US) or 785-424-1052 (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, congenital adrenal hyperplasia, 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)*

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 Neurocrine's 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; the collaboration with Voyager Therapeutics; 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: the Company's future financial and operating performance; risks and uncertainties associated with the commercialization of INGREZZA and ORILISSA, including the likelihood of continued revenue and prescription growth 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 or uncertainties related to the development of the Company's product candidates; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA, ORILISSA, or a product candidate; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA and the Company's product candidates, and the ability of the Company to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding INGREZZA, ORILISSA, opicapone, or the Company's other product candidates; risks associated with the Company's dependence on AbbVie for the commercialization of ORILISSA and the development of elagolix; risks associated with the Company's dependence on BIAL for development and manufacturing activities related to opicapone, and the ability of the Company to manage BIAL; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities 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 benefits of the agreements with our collaboration partners may never be realized, including Voyager, BIAL, and Mitsubishi Tanabe; risks that INGREZZA, ORILISSA, 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 the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's 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.*

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(unaudited)

	Three Months Ended September 30,	Nine Months Ended September 30,

(in thousands, except per share data)	2019	2018	2019	2018
Revenues:				
Product sales, net	$ 198,094	$ 111,291	$ 515,069	$ 279,282
Collaboration revenue	24,000	40,466	29,008	40,466
Total revenues	222,094	151,757	544,077	319,748
Operating expenses:				
Cost of sales	2,229	1,551	4,966	3,355
Research and development	45,278	35,482	144,617	121,417
Acquired in-process research and development	—	—	118,081	—
Selling, general and administrative	84,489	60,401	252,851	179,952
Total operating expenses	131,996	97,434	520,515	304,724
Operating income	90,098	54,323	23,562	15,024
Other (expense) income:				
Interest expense	(8,038)	(7,672)	(23,833)	(22,767)
Unrealized loss on restricted equity securities	(28,450)	—	(5,805)	—
Investment income and other, net	4,797	4,113	13,980	10,776
Total other expense, net	(31,691)	(3,559)	(15,658)	(11,991)
Income before provision for income taxes	58,407	50,764	7,904	3,033
Provision for income taxes	4,618	—	4,892	—
Net income	$ 53,789	$ 50,764	$ 3,012	$ 3,033
Net income per share, basic	$ 0.59	$ 0.56	$ 0.03	$ 0.03
Net income per share, diluted	$ 0.56	$ 0.52	$ 0.03	$ 0.03
Weighted average common shares outstanding, basic	91,859	90,555	91,440	90,064
Weighted average common shares outstanding, diluted	96,074	96,798	95,231	95,272

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

(in thousands)	September 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 670,162	$ 650,913
Other current assets	149,070	86,864
Total current assets	819,232	737,777
Property and equipment, net	40,302	33,869
Long-term investments	204,793	216,028
Investment in restricted equity securities	48,915	-
Operating lease assets	61,987	-
Restricted cash	4,706	5,477
Total assets	$ 1,179,935	$ 993,151
Current liabilities	$ 115,652	$ 88,233
Noncurrent operating lease liabilities	74,482	-
Convertible senior notes	403,589	388,496
Other long-term liabilities	11,697	35,657
Stockholders' equity	574,515	480,765
Total liabilities and stockholders' equity	$ 1,179,935	$ 993,151

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SOURCE Neurocrine Biosciences, Inc.

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