Neurocrine Biosciences Reports Fourth Quarter and Year-End 2018 Financial Results

February 5, 2019

INGREZZA® (valbenazine) Fourth Quarter Net Product Sales of $130.3 Million with Approximately 22,900 TRx
INGREZZA® (valbenazine) Full-Year 2018 Net Product Sales of $409.6 Million with Approximately 71,500 TRx
Congenital Adrenal Hyperplasia Phase II Study Initial Results Expected in Q1 2019
Neurocrine Biosciences and Voyager Therapeutics Form Strategic Gene Therapy Collaboration for Key Neuroscience Programs

SAN DIEGO, Feb. 5, 2019 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter ended December 31, 2018 and provided an update on the launch of INGREZZA® (valbenazine) and its clinical development programs.

"We are extremely proud of what we have accomplished since INGREZZA was approved in 2017 and the impact INGREZZA is having on the lives of many patients with tardive dyskinesia. Our field sales team expansion and educational efforts position us to further help patients struggling with tardive dyskinesia," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "Beyond INGREZZA, we are gearing up to file an NDA for opicapone to treat Parkinson's disease and anticipating the Phase IIa data readout for our congenital adrenal hyperplasia program. And now, our pipeline includes the collaboration programs with Voyager in Parkinson's disease and Friedreich's ataxia. These efforts, along with AbbVie's anticipated mid-year NDA submission for elagolix in uterine fibroids, put Neurocrine in an exciting position to have the potential of three approved drugs in four indications in 2020 with a robust and highly diversified pipeline."

Financial Results

Total revenue was $131.5 million for the fourth quarter of 2018, compared to $94.5 million for the same period in 2017. For the year ended December 31, 2018, total revenue was $451.2 million, compared to $161.6 million for the same period in 2017.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenues:				
INGREZZA product sales, net	$ 130,326	$ 64,517	$ 409,608	$ 116,626
Collaboration revenue	1,166	30,000	41,632	45,000
Total revenue	$ 131,492	$ 94,517	$ 451,240	$ 161,626

INGREZZA was made available for commercial distribution on May 1, 2017 and ORILISSA® (elagolix) was approved by the U.S. Food and Drug Administration (FDA) for the treatment of endometriosis with associated moderate to severe pain during the third quarter of 2018, with AbbVie sales beginning in August 2018. With the FDA approval of ORILISSA, the Company recognized a $40 million event-based milestone as revenue under the Company's collaboration agreement with AbbVie during the third quarter of 2018. Total revenue for 2017 was inclusive of milestone revenue of $45 million recognized pursuant to the Company's collaboration agreements with AbbVie and Mitsubishi Tanabe Pharma Corporation (MTPC).

The Company reported net income of $18.1 million, or $0.19 diluted net income per share, for the fourth quarter of 2018, compared to $6.9 million, or $0.07 diluted net income per share, for the same period in 2017. For the year ended December 31, 2018, the Company reported net income of $21.1 million, or $0.22 diluted net income per share, compared to a net loss of $142.5 million, or $1.62 net loss per share, for the same period in 2017. The increase in net income across both periods is primarily due to increased INGREZZA net product sales.

Research and development (R&D) expenses increased to $39.1 million for the fourth quarter of 2018, from $25.6 million for the

same period in 2017. For the year ended December 31, 2018, R&D expenses increased to $160.5 million from $121.8 million for the same period in 2017. The increase in R&D expenses across both periods is primarily due to advancement of the Company's clinical programs, including congenital adrenal hyperplasia (CAH), a vesicular monoamine transporter 2 (VMAT2) inhibitor, and a first-in-class central nervous system (CNS) compound, as well as activities to prepare for the Company's intended opicapone new drug application (NDA) submission in the second quarter of 2019.

Sales, general and administrative (SG&A) expenses increased to $69.0 million for the fourth quarter of 2018, from $56.3 million for same period in 2017. For the year ended December 31, 2018, SG&A expenses increased to $248.9 million from $169.9 million for the same period in 2017. The increase in SG&A expenses across both periods is primarily due to the hiring of the Company's sales force, including the third quarter 2018 sales force expansion, and commercialization activities for INGREZZA, which launched in the third quarter of 2017.

The Company's balance sheet at December 31, 2018, reflected total assets of $993.2 million, including cash and investments of $866.9 million, compared to total assets of $817.6 million at December 31, 2017.

2019 Financial Guidance

Revenue milestones under the AbbVie agreement for 2019 are expected to be $20 million contingent on FDA's acceptance of the NDA submission of elagolix for uterine fibroids. Ongoing SG&A and R&D expenses for 2019, excluding upfront expenses associated with the recently announced Voyager Therapeutics collaboration, should approximate $550 to $600 million. The 2019 anticipated expenses include an estimated $80 million of share-based compensation expense. The increase in expenses is largely attributable to the Voyager collaboration's ongoing program costs, increased investment in INGREZZA patient education, sales and marketing activities, opicapone NDA submission and increased R&D pipeline activities.

Pipeline Highlights

INGREZZA (valbenazine) Update

INGREZZA received FDA approval on April 11, 2017, becoming the first medicine approved in the United States for the treatment of adults with tardive dyskinesia.

In March 2015, the Company announced that it had entered into an exclusive collaboration and licensing agreement for the development and commercialization of INGREZZA in Japan and other select Asian markets with MTPC. In 2017, MTPC initiated a pivotal trial of INGREZZA in Japan for the treatment of tardive dyskinesia.

ORILISSA (elagolix) Update

On July 24, 2018, AbbVie, in collaboration with Neurocrine, announced FDA approval and in October 2018 Health Canada approval for ORILISSA for the management of endometriosis with associated moderate to severe pain. The FDA granted priority review to ORILISSA. The FDA grants priority review designation to medicines that, if approved, would provide a significant improvement in the safety or effectiveness of treatment of a serious condition. AbbVie began commercialization of ORILISSA in the United States in August 2018.

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 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. These replicate Phase III studies were randomized, parallel, double-blind, placebo-controlled clinical trials evaluating elagolix alone or in combination with low-dose hormone (add-back) therapy in women with heavy uterine bleeding associated with uterine fibroids. The studies enrolled approximately 400 patients each for an initial six-month placebo-controlled dosing period. At the end of the six months of placebo-controlled evaluation, patients were eligible to enter an additional six-month safety extension study. The primary efficacy endpoint of the study was an assessment of the change in menstrual blood loss utilizing the alkaline hematin method comparing baseline to month six. Additional secondary efficacy endpoints were evaluated including the change in fibroid volume and hemoglobin. Bone mineral density was assessed via dual-energy x-ray absorptiometry (DEXA) scan at baseline at the conclusion of dosing and at six months post-dosing. Results from these studies will form the basis for an anticipated NDA submission to the FDA for the approval of elagolix in the treatment of uterine fibroids in the middle of 2019.

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, peripherally-acting, highly-selective catechol-O-methyltransferase inhibitor, being developed as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors for adult patients with Parkinson's disease and motor fluctuations. The Company met with the FDA in January 2018 and based upon the BIPARK-I and BIPARK-II pivotal Phase III studies conducted by BIAL, the FDA did not require additional Phase III trials to form an NDA submission. The Company is in the process of preparing for an NDA submission which it anticipates will occur during the second quarter of 2019.

CAH Program (NBI-74788) Update

In the second quarter of 2017, the Company successfully completed the Phase I investigational new drug (IND)-opening study of

NBI-74788 in healthy volunteer participants. The study was a randomized, open-label, two-period crossover study to evaluate the pharmacokinetics, the effect of food on pharmacokinetics, and the safety of NBI-74788 in a total of 16 healthy adults.

The Company began a Phase II proof-of-concept study examining the pharmacokinetics, pharmacodynamics, and safety of NBI-74788 in adult males and females with classic 21-hydroxylase deficiency CAH in November of 2017. This study will evaluate 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. Initial results from this trial are expected during the first quarter of 2019.

New VMAT2 Inhibitor

The Company has filed an IND and completed dosing in the single ascending dose portion of a Phase I study designed to assess initial safety, tolerability and pharmacokinetics of a novel, internally discovered VMAT2 inhibitor. This compound has the potential to be used in the treatment of several neurology and/or psychiatry disorders. The multiple dosing portion of this Phase I study is ongoing and is expected to be completed during the first half of 2019.

New CNS Compound

The Company has filed an IND and completed dosing in a Phase I single ascending dose study for an internally discovered first-in-class CNS compound with potential use in the treatment of several neurology and/or psychiatry disorders. The study is a randomized, double-blind, single ascending dose study to evaluate the safety, tolerability, and pharmacokinetic profile of the compound in healthy participants. The Company is currently analyzing the data from this study to inform the design of future clinical studies for the program.

Voyager Collaboration

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. This transaction is anticipated to close in the first quarter subject to standard Hart-Scott-Rodino waiting periods.

Conference Call and Webcast Today at 4:30 PM Eastern Time

Neurocrine 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 877-876-9174 (US) or 785-424-1669 (International) using the conference ID: NBIX. The webcast can also be accessed on Neurocrine's 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 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.

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, a San Diego based biopharmaceutical company, is focused on developing treatments for neurological and endocrine related disorders. The company discovered, developed and markets INGREZZA® (valbenazine) capsules, the first FDA-approved product indicated for the treatment of adults with tardive dyskinesia, an involuntary movement disorder. Discovered and developed through Phase II clinical trials by Neurocrine, ORILISSA® (elagolix), the first FDA-approved oral medication for the management of endometriosis with associated moderate to severe pain in over a decade, is marketed by AbbVie as part of a collaboration to develop and commercialize elagolix for women's health. Neurocrine's clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's disease patients, elagolix for uterine fibroids with AbbVie, valbenazine for the treatment of Tourette syndrome, and NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH). For more information and the latest updates from Neurocrine Biosciences, please visit www.neurocrine.com.

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 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; risk that the collaboration with Voyager may not close on a timely basis or at all; 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, or the Company's product candidates; risks associated with the Company's dependence on AbbVie for the commercialization of ORILISSA and the development of elagolix; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory 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; risks associated with the Company's dependence on BIAL for regulatory, development and manufacturing activities related to opicapone; risks associated with the Company's dependence on Mitsubishi Tanabe for the development and commercialization of valbenazine in Japan and other Asian countries; 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, 2018. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$ 130,326	$ 64,517	$409,608	$ 116,626
Collaboration revenue	1,166	30,000	41,632	45,000
Total revenues	131,492	94,517	451,240	161,626
Operating expenses:				
Cost of sales	1,534	760	4,889	1,254
Research and development	39,107	25,614	160,524	121,827

Sales, general and administrative	68,980	56,309	248,932	169,906
Total operating expenses	109,621	82,683	414,345	292,987
Income (loss) from operations	21,871	11,834	36,895	(131,361)
Other (expense) income:				
Interest expense	(7,763)	(7,419)	(30,530)	(19,523)
Investment income and other, net	4,700	2,479	15,476	8,342
Total other expense, net	(3,063)	(4,940)	(15,054)	(11,181)
Income (loss) before provision for income taxes	18,808	6,894	21,841	(142,542)
Provision for income taxes	730	-	730	-
Net income (loss)	$ 18,078	$ 6,894	$ 21,111	$(142,542)
Net income (loss) per common share:				
Basic	$ 0.20	$ 0.08	$ 0.23	$ (1.62)
Diluted	$ 0.19	$ 0.07	$ 0.22	$ (1.62)
Shares used in the calculation of net income (loss) per common share:				
Basic	90,742	88,665	90,235	88,089
Diluted	95,724	92,659	95,386	88,089

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

	December 31, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 650,913	$ 515,929
Other current assets	86,864	38,990
Total current assets	737,777	554,919
Property and equipment, net	33,869	10,811
Long-term investments	216,028	247,361
Restricted cash	5,477	4,500
Total assets	$ 993,151	$ 817,591
Current liabilities	$ 88,233	$ 54,426
Convertible senior notes	388,496	369,618
Other long-term liabilities	35,657	21,409
Stockholders' equity	480,765	372,138
Total liabilities and stockholders' equity	$ 993,151	$ 817,591

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SOURCE Neurocrine Biosciences, Inc.

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