Neurocrine Biosciences Reports Fourth Quarter and Year-End 2017 Financial Results and Provides Investor Update for 2018

February 13, 2018

INGREZZA® (valbenazine) Fourth Quarter Net Product Sales of $64.5 Million with Approximately 9,100 TRx
INGREZZA Net Product Sales of $116.6 Million with Approximately 14,900 TRx Since Commercial Launch on May 1, 2017
Total Revenue for the Fourth Quarter of 2017 was $94.5 Million and $161.6 Million for the Full-Year 2017
Elagolix PDUFA Action Date for Endometriosis in Q2 2018 and Uterine Fibroids Data from Two Phase III Studies Expected in Q1 2018
Results from Phase IIb Study of Valbenazine for Pediatric Tourette Syndrome Anticipated in Late 2018

SAN DIEGO, Feb. 13, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the fourth quarter and year-end of 2017, and provided an update on the launch of INGREZZA® (valbenazine) and clinical development programs for 2018.

"This past year was a year of tremendous progress for Neurocrine with the approval and successful launch of INGREZZA. I am proud of our team's dedication and commitment to successfully launching INGREZZA while also advancing key development programs in our pipeline," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "For 2018, we remain focused on maximizing our opportunity with INGREZZA to aid patients impacted by tardive dyskinesia through further disease state awareness and positive patient outcomes. In addition, we expect to make great strides in our many research and development programs, including a potential FDA approval from our collaboration with AbbVie for elagolix in endometriosis, results from a Phase IIb study of INGREZZA for Tourette syndrome, and progressing opicapone for the treatment of Parkinson's disease."

Fourth Quarter and Year-End 2017 Sales Results

Neurocrine reported net product sales for INGREZZA of $64.5 million for the fourth quarter ended December 31, 2017. Total Company revenues for the fourth quarter were $94.5 million inclusive of a $30 million milestone payment received from AbbVie for the U.S. Food and Drug Administration (FDA) acceptance of the elagolix endometriosis NDA filing in the fourth quarter.

For the year ended December 31, 2017, net product sales of INGREZZA were $116.6 million and total Company revenues of $161.6 million inclusive of $45 million revenue recognized from our collaboration agreements with AbbVie and Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe).

No similar net product sales were reported for the comparable periods of 2016. INGREZZA was made available for commercial distribution on May 1, 2017, and the Company recognizes revenue using a sell-in methodology when products are delivered to select pharmacies or distributors.

For the fourth quarter of 2017, the Company reported net income of $6.9 million, or $0.07 diluted earnings per share, compared to a net loss of $44.7 million, or $0.51 loss per share for the same period in 2016. For the year ended December 31, 2017, the Company reported a net loss of $142.5 million, or $1.62 loss per share, as compared to a net loss of $141.1 million, or $1.63 loss per share for 2016.

Research and development (R&D) expenses were $25.6 million during the fourth quarter of 2017 compared to $22.6 million for the fourth quarter of 2016. The increase in R&D expense is principally due to increased program activity in R&D. For the year ended December 31, 2017, R&D expenses were $121.8 million, compared to $94.3 million for the same period in 2016. This increase is primarily due to a $30 million payment in the first quarter of 2017 from the Company's entering 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, which was expensed as in-process R&D.

Sales, general and administrative (SG&A) expenses increased to $56.3 million for the fourth quarter of 2017 from $23.7 million for the fourth quarter of 2016. For the year ended December 31, 2017, SG&A expenses were $169.9 million, compared to $68.1 million for the same period in 2016. The increase in SG&A expense, across both periods, is primarily due to commercialization activities for INGREZZA.

The Company's balance sheet at December 31, 2017, reflected total assets of $817.6 million, including cash, investments and receivables of $797.6 million, compared with total asset balances at December 31, 2016 of $365.1 million.

2018 Financial Guidance

Revenue milestones under the AbbVie agreement for 2018 are expected to be $40 million contingent on an FDA approval of elagolix for endometriosis. Ongoing operating expenses for 2018 should approximate $365 to $395 million. The 2018 anticipated expenses include an estimated $50 million of share-based compensation expense. The increase in operating expenses is largely attributable to increased investment in INGREZZA sales and marketing activities coupled with increased R&D efforts for Tourette syndrome, opicapone, new early stage programs, and post-marketing clinical activities.

Pipeline Highlights and Upcoming Events in 2018

INGREZZA 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. Full commercial efforts for the 40 mg capsule of INGREZZA began on May 1, 2017. On October 4, 2017, the FDA approved the supplemental New Drug Application (NDA) for the 80 mg capsule strength of INGREZZA.

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 Mitsubishi Tanabe. In 2017, Mitsubishi Tanabe initiated a pivotal trial of INGREZZA in Asia for the treatment of tardive dyskinesia which generated a $15 million milestone during the third quarter of 2017.

INGREZZA is being investigated in Tourette syndrome and has been granted Orphan Drug Designation by the FDA for the treatment of pediatric patients with Tourette syndrome. Orphan Drug Designation is granted by the FDA to drugs that are intended to treat rare diseases or conditions in the United States.

In addition, the Company has advanced the valbenazine Tourette syndrome program into Phase IIb by initiating the T-Force GOLD study in pediatric patients with Tourette syndrome. This study is a multicenter, randomized, double-blind, placebo-controlled, parallel group, Phase IIb study to evaluate the safety, tolerability, efficacy and optimal dose of once-daily valbenazine in up to 120 pediatric patients with moderate to severe Tourette syndrome over 12 weeks of treatment. The primary endpoint of this study is the change from baseline of the Yale Global Tic Severity Scale between placebo and active treatment groups at the end of week 12 with top-line data expected in late 2018.

Elagolix Update

On October 27, 2017, AbbVie, in collaboration with Neurocrine, announced that the FDA had granted Priority Review to elagolix for the management of endometriosis with associated pain. The FDA grants Priority Review to medicines that it determines have potential to provide significant improvements in the safety and effectiveness of the treatment of a serious disease. Priority Review shortens the FDA review timeframe from ten months from acceptance of the NDA filing to six months. The Prescription Drug User Fee Act (PDUFA) date for the FDA to complete its review is in the second quarter of 2018.

AbbVie is currently completing two replicate Phase III randomized, parallel, double-blind, placebo-controlled clinical trials evaluating elagolix alone or in combination with add-back therapy in women with heavy uterine bleeding associated with uterine fibroids. The studies enrolled approximately 400 subjects each for an initial six-month placebo-controlled dosing period. At the end of the six months of placebo-controlled evaluation, subjects are eligible to enter an additional six-month safety extension study. The primary efficacy endpoint of the study is an assessment of the change in menstrual blood loss utilizing the alkaline hematin method comparing baseline to month six. Additional secondary efficacy endpoints will be evaluated including assessing the change in fibroid volume and hemoglobin. Bone mineral density will be assessed via dual-energy x-ray absorptiometry (DEXA) scan at baseline, at the conclusion of dosing, and six months post-dosing. AbbVie expects initial top-line efficacy data from the uterine fibroid Phase III program during the first quarter of 2018. These two studies will form the basis for an anticipated 2019 supplemental NDA submission to the FDA for the approval of elagolix in the treatment of uterine fibroids.

Opicapone Update

In February 2017, the Company entered into an exclusive licensing agreement with BIAL for the development and commercialization of opicapone in the United States and Canada. Opicapone is a once-daily, 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 to discuss the necessary activities to support an NDA submission and will provide an update on the regulatory path and program timing after official meeting minutes are received later this month.

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

In the second quarter of 2017, the Company successfully completed the Phase I, IND-opening study of NBI-74788 in healthy volunteer subjects. The study was a randomized, open-label, two-period crossover study to evaluate the pharmacokinetics (PK), the effect of food on PK, and the safety of NBI-74788 in a total of 16 healthy adults.

The Company began recruitment for a Phase II, proof-of-concept study examining the PK, pharmacodynamics, and safety of NBI-74788 in adult males and females with classic, 21-hydroxylase deficiency CAH in November of 2017. The study will evaluate the relationship between NBI-74788 exposures and specific steroid hormone levels in these subjects and expect data to be available during the first half of 2018.

Conference Call and Webcast Today at 5:00 PM Eastern Time

Neurocrine will hold a live conference call and webcast today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Participants can access the live conference call by dialing 888-632-3389 (US) or 785-424-1673 (International) using the conference ID: NBIX. The call can also be accessed via the webcast through the Company's website at http://www.neurocrine.com.

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 trunk, extremities and/or face.

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 in 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
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/HCP

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. The Company markets INGREZZA® (valbenazine) capsules in the United States for the treatment of adults with tardive dyskinesia. INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first FDA approved product indicated for the treatment of adults with tardive dyskinesia. The Company's three late-stage clinical programs are: elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc.; opicapone, a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase inhibitor under investigation as adjunct therapy to levodopa in Parkinson's patients; and INGREZZA, a novel, once-daily, selective VMAT2 inhibitor under investigation for the treatment of Tourette syndrome.

Neurocrine Biosciences, Inc. news releases are available through the Company's website via the internet at http://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; the value INGREZZA and our product candidates may bring to patients; the success of the continued launch of INGREZZA; and the timing of completion of our clinical 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, including the likelihood of continued revenue growth of INGREZZA; 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 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 or the Company's product candidates; risks associated with the Company's dependence on AbbVie for the development and commercialization 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

BIAL and Mitsubishi Tanabe may never be realized; risks associated with the Company's dependence on BIAL for tech transfer, 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 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, 2017. 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,		Twelve Months Ended December 31,	
	2017	**2016**	**2017**	**2016**
Revenues:				
Product sales, net	$ 64,517	$ -	$ 116,626	$ -
Milestones	30,000	-	45,000	15,000
Total revenues	94,517	-	161,626	15,000
Operating expenses:				
Cost of product sales	760	-	1,254	-
Research and development	25,614	22,583	121,827	94,291
Sales, general and administrative	56,309	23,668	169,906	68,081
Total operating expenses	82,683	46,251	292,987	162,372
Income (loss) from operations	11,834	(46,251)	(131,361)	(147,372)
Other (expense) income:				
Deferred gain on real estate	183	863	2,124	3,423
Interest expense	(7,419)	-	(19,523)	-
Investment income, net	2,323	716	6,238	2,838
Other (loss) income, net	(27)	13	(20)	21
Total other (expense) income	(4,940)	1,592	(11,181)	6,282
Net Income (Loss)	$ 6,894	$ (44,659)	$(142,542)	$(141,090)
Net income (loss) per common share:				
Basic	$ 0.08	$ (0.51)	$ (1.62)	$ (1.63)

Diluted	$ 0.07	$ (0.51)	$ (1.62)	$ (1.63)

Shares used in the calculation of net income (loss) per common share:

Basic	88,665	86,874	88,089	86,713
Diluted	92,659	86,874	88,089	86,713

NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2017	December 31, 2016
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 515,929	$ 307,350
Other current assets	38,990	3,092
Total current assets	554,919	310,442
Property and equipment, net	10,811	6,271
Long-term investments	247,361	43,490
Restricted cash	4,500	4,883
Total assets	$ 817,591	$365,086
Current liabilities	$ 54,426	$ 30,414
Convertible senior notes	369,618	-
Other long-term liabilities	21,409	19,795
Stockholders' equity	372,138	314,877
Total liabilities and stockholders' equity	$ 817,591	$365,086

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