Neurocrine Biosciences Reports Second Quarter 2018 Financial Results

July 31, 2018

INGREZZA® (valbenazine) Second Quarter Net Product Sales of $96.9 Million with Approximately 16,700 TRx
ORILISSA™ (elagolix), the First FDA-Approved Oral Treatment for Moderate to Severe Endometriosis Pain in Over a Decade, Expected to be Launched by AbbVie in August 2018

SAN DIEGO, July 31, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter ended June 30, 2018, and provided an update on the launch of INGREZZA® (valbenazine), the U.S. Food and Drug Administration (FDA) approval for ORILISSA™ (elagolix), and its clinical development programs.

"Neurocrine is making great progress with the continued adoption of INGREZZA by physicians and patients, the recent FDA approval of ORILISSA for endometriosis, and the advancement of our clinical development programs," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "AbbVie's approval of ORILISSA marks the second FDA-approved drug discovered by scientists at Neurocrine and is a testament to our discovery and development capabilities. We remain committed toward our goal of having four commercial products with six indications, four years from now, to help patients with significant unmet medical needs."

Financial Results

Neurocrine reported net product sales for INGREZZA of $96.9 million for the three months ended June 30, 2018 compared to $6.3 million for the three months ended June 30, 2017. For the six months ended June 30, 2018 and 2017, Neurocrine reported net product sales for INGREZZA of $168.0 million and $6.3 million, respectively. INGREZZA was made available for commercial distribution on May 1, 2017.

For the second quarter of 2018, the Company reported a net loss of $5.9 million, or $0.07 loss per share, compared to a net loss of $60.0 million, or $0.68 loss per share, for the same period in 2017. For the six months ended June 30, 2018, the Company reported a net loss of $47.7 million, or $0.53 loss per share, compared to a net loss of $138.3 million, or $1.58 loss per share, for the same period in 2017.

Research and development (R&D) expenses were $37.0 million during the second quarter of 2018 compared to $21.9 million for the second quarter of 2017. The increase in R&D expense is principally due to the advancement of our Tourette clinical program and activity preparing for our intended opicapone New Drug Application (NDA) submission in the first half of 2019. For the six months ended June 30, 2018, R&D expenses were $85.9 million, compared to $73.8 million for the same period last year. The increase from the prior year is primarily due to the ongoing progression of our clinical pipeline, an approximately $8 million non-recurring share-based compensation charge, and a $10 million event-based payment to BIAL – Portela & CA, S.A. (BIAL) resulting from the ability to submit the opicapone NDA based on the existing clinical dataset, partially offset by a $30 million payment in 2017 to BIAL for the exclusive licensing of opicapone.

Sales, general and administrative (SG&A) expenses increased to $60.9 million for the second quarter of 2018 from $41.7 million for the second quarter of 2017. For the six months ended June 30, 2018, SG&A expenses were $119.6 million, compared to $69.7 million for the same period last year. The increase in SG&A expense for both periods is primarily due to the hiring of our sales force and commercialization activities for INGREZZA, which launched in the second quarter of 2017.

The Company's balance sheet at June 30, 2018 reflected assets of $841.3 million, including cash, investments and receivables of $806.3 million, compared with total assets balances at March 31, 2018 and December 31, 2017 of $806.4 million and $817.6 million, respectively.

Pipeline Highlights

INGREZZA (valbenazine) Update

INGREZZA received U.S. Food and Drug Administration (FDA) approval on April 11, 2017, becoming the first medicine approved

in the United States for the treatment of adults with tardive dyskinesia.

Valbenazine 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 the fourth quarter of 2017, the Company initiated T-Force GOLD, a Phase IIb study of valbenazine in pediatric patients with Tourette syndrome. This study is a multicenter, randomized, double-blind, placebo-controlled, parallel-group, which will evaluate the safety, tolerability, efficacy and optimized dosing 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 comparison of the change from baseline of the Yale Global Tic Severity Scale between placebo and active treatment groups at the end of week 12. Top-line data are expected in late 2018.

The Company also recently started T-Force PLATINUM, a double-blind, placebo-controlled, randomized withdrawal study of valbenazine in pediatric patients with Tourette syndrome. This study is designed to evaluate longer term efficacy and safety in patients who initially respond to open-label therapy with optimized doses of valbenazine. Approximately 180 patients will participate in the study with top-line data expected in late 2019.

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 Pharma Corporation (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 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 intends to commercialize ORILISSA in August 2018. With this FDA approval, a $40 million event-based payment will be made by AbbVie under our collaboration agreement and recognized as revenue in the third quarter of 2018.

During the first quarter of 2018, AbbVie provided positive top-line efficacy data from two Phase III studies in women with uterine fibroids. 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 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 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 first half of 2019.

Congenital Adrenal Hyperplasia (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 (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 patients. Data are expected to be available later in 2018.

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 877-876-9177 (US) or 785-424-1669 (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 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 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.INGREZZAHCP.com

About Neurocrine Biosciences, Inc.
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), the first FDA-approved product indicated for the treatment of adults with tardive dyskinesia, a 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, please visit www.neurocrine.com.

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 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; 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 and ORILISSA, including the likelihood of continued revenue and prescription 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, 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 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, 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 March 31, 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 June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Product sales, net	$ 96,905	$ 6,335	$ 167,991	$ 6,335
Total revenues	96,905	6,335	167,991	6,335
Operating expenses:				
Cost of product sales	854	61	1,804	61
Research and development	36,988	21,868	85,935	73,750
Sales, general and administrative	60,915	41,674	119,551	69,724
Total operating expenses	98,757	63,603	207,290	143,535
Loss from operations	(1,852)	(57,268)	(39,299)	(137,200)
Other (expense) income:				
Deferred gain on real estate	183	879	366	1,758
Interest expense	(7,591)	(4,767)	(15,095)	(4,767)
Investment income and other, net	3,347	1,171	6,297	1,898
Total other expense, net	(4,061)	(2,717)	(8,432)	(1,111)
Net loss	$ (5,913)	$ (59,985)	$ (47,731)	$ (138,311)
Net loss per common share:				
Basic and diluted	$ (0.07)	$ (0.68)	$ (0.53)	$ (1.58)
Shares used in the calculation of net loss per common share:				
Basic and diluted	90,100	88,063	89,814	87,675

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	June 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 508,740	$ 515,929
Other current assets	58,937	38,990
Total current assets	567,677	554,919
Property and equipment, net	18,775	10,811
Long-term investments	249,388	247,361
Restricted cash	5,477	4,500
Total assets	$ 841,317	$ 817,591
Current liabilities	$ 61,762	$ 54,426
Convertible senior notes	378,885	369,618
Other long-term liabilities	23,234	21,409
Stockholders' equity	377,436	372,138
Total liabilities and stockholders' equity	$ 841,317	$ 817,591

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