Neurocrine Biosciences Reports Third Quarter 2017 Results

November 1, 2017

- INGREZZA® (valbenazine) Net Product Sales of $45.8 Million for Initial Full Quarter of Commercialization as the First U.S. Food and Drug Administration Approved Product for the Treatment of Tardive Dyskinesia

- Elagolix New Drug Application for Endometriosis Granted Priority Review by FDA, PDUFA action date in Second Quarter of 2018

- Initiated INGREZZA T-Force GOLD Phase IIb Study to Assess Children and Adolescents with Tourette Syndrome

- Received $15 Million from Mitsubishi Tanabe for Initiating Pivotal Studies of INGREZZA in Asia

SAN DIEGO, Nov. 1, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended September 30, 2017.

"We are very pleased with the positive impact INGREZZA is having on patients suffering from tardive dyskinesia and the strength of our initial product launch. Prescriber use of INGREZZA for treating tardive dyskinesia is continuing to rapidly expand across both psychiatrists and neurologists as disease state and brand awareness broadens," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We have also made great strides in R&D with elagolix being granted priority review status by the FDA for endometriosis, the initiation of a Phase IIb study of INGREZZA in pediatric patients with Tourette's and INGREZZA commencing pivotal studies in Asia."

Financial Results

Neurocrine reported net product sales of $45.8 million for the three months ended September 30, 2017. For the nine months ended September 30, 2017, net product sales were $52.1 million. No similar net product sales were reported for the comparable periods of 2016. INGREZZA® (valbenazine) capsules were 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 third quarter of 2017, the Company reported a net loss of $11.1 million, or $0.13 loss per share, compared to a net loss of $36.9 million, or $0.43 loss per share, for the same period in 2016. For the nine months ended September 30, 2017, the Company reported a net loss of $149.4 million, or $1.70 loss per share, as compared to a net loss of $96.4 million, or $1.11 loss per share, for the first nine months of last year.

Research and development (R&D) expenses were $22.5 million during the third quarter of 2017 compared to $20.9 million for the same period in 2016. The increase in R&D expense is principally due to increased headcount in R&D. For the nine months ended September 30, 2017, R&D expenses were $96.2 million, compared to $71.7 million for the same period last year. 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 $43.9 million for the third quarter of 2017 from $17.5 million for the third quarter of 2016. For the nine months ended September 30, 2017, SG&A expenses were $113.6 million, compared to $44.4 million for the first nine months of 2016. The increase in SG&A expense, across both periods, is primarily due to commercialization activities for INGREZZA.

The Company's balance sheet at September 30, 2017, reflected total assets of $772.5 million, including cash, investments and receivables of $754.0 million, compared with total asset balances at December 31, 2016 of $365.1 million. Current cash and investments includes net proceeds of $502.8 million which was raised during the second quarter of 2017 via the Company's convertible notes offering.

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. 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 Pharma Corporation (Mitsubishi Tanabe). 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 was recently 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 INGREZZA Tourette's 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 INGREZZA 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.

The Company is also conducting an open-label, fixed-dose study of INGREZZA in up to 180 subjects with Tourette syndrome who have completed

either of the two placebo-controlled Tourette clinical trials, T-Force GREEN or T-Forward. This Phase II study will assess the long-term safety and tolerability of INGREZZA in children and adults with Tourette syndrome.

Elagolix Update

On October 27, 2017, AbbVie 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.

Recently, AbbVie presented six scientific abstracts at the 2017 American Society for Reproductive Medicine Scientific Congress & Expo (ASRM) in San Antonio, Texas. Detailed results from two replicate long-term Phase III extension studies evaluating the efficacy and safety of elagolix for the management of endometriosis with associated pain were presented. In these two Phase III extension studies, elagolix demonstrated sustained reduction in average monthly menstrual pelvic pain and non-menstrual pelvic pain in women through the 12 month treatment period. The safety and tolerability of elagolix was also consistent with the anticipated effects of reduced estradiol levels and no new safety concerns were identified with elagolix use during the 12 month treatment period. In addition, efficacy and safety data, as well as an assessment of the impact on quality of life, from a Phase IIb study of elagolix in uterine fibroids patients was also presented at ASRM.

AbbVie is currently conducting 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 are expected to enroll 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 around the end of 2017. 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 end-of-dose motor fluctuations who cannot be stabilized on those combinations. The Company will be meeting with the FDA to inform the activities needed to support an NDA submission.

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 will initiate 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.

Conference Call and Webcast Today at 5:00PM 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 866-831-8713 (US) or 203-518-9713 (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. INGREZZA is currently in clinical development for the treatment of Tourette syndrome.

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 timing of completion of clinical and other development activities; and whether results from INGREZZA's clinical trials can be replicated or are indicative of real-world results. 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 Neurocrine'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 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 September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues:				
Product sales, net	$ 45,774	$ -	$ 52,109	$ -
License fees and milestones	15,000	-	15,000	15,000
Total revenues	60,774	-	67,109	15,000
Operating expenses:				
Cost of product sales	433	-	494	-
Research and development	22,463	20,942	96,213	71,708
Sales, general and administrative	43,873	17,494	113,597	44,413

Total operating expenses	66,769	38,436	210,304	116,121
Loss from operations	(5,995)	(38,436)	(143,195)	(101,121)
Other (expense) income:				
Gain (loss) on sale/disposal of assets	5	(9)	7	8
Deferred gain on real estate	183	853	1,941	2,560
Interest expense	(7,337)	-	(12,104)	-
Investment income, net	2,019	705	3,915	2,122
Total other (expense) income	(5,130)	1,549	(6,241)	4,690
Net Loss	$ (11,125)	$ (36,887)	$(149,436)	$(96,431)
Net loss per common share:				
Basic and diluted	$ (0.13)	$ (0.43)	$ (1.70)	$ (1.11)
Shares used in the calculation of net loss per common share:				
Basic and diluted	88,325	86,784	87,894	86,659

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

	September 30, 2017	**December 31, 2016**
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 511,018	$ 307,350
Other current assets	37,467	3,092
Total current assets	548,485	310,442
Property and equipment, net	9,140	6,271
Long-term investments	210,258	43,490
Restricted cash	4,613	4,883
Total assets	$ 772,496	$365,086

Current liabilities	$ 38,141	$ 30,414
Convertible senior notes	365,110	-
Other long-term liabilities	21,733	19,795
Stockholders' equity	347,512	314,877
Total liabilities and stockholders' equity	$ 772,496	$365,086

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