Neurocrine Biosciences Reports Second Quarter 2017 Results

August 3, 2017

- INGREZZA® Net Product Sales of $6.3 Million in Initial Two Months of Commercialization as the First and Only U.S. Food and Drug Administration Approved Product for the Treatment of Tardive Dyskinesia

- Partner AbbVie Expected to Submit Elagolix NDA for Endometriosis During the Third Quarter of 2017 and Pay $30 Million Milestone in Fourth Quarter of 2017

- Partner Mitsubishi Tanabe Expected to Initiate Pivotal Trial of INGREZZA in Asia for the Treatment of Tardive Dyskinesia and Pay $15 Million in Milestones during Third Quarter of 2017

- Completed Offering of $517.5 Million Convertible Senior Notes Due 2024

SAN DIEGO, Aug. 3, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended June 30, 2017, highlighted by the successful regulatory approval and commercial launch of INGREZZA® (valbenazine) capsules in tardive dyskinesia, as well as other recent progress on its pipeline.

"We are very pleased with the initial months of INGREZZA's launch and are encouraged by the positive feedback we are receiving from patients, physicians, and caregivers," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We successfully deployed our sales force on May 1st and activated our patient and prescriber support system, INBRACE; we are continuing to expand awareness of INGREZZA among healthcare professionals through multiple initiatives ranging from symposia at major medical meetings to local speaker programs; we are working with payors to make INGREZZA available to eligible patients; and we continue to see strong growth in prescription volume. Finally, we remain as committed as ever to our science and to advancing our robust pipeline."

Financial Results

Neurocrine reported net product sales of $6.3 million for the three months ended June 30, 2017. No similar net product sales were reported for the comparable period 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 second quarter of 2017, the Company reported a net loss of $60.0 million, or $0.68 loss per share, compared to a net loss of $40.3 million, or $0.46 loss per share, for the same period in 2016. For the six months ended June 30, 2017, the Company reported a net loss of $138.3 million, or $1.58 loss per share, as compared to a net loss of $59.5 million, or $0.69 loss per share, for the first half of last year.

Research and development (R&D) expenses were $21.9 million during the second quarter of 2017 compared to $26.9 million for the same period in 2016. The decrease in R&D expense is principally due to the completion of pivotal studies for INGREZZA. For the six months ended June 30, 2017, R&D expenses were $73.8 million, compared to $50.8 million for the same period last year. This increase is primarily due 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.

Selling, general and administrative (SG&A) expenses increased to $41.7 million for the second quarter of 2017 from $15.0 million for the second quarter of 2016. For the six months ended June 30, 2017, SG&A expenses were $69.7 million, compared to $26.9 million for the first half of 2016. The increase in SG&A expense is primarily due to commercialization activities for INGREZZA and, in particular, the on-boarding of our full sales organization.

The Company's balance sheet at June 30, 2017, reflected total assets of $754.1 million, including cash, investments and receivables of $739.6 million, compared with total asset balances at March 31, 2017 and December 31, 2016 of $289.4 million and $365.1 million, respectively. These assets include the $502.8 million raised, net of expenses, via the Company's convertible notes offering which closed on May 2, 2017.

Pipeline Highlights

INGREZZA (valbenazine) Update

INGREZZA received U.S. Food and Drug Administration (FDA) approval on April 11, 2017, becoming the first and only medicine approved in the United States for adults with tardive dyskinesia. Full commercial efforts began on May 1, 2017. On June 14, 2017, the Company submitted a supplemental New Drug Application (NDA) with the FDA for the approval of 80 mg capsules of INGREZZA for the treatment of tardive dyskinesia. Pending notification of the acceptance by the FDA of the supplemental NDA, the Company has been advised that the Prescription Drug User Fee Act (PDUFA) goal date is October 14, 2017. In July 2017, Neurocrine completed the INGREZZA roll-over study for those patients who had previously completed one year of dosing in either the Kinect 3 or Kinect 4 study.

In March 2015, the Company announced that it has 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 expects to initiate a pivotal trial of INGREZZA in Asia for the treatment of tardive dyskinesia and pay $15 million in related milestones in the third quarter of 2017.

INGREZZA is also being investigated in Tourette syndrome for both adult and pediatric patients.

The T-Force GREEN study was a randomized, double-blind, placebo-controlled, multi-dose, parallel-group Phase II study that enrolled 94 children and adolescents. Pediatric subjects with Tourette syndrome receive once-daily dosing of INGREZZA or placebo during a six-week treatment period to

assess the safety, tolerability and efficacy of INGREZZA. The primary endpoint of this study was the change from baseline of the Yale Global Tic Severity Scale (YGTSS) at the end of Week 6 in the intent-to-treat (ITT) population between placebo and active treatment groups. On May 23, 2017, the Company reported that the T-Force GREEN study did not meet its primary endpoint. Exposure-response analysis showed that the selected doses for this placebo-controlled Phase II study were below the therapeutic range for adequate tic reduction in the majority of pediatric subjects and provided insight into the level of dosing required for future studies.

Additionally, 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.

Data from the Tourette studies has been utilized to design a Phase IIB trial for INGREZZA in treating Tourette syndrome with study initiation planned for late 2017.

Elagolix Update

AbbVie is on track to submit the NDA to the FDA for elagolix in endometriosis during the third quarter of 2017.

In May 2017, AbbVie presented seven scientific abstracts at the 13th World Congress on Endometriosis (WCE) in Vancouver, Canada. The presentations and posters highlighted the positive efficacy and safety data from the Phase III studies of elagolix in premenopausal women who suffer from endometriosis. Following the presentations at the WCE, AbbVie published a comprehensive disclosure of the elagolix Phase III program in the New England Journal of Medicine (Treatment of Endometriosis-Associated Pain with Elagolix, an Oral GnRH Antagonist; Taylor, et al.).

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 in late 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 COMT 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 and BIAL have completed the transfer of materials needed to update the Investigational New Drug (IND) application and prepare a briefing package to support a discussion with the FDA later this year. The outcome of this meeting will inform the activities needed to support regulatory submission to the FDA.

Congenital Adrenal Hyperplasia 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 exposure data from this study support the doses and formulation of NBI-74788 that will be investigated in a follow-up clinical trial in classic congenital adrenal hyperplasia (CAH) patients.

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 the third quarter of 2017. The study will evaluate the relationship between NBI-74788 exposures and specific steroid hormone levels in these subjects.

Essential Tremor Program (NBI-640756) Update

The Company is conducting a Phase I, single site, randomized, double-blind, placebo-controlled, multiple-dose, sequential dose-escalation study to evaluate the safety, tolerability and pharmacokinetics of NBI-640756 in up to 30 healthy volunteers over a week of continuous dosing. The study is being conducted in multiple sequential cohorts of ten subjects per cohort; data from this second Phase I study is expected in the third quarter of 2017. The data from this study, in conjunction with the single dose Phase I study and preclinical studies, will be evaluated and utilized in the design of the anticipated Phase II program for NBI-640756 in subjects with essential tremor.

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 888-632-3381 (US) or 785-424-1678 (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 Neurocrine Biosciences, Inc.

Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. In April of 2017, the FDA approved INGREZZA® (valbenazine) capsules for the treatment of adults with tardive dyskinesia. INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first and only FDA-approved product indicated for the treatment of adults with tardive dyskinesia. The Company markets INGREZZA in the United States. 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 (valbenazine), 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.

About INGREZZA

INGREZZA, a selective VMAT2 inhibitor, is the first and only approved product indicated for the treatment of adults with tardive dyskinesia. INGREZZA inhibits VMAT2 and 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 once-daily, and together with psychiatric medications such as antipsychotics or antidepressants.

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; and whether results from INGREZZA's clinical trials 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; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA 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; 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 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 Annual Report on Form 10-K for the year ended December 31, 2016, and Quarterly Report on Form 10-Q for the quarter ended March 31, 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 June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenues:				
Product sales, net	$ 6,335	$ -	$ 6,335	$ -
License fees and milestones	-	-	-	15,000
Total revenues	6,335	-	6,335	15,000
Operating expenses:				
Cost of product sales	61	-	61	-
Research and development	21,868	26,863	73,750	50,766
General and administrative	41,674	14,965	69,724	26,919
Total operating expenses	63,603	41,828	143,535	77,685
Loss from operations	(57,268)	(41,828)	(137,200)	(62,685)
Other (expense) income:				

Gain on sale/disposal of assets	2	14	2	17
Deferred gain on real estate	879	854	1,758	1,707
Interest expense	(4,767)	-	(4,767)	-
Investment income, net	1,169	680	1,896	1,417
Total other (expense) income	(2,717)	1,548	(1,111)	3,141
Net Loss	$ (59,985)	$ (40,280)	$(138,311)	$(59,544)
Net loss per common share:				
Basic and diluted	$ (0.68)	$ (0.46)	$ (1.58)	$ (0.69)
Shares used in the calculation of net loss per common share:				
Basic and diluted	88,063	86,694	87,675	86,595

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

	June 30, 2017	**December 31, 2016**
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 525,020	$ 307,350
Other current assets	11,731	3,092
Total current assets	536,751	310,442
Property and equipment, net	6,954	6,271
Long-term investments	205,768	43,490
Restricted cash	4,613	4,883
Total assets	$ 754,086	$365,086
Current liabilities	$ 27,721	$ 30,414
Convertible senior notes	360,681	-
Other long-term liabilities	20,446	19,795
Stockholders' equity	345,238	314,877
Total liabilities and stockholders' equity	$ 754,086	$365,086

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