Neurocrine Biosciences Reports Third Quarter 2018 Financial Results

November 5, 2018

INGREZZA® (valbenazine) Third Quarter Net Product Sales of $111.3 Million with Approximately 19,400 TRx
Expanded Clinical Development Pipeline - Phase I Studies Initiated with a Novel VMAT2 Inhibitor and a First-in-Class CNS Compound

SAN DIEGO, Nov. 5, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter ended September 30, 2018, and provided an update on the launch of INGREZZA® (valbenazine) and its clinical development programs.

"We remain committed to delivering hope for patients with serious unmet medical needs as evidenced by the growing adoption of INGREZZA and the recent commercial launch of ORILISSA - both treatments were discovered at Neurocrine Biosciences," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "With the recently completed salesforce expansion, we continue to focus on educating healthcare providers on the benefits of INGREZZA to treat patients with tardive dyskinesia. We have also made great progress in our research and development programs with the advancement of two new internally discovered compounds into the clinic and our research collaboration with Jnana Therapeutics to develop new medicines to treat neurological diseases."

Financial Results

Total revenue for the three and nine months ended September 30, 2018 was $151.8 million and $319.7 million, respectively, compared to $60.8 million and $67.1 million for the same periods in 2017. Total revenues were comprised of the following (*in thousands*):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
INGREZZA product sales, net	$ 111,291	$ 45,774	$ 279,282	$ 52,109
Collaboration revenue	40,466	15,000	40,466	15,000
Total revenue	$ 151,757	$ 60,774	$ 319,748	$ 67,109

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

For the third quarter of 2018, the Company reported net income of $50.8 million, or $0.52 diluted net income per share, compared to a net loss of $11.1 million, or $0.13 net loss per share, for the same period in 2017. For the nine months ended September 30, 2018, the Company reported net income of $3.0 million, or $0.03 diluted net income per share, compared to a net loss of $149.4 million, or $1.70 net loss per share, for the same period in 2017. The increase in income across both periods is due to increased INGREZZA net product sales and the $40 million event-based milestone from AbbVie.

Research and development (R&D) expenses were $35.5 million during the third quarter of 2018, compared to $22.5 million for the third quarter of 2017. For the nine months ended September 30, 2018, R&D expenses were $121.4 million, compared to $96.2 million for the same period last year. The increase in R&D expenses across both periods is principally due to expanded research efforts, the advancement of the Company's clinical programs including Tourette syndrome, congenital adrenal hyperplasia (CAH), and the two new programs announced today, 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 $60.4 million for the third quarter of 2018 from $43.9 million for the third quarter of 2017. For the nine months ended September 30, 2018, SG&A expenses were $180.0 million, compared to $113.6 million for the same period last year. The increase in SG&A expense for both periods is primarily due to the hiring 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 September 30, 2018 reflected total assets of $933.7 million, including cash and investments of $820.6 million, compared with total assets at December 31, 2017 of $817.6 million.

Updated 2018 Expense Guidance

Ongoing operating expenses for 2018 are now expected to approximate $410 million to $420 million, which compares to the prior operating expense guidance of $395 million to $420 million. The operating expense guidance range includes the clinical pipeline expansion and the recently announced research collaboration with Jnana Therapeutics.

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.

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 December 2018.

In the second quarter of 2018, the Company commenced enrollment into the open-label extension study, T-Force GOLD Plus, for pediatric patients with Tourette syndrome. Patients who complete participation in the T-Force GOLD study are eligible to roll over into participation in this open-label extension study for an additional six months of treatment with optimized doses of valbenazine. The study will collect longer-term safety and tolerability data in children and adolescents as well as providing useful information about the maintenance of efficacy in these patients over the six months period of dosing.

In the second quarter of 2018, the Company 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 responded 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 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 2019 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 – Portela & CA, S.A. (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 second quarter 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, the effect of food on pharmacokinetics, 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 pharmacokinetics, 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. The Company recently expanded this study to include additional patients to further optimize dosing flexibility and convenience. Data are expected during the first quarter of 2019.

New VMAT2 Inhibitor

The Company has filed an IND and initiated a Phase I study for a novel, internally discovered vesicular monoamine transporter 2 (VMAT2) inhibitor with potential use in the treatment of several neurology and/or psychiatry disorders. The initial randomized, double-blind, single ascending dose study to evaluate the safety, tolerability, and pharmacokinetic profile of the compound in healthy participants is anticipated to be completed during the fourth quarter of 2018.

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 Central Nervous System (CNS) compound with potential use in the treatment of several neurology and/or psychiatry disorders. This 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.

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 877-876-9176 (US) or 785-424-1667 (International) using the conference ID: NBIX. The webcast and supplemental information in the form of a slide presentation can also be accessed on Neurocrine's website under Investors at www.neurocrine.com. The webcast and slide presentation will be archived for approximately one month.

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 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 or functional inhibition 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.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) 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; 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; 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 June 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)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$ 111,291	$ 45,774	$ 279,282	$ 52,109
Collaboration revenue	40,466	15,000	40,466	15,000
Total revenues	151,757	60,774	319,748	67,109
Operating expenses:				
Cost of sales	1,551	433	3,355	494

Research and development	35,482	22,463	121,417	96,213
Sales, general and administrative	60,401	43,873	179,952	113,597
Total operating expenses	97,434	66,769	304,724	210,304
Income (loss) from operations	54,323	(5,995)	15,024	(143,195)
Other (expense) income:				
Interest expense	(7,672)	(7,337)	(22,767)	(12,104)
Investment income and other, net	4,113	2,207	10,776	5,863
Total other expense, net	(3,559)	(5,130)	(11,991)	(6,241)
Net income (loss)	$ 50,764	$ (11,125)	$ 3,033	$ (149,436)
Net income (loss) per common share:				
Basic	$ 0.56	$ (0.13)	$ 0.03	$ (1.70)
Diluted	$ 0.52	$ (0.13)	$ 0.03	$ (1.70)
Shares used in the calculation of net income (loss) per common share:				
Basic	90,555	88,325	90,064	87,894
Diluted	96,798	88,325	95,272	87,894

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

	September 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 635,343	$ 515,929
Other current assets	79,051	38,990
Total current assets	714,394	554,919
Property and equipment, net	28,618	10,811
Long-term investments	185,257	247,361
Restricted cash	5,477	4,500
Total assets	$ 933,746	$ 817,591
Current portion of convertible senior notes	$ 383,647	$ —
Other current liabilities	72,753	54,426
Convertible senior notes	—	369,618
Other long-term liabilities	29,833	21,409
Stockholders' equity	447,513	372,138
Total liabilities and stockholders' equity	$ 933,746	$ 817,591

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SOURCE Neurocrine Biosciences, Inc.

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