Neurocrine Biosciences Reports Second Quarter 2019 Financial Results

July 29, 2019

INGREZZA® (valbenazine) Second Quarter Net Product Sales of $180.5 Million with Approximately 31,600 TRx
FDA Accepts Opicapone New Drug Application with PDUFA Date of April 26, 2020
Congenital Adrenal Hyperplasia Program Advances with Initiation of Adaptive Pediatric Trial and FDA Input on Adult Program in Q3 2019

SAN DIEGO, July 29, 2019 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its financial results for the quarter ended June 30, 2019 and provided an update on the launch of INGREZZA® (valbenazine) and its clinical development programs.

"Over the past two years, our team has done an excellent job building awareness of tardive dyskinesia within the healthcare community and providing patients access to INGREZZA. We continue to focus on educating about tardive dyskinesia and the benefits of INGREZZA in providing relief for patients suffering from this debilitating movement disorder," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We have also made progress across our development pipeline with the FDA acceptance of our New Drug Application for opicapone and the anticipated regulatory submission of elagolix for uterine fibroids by AbbVie. In addition, we continued to advance our congenital adrenal hyperplasia program with the recent initiation of our pediatric trial and look forward to our planned discussion with the FDA on the adult program. We are pleased with this exciting progress and remain on track to have three FDA-approved treatments in four indications by 2020."

Financial Results

Total revenues for the three and six months ended June 30, 2019, was $183.6 million and $322.0 million, respectively, compared to $96.9 million and $168.0 million for the same periods in 2018.

Total revenues were comprised of the following (*unaudited*):

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2019**	**2018**	**2019**	**2018**
INGREZZA product sales, net	$ 180,544	$ 96,905	$316,975	$167,991
Collaboration revenue	3,036	—	5,008	—
Total revenues	$ 183,580	$ 96,905	$321,983	$167,991

For the second quarter of 2019, the Company reported net income of $51.3 million, or $0.54 diluted earnings per share, compared to a net loss of $5.9 million, or $0.07 net loss per share, for the same period in 2018. The increase in net income is due to increased INGREZZA net product sales and a $21.0 million unrealized gain on the Company's Voyager Therapeutics equity investment. For the six months ended June 30, 2019, the Company reported a net loss of $50.8 million, or $0.56 net loss per share, compared to a net loss of $47.7 million, or $0.53 net loss per share, for the same period in 2018. The increase in net loss for the first half of 2019 is primarily due to $118.1 million of in-process research and development (IPR&D) in connection with the strategic collaboration with Voyager. This was partially offset by increased INGREZZA net product sales and a $22.6 million unrealized gain on the Company's equity investment in Voyager.

Research and development (R&D) expenses increased to $61.7 million for the second quarter of 2019 from $37.0 million for the same period in 2018. The increase in R&D expenses primarily reflects funding of development activities and a $10.0 million milestone expense related to the U.S. Food and Drug Administration (FDA) acceptance of the opicapone New Drug Application (NDA). For the six months ended June 30, 2019, R&D expenses increased to $99.3 million, compared to $85.9 million for the same period in 2018. The increase in R&D expenses for the first half of 2019 primarily reflects funding of development activities in connection with the Company's collaboration with Voyager.

In connection with the Voyager collaboration, the Company recognized IPR&D of $118.1 million during the first six months of 2019, including a $5.0 million payment during the second quarter to obtain rights outside the United States to the Friedreich's ataxia program. In addition, the Company made an equity investment in Voyager which is required to be marked to market each quarter resulting in an unrealized gain of $21.0 million and $22.6 million for the second quarter and first six months, respectively, and is reflected in Other Income.

Sales, general and administrative (SG&A) expenses increased to $80.8 million for the second quarter of 2019, from $60.9 million for the same period in 2018. For the six months ended June 30, 2019, SG&A expenses increased to $168.4 million, compared to $119.6 million for the same period in 2018. The increase in SG&A expenses for both periods is primarily due to the sales force expansion completed in the third quarter of 2018, the national launch of a patient-focused disease state awareness campaign, Talk About TD, and an increase in the Branded Pharmaceutical Drug fee expense.

As of June 30, 2019, the Company's cash and available-for-sale investments was $766.5 million.

Updated 2019 SG&A and R&D Expense Guidance

SG&A, IPR&D, and R&D expenses for 2019 are expected to be $658 million to $688 million. Ongoing SG&A and R&D expenses for 2019, excluding IPR&D, are now expected to approximate $540 to $570 million, which compares to the prior SG&A and R&D expense guidance of $550 million to $600 million.

Pipeline Highlights

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, oral, selective catechol-O-methyltransferase inhibitor, being developed as an adjunctive therapy to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes. The Company met with the FDA in January 2018 and based upon the BIPARK-1 and BIPARK-2 pivotal Phase III studies conducted by BIAL, the FDA did not require additional Phase III trials to form an NDA submission. The NDA for opicapone was submitted to the FDA during the second quarter of 2019. The NDA was accepted by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of April 26, 2020. As a result of the FDA's acceptance of the NDA submission, the Company will pay a $10.0 million milestone payment to BIAL.

Elagolix Update

On July 24, 2018, AbbVie, in collaboration with Neurocrine Biosciences, announced FDA approval and in October 2018 Health Canada approval for ORILISSA® (elagolix) 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 study 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. Results from these studies will form the basis for an anticipated NDA submission to the FDA for the approval of elagolix in the treatment of uterine fibroids in 2019.

AbbVie intends to initiate a study of elagolix in women with polycystic ovary syndrome (PCOS).

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

The Company began an adaptive, Phase II proof-of-concept study examining the pharmacokinetics, pharmacodynamics, and safety of NBI-74788 in adults with classic 21-hydroxylase deficiency congenital adrenal hyperplasia (CAH) in November 2017. This study evaluates the safety and tolerability of NBI-74788 in patients with CAH together with the relationship between exposure and specific steroid hormone levels in these patients. In March 2019, positive interim results from this ongoing study demonstrated a clinically meaningful reduction in key biomarkers associated with the management of CAH. NBI-74788 was shown to be well tolerated with no serious adverse events reported to date. The Company plans to discuss the NBI-74788 program in adult CAH patients with the FDA during the third quarter of 2019.

In July 2019, the Company initiated an adaptive, Phase II proof-of-concept study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of NBI-74788 in pediatric patients with classic CAH.

Voyager Collaboration and VY-AADC Program

During the first quarter of 2019, Neurocrine Biosciences formed a strategic collaboration with Voyager Therapeutics focused on the development and commercialization of Voyager's gene therapy programs, VY-AADC for Parkinson's disease and VY-FXN01 for Friedreich's ataxia, as well as rights to two programs to be determined. This collaboration combines Neurocrine Biosciences' expertise in neuroscience, drug development and commercialization with Voyager's innovative gene therapy programs targeting severe neurological diseases.

Based on the results from the VY-AADC Phase I programs in Parkinson's disease, RESTORE-1, a Phase II, randomized, placebo-surgery controlled, double-blinded, multi-center, clinical trial was initiated to evaluate the safety and efficacy of VY-AADC in patients who have been diagnosed with Parkinson's disease for at least four years, are not responding adequately to oral medications, and have at least three hours of OFF time during the day as measured by a validated self-reported patient diary.

Conference Call and Webcast Today at 4:30 PM Eastern Time

Neurocrine Biosciences 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 866-342-8591 (US) or 203-518-9713 (International) using the conference ID: NBIX. The webcast can also be accessed on Neurocrine Biosciences' website under Investors at www.neurocrine.com. A replay of the webcast will be available on the website approximately one hour after the conclusion of the event and will be archived for approximately one month.

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 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 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.

Parkinsonism
INGREZZA may cause Parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

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/PI.

About Neurocrine Biosciences
Neurocrine Biosciences (Nasdaq: NBIX) is a neuroscience-focused, biopharmaceutical company with more than 25 years of experience discovering and developing life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia and endometriosis* and clinical development programs in multiple therapeutic areas including Parkinson's disease, congenital adrenal hyperplasia, uterine fibroids* and polycystic ovary syndrome*. Headquartered in San Diego, Neurocrine Biosciences specializes in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit neurocrine.com, and follow the company on LinkedIn. *(*in collaboration with AbbVie)*

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; our financial and operating performance; the collaboration with Voyager Therapeutics; 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 and ORILISSA; risks that the opicapone NDA may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; 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, opicapone, or the Company's other product candidates; risks associated with the Company's dependence on AbbVie for the commercialization of ORILISSA and the development of elagolix; risks associated with the Company's dependence on BIAL for development and manufacturing activities related to opicapone, and the ability of the Company to manage BIAL; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory, manufacturing, 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 our collaboration partners may never be realized, including Voyager, BIAL, and Mitsubishi Tanabe; 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, 2019. 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
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except per share data)	**2019**	**2018**	**2019**	**2018**
Revenues:				
Product sales, net	$ 180,544	$ 96,905	$316,975	$167,991
Collaboration revenue	3,036	—	5,008	—
Total revenues	183,580	96,905	321,983	167,991
Operating expenses:				
Cost of sales	1,608	854	2,737	1,804
Research and development	61,687	36,988	99,339	85,935
Acquired in-process research and development	5,000	—	118,081	—
Selling, general and administrative	80,824	60,915	168,362	119,551
Total operating expenses	149,119	98,757	388,519	207,290
Operating income (loss)	34,461	(1,852)	(66,536)	(39,299)
Other (expense) income:				
Interest expense	(7,942)	(7,591)	(15,795)	(15,095)
Unrealized gain on restricted equity securities	20,965	—	22,645	—
Investment income and other, net	4,607	3,530	9,183	6,663
Total other income (expense), net	17,630	(4,061)	16,033	(8,432)
Income (loss) before provision for income taxes	52,091	(5,913)	(50,503)	(47,731)
Provision for income taxes	753	—	274	—
Net income (loss)	$ 51,338	$ (5,913)	$(50,777)	$(47,731)
Net income (loss) per share, basic	$ 0.56	$ (0.07)	$ (0.56)	$ (0.53)
Net income (loss) per share, diluted	$ 0.54	$ (0.07)	$ (0.56)	$ (0.53)
Weighted average common shares outstanding, basic	91,389	90,100	91,226	89,814
Weighted average common shares outstanding, diluted	94,779	90,100	91,226	89,814

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

	June 30, 2019	December 31, 2018
(in thousands)		

Cash, cash equivalents and short-term investments	$ 619,978	$ 650,913
Other current assets	128,830	86,864
Total current assets	748,808	737,777
Property and equipment, net	39,623	33,869
Long-term investments	146,503	216,028
Investment in restricted equity securities	77,365	-
Operating lease assets	49,085	-
Restricted cash	5,477	5,477
Total assets	$ 1,066,861	$ 993,151
Current liabilities	$ 100,589	$ 88,233
Noncurrent operating lease liabilities	66,185	-
Convertible senior notes	398,466	388,496
Other long-term liabilities	17,915	35,657
Stockholders' equity	483,706	480,765
Total liabilities and stockholders' equity	$ 1,066,861	$ 993,151

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SOURCE Neurocrine Biosciences, Inc.

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