Neurocrine Biosciences Reports First Quarter 2020 Financial Results

May 6, 2020

INGREZZA® (valbenazine) First Quarter Net Product Sales of $231 Million with Approximately 41,500 TRx
ONGENTYS® (opicapone) Approved by the U.S. Food and Drug Administration (FDA) as a Once-Daily Adjunctive Treatment for Patients with Parkinson's Disease Experiencing "Off" Episodes
Results of the Phase II Proof-of-Concept Study of Crinecerfont in Adult Patients with Congenital Adrenal Hyperplasia to be Presented at the Virtual ENDO Online 2020 Meeting on June 8th

SAN DIEGO, May 6, 2020 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the first quarter ended March 31, 2020 and provided revised full-year 2020 financial expense guidance.

"First and foremost, I would like to thank our employees, healthcare providers and suppliers for their commitment and dedication in managing these tough times. Together, we remain focused on ensuring that patients with tardive dyskinesia, many of whom are managing their involuntary movements with a mental health condition, are well supported and have uninterrupted access to INGREZZA," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "Even during these challenging times, we continue to see strong persistency and compliance with INGREZZA."

"With the recent FDA approval of ONGENTYS for patients with Parkinson's disease, we're excited to add another treatment for movement disorders to our portfolio and look forward to making it available to patients later this year. In addition, we are well positioned to launch clinical studies of several compounds in our pipeline and plan to have on-going studies in three registrational programs and four mid-stage programs by the end of this year," Gorman added. "The company is in a strong financial position, enabling us to navigate through this pandemic while continuing to execute on our mission to discover, develop and deliver important medicines to treat patients with neurological, endocrine, and psychiatric disorders."

First Quarter 2020 Financial Highlights

	Three Months Ended March 31,	
(unaudited, in millions, except per share data)	**2020**	**2019**
Revenues:		
INGREZZA® (valbenazine) product sales, net	$ 231.1	$ 136.4
Collaboration revenue	6.0	2.0
Total revenues	$ 237.1	$ 138.4
GAAP Research and Development (R&D)	$ 58.3	$ 37.7
Non-GAAP R&D	$ 50.6	$ 32.3
GAAP Selling, General and Administrative (SG&A)	$ 117.8	$ 87.5
Non-GAAP SG&A	$ 102.7	$ 77.1
GAAP net income (loss)	$ 37.4	$ (102.1)
GAAP net income per share – diluted	$ 0.39	$ (1.12)
Non-GAAP net income	$ 79.1	$ 27.7
Non-GAAP net income per share – diluted	$ 0.82	$ 0.29

(unaudited, in millions)	**March 31, 2020**	**December 31, 2019**
Cash and cash equivalents and debt securities available-for-sale	$ 1,007.6	$ 970.2

First Quarter Net Product Sales Highlights:

- INGREZZA net product sales for the first quarter 2020 were $231 million, representing a year-over-year increase of 69%.
- Successfully navigated through the annual seasonal payor dynamics driving steady persistency and strong momentum in the second half of the first quarter.
- End of first quarter 2020 days-on-hand channel inventory slightly increased relative to the fourth quarter 2019 resulting in an approximate $4 million benefit to net product sales.

Financial Highlights:

- Research and Development (R&D) investment increased in the first quarter of 2020 versus the first quarter of 2019 primarily due to the Company's increased investment in its gene therapy programs in collaboration with Voyager Therapeutics and increased activity to support advancing its expanded clinical portfolio.
- Selling, General and Administrative (SG&A) investment increased in the first quarter of 2020 versus the first quarter of 2019, primarily due to increased headcount costs and continued investment in the patient-focused disease state awareness campaign, "Talk About TD".
- First quarter of 2020 GAAP net income and diluted earnings per share were $37 million and $0.39, respectively, compared to a net loss and net loss per share of $102 million and $1.12, respectively, in the first quarter of 2019, largely attributable to IPR&D expense of $113.1 million.
- First quarter of 2020 non-GAAP net income and diluted earnings per share were $79 million and $0.82, respectively, compared to $28 million and $0.29, respectively, in the first quarter of 2019.
- At March 31, 2020, the Company had cash, cash equivalents and debt securities available-for-sale over $1 billion.

A reconciliation of GAAP to non-GAAP quarterly financial results can be found in Table 3 at the end of this earnings release.

Recent Events

- On April 3, 2020, the Company provided an update on its business operations as a result of the COVID-19 pandemic as part of its commitment to prioritize the safety, health and well-being of patients, their caregivers, healthcare providers and employees. Please refer to the press release for additional information pertaining to the status of our programs and ongoing company initiatives through the COVID-19 crisis. Key updates included:
  - Employees, including customer-facing teams, have been working from home since March and have been utilizing remote technologies to ensure continued support for patients and healthcare professionals.
  - Patients taking INGREZZA have assurance of continued supply, and specialty and mental health pharmacies remain engaged with patients to ensure they receive continuity of care and support their overall health and well-being.
  - Enrollment has been paused for clinical studies and will be reinstated when it is safe and appropriate to do so. In parallel, the Company continues preparations to launch new clinical studies in the second half of the year. By the end of 2020, Neurocrine Biosciences plans to have studies ongoing in three registrational and four mid-stage programs.
- On April 24, 2020, the FDA approved ONGENTYS® (opicapone), the first and only once-daily COMT inhibitor, as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes – periods of time when motor symptoms such as tremor, slowed movement and difficulty walking occur. ONGENTYS also increases "on" time without troublesome dyskinesia, the time when the motor symptoms of a patient with Parkinson's disease are better controlled. The FDA approval of ONGENTYS for Parkinson's disease triggered a $20 million milestone under the terms of the collaboration agreement with BIAL. The commercial launch of ONGENTYS is expected to occur later in 2020.

Full-Year 2020 Revised Expense Guidance

	Range	
(*in millions*)	Low	High
Combined GAAP R&D and SG&A expenses	$675	$725
Combined Non-GAAP R&D and SG&A expenses	$550	$600

- Previously, the Company expected combined GAAP R&D and SG&A expenses in the range of $740 million to $770 million and combined non-GAAP R&D and SG&A expenses in the range of $620 million to $650 million.
- GAAP and non-GAAP expense guidance range reflects increased investment in R&D programs including three registrational programs, meaningful investments across early stage programs including Voyager and Xenon collaborations, continued investment in INGREZZA and marketing costs associated with the anticipated launch of ONGENTYS.
- GAAP-only guidance includes approximately $105 million of share-based compensation and a $20 million milestone to BIAL connected with the approval of ONGENTYS by the FDA. GAAP-only guidance does not include any other potential milestones or in-process research and development costs associated with current collaborations or future business development activities.

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 800-894-5910 (US) or 785-424-1052 (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 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 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.

Please see INGREZZA full Prescribing Information at www.INGREZZA.com/PI.

About ONGENTYS® (opicapone) Capsules

ONGENTYS is a novel, once-daily, oral, peripheral, selective and reversible catechol-O-methyltransferase (COMT) inhibitor approved by the U.S. Food and Drug Administration (FDA) as an add-on treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes. ONGENTYS inhibits the COMT enzyme, which breaks down levodopa, making more levodopa available to reach the brain.

Important Safety Information

Contraindications

ONGENTYS is contraindicated in patients with:

- Concomitant use of non-selective monoamine oxidase (MAO) inhibitors.
- Pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms.

Warnings & Precautions

Cardiovascular Effects with Concomitant Use of Drugs Metabolized by Catechol-O-Methyltransferase (COMT)

Possible arrhythmias, increased heart rate, and excessive changes in blood pressure may occur with concomitant use of ONGENTYS and drugs metabolized by COMT, regardless of the route of administration (including inhalation). Monitor patients treated concomitantly with ONGENTYS and drugs metabolized by COMT.

Falling Asleep During Activities of Daily Living and Somnolence

Patients treated with dopaminergic medications and medications that increase levodopa exposure, including ONGENTYS, have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes has resulted in accidents. If a patient develops daytime sleepiness or somnolence, consider discontinuing ONGENTYS or adjusting

other dopaminergic or sedating medications and advise patients to avoid driving and other potentially dangerous activities.

Hypotension/Syncope
Monitor patients for hypotension and advise patients about the risk for syncope. If these adverse reactions occur, consider discontinuing ONGENTYS or adjusting the dosage of other medications that can lower blood pressure.

Dyskinesia
ONGENTYS potentiates the effects of levodopa which may result in dyskinesia or exacerbate pre-existing dyskinesia. Reducing the patient's levodopa dosage or the dosage of another dopaminergic drug may reduce dyskinesia that occurs during treatment with ONGENTYS.

Hallucinations and Psychosis
Consider stopping ONGENTYS if hallucinations or psychotic-like behaviors occur. Patients with a major psychotic disorder should ordinarily not be treated with ONGENTYS.

Impulse Control/Compulsive Disorders
Patients may experience intense urges (e.g., gambling, sexual, spending money, binge eating) and the inability to control them. It is important for prescribers to specifically ask patients or their caregivers about the development of new or increased urges. Re-evaluate the patient's current therapies for Parkinson's disease and consider stopping ONGENTYS if a patient develops such urges while taking ONGENTYS.

Withdrawal-Emergent Hyperpyrexia and Confusion
A symptom complex resembling neuroleptic malignant syndrome (elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), has been reported in association with rapid dose reduction or withdrawal of drugs that increase central dopaminergic tone. There were no reports of neuroleptic malignant syndrome in ONGENTYS controlled clinical studies. When discontinuing ONGENTYS, monitor patients and consider adjustment of other dopaminergic therapies as needed.

Adverse Reactions
The most common adverse reactions (incidence at least 4% and greater than placebo) were dyskinesia, constipation, blood creatine kinase increase, hypotension/syncope, and weight decrease.

Please see ONGENTYS full Prescribing Information at www.neurocrine.com/ongentyspi.

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.

About Neurocrine Biosciences
Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with 28 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, Parkinson's disease and endometriosis* and clinical development programs in multiple therapeutic areas including a gene therapy for Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, epilepsy, 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)*

Non-GAAP Financial Measures
In addition to the financial results and financial guidance that are provided in accordance with accounting principles generally accepted in the United States (GAAP), this press release also contains certain non-GAAP financial measures. When preparing these supplemental non-GAAP financial results and guidance, the Company excludes certain GAAP items that management does not consider to be normal, including recurring cash operating expenses that might not meet the definition of unusual or non-recurring items. In particular, the non-GAAP measures exclude: milestones received from licenses and collaborations, milestones paid related to licenses and collaborations, non-cash collaboration revenue, acquired in-process research and development, share-based compensation expense, non-cash interest expense related to convertible debt, changes in fair value of equity security investments and certain adjustments to income tax expense. These non-GAAP measures are provided as a complement to results provided in accordance with GAAP as management believes these non-GAAP financial measures help indicate underlying trends in the Company's business, are important in comparing current results with prior period results and provide additional information regarding the Company's financial position. Management also uses these non-GAAP financial measures to establish budgets and operational goals that are communicated internally and externally and to manage the Company's business and evaluate its performance. The Company provides guidance regarding combined research and development and sales, general, and administrative expenses on both a GAAP and a non-GAAP basis. The guidance regarding GAAP research and development expenses and sales, general and administrative expenses does not include estimates for expenses associated with any potential future business development activities. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the attached financial information.

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 our products

and product candidates, including INGREZZA, ONGENTYS, and our partnered product, ORILISSA; the value INGREZZA, ONGENTYS, ORILISSA, and/or our product candidates may bring to patients; the continued success of INGREZZA; the timing of our launch of ONGENTYS; our financial and operating performance, including our future expenses; our collaborative partnerships; expectations regarding the impact of COVID-19 on our business; expectations regarding our ability to adapt our business to the evolving COVID-19 pandemic, mitigate its impact on our business and maintain business continuity, including our ability to protect the safety and well-being of our employees, to continue to support uninterrupted supply of INGREZZA, including patient and healthcare provider access to INGREZZA, to continue our ongoing clinical trials and other development activities, and to otherwise advance our business objectives; 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: our future financial and operating performance; risks associated with the commercialization of INGREZZA, ONGENTYS, and ORILISSA; risks that the launch of ONGENTYS may be delayed; the impact of the COVID-19 pandemic and efforts to mitigate its spread on our business; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risk and uncertainties related to any COVID-19 quarantines, shelter-in-place and similar government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our business operations and the business operations of the third parties on which we rely; risks related to the development of our product candidates; risks associated with our dependence on third parties for development and manufacturing activities related to INGREZZA and our product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks associated with our dependence on AbbVie for the commercialization of ORILISSA and the continued development of elagolix; risks associated with our dependence on BIAL for manufacturing activities for ONGENTYS, and our ability to manage BIAL; risks that clinical development activities may not be completed on time or at all, or may be delayed for regulatory, manufacturing, COVID-19 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 potential benefits of the agreements with our collaboration partners may never be realized; risks that our products, 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 our periodic reports filed with the SEC, including without limitation our quarterly report on Form 10-Q for the quarter ended March 31, 2020. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

This press release refers to certain non-GAAP financial measures. These non-GAAP financial measures should not be considered replacements for, and should be read together with, the most comparable GAAP financial measures. Reconciliations of non-GAAP financial results to the most directly comparable GAAP financial results are included at the end of this press release, which has been filed with the SEC in a Current Report on Form 8-K dated as of even date herewith. In addition, Neurocrine provides guidance regarding combined research and development and sales, general and administrative expenses on both a GAAP and non-GAAP basis.

TABLE 1

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

(in millions, except per share data)	**March 31, 2020**	**March 31, 2019**
Revenues:		
Product sales, net	$ 231.1	$ 136.4
Collaboration revenue	6.0	2.0
Total revenues	237.1	138.4
Operating expenses:		
Cost of sales	2.1	1.1
Research and development	58.3	37.7
Acquired in-process research and development	—	113.1
Selling, general and administrative	117.8	87.5
Total operating expenses	178.2	239.4
Operating income (loss)	58.9	(101.0)
Other (expense) income:		
Interest expense	(8.2)	(7.9)
Unrealized (losses) gains on equity securities	(16.5)	1.7
Investment income and other, net	4.7	4.6
Total other expense, net	(20.0)	(1.6)
Income (loss) before provision for (benefit from) income taxes	38.9	(102.6)
Provision for (benefit from) income taxes	1.5	(0.5)
Net income (loss)	$ 37.4	$ (102.1)
Net income (loss) per share, basic	$ 0.40	$ (1.12)

Net income (loss) per share, diluted	$ 0.39	$ (1.12)
Weighted average common shares outstanding, basic	92.6	91.1
Weighted average common shares outstanding, diluted	97.0	91.1

TABLE 2

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

(in millions)	March 31, 2020	December 31, 2019
Cash and cash equivalents and debt securities available-for-sale	$ 771.7	$ 670.5
Other current assets	196.5	160.5
Total current assets	968.2	831.0
Property and equipment, net	41.9	41.9
Debt securities available-for-sale	235.9	299.7
Equity securities	39.4	55.9
Right-of-use assets	73.3	74.3
Restricted cash	3.2	3.2
Total assets	$ 1,361.9	$ 1,306.0
Convertible senior notes	$ —	$ 408.8
Other current liabilities	140.3	156.5
Total current liabilities	140.3	565.3
Operating lease liabilities	85.6	86.7
Convertible senior notes	414.1	—
Other long-term liabilities	21.6	17.1
Stockholders' equity	700.3	636.9
Total liabilities and stockholders' equity	$ 1,361.9	$ 1,306.0

TABLE 3

NEUROCRINE BIOSCIENCES, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(unaudited)

(in millions, except per share data)	Three Months Ended March 31, 2020	2019
GAAP net income (loss)	$ 37.4	$ (102.1)
Adjustments:		
Non-cash collaboration revenue [A]	(1.3)	—
Acquired in-process research and development (IPR&D) [B]	—	113.1
Share-based compensation expense – R&D	7.7	5.4
Share-based compensation expense – SG&A	15.1	10.4
Non-cash interest related to convertible debt	5.3	4.9
Changes in fair value of equity security investments [C]	16.5	(1.7)
Income tax effect related to reconciling items [D]	(1.6)	(2.3)
Non-GAAP net income	$ 79.1	$ 27.7
Net income (loss) per diluted common share:		
GAAP	$ 0.39	$ (1.12)
Non-GAAP [E]	$ 0.82	$ 0.29

[A] During the first quarter of 2020, the Company recognized non-cash collaboration revenue from Mitsubishi Tanabe Pharma Corporation under the collaboration and license agreement entered into in 2015.

[B] During the first quarter of 2019, the Company incurred IPR&D expenses of $113.1 million in association with the collaboration and license agreement entered into with Voyager in 2019.

[C] The Company recognized an unrealized loss of $16.5 million for the first quarter of 2020 and an unrealized gain of $1.7 million for the first quarter of 2019 to adjust its equity security investments to fair value.

[D] Estimated income tax effect of non-GAAP reconciling items are calculated using applicable statutory tax rates, taking into consideration any valuation allowance.

[E] Non-GAAP net income per diluted common share for the first quarter of 2019 reflects diluted shares of 94.8 million, which were calculated in accordance with the guidance on earnings per share in ASC 260.

View original content to download multimedia:http://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-first-quarter-2020-financial-results-301054232.html

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc., Navjot Rai (Media), 858-617-7623, media@neurocrine.com; or Todd Tushla (Investors), 858-617-7143, ir@neurocrine.com