Neurocrine Biosciences Reports Second Quarter 2020 Financial Results

August 3, 2020

INGREZZA® (valbenazine) Second Quarter Net Product Sales of $268 million with Approximately 46,400 TRx

Two Medicines Approved by the U.S. Food and Drug Administration (FDA) During the Second Quarter, ONGENTYS® (opicapone) for Parkinson's Disease and ORIAHNN™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) for Uterine Fibroids by AbbVie

Strategic Partnership with Takeda on Seven Compounds Expands and Diversifies Research and Development Pipeline

Single Phase III Global Registration Study of Crinecerfont in Adult Patients with Congenital Adrenal Hyperplasia Now Enrolling

SAN DIEGO, Aug. 3, 2020 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the second quarter ended June 30, 2020 and provided revised full-year 2020 financial expense guidance.

"I want to thank healthcare providers and our employees for the perseverance they showed during the second quarter to ensure patients had uninterrupted access to INGREZZA under the challenging circumstances caused by the COVID-19 pandemic. As we move into the second half of 2020, we remain focused on improving the diagnosis and treatment rates for people with tardive dyskinesia, preparing to make ONGENTYS available to people living with Parkinson's disease, and advancing our programs in clinical development," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "With four U.S. FDA approved treatments that address four unique patient populations and a diverse and expanding pipeline, Neurocrine Biosciences is well positioned to be a leading neuroscience-focused biopharmaceutical company."

Financial Highlights

	Three Months Ended June 30,		Six Months Ended June 30,	
(unaudited, in millions, except per share data)	**2020**	**2019**	**2020**	**2019**
Revenues:				
INGREZZA product sales, net	$ 267.6	$ 180.5	$ 498.7	$ 316.9
Collaboration revenue	34.8	3.0	40.8	5.0
Total revenues	$ 302.4	$ 183.5	$ 539.5	$ 321.9
GAAP Research and Development (R&D)	$ 80.9	$ 61.7	$ 139.2	$ 99.4
Non-GAAP R&D	$ 51.0	$ 45.7	$ 101.6	$ 78.0
GAAP Selling, General and Administrative (SG&A)	$ 96.5	$ 80.8	$ 214.3	$ 168.3
Non-GAAP SG&A	$ 76.9	$ 68.9	$ 179.6	$ 146.0
GAAP net income (loss)	$ 79.6	$ 51.3	$ 117.0	$ (50.8)
GAAP net income (loss) per share – diluted	$ 0.81	$ 0.54	$ 1.20	$ (0.56)
Non-GAAP net income	$ 139.1	$ 67.2	$ 218.2	$ 94.9
Non-GAAP net income per share – diluted	$ 1.42	$ 0.71	$ 2.24	$ 1.00

(unaudited, in millions)	June 30, 2020	December 31, 2019
Total cash and cash equivalents and debt securities available-for-sale	$1,143.5	$ 970.2

Second Quarter Net Product Sales Highlights:

- INGREZZA net product sales for the second quarter of 2020 were $268 million, representing a year-over-year increase of 48%.

- Continued strength in refill and persistency rates for existing INGREZZA patients.
- End of second quarter 2020 days-on-hand channel inventory increased relative to end of first quarter 2020, resulting in an approximate $12 million benefit to net product sales.

Financial Highlights:

- Second quarter 2020 GAAP net income and diluted earnings per share were approximately $80 million and $0.81, respectively, compared with approximately $51 million and $0.54, respectively, in the second quarter of 2019, primarily driven by higher INGREZZA sales offset by higher in-process Research and Development (IPR&D) costs and operating expenses.
- Second quarter 2020 non-GAAP net income and diluted earnings per share were approximately $139 million and $1.42, respectively, compared with approximately $67 million and $0.71, respectively, in the second quarter of 2019 driven by higher INGREZZA sales.
- Research and Development (R&D) expense increased in the second quarter of 2020 versus the second quarter of 2019, primarily due to milestone payments to BIAL associated with the approval of ONGENTYS and increased headcount costs.
- Selling, General and Administrative (SG&A) expense increased in the second quarter of 2020 versus the second quarter of 2019, primarily due to increased headcount costs.
- At June 30, 2020, the Company had cash, cash equivalents and debt securities available-for-sale of $1.1 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

- In April 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 payment to BIAL. The commercial launch of ONGENTYS is expected to occur later in 2020.
- In May 2020, AbbVie received approval from the FDA for ORIAHNN™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. FDA approval for ORIAHNN for uterine fibroids resulted in the achievement of a $30 million milestone. The Company will receive royalties at tiered percentage rates on net sales of ORIAHNN.
- In May 2020, the Company exercised its option with Idorsia Pharmaceuticals Ltd. paying $45 million to license the global rights to NBI-827104 (ACT-709478), a potent, selective, orally active and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy. The option also included a research collaboration to discover novel T-type calcium channel blockers.
- In June 2020, the Company reported positive Phase II data for crinecerfont in adults with congenital adrenal hyperplasia (CAH) and highlighted the resumption of enrollment in the Phase IIa pediatric study in adolescents with classic CAH. In July 2020, the Company initiated the CAHtalyst Study (www.cahtalyststudy.com), a single, global registrational study of crinecerfont in adult patients with classic CAH.
- In June 2020, the Company entered an exclusive license with Takeda Pharmaceutical Company Limited, or Takeda, for the right to develop and commercialize certain compounds in Takeda's early-to-mid-stage psychiatry pipeline. Specifically, Takeda granted the Company an exclusive license to seven pipeline programs, including three clinical-stage assets for negative effects of schizophrenia, treatment-resistant depression, and anhedonia. The agreement became effective in July 2020, upon expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, at which time the Company paid $120 million upfront (minus an earnest money deposit already paid by the Company to Takeda) to gain the exclusive license.

Full-Year 2020 Revised Expense Guidance

	Range	
(in millions)	**Low**	**High**
Combined GAAP R&D and SG&A expenses	$850	$900
Combined Non-GAAP R&D and SG&A expenses	$570	$610

- Previously, the Company expected combined GAAP R&D and SG&A expenses in the range of $675 million to $725 million and combined non-GAAP R&D and SG&A expenses in the range of $550 million to $600 million.
- The $175 million increase in GAAP expense guidance range primarily reflects $45 million paid to Idorsia upon exercising the option to license the global rights to NBI-827104 (ACT-709478) and $120 million paid to Takeda for the exclusive license for the right to develop and commercialize certain compounds in Takeda's early-to-mid-stage psychiatry pipeline.

- GAAP-only guidance includes approximately $105 million of share-based compensation. GAAP-only guidance does not include any other potential milestones or in-process research and development costs associated with current collaborations or potential 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 877-876-9173 (US) or 785-424-1667 (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 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, endometriosis* and uterine fibroids*, with three pivotal and five mid-stage clinical programs in multiple therapeutic areas. 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; the value our products 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 and our other products; 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 ORIAHNN, as well as 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 June 30, 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 event 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)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Revenues:				
Product sales, net	$ 267.6	$ 180.5	$ 498.7	$ 316.9
Collaboration revenue	34.8	3.0	40.8	5.0
Total revenues	302.4	183.5	539.5	321.9
Operating expenses:				
Cost of sales	2.4	1.6	4.5	2.7
Research and development	80.9	61.7	139.2	99.4
Acquired in-process research and development	46.0	5.0	46.0	118.1
Selling, general and administrative	96.5	80.8	214.3	168.3
Total operating expenses	225.8	149.1	404.0	388.5
Operating income (loss)	76.6	34.4	135.5	(66.6)
Other income (expense):				
Interest expense	(8.3)	(7.9)	(16.5)	(15.8)
Unrealized gain (loss) on equity securities	11.3	21.0	(5.2)	22.7
Investment income and other, net	3.6	4.6	8.3	9.2
Total other income (expense), net	6.6	17.7	(13.4)	16.1
Income (loss) before provision for income taxes	83.2	52.1	122.1	(50.5)
Provision for income taxes	3.6	0.8	5.1	0.3
Net income (loss)	$ 79.6	$ 51.3	$ 117.0	$ (50.8)
Net income (loss) per share, basic	$ 0.86	$ 0.56	$ 1.26	$ (0.56)
Net income (loss) per share, diluted	$ 0.81	$ 0.54	$ 1.20	$ (0.56)
Weighted average common shares outstanding, basic	93.0	91.4	92.8	91.2
Weighted average common shares outstanding, diluted	98.2	94.8	97.6	91.2

TABLE 2

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

(in millions)	June 30, 2020	December 31, 2019
Cash and cash equivalents and debt securities available-for-sale	$ 948.3	$ 670.5
Other current assets	197.9	160.5
Total current assets	1,146.2	831.0
Debt securities available-for-sale	195.2	299.7
Right-of-use assets	72.1	74.3
Equity securities	50.7	55.9
Property and equipment, net	44.6	41.9
Restricted cash and other long-term assets	6.8	3.2
Total assets	$1,515.6	$ 1,306.0
Convertible senior notes	$ 419.5	$ 408.8
Other current liabilities	153.5	156.5
Total current liabilities	573.0	565.3
Operating lease liabilities	84.3	86.7
Other long-term liabilities	27.1	17.1
Stockholders' equity	831.2	636.9
Total liabilities and stockholders' equity	$1,515.6	$ 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 June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
GAAP net income (loss)	$ 79.6	$ 51.3	$ 117.0	$ (50.8)
Adjustments:				
Milestones received from licenses and collaborations [A]	(30.0)	—	(30.0)	—
Non-cash collaboration revenue [B]	—	—	(1.3)	—
Acquired in-process research and development (IPR&D) [C]	46.0	5.0	46.0	118.1
Milestones paid related to licenses and collaborations - R&D	20.0	10.0	20.0	10.0
Share-based compensation expense - R&D	9.9	6.0	17.6	11.4
Share-based compensation expense - SG&A	19.6	11.9	34.7	22.3
Non-cash interest related to convertible debt	5.4	5.1	10.7	10.0
Changes in fair value of equity security investments [D]	(11.3)	(21.0)	5.2	(22.7)
Income tax effect related to reconciling items [E]	(0.1)	(1.1)	(1.7)	(3.4)
Non-GAAP net income	$ 139.1	$ 67.2	$ 218.2	$ 94.9
Net income (loss) per diluted common share:				
GAAP	$ 0.81	$ 0.54	$ 1.20	$ (0.56)
Non-GAAP [F]	$ 1.42	$ 0.71	$ 2.24	$ 1.00

[A] During the three months ended June 30, 2020, the Company recognized a $30.0 million event-based milestone as revenue upon FDA approval for ORIAHNN for uterine fibroids.

[B] During the six months ended June 30, 2020, the Company recognized non-cash collaboration revenue from Mitsubishi Tanabe Pharma Corporation under the collaboration and license agreement entered into in 2015.

[C] The Company incurred IPR&D expenses of $46.0 million during the three and six months ended June 30, 2020, respectively, in association with the Company's exercise of its option to license NBI-827104 in May 2020, and $5.0 million and $118.1 million during the three and six months ended June 30, 2019, respectively, in association with the collaboration and license agreement entered into with Voyager Therapeutics in 2019.

[D] The Company recognized unrealized gains of $11.3 million and $21.0 million for the three months ended June 30, 2020 and 2019, respectively, to adjust its equity security investments to fair value. For the six months ended June 30, 2020 and 2019, the Company recognized an unrealized loss of $5.2 million and an unrealized gain of $22.7 million, respectively, to adjust its equity security investments to fair value.

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

[F] Non-GAAP net income per diluted common share for the six months ended June 30, 2019 reflects diluted shares of 94.8 million, which were calculated in accordance with the guidance on earnings per share in ASC 260.

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