Neurocrine Biosciences Reports First Quarter 2023 Financial Results

May 3, 2023

INGREZZA® (valbenazine) First Quarter Net Product Sales of $410 Million

INGREZZA® (valbenazine) 2023 Net Product Sales Guidance Reiterated at $1.67 - $1.77 Billion

SAN DIEGO, May 3, 2023 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the first quarter ended March 31, 2023 and provided an update on its 2023 financial guidance.

"INGREZZA's first quarter results highlight the steady progress we are making to help improve the lives of patients living with tardive dyskinesia, yet we still have a tremendous opportunity to help even more patients for many years to come," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "We are executing well across our clinical portfolio and anticipate several important milestones in the months ahead including the August 20th PDUFA date for valbenazine for the treatment of chorea associated with Huntington disease. In addition, we remain on-track for top-line data in the second half of this year for several investigational programs, including crinecerfont for the treatment of pediatric and adult congenital adrenal hyperplasia."

	Three Months Ended March 31,	
(unaudited, in millions, except per share data)	**2023**	**2022**
Revenues:		
Product sales, net	$ 415.3	$ 305.0
Collaboration revenue	5.1	5.6
Total revenues	$ 420.4	$ 310.6
GAAP Research and Development (R&D)	$ 139.5	$ 102.2
Non-GAAP R&D	$ 125.7	$ 89.7
GAAP Selling, General and Administrative (SG&A)	$ 242.7	$ 200.7
Non-GAAP SG&A	$ 216.6	$ 176.2
GAAP net (loss) income	$ (76.6)	$ 13.9
GAAP (loss) earnings per share – diluted	$ (0.79)	$ 0.14
Non-GAAP net (loss) income	$ (49.5)	$ 29.7
Non-GAAP (loss) earnings per share – diluted	$ (0.51)	$ 0.30

(unaudited, in millions)	**March 31, 2023**	**December 31, 2022**
Total cash, cash equivalents and marketable securities	$ 1,139.2	$ 1,288.7

First Quarter INGREZZA Net Product Sales Highlights:

- INGREZZA first quarter 2023 net product sales were $410 million and grew 36% compared vs. the first quarter 2022
- Record number of new patients received therapy during the first quarter of 2023

First Quarter Financial Highlights:

- First quarter 2023 GAAP net loss and loss per share of $77 million and $0.79, respectively, compared with first quarter 2022 GAAP net income and earnings per share of $14 million and $0.14, respectively
- First quarter 2023 non-GAAP net loss and loss per share of $50 million and $0.51, respectively, compared with first quarter 2022 non-GAAP net income and earnings per share of $30 million and $0.30, respectively

- Differences in first quarter 2023 GAAP and non-GAAP operating expenses compared with first quarter 2022 driven by:
  - Acquired In-Process R&D (IPR&D) expense of $144 million in first quarter 2023 associated with expansion of strategic partnership with Voyager Therapeutics, Inc. (Voyager)
  - Increased R&D expense in support of an expanded and advancing clinical portfolio
  - Increased SG&A expense primarily due to ongoing commercial initiatives, including the deployment of the expanded salesforce in April 2022
- At March 31, 2023, the Company had cash, cash equivalents and marketable securities of approximately $1.1 billion

A reconciliation of GAAP to non-GAAP financial results can be found in Table 3 and Table 4 at the end of this earnings release.

Recent Events:

- On January 8, 2023, we entered into a new strategic collaboration with Voyager, which became effective on February 21, 2023, to acquire the worldwide rights to Voyager's GBA1 gene therapy program for Parkinson's disease and other GBA1-mediated diseases and three gene therapy programs directed to rare central nervous system targets for up-front consideration of $175 million.
- In the first quarter of 2023, we provided BIAL with written notice of termination of the license agreement to commercialize and market ONGENTYS® (opicapone), an approved adjunctive therapy for patients with Parkinson's disease, in the United States and Canada. We determined that continued commercialization of ONGENTYS is unsustainable. The termination is anticipated to be effective in December 2023. ONGENTYS is an important, safe and effective adjunctive treatment option for Parkinson's disease patients. We intend to work with BIAL to ensure an orderly transition of the commercialization of ONGENTYS and to ensure patients have continued access to ONGENTYS.

Reiterated 2023 INGREZZA Sales and Updated Operating Expense Guidance:

	Range	
(in millions)	**Low**	**High**
INGREZZA Net Product Sales [1]	$ 1,670	$ 1,770
GAAP R&D expense [2]	$ 550	$ 580
Non-GAAP R&D expense [5]	$ 495	$ 525
GAAP and Non-GAAP IPR&D [3]	$ 144	$ 144
GAAP SG&A expense [4]	$ 850	$ 870
Non-GAAP SG&A expense [5]	$ 730	$ 750

1. INGREZZA sales guidance for fiscal 2023 reflects expected sales of INGREZZA in tardive dyskinesia only.
2. GAAP R&D guidance reflects the progression of the Company's pipeline including multiple compounds in mid- to late-phase clinical development, meaningful investments in the muscarinic portfolio and expanded pre-clinical research efforts. GAAP R&D guidance includes amounts for milestones that are probable of achievement or have been achieved.
3. IPR&D guidance reflects acquired in-process research and development once significant collaboration and licensing arrangements have been completed. IPR&D guidance includes $143.9 million associated with the new strategic collaboration with Voyager.
4. GAAP SG&A guidance reflects the continued investment in the expanded commercial organization to support INGREZZA and to support the anticipated approval for valbenazine to treat patients with chorea associated with Huntington disease.
5. Non-GAAP guidance adjusted to exclude estimated non-cash stock-based compensation expense of $55 million in R&D and $120 million in SG&A.

2023 Expected Pipeline Milestones and Key Activities

Program	**Indication**	**2023 Milestones / Key Activities**
Valbenazine* (Selective VMAT2 Inhibitor)	Chorea in Huntington Disease	PDUFA Aug. 20, 2023
Crinecerfont (CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Adult)	Top-Line Registrational Data in Early Q4 2023
	Congenital Adrenal Hyperplasia (Pediatric)	Top-Line Registrational Data in Early Q4 2023
NBI-921352** (Selective $Na_V1.6$ Channel Blocker)	Focal Onset Seizure in Adults	Top-Line Phase 2 Data in Q4 2023
NBI-1065846† (GPR-139 Agonist)	Anhedonia in Major Depressive Disorder	Top-Line Phase 2 Data in Q4 2023
NBI-1117570‡ (Dual M1/ M4 Agonist)	Treatment of Schizophrenia	Initiate Phase 1 Study

New Chemical Entity or Entities	Indication(s) TBD	Initiate at Least One Phase 1 Study

Key: VMAT2 = Vesicular Monoamine Transporter 2; CFR1 = Corticotropin-Releasing Factor Type 1; $Na_V1.6$ = Sodium Channel, Voltage-Gated; M1 / M4 = M1 / M4 Muscarinic Receptor; GPR = Orphan G Protein Coupled Receptor

*Neurocrine Biosciences Partners: * Mitsubishi Tanabe Pharma Corporation has commercialization rights in East Asia; ** In-Licensed from Xenon Pharmaceuticals; † Partnered with Takeda Pharmaceutical Company Limited; ‡ In-Licensed from Sosei Group Corporation*

Conference Call and Webcast Today at 8:00 AM Eastern Time

Neurocrine Biosciences will hold a live conference call and webcast today at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time). Participants can access the live conference call by dialing 800-895-3361 (US) or 785-424-1062 (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 a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine, and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, Twitter and Facebook. (**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 the following non-GAAP financial measures: non-GAAP R&D expense, non-GAAP SG&A expense, and non-GAAP net income and net income per share. When preparing the 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, these non-GAAP financial measures exclude: non-cash stock-based compensation expense, loss on extinguishment of convertible senior notes, non-cash interest expense related to convertible debt, non-cash amortization expense related to acquired intangible assets, acquisition-related transaction costs, changes in fair value of equity security investments, changes in foreign currency exchange rates and certain adjustments to income tax expense. These non-GAAP financial 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 R&D and SG&A expenses on both a GAAP and a non-GAAP basis. A reconciliation of these 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; our financial and operating performance, including our future revenues, expenses, or profits; our collaborative partnerships; expected future clinical and regulatory milestones; and the timing of the initiation and/or 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 and uncertainties associated with the commercialization of INGREZZA; risks related to the development of our product candidates; risks associated with our dependence on third parties for development, manufacturing, and commercialization activities for our products and 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 that clinical development activities may not be initiated or completed on time or at all, or 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 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; risks associated with U.S. federal or state legislative or regulatory and/or policy efforts which may result in, among other things, an adverse impact on our revenues or potential revenue; risks associated with potential generic entrants for our products; and other risks described in our periodic reports filed with the SEC, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

TABLE 1

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

	Three Months Ended March 31,	
(in millions, except per share data)	**2023**	**2022**

Revenues:		
Product sales, net	$ 415.3	$ 305.0
Collaboration revenue	5.1	5.6
Total revenues	420.4	310.6
Operating expenses:		
Cost of revenues	8.5	4.6
Research and development	139.5	102.2
Acquired in-process research and development	143.9	—
Selling, general and administrative	242.7	200.7
Total operating expenses	534.6	307.5
Operating (loss) income	(114.2)	3.1
Other income (expense):		
Interest expense	(1.1)	(2.6)
Unrealized gain on equity security investments	2.2	19.9
Investment income and other, net	9.8	1.0
Total other income, net	10.9	18.3
(Loss) income before (benefit from) provision for income taxes	(103.3)	21.4
(Benefit from) provision for income taxes	(26.7)	7.5
Net (loss) income	$ (76.6)	$ 13.9
(Loss) earnings per share, basic	$ (0.79)	$ 0.15
(Loss) earnings per share, diluted	$ (0.79)	$ 0.14
Weighted average common shares outstanding, basic	97.1	95.3
Weighted average common shares outstanding, diluted	97.1	97.6

TABLE 2

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

(in millions)	**March 31, 2023**	**December 31, 2022**
Cash, cash equivalents and debt securities available-for-sale	$ 894.6	$ 989.3
Other current assets	538.2	464.2
Total current assets	1,432.8	1,453.5
Deferred tax assets	337.4	305.9
Debt securities available-for-sale	244.6	299.4
Right-of-use assets	84.4	87.0
Equity security investments	135.7	102.1
Property and equipment, net	62.8	58.6
Intangible assets, net	37.2	37.2
Other assets	24.9	25.0
Total assets	$ 2,359.8	$ 2,368.7
Convertible senior notes	$ —	$ 169.4
Other current liabilities	374.1	368.3
Total current liabilities	374.1	537.7
Convertible senior notes	169.5	—
Operating lease liabilities	90.4	93.5
Other long-term liabilities	41.3	29.7
Stockholders' equity	1,684.5	1,707.8
Total liabilities and stockholders' equity	$ 2,359.8	$ 2,368.7

TABLE 3

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

	Three Months Ended March 31,	
(in millions, except per share data)	**2023**	**2022**
GAAP net (loss) income	$ (76.6)	$ 13.9
Adjustments:		
Stock-based compensation expense - R&D	13.8	12.5
Stock-based compensation expense - SG&A	26.1	24.5
Non-cash interest related to convertible senior notes	0.2	0.4
Non-cash amortization related to acquired intangible assets	0.9	—
Changes in fair value of equity security investments [1]	(2.2)	(19.9)
Income tax effect related to reconciling items [2]	(11.7)	(1.7)
Non-GAAP net (loss) income	$ (49.5)	$ 29.7
Diluted (loss) earnings per share:		
GAAP	$ (0.79)	$ 0.14
Non-GAAP	$ (0.51)	$ 0.30

1. Reflects periodic fluctuations in the fair values of the Company's equity security investments.
2. Estimated income tax effect of non-GAAP reconciling items are calculated using applicable statutory tax rates, taking into consideration any valuation allowance and adjustments to exclude tax benefits or expenses associated with non-cash stock-based compensation.

TABLE 4

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

	Three Months Ended March 31,	
(in millions)	**2023**	**2022**
GAAP cost of revenues	$ 8.5	$ 4.6
Adjustments:		
Non-cash amortization related to acquired intangible assets	0.9	—
Non-GAAP cost of revenues	$ 7.6	$ 4.6

	Three Months Ended March 31,	
(in millions)	**2023**	**2022**
GAAP R&D	$ 139.5	$ 102.2
Adjustments:		
Stock-based compensation expense	13.8	12.5
Non-GAAP R&D	$ 125.7	$ 89.7

	Three Months Ended March 31,	
(in millions)	**2023**	**2022**
GAAP SG&A	$ 242.7	$ 200.7
Adjustments:		
Stock-based compensation expense	26.1	24.5

Non-GAAP SG&A	$ 216.6	$ 176.2

	Three Months Ended March 31,	
(in millions)	**2023**	**2022**
GAAP other income, net	$ 10.9	$ 18.3
Adjustments:		
Non-cash interest related to convertible senior notes	0.2	0.4
Changes in fair value of equity security investments	(2.2)	(19.9)
Non-GAAP other income (expense), net	$ 8.9	$ (1.2)

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