
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of the earliest event reported): January 5, 2018

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

0-22705
(Commission
File Number)

33-0525145
(IRS Employer
Identification No.)

12780 El Camino Real, San Diego, California
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: (858) 617-7600

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On January 7, 2018, Neurocrine Biosciences, Inc. (the “*Company*”), issued a press release announcing preliminary fourth quarter 2017 and full year 2017 sales results. The Company’s financial statements for the fourth quarter 2017 and full year 2017 have not yet been completed and could result in changes to these preliminary sales results. The press release also contained certain updates related to the Company’s product candidates. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 of this Current Report on Form 8-K, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 5, 2018, Christopher O’Brien, M.D., the Company’s Chief Medical Officer, notified the Company of his intent to retire from his position with the Company in February 2018, following the completion of transition activities.

A copy of the press release announcing Dr. O’Brien’s retirement is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Special Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause the Company’s actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may”, “will”, “should”, “could”, “would”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “projects”, “predicts”, “potential” and similar expressions intended to identify forward-looking statements. These statements reflect the Company’s current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent the Company’s estimates and assumptions only as of the date of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Neurocrine Biosciences, Inc., dated January 7, 2018
99.2	Press Release of Neurocrine Biosciences, Inc., dated January 7, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 8, 2018

NEUROCRINE BIOSCIENCES, INC.

By: /s/ Darin M. Lippoldt
Darin M. Lippoldt
Chief Legal Officer

FOR IMMEDIATE RELEASE

Neurocrine Biosciences Provides Preliminary Fourth Quarter and Full-Year 2017 Sales Results and 2018 Program Milestones

- *Total Preliminary Revenue for the Fourth Quarter of 2017 was Approximately \$94 Million and \$161 Million for the Full-Year 2017*
- *INGREZZA® (valbenazine) Preliminary Fourth Quarter Net Product Sales of Approximately \$64 Million with Approximately 9,100 TRx*
- *Received \$30 Million Milestone from AbbVie for the Elagolix Endometriosis NDA Acceptance During the Fourth Quarter of 2017*
- *INGREZZA® (valbenazine) Preliminary Net Product Sales of Approximately \$116 Million with Approximately 14,900 TRx Sold Since Commercial Launch on May 1, 2017*

SAN DIEGO, Jan. 7, 2018 - Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced an update on its business performance, including preliminary sales results for 2017 and key program initiatives for 2018. Kevin Gorman, CEO of Neurocrine, will discuss these updates as part of a webcast presentation at the 36th Annual J.P. Morgan Healthcare Conference in San Francisco on Monday, January 8 at 3:00 p.m. PT (6:00 p.m. ET).

“In 2017, we made exceptional progress as an organization with the launch of INGREZZA, aiding adult patients suffering from tardive dyskinesia. Our fourth quarter sales reflect continued strong prescription growth for INGREZZA which more than offset the net sales impact from the transition to the 80 mg capsules. Increase in psychiatrist and neurologist uptake reflects expanded brand awareness with positive treatment outcomes,” said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. “Entering 2018, we are excited about our opportunities to continue our INGREZZA launch and clinical development efforts in Tourette syndrome as well as achieving meaningful pipeline milestones in collaboration with AbbVie for elagolix in both endometriosis and uterine fibroids.”

Preliminary Fourth Quarter and Full-Year 2017 Sales Results (Unaudited)

Based on preliminary unaudited financial information, the Company expects net product sales of INGREZZA® (valbenazine) to be approximately \$64 million for the fourth quarter ended December 31, 2017. Total Company revenues for the fourth quarter are expected to be approximately \$94 million inclusive of a \$30 million milestone payment received from AbbVie for the FDA’s acceptance of the elagolix endometriosis NDA in the fourth quarter.

Preliminary full-year unaudited net product sales of INGREZZA are expected to be approximately \$116 million and total Company revenues of approximately \$161 million inclusive of \$45 million revenue recognized from our collaboration agreements with AbbVie and Mitsubishi Tanabe Pharma Corporation.

No similar net product sales were reported for the comparable periods of 2016. INGREZZA capsules were made available for commercial distribution on May 1, 2017, and the Company recognizes revenue using a sell-in methodology when products are delivered to select pharmacies or distributors.

2018 Expected Program Milestones

INGREZZA for Tardive Dyskinesia

- Continued launch progress through tardive dyskinesia disease state education and enhanced brand awareness
- Execution of post-marketing clinical studies
- Presentations at key scientific annual meetings, including American Academy of Neurology, American Psychiatry Association, International Parkinson and Movement Disorder Society

INGREZZA for Tourette Syndrome

- Phase II trial enrollment with data expected late 2018

Elagolix in Collaboration with AbbVie

- Elagolix for endometriosis PDUFA decision in Q2 2018
- Elagolix for uterine fibroids Phase III data Q1 2018 with expected 2019 NDA filing

Opicapone for Parkinson's Disease

- FDA meeting for determination of NDA path forward in January 2018

Congenital Adrenal Hyperplasia (CAH)/NBI-74788

- Phase IIa data for CAH (adults) in 1H 2018
- Phase II initiation for CAH (pediatric) in 2H 2018
- Phase III initiation for CAH (adults) in 2H 2018

New Internally Discovered Program

- IND submission and initiation of a Phase I trial

Management Update

In a separate press release issued today, Neurocrine also announced the retirement of Christopher O'Brien, M.D., in February 2018 and the appointment of Eiry W. Roberts, M.D., as Chief Medical Officer.

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 trunk, extremities and/or face.

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 in 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

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 (35% and twice the rate of placebo) is somnolence. Other adverse reactions (32% 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/HCP

About Neurocrine Biosciences, Inc.

Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. The Company markets INGREZZA® (valbenazine) capsules in the United States for the treatment of adults with tardive dyskinesia. INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first FDA approved product indicated for the treatment of adults with tardive dyskinesia. The Company's three late-stage clinical programs are: elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc.; opicapone, a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase inhibitor under investigation as adjunct therapy to levodopa in Parkinson's patients; and INGREZZA, a novel, once-daily, selective VMAT2 inhibitor under investigation for the treatment of Tourette syndrome.

Neurocrine Biosciences, Inc. news releases are available through the Company's website via the internet at <http://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 our preliminary financial information, to the benefits to be derived from Neurocrine's products and product candidates, including INGREZZA; the value INGREZZA and our product candidates may bring to patients; the success of the continued launch of INGREZZA; and the timing of completion of clinical and other development activities. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks and uncertainties associated with items that may be identified during its financial statement closing process that cause adjustments to the estimates included in this press release; Neurocrine's future financial and operating performance; risks and uncertainties associated with the commercialization of INGREZZA, including the likelihood of continued revenue 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 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 or the Company's product candidates; risks associated with the Company's dependence on AbbVie for the development and commercialization 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 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 September 30, 2017. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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Contact: Neurocrine Biosciences, Inc.

Navjot Rai (Media & Investors)

858-617-7623

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FOR IMMEDIATE RELEASE**Neurocrine Biosciences Announces Retirement of Christopher O'Brien, M.D., and Appointment of Eiry W. Roberts, M.D., as Chief Medical Officer**

SAN DIEGO, Jan. 7, 2018 - Neurocrine Biosciences, Inc. (NASDAQ: NBIX), a biotechnology company focused on neurological and endocrine related disorders, today announced that Christopher O'Brien, M.D., Chief Medical Officer, has notified the Company he plans to retire in February 2018, after a transition period with his successor. Dr. O'Brien joined Neurocrine in 2005, and has led the clinical development and medical affairs activities for more than 12 years. Dr. O'Brien will remain as an exclusive consultant for Neurocrine.

"On behalf of the board, shareholders and our employees, I want to thank Chris for his tremendous contributions as Chief Medical Officer of Neurocrine," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "With his considerable expertise and leadership, we successfully developed and obtained FDA approval of INGREZZA capsules for the treatment of adults with tardive dyskinesia and advanced our clinical development programs for Tourette syndrome, Parkinson's disease, endometriosis and congenital adrenal hyperplasia. I am very pleased that Chris will continue to be a part of the Neurocrine team for the foreseeable future."

Eiry W. Roberts, M.D., will join the company as Chief Medical Officer, effective January 8, 2018.

"We are very pleased to welcome Eiry to Neurocrine as she brings extensive senior leadership and pharmaceutical management experience to the team," Dr. Gorman said. "Eiry's strong background in implementing strategic clinical development programs and navigating the regulatory approvals process across phases of drug development from research to commercialization in multiple therapeutic areas, including neuroscience, will be valuable as we execute on our commercialization and clinical plans and advance our pipeline in support of our commitment to relieve patient suffering and enhance lives."

Dr. Roberts has over 25 years of research and development experience in the pharmaceutical industry across all phases of drug development from research through commercialization in multiple therapeutic areas, including neuroscience, inflammation, oncology and metabolic diseases. She joins Neurocrine from Eli Lilly and Company where she held various positions during her tenure, including Vice President, Clinical Pharmacology and Vice President of R&D, BioMedicines Business Unit.

Dr. Roberts was the Chair of the Medical Review Committee, where she was responsible for review and approval of all the integrated clinical plans for molecules in the Lilly portfolio. She was also a member of Lilly's Corporate Portfolio Management Committee and Lilly Ventures Steering Committee. Dr. Roberts was accountable for early clinical development programs

across all therapeutic areas within Lilly, as well as registration for new chemical entities and biproducts in Phase III development. During her time at Lilly, Dr. Roberts established a new therapeutic area, which resulted in the development of five potential novel medicines from Phase I through to approval, with two of them successfully receiving regulatory approval. Dr. Roberts also has extensive leadership and business development experience, including the management of strategic alliances, business partnerships and venture capital collaborations.

Dr. Roberts is a physician who trained in pharmacology and medicine in the UK, qualifying from the University of London in 1987. Her post-graduate clinical training was in clinical pharmacology and cardiology at St. Bartholomew's Hospital and the Royal London Hospital.

Neurocrine also announced the grant of an inducement award to Dr. Roberts pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules. In connection with her employment by Neurocrine, Dr. Roberts will be granted an inducement award consisting of a stock option to purchase 70,000 shares of Neurocrine common stock. The stock option will vest over a period of four years, with 25% vesting on the first anniversary of its grant date and the balance vesting each month over the remaining three years. Dr. Roberts also received 20,000 restricted stock units which vest in equal increments over four years, with 25% vesting each year. These awards are subject to the terms and conditions of Neurocrine's Inducement Plan, and will be effective on January 8, 2018. The stock option grant will have an exercise price equal to the closing price of Neurocrine's common stock on the NASDAQ Global Select Market on that date. These awards were granted as an inducement material to Dr. Roberts' employment pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules.

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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 our ability to execute on the Company's commercialization and clinical plans, and the Company's ability to advance its product candidate pipeline. Among the factors

that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks and uncertainties associated with Neurocrine's business and finances in general as well as risks and uncertainties associated with the commercialization of INGREZZA; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA 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; risks that INGREZZA clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that INGREZZA may be alleged to infringe upon the proprietary 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 September 30, 2017. The Company disclaims any obligation to update the statements contained in this press release after the date hereof.

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