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): May 9, 2017

NEUROCRINE BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**0-22705**	**33-0525145**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12780 El Camino Real, San Diego, California	**92130**
(Address of principal executive offices)	**(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 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 May 9, 2017, Neurocrine Biosciences, Inc. announced its financial results for the first quarter ended March 31, 2017. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) EXHIBITS.

Exhibit Number	Description of Exhibit
99.1	Press Release dated May 9, 2017

SIGNATURES

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

Dated: May 9, 2017

NEUROCRINE BIOSCIENCES, INC.

/s/ David-Alexandre Gros

David-Alexandre Gros

President, Chief Operating Officer and interim Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
99.1	Press Release dated May 9, 2017

Exhibit 99.1

Neurocrine Biosciences Reports First Quarter 2017 Results

- Launched INGREZZA® Commercially after Approval by the U.S. Food and Drug Administration for the Treatment of Tardive Dyskinesia

- Phase II Study Results of INGREZZA in Pediatric Tourette Syndrome Expected in May 2017

- Acquired U.S. and Canadian Rights to Opicapone for Parkinson's Disease

- Partner AbbVie Expected to Submit New Drug Application for Elagolix in Third Quarter of 2017 and Report Phase III Results in Uterine Fibroids by End of Year

San Diego, CA, May 9, 2017 - Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced its financial results for the quarter ended March 31, 2017, highlighted by the launch of INGREZZA® (valbenazine) capsules in tardive dyskinesia as well as other recent progress on its pipeline.

"2016 was a very successful year for Neurocrine and we have carried this momentum fully into 2017 with the approval and launch of INGREZZA in tardive dyskinesia," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "On the commercial front, we accelerated the on-boarding of our sales force and we began calling on prescribers on May 1st. While we are focused on the launch of INGREZZA, we also continue to advance our pipeline. We will have data with INGREZZA in pediatric patients with Tourette syndrome later this month. Our partner, AbbVie, remains on track to submit the NDA for elagolix in endometriosis during the third quarter of this year. Together with our partner BIAL, we are progressing with our technology transfer activities in order to initiate discussions with the FDA on opicapone in Parkinson's disease in the second half of the year. Our second Phase I study in essential tremor with NBI-640756 in healthy volunteers continues, and we initiated a Phase I, healthy volunteer, study of our candidate NBI-74788 for congenital adrenal hyperplasia in March."

For the first quarter of 2017, the Company reported a net loss of $78.3 million, or $0.90 loss per share, compared to a net loss of $19.3 million, or $0.22 loss per share, for the same period in 2016.

The Company's balance sheet at March 31, 2017 reflected total assets of $289.4 million, including cash, investments and receivables of $274.4 million compared with balances at December 31, 2016 of $365.1 million and $352.1 million, respectively. These assets do not include the approximately $502.2 million raised, after expenses, via the Company's convertible notes offering which closed on May 2, 2017.

The Company did not report any revenue for the first quarter of 2017 compared to $15.0 million of revenue for the first quarter of 2016, which represented a milestone payment from AbbVie related to the commencement of Phase III studies of elagolix in uterine fibroids.

Research and development expenses increased to $51.9 million during the first quarter of 2017 from $23.9 million during the same period in 2016. This increase was primarily due to the $30.0 million up-front payment for in-licensing opicapone from BIAL – Portela & CA, S.A. (BIAL) during the first quarter of 2017.

General and administrative expenses increased from $12.0 million in the first quarter of 2016 to $28.1 million for the first quarter of 2017, primarily due to increased pre-commercialization activities for INGREZZA. Personnel-related costs increased by $6.9 million quarter over quarter primarily due to the expansion of sales, marketing, and medical affairs personnel. This increase in personnel-related costs includes a $1.4 million increase in non-cash, share-based compensation expense. Additionally, external costs related to market research, commercial launch preparation and other professional services were $7.2 million higher for the first quarter of 2017 when compared to the same period in 2016.

Pipeline Highlights

INGREZZA (valbenazine) Capsules Update

INGREZZA received FDA approval on April 11, 2017, becoming the first and only medicine approved in the United States for adults with tardive dyskinesia. Full commercial efforts began for INGREZZA on May 1, 2017.

During March of 2017, the Company published positive efficacy results from the Kinect 3 study, a Phase III trial that included moderate to severe tardive dyskinesia in patients with underlying schizophrenia, schizoaffective disorder, bipolar or major depressive disorder who underwent six weeks of placebo controlled assessment, and for a subset, an additional 42 weeks of safety assessment.

In addition to the long-term safety assessment of Kinect 3, the Company announced that it completed in March 2017 its separate one-year open-label safety study of INGREZZA, Kinect 4. Data publication is anticipated later this year. The Company also announced that in July 2017 it plans to complete the INGREZZA roll-over study for those patients who had previously completed one year of dosing in either the Kinect 3 or Kinect 4 studies.

INGREZZA is also being investigated in Tourette syndrome for both adult and pediatric patients.

The T-Forward study of adult Tourette syndrome patients reported top-line data in January 2017. This randomized, double-blind, placebo-controlled, multi-dose, parallel group Phase II study enrolled 124 adults with moderate to severe Tourette syndrome. The subjects received once-daily dosing of INGREZZA or placebo during the eight-week treatment period to assess the safety, tolerability and efficacy of INGREZZA. The primary endpoint of T-Forward was a change from baseline of placebo vs. active scores utilizing the Yale Global Tic Severity Scale (YGTSS) at the end of Week 8. The primary endpoint of YGTSS was not met at Week 8 ($p=0.18$), however the study showed a significant improvement in overall symptoms of Tourette as evidenced by the Clinical Global Impression of Change ($p=0.015$). Adverse events (AEs) in this trial were dose dependent and consistent with those observed in previous clinical studies of INGREZZA.

The T-Force GREEN study is a randomized, double-blind, placebo-controlled, multi-dose, parallel group Phase II study that has enrolled approximately 90 children and adolescents. Pediatric Tourette subjects receive once-daily dosing of INGREZZA or placebo during a six-week treatment period to assess the safety, tolerability and efficacy of INGREZZA. The primary endpoint of this study is the change from baseline of the YGTSS between placebo and active treatment groups at the end of Week 6. Top-line data from this study is expected in late May 2017.

Additionally, the Company is also conducting an open-label, fixed-dose study of INGREZZA in up to 180 subjects with Tourette syndrome. This study is designed to enroll up to 90 children and adolescents and up to 90 adults who have completed either of the two placebo-controlled Tourette clinical trials: T-Force GREEN or T-Forward. This Phase II study will assess the long-term safety and tolerability of INGREZZA in children and adults with Tourette's.

Data from the Tourette studies is planned to be utilized to design a Phase III pivotal program for INGREZZA in treating Tourette syndrome.

Elagolix Update

AbbVie has completed the treatment portion of both Phase III studies of elagolix in endometriosis. The first study (Violet PETAL) has completed its off-drug follow-up period. The second study (Solstice) will complete the off-drug follow-up period during the second quarter of 2017. The top-line results from both trials were consistent, showing that after six months of treatment, both doses of elagolix (150 mg once-daily and 200 mg twice-daily) met the study's co-primary endpoints of reducing scores of non-menstrual pelvic pain and menstrual pain (or dysmenorrhea) associated with endometriosis at month three, as well as month six, as measured by the Daily Assessment of Endometriosis Pain Scale. Among the most common AEs in both studies were hot flush, headache and nausea. While most AEs were similar across treatment groups some, such as hot flush and bone mineral density loss, were dose-dependent.

AbbVie is targeting an NDA submission with the FDA for elagolix in endometriosis during the third quarter of 2017.

In April 2017, AbbVie presented multiple scientific abstracts at the Congress of the Society of Endometriosis and Uterine Disorders (SEUD) in Singapore. The posters highlighted positive primary and secondary efficacy endpoint data from the Phase III studies of elagolix in premenopausal women who suffer from endometriosis as well as positive efficacy and safety data from the Phase IIb study of elagolix with and without add-back therapy in the management of heavy menstrual bleeding associated with uterine fibroids:

- *Rapid and Sustained Improvement in Dysmenorrhea and Non-Menstrual Pelvic Pain with Elagolix Treatment in Women with Endometriosis-associated pain; Taylor, et al.*
- *Effective and Rapid Control of Bleeding with Elagolix with or without Add-Back Therapy in Women with Heavy Menstrual Bleeding Associated with Uterine Fibroids; Gordon, et al*.

AbbVie is currently conducting two replicate Phase III randomized, parallel, double-blind, placebo-controlled clinical trials evaluating elagolix alone or in combination with add-back therapy in women with heavy uterine bleeding associated with uterine fibroids. The studies are expected to enroll approximately 400 subjects each for an initial six-month placebo-controlled dosing period. At the end of the six-months of placebo-controlled evaluation, subjects are eligible to enter an additional six-month safety extension study. The primary efficacy endpoint of the study is an assessment of the change in menstrual blood loss utilizing the alkaline hematin method comparing baseline to month six. Additional secondary efficacy endpoints will be evaluated including assessing the change in fibroid volume and hemoglobin. Bone mineral density will be assessed via dual-energy x-ray absorptiometry (DEXA) scan at baseline, the conclusion of dosing and six months post-dosing. The Company expects the initial top-line efficacy data from the uterine fibroid Phase III program in late 2017. These two studies will form the basis for an anticipated 2019 submission with the FDA for the approval of elagolix in the treatment of uterine fibroids.

Opicapone Update

On February 9, 2017, the Company entered into an exclusive licensing agreement with BIAL for the development and commercialization of opicapone in the United States and Canada. Opicapone is a once-daily, peripherally-acting, highly-selective COMT inhibitor that was approved in June 2016 by the European Commission as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors for adult patients with Parkinson’s disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations. The Company intends to meet with the FDA in late 2017 to discuss a potential New Drug Application submission.

Essential Tremor Program (NBI-640756) Update

The Company has successfully completed an initial Phase I single site, randomized, double-blind, placebo-controlled, sequential dose-escalation, pharmacokinetic study assessing the safety and tolerability of a single dose of NBI-640756 in up to 32 healthy volunteers.

Based on the results of this initial study, the Company initiated a second Phase I, single site, randomized, double-blind, placebo-controlled, multiple-dose, sequential dose-escalation study to evaluate the safety, tolerability and pharmacokinetics of NBI-640756 in up to 30 healthy volunteers over a week of continuous dosing. The study is being conducted in multiple sequential cohorts of ten subjects per cohort; data from this second Phase I study is expected later in 2017. The data from this study, in conjunction with the single dose Phase I study and preclinical studies, will be evaluated and utilized in the design of the anticipated Phase II program for NBI-640756 in subjects with essential tremor.

Congenital Adrenal Hyperplasia Program (NBI-74788) Update

In the fourth quarter of 2016, the Company submitted an Investigational New Drug application with the FDA for its CRF receptor antagonist NBI-74788 to treat patients with classic congenital adrenal hyperplasia (CAH). The Company has enrolled subjects in a Phase I safety and pharmacokinetics study exploring NBI-74788 in healthy volunteers that is nearing completion.

Conference Call and Webcast Today at 5:00PM Eastern Time

Neurocrine will hold a live conference call and webcast today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Participants can access the live conference call by dialing 877-876-9177 (US) or 785-424-1666 (International) using the conference ID: NBIX. The call can also be accessed via the webcast through the Company's website at http://www.neurocrine.com.

About Neurocrine Biosciences, Inc.

Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. In April of 2017, the FDA approved INGREZZA® (valbenazine) capsules for the treatment of adults with Tardive Dyskinesia (TD). INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first and only FDA-approved product indicated for the treatment of adults with TD. The Company markets INGREZZA in the United States. 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 (valbenazine), 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.

About INGREZZA

INGREZZA, a selective VMAT2 inhibitor, is the first and only product indicated for the treatment of adults with tardive dyskinesia. INGREZZA inhibits VMAT2 and 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 TD. 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 once-daily, and together with psychiatric medications such as antipsychotics or antidepressants.

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; the value INGREZZA brings to patients; and whether results from INGREZZA's clinical trials are indicative of real-world results. 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 or the development of the Company's product candidates; 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 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 agreement with BIAL may never be realized; risks associated with the Company's dependence on BIAL for tech transfer, development and manufacturing activities related to opicapone; risks that INGREZZA and/or our product candidates may be precluded from commercialization by 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 Annual Report on Form 10-K for the year ended December 31, 2016. Neurocrine disclaims obligation to update the statements contained in this press release after the date hereof.

Contact Information

For further information contact:

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NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	Three Months Ended March 31,	
	2017	2016
	(unaudited)	
Revenues:		
License fees and milestones	$ —	$ 15,000
Total revenues	—	15,000
Operating expenses:		
Research and development	51,882	23,903
General and administrative	28,050	11,954
Total operating expenses	79,932	35,857
Loss from operations	(79,932)	(20,857)
Other income:		
Interest and other income	727	737
Gain on sale of assets	879	856
Total other income	1,606	1,593
Net loss	$(78,326)	$(19,264)
Net loss per common share:		
Basic and Diluted	$ (0.90)	$ (0.22)
Shares used in the calculation of net loss per common share:		
Basic and Diluted	87,283	86,497

NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2017	December 31, 2016
	(unaudited)	
Cash, cash equivalents and short-term marketable securities	$235,580	$ 307,350
Other current assets	3,871	3,092
Total current assets	239,451	310,442
Property and equipment, net	7,144	6,271
Long-term investments	37,686	43,490
Restricted cash	5,083	4,883
Total assets	$289,364	$ 365,086
Current liabilities	$ 23,563	$ 30,414
Long-term liabilities	18,660	19,795
Stockholders' equity	247,141	314,877
Total liabilities and stockholders' equity	$289,364	$ 365,086