NEUROCRINE BIOSCIENCES INC
Form 8-K
April 25, 2017

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 earliest event reported): April 25, 2017

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-22705**	**33-0525145**
(State or other jurisdiction of incorporation)	**(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 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 1.01 Entry into a Material Definitive Agreement.

The Patheon Agreements and Packaging Agreement (each as defined below) described below were not material to Neurocrine Biosciences, Inc. (the ***Company***) when executed, but became material to the Company during the quarter ending June 30, 2017.

Master Manufacturing Services Agreement and Product Agreement

On November 28, 2016, the Company and Patheon UK Limited (***Patheon***) entered into a Master Manufacturing Services Agreement (the ***Services Agreement***) and a related Product Agreement (the ***Product Agreement*** and together with the Services Agreement, the ***Patheon Agreements***) for Patheon s manufacture of commercial supplies of INGREZZA™ (valbenazine) at Patheon s manufacturing site. Under the terms of the Services Agreement, the Company is responsible for supplying the active pharmaceutical ingredients for INGREZZA to Patheon. Patheon is responsible for manufacturing the INGREZZA capsules, conducting quality control, quality assurance, validation activities, stability testing, packaging and providing related services for the manufacture of the INGREZZA capsules.

Pursuant to the Patheon Agreements, the Company has agreed to order from Patheon certain annual binding minimum amounts of INGREZZA capsules in the United States based on an agreed upon pricing schedule. The Patheon Agreements have an initial term ending December 31, 2021, and will automatically renew after the initial term for successive terms of two years, unless either party gives notice of its intention to terminate the Patheon Agreements within at least 18 months prior to the end of the then current term.

The Company may terminate the Product Agreement upon 30 days prior written notice if any governmental agency takes any action that prevents the Company from importing, exporting, purchasing or selling INGREZZA. Further, the Company must give at least six months advance notice (or such shorter period if required pursuant to action taken by a governmental agency) if the Company intends to no longer order manufacturing services for INGREZZA due to discontinuance of INGREZZA in the market.

Either party may terminate the Services Agreement or the Product Agreement (a) if the other party has failed to remedy a material breach under the Services Agreement or the Product Agreement within 90 days following receipt of a written notice, (b) immediately upon written notice to the other party in the event that the other party is declared insolvent or bankrupt, a voluntary petition of bankruptcy is filed in any court by such other party or the Patheon Agreements are assigned by such other party for the benefit of creditors, and (c) upon six months written notice if the other party assigns the Services Agreement or the Product Agreement to an assignee that, in the opinion of the non-assigning party acting reasonably, is (i) not a credit worthy substitute for the other party or (ii) a competitor of the non-assigning party.

The Patheon Agreements contain certain representations, warranties, limitations of liabilities, confidentiality and indemnity obligations and other provisions customary for agreements of their type.

The foregoing description of the terms of the Patheon Agreements does not purport to be complete and is qualified in its entirety by reference to the full text of the Services Agreement and the Product Agreement, copies of which are attached to this report as Exhibits 99.1 and 99.2, respectively.

Commercial Packaging Agreement

On December 12, 2016, the Company and AndersonBrecon Inc., doing business as PCI of Illinois (***PCI***), entered into a Commercial Packaging Agreement (the ***Packaging Agreement***) for PCI s commercial packaging services. Under the terms of the Packaging Agreement, PCI will be responsible for, among other things, the packaging of certain of the Company s products, tooling purchases and repair, analytical work, stability testing, auditing of suppliers and storage. The Company is responsible for supplying the product materials to PCI. Pursuant to the Packaging Agreement, the

Company has agreed to submit rolling forecasts, some of which will be binding on the Company. The Company will compensate PCI for services rendered, based on an agreed upon fee schedule and subject to certain price adjustments.

The Packaging Agreement has an initial term ending September 30, 2019, unless earlier terminated in accordance with its terms. The Packaging Agreement will automatically renew after the initial term for successive terms of two years, unless either party gives notice of its intention to terminate the Packaging Agreement at least one year prior to the end of the then current term.

Either party may terminate the Packaging Agreement (a) if the other party has failed to remedy a material breach within 60 days following receipt of a written notice, or (b) immediately upon written notice to the other party in the event that the other party files a

petition of bankruptcy, enters into an agreement with its creditors, applies for or consents to the appointment of a receiver, trustee or administrator, permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 30 days, or takes any equivalent action in consequence of debt in any jurisdiction. Either party may terminate the Packaging Agreement for any reason or no reason upon 24 months prior written notice to the other party.

The Packaging Agreement contains certain representations, warranties, limitations of liabilities, confidentiality and indemnity obligations and other provisions customary for agreements of this type.

The foregoing description of the terms of the Packaging Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Packaging Agreement, a copy of which is attached to this report as Exhibit 99.3.

License Agreement

Also attached to this report as Exhibit 99.4 is a copy of the License Agreement between the Company and BIAL Portela & CA, S.A., dated February 9, 2017, the terms of which are described in the Company s Current Report on Form 8-K that was filed with the Securities and Exchange Commission on February 10, 2017.

Item 2.02 Results of Operations and Financial Condition.

The disclosure contained under the heading Quarter-End Cash, Investments and Receivables in Item 8.01 below is incorporated herein by reference.

Item 8.01 Other Events.

Recent Developments

On April 11, 2017, the U.S. Food and Drug Administration (the ***FDA***) approved INGREZZA™ (valbenazine) capsules for the treatment of adults with tardive dyskinesia. INGREZZA, a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is the first and only FDA-approved product indicated for the treatment of adults with tardive dyskinesia.

The Company has established the wholesale acquisition cost (***WAC***) for a 30-count bottle of INGREZZA 40mg capsules at $5,275. The Company anticipates obtaining FDA approval for an 80mg capsule formulation of INGREZZA by the end of 2017, and expects the WAC price for a 30-count bottle of the 80 mg capsule formulation of INGREZZA to be priced substantially similar to the price of a 30-count bottle of INGREZZA 40 mg capsules.

Quarter-End Cash, Investments and Receivables

The Company expects to end the first quarter of 2017 with cash, investments and receivables totaling approximately $274 million. The Company s financial statements for the quarter ended March 31, 2017 have not yet been completed and could result in changes to these anticipated financial results.

Convertible Senior Notes

On April 25, 2017, the Company issued a press release announcing its proposed plans to offer, subject to market and other conditions, up to approximately $450 million in aggregate principal amount of convertible senior notes due 2024

(the notes) in a private offering to qualified institutional buyers pursuant to Rule 144A of the Securities Act of 1933, as amended (the ***Securities Act***). The Company also expects to grant the initial purchasers for the offering a 30-day option to purchase up to an additional $67.5 million principal amount of notes. A copy of the press release is attached hereto as Exhibit 99.5 and incorporated by reference herein.

This Form 8-K does not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any offer, solicitation or sale of these securities in any state in which such offer, solicitation or sale would be unlawful. Any offers of the securities would be made only by means of a confidential offering circular. These securities have not been registered under the Securities Act, or any state securities laws and, unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act and applicable state laws.

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 of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 , an 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.

Exhibit

No.	Description
99.1	Master Manufacturing Services Agreement dated November 28, 2016, by and between Patheon UK Limited and Neurocrine Biosciences, Inc.
99.2	Product Agreement dated November 28, 2016, by and between Patheon UK Limited and Neurocrine Biosciences, Inc.
99.3	Commercial Packaging Agreement dated December 12, 2016, by and between AndersonBrecon Inc., d/b/a PCI of Illinois, and Neurocrine Biosciences, Inc.
99.4	License Agreement dated February 9, 2017, by and between Bial Portela & CA, S.A. and Neurocrine Biosciences, Inc.
99.5	Press release dated April 25, 2017

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: April 25, 2017

NEUROCRINE BIOSCIENCES, INC.

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