NEUROCRINE BIOSCIENCES INC
Form 8-K
January 29, 2019

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): January 28, 2019

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.

Collaboration and License Agreement

On January 28, 2019 (the ***Agreement Date***), Neurocrine Biosciences, Inc. (the ***Company***) entered into a Collaboration and License Agreement (the ***Collaboration Agreement***) with Voyager Therapeutics, Inc. (***Voyager***) for the research, development and commercialization of adeno-associated virus (***AAV***)-based gene therapy products.

Collaboration and Licenses. Under the Collaboration Agreement, upon the expiration or termination of applicable waiting periods and the receipt of any required approvals or clearances under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (such date, the ***Effective Date*** and such clearance, ***Antitrust Clearance***), the Company and Voyager have agreed to collaborate on the conduct of four collaboration programs (the ***Programs***): Voyager s VY-AADC program, intended to advance Voyager s VY-AADC product candidate for the treatment of Parkinson s disease, which is currently in an ongoing Phase 2 trial (the ***AADC Program***); Voyager s program intended to generate gene therapy product candidates for the treatment of Friedreich s ataxia, including Voyager s VY-FXN01 product candidate (the ***FA Program*** and, collectively with the AADC Program, the ***Existing Programs***); and two programs to be determined by the Company and Voyager at a later date, as described below (each a ***Discovery Program*** and, collectively, the ***Discovery Programs***).

Under the terms of the Collaboration Agreement, subject to the rights retained by Voyager thereunder, Voyager has agreed to collaborate with the Company on, and to grant, as of the Effective Date, exclusive, royalty-bearing, non-transferable, sublicensable licenses to certain of Voyager s intellectual property rights, for all human and veterinary diagnostic, prophylactic, and therapeutic uses, for the research, development, and commercialization of gene therapy products (the ***Collaboration Products***) under (i) the AADC Program, on a worldwide basis; (ii) the FA program, for the United States and, upon expiration of Sanofi Genzyme s option to the FA Program pursuant to its ongoing collaboration with Voyager (the ***Sanofi Genzyme Collaboration***) without exercise of such option, all countries in the world in which the Collaboration Agreement remained in effect with respect to the FA Program; and (iii) each Discovery Program, on a worldwide basis.

Pursuant to development plans agreed to by the Company and Voyager, and as overseen by a joint steering committee (***JSC***), Voyager has operational responsibility, subject to certain exceptions, for the conduct of each Program (prior to the Transition Event (as defined below) for each Program) and is required to use commercially reasonable efforts to develop the Collaboration Products. The Company has agreed to be responsible for all costs incurred by Voyager in conducting these activities for each Program, in accordance with an agreed budget. If Voyager breaches its development responsibilities or in certain circumstances upon a change in control of Voyager, the Company has the right but not the obligation to assume the activities under such Program.

Upon the occurrence of a specified event for each Program (a ***Transition Event***), the Company agrees to assume responsibility for development, manufacturing and commercialization activities for such Program from Voyager and to pay milestones and royalties on future net sales as described further below. For each Existing Program, Voyager has the option (a ***Co-Co Option***) to co-develop and co-commercialize such Program upon the occurrence of a specified event (a ***Co-Co Trigger Event***). Should Voyager elect to exercise its Co-Co Option, the Company and Voyager agree to enter into a cost- and profit-sharing arrangement (a ***Co-Co Agreement***) whereby the Company and Voyager agree to jointly develop and commercialize Collaboration Products for such Program (***Co-Co Products***) and share in its costs, profits and losses, and Voyager agrees to forfeit certain milestones and royalties on net sales in the United States during the effective period of the applicable Co-Co Agreement. The Transition Events are (i) with respect to the AADC Program, Voyager s receipt of topline data for the ongoing Phase 2 clinical trial for VY-AADC; (ii) with respect to the FA Program, Voyager s receipt of topline data for the initial Phase 1 clinical trial for an FA Program product candidate; and (iii) with respect to each Discovery Program, the preparation by Voyager and the approval by the Company of an investigational new drug application to be filed with the U.S. Food and Drug

Administration (***FDA***) by the Company for the first development candidate in such Discovery Program. The Co-Co Trigger Events are (i) with respect to the AADC Program, Voyager s receipt of topline data for the ongoing Phase 2 clinical trial for VY-AADC and (ii) with respect to the FA Program, the achievement of milestones or metrics specified in the applicable development plan, as determined by the JSC.

Subject to exceptions specified in the Collaboration Agreement, profits and losses under Voyager s Co-Co Option are agreed to be allocated (i) 50% to the Company and 50% to Voyager for a Collaboration Product from the AADC Program and (ii) 60% to the Company and 40% to Voyager for a Collaboration Product from the FA Program; provided, however, that the Company may elect, within a specified period following the acceptance for filing of a biologics license application from the FDA, to pay a $35 million rate-shifting fee to Voyager to change the allocation for the AADC Program to 55% to the Company and 45% to Voyager. The parties have agreed that each Co-Co Agreement will provide Voyager the right to terminate for any reason upon prior written notice to the Company, and the Company the right to terminate in certain circumstances upon a change of control of Voyager.

Candidate Selection. The Company and Voyager have committed, following the Effective Date, to agree on a list of up to eight target genes (***Targets***), from which the Company has the right to nominate Targets for the two Discovery Programs. Each Target for the Discovery Programs must be approved by a consensus of the JSC or the executive officers of the parties.

Financial Terms. Under the terms of the Collaboration Agreement, the Company has agreed to pay Voyager an upfront payment of $115 million (the ***Upfront Payment***) within five business days after the Effective Date. The Collaboration Agreement provides for aggregate development milestone payments from the Company to Voyager for Collaboration Products under (i) the AADC Program of up to $170 million; (ii) the FA Program of up to $195 million, and (iii) each of the two Discovery Programs of up to $130 million per Discovery Program. Voyager may be entitled to receive aggregate commercial milestone payments for each Collaboration Product of up to $275 million, subject to an aggregate cap on commercial milestones across all Programs of $1.1 billion.

The Company has also agreed to pay Voyager royalties, based on future net sales of the Collaboration Products. Such royalty percentages, for net sales in and outside the United States, range from (i) for the AADC Program, the mid-teens to thirty and the low-teens to twenty, respectively; (ii) for the FA Program, low-teens to high-teens and high-single digits to mid-teens, respectively; and (iii) for each Discovery Program, high-single digits to mid-teens and mid-single digits to low-teens, respectively. On a country-by-country and Program-by-Program basis, royalty payments would commence on the first commercial sale of a Collaboration Product and terminate on the later of (a) the expiration of the last patent covering the Collaboration Product or its method of use in such country, (b) 10 years from the first commercial sale of the Collaboration Product in such country and (c) the expiration of regulatory exclusivity in such country (the ***Royalty Term***).

Termination. Unless earlier terminated, the Collaboration Agreement expires on the later of (i) the expiration of the last to expire Royalty Term with respect to a Collaboration Product in all countries in the relevant territory or (ii) the expiration or termination of all Co-Co Agreements. The Company may terminate the Collaboration Agreement in its entirety or on a Program-by-Program or country-by-country basis by providing at least (x) 180-day advance notice if such notice is provided prior to the first commercial sale of the Collaboration Product to which the termination applies or (y) one-year advance notice if such notice is provided after the first commercial sale of the Collaboration Product to which the termination applies. Voyager may terminate the Collaboration Agreement, subject to specified conditions, if (i) the Company fails to make the equity purchase described in greater detail below or (ii) the Company challenges the validity or enforceability of certain Voyager intellectual property rights. Subject to a cure period, either party may terminate the Collaboration Agreement in the event of a material breach in whole or in part, subject to specified conditions. Either party may also terminate the Collaboration Agreement if specified regulatory agencies seek to enjoin the transaction or if the parties are unable to obtain Antitrust Clearance within 180 days of the Agreement Date.

The foregoing description of the terms of the Collaboration Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Collaboration Agreement, a copy of which will be filed with the Securities and Exchange Commission as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2018.

Stock Purchase Agreement

In connection with the execution of the Collaboration Agreement, the Company and Voyager also entered into a stock purchase agreement on the Agreement Date (the ***Stock Purchase Agreement***) for the sale and issuance of 4,179,728 shares of common stock (the ***Shares***) to the Company at a price of $11.9625 per share, for an aggregate purchase price of approximately $50.0 million.

The consummation of the transactions contemplated by the Stock Purchase Agreement is subject to the parties obtaining Antitrust Clearance, the Collaboration Agreement and Investor Agreement (as defined below) remaining in

full force and effect, and the satisfaction or waiver of other customary closing conditions. The parties have agreed to hold the closing of the purchase and sale of the Shares (the ***Closing***) on the second business day after the satisfaction or waiver of such closing conditions.

The Stock Purchase Agreement may be terminated upon the mutual consent of the parties. Either party may terminate the Stock Purchase Agreement upon written notice to the other party if certain closing conditions are unable to be met within 180 days of applicable antitrust filings. Subject to specified exceptions, either party also may terminate the Stock Purchase Agreement prior to the Closing upon material breach of certain covenants or agreements by the other party or upon certain representations and warranties of such other party becoming untrue.

The foregoing description of the terms of the Stock Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Stock Purchase Agreement, a copy of which will be filed with the Securities and Exchange Commission as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2018.

Investor Agreement

In connection with the execution of the Collaboration Agreement, the Company and Voyager also entered into an investor agreement on the Agreement Date (the ***Investor Agreement***) providing for standstill and lock-up restrictions and a voting agreement with respect to the Shares.

Pursuant to the terms of the Investor Agreement, the Company has agreed not to, without the prior written approval of Voyager and subject to specified conditions, directly or indirectly acquire shares of Voyager s outstanding common stock, seek or propose a tender or exchange offer or merger between the parties, solicit proxies or consents with respect to any matter, or undertake other specified actions related to the potential acquisition of additional equity interests in Voyager (the ***Standstill Restrictions***). Further, the Company has also agreed not to, and to cause its affiliates not to, sell or transfer the Shares without the prior written approval of Voyager, subject to specified conditions (the ***Lock-Up Restrictions***).

In addition, pursuant to the terms of the Investor Agreement, the Company has agreed that the Shares are subject to a voting agreement such that, subject to specified conditions and excluding specified extraordinary matters, the Company has agreed to, and has agreed to cause its permitted transferees to, vote in accordance with the recommendation of Voyager s Board of Directors and has granted Voyager an irrevocable proxy with respect to the foregoing (the ***Voting Agreement***).

Each of the Standstill Restrictions, the Lock-Up Restrictions, and the Voting Agreement terminate upon the earliest to occur of (i) a liquidation or dissolution of Voyager, and (ii) the later of the third anniversary of the date of the Closing and the initial announcement or release of topline results from Voyager s anticipated second pivotal clinical trial. The Standstill Restrictions and Voting Agreement also terminate upon the expiration or termination of the Collaboration Agreement, if earlier. The Standstill Restrictions and Lock-Up Restrictions also terminate upon the deregistration of Voyager s common stock, if earlier. The Lock-Up Restrictions and Voting Agreement also terminate on a change in control of Voyager or the date on which the Company and its affiliates beneficially own less than three percent of the common stock of Voyager on an outstanding basis.

The foregoing description of the terms of the Investor Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Investor Agreement, a copy of which will be filed with the Securities and Exchange Commission as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2018.

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

99.1 Joint Press Release of Neurocrine Biosciences, Inc. and Voyager Therapeutics, Inc. dated January 29, 2019.

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 29, 2019

NEUROCRINE BIOSCIENCES, INC.

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