

**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): June 12, 2020

NEUROCRINE BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.001 par value	NBIX	Nasdaq Global Select Market

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 (see General Instructions A.2. below):

- 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.

Exclusive License Agreement

On June 12, 2020 (the “**Agreement Date**”), Neurocrine Biosciences, Inc. (the “**Company**”) entered into an Exclusive License Agreement (the “**License Agreement**”) with Takeda Pharmaceutical Company Limited (“**Takeda**”) for the development and commercialization of various compounds encompassing the following seven assets (collectively, the “**Licensed Products**”): (i) TAK-831 for schizophrenia (the “**Phase II Asset**”), (ii) TAK-653 for treatment-resistant depression (the “**TAK-653 Program**”), (iii) TAK-041 for anhedonia (the “**TAK-041 Program**” and together with the TAK-653 Program, the “**Phase II Ready Assets**”), and (iv) four non-clinical stage assets (the “**Non-Clinical Assets**”).

License. Under the License 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**”), Takeda has agreed to grant, as of the Effective Date, exclusive, non-transferable, sublicensable licenses to certain of Takeda’s intellectual property rights in all fields of use on a worldwide basis to develop, manufacture and commercialize the Licensed Assets.

Profit and Loss Sharing Options. As of the Effective Date, the Phase II Asset will be deemed a royalty-bearing product under the License Agreement pursuant to which the Company will be responsible for all costs and expenses associated with the development, manufacture and commercialization of such asset, subject to certain exceptions, and Takeda will be eligible to receive development and commercial milestones and royalties with respect to such asset (a “**Royalty-Bearing Product**”), and Takeda will retain the right to opt-in to a profit sharing arrangement pursuant to which the Company and Takeda will equally share in the operating profits and losses related to such asset, subject to certain exceptions, in lieu of receiving milestones and royalties (a “**Profit-Share Product**”). Subject to specified conditions, Takeda may elect to exercise such opt-in right for the Phase II Asset before the Company initiates a Phase III clinical trial for such Phase II Asset. As of the Effective Date, each of the Phase II Ready Assets will be deemed a Profit-Share Product and Takeda will retain the right to opt-out of the profit sharing arrangement for such asset pursuant to which such asset would become a Royalty-Bearing Product. Takeda may elect to exercise such opt-out rights with respect to a Phase II Ready Asset immediately following the completion of the second Phase II clinical trial for such Phase II Ready Asset. In addition, under certain circumstances related to the development and commercialization activities to be performed by the Company, Takeda may elect to opt-out of the profit sharing arrangement for a Profit-Share Product before the initiation of a Phase III clinical trial for such product.

Each of the Non-Clinical Assets will be Royalty-Bearing Products pursuant to which the Company will be responsible for all costs and expenses associated with the development, manufacture and commercialization of such assets, subject to certain exceptions.

Development Plans and Diligence Obligations. For each Licensed Product, except as otherwise agreed by the parties in writing, the Company will be principally responsible for performing all development activities. The parties will establish a joint steering committee (the “**JSC**”) that will monitor and provide strategic oversight of the activities under the License Agreement.

The Company will use commercially reasonable efforts to develop and seek regulatory approval and, as applicable, pricing approval for (i) at least one Licensed Product that comprises a Phase II Ready Asset and at least one Licensed Product that comprises a Phase II Asset, in each case, in each of the United States, Japan, the European Union, and the United Kingdom (the “**Major Markets**”) and (ii) at least one Licensed Product that comprises a Non-Clinical Asset in each of two specified Target Classes (as defined below), in each case, in at least one Major Market.

Takeda will be solely responsible for conducting the two ongoing Phase II clinical trials currently being conducted by Takeda (“**Phase II Ongoing Trials**”) with an option to fund, on an equal basis with the Company, any additional Phase II clinical trials that are necessary to advance the Phase II Asset to Phase III clinical trials, subject to specified conditions. Takeda will use commercially reasonable efforts to conduct the Phase II Ongoing Trials and all associated Phase II ongoing activities.

Financial Terms. Under the terms of the License Agreement, the Company has agreed to pay Takeda an upfront payment of \$120.0 million (minus an earnest money deposit already paid by the Company to Takeda) within five business days after the Effective Date. In addition, Takeda will be entitled to development milestones of up to \$495.0 million in the aggregate and commercial milestones of up to \$1.4 billion in the aggregate for Royalty-Bearing Products. The Company has also agreed to pay Takeda royalties up to high-teen percentage rates based upon sales tiers on future net sales of Royalty-Bearing Products. On a country-by-country and product-by-product basis, royalty payments would commence on the first commercial sale of a Royalty-Bearing Product and terminate on the later of (i) the expiration of the last patent covering such Royalty-Bearing Product in such country, (ii) a number of years from the first commercial sale of such Royalty-Bearing Product in such country and (iii) the expiration of regulatory exclusivity for Royalty-Bearing Product in such country (the “**Royalty Term**”).

Termination. Unless earlier terminated, the License Agreement will continue on a Licensed Product-by-Licensed Product and country-by-country basis until the date on which, (i) for any Royalty-Bearing Product, the Royalty Term has expired in such country; and (ii) for any Profit-Share Product, for so long as the Company continues to develop, manufacture or commercialize such Licensed Product (collectively, the “**Term**”). The Company may terminate the License Agreement for convenience in its entirety or in one or more (but not all) of the Major Markets on six months’ written notice to Takeda (i) with respect to all Licensed Products prior to the first commercial sale of the first Licensed Product for which first commercial sale occurs, or (ii) with respect to all Licensed Products in

one or more given Target Classes prior to the First Commercial Sale of the first Licensed Product in such Target Class(es) for which first commercial sale occurs. “**Target Classes**” means the group of all Licensed Products that share a certain mechanism of action. The Company may terminate the License Agreement for convenience in its entirety or in one or more (but not all) of the Major Markets on 12 months’ written notice to Takeda (i) with respect to all Licensed Products following the first commercial sale of the first Licensed Product for which first commercial sale occurs, or (ii) with respect to all Licensed Products in one or more given Target Classes following the first commercial sale of the first Licensed Product in such Target Class(es) for which first commercial sale. Takeda may terminate the License Agreement, subject to specified conditions, (i) if the Company challenges the validity or enforceability of certain Takeda intellectual property rights or (ii) on a Target Class-by-Target Class basis, in the event that the Company does not conduct any material development or commercialization activities with respect to any Licensed Product within such Target Class for a specified continuous period. Subject to a cure period, either party may terminate the License Agreement in the event of any material breach, solely with respect to the Target Class of a Licensed Product to which such material breach relates, or in its entirety in the event of any material breach that relates to all Licensed Products. Either party may also terminate the License Agreement if the parties are unable to obtain Antitrust Clearance within 120 days of the Agreement Date and the parties have not agreed in writing to extend the Antitrust Clearance date.

The foregoing description of the terms of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement, a copy of which will be filed with the Securities and Exchange Commission as an exhibit to the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2020.

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”, “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.

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated June 16, 2020
104	Cover Page Interactive Data File

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 thereunto duly authorized.

Date: June 16, 2020

NEUROCRINE BIOSCIENCES, INC.

/s/ Darin M. Lippoldt

Darin M. Lippoldt

Chief Legal Officer



Neurocrine Biosciences and Takeda Announce Collaboration to Develop and Commercialize Potential Therapies for Psychiatric Disorders

- *Strategic partnership agreement provides Neurocrine Biosciences exclusive worldwide rights to early-to-mid-stage psychiatry pipeline compounds within Takeda's Neuroscience portfolio*
- *Collaboration includes three clinical-stage assets with the most advanced molecule in Phase II for negative symptoms of schizophrenia*
- *Takeda retains ability to opt in or out of a 50:50 profit share on all clinical programs at certain development events*

SAN DIEGO and Osaka, Japan, June 16, 2020 – Neurocrine Biosciences, Inc. ([Nasdaq: NBIX](#)) and Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](#)) (“Takeda”) today announced a strategic collaboration to develop and commercialize compounds in Takeda’s early-to-mid-stage psychiatry pipeline. Specifically, Takeda granted an exclusive license to Neurocrine Biosciences for seven pipeline programs, including three clinical stage assets for schizophrenia, treatment-resistant depression and anhedonia.

“We are excited to collaborate with Takeda to bring life-changing therapies to people living with serious, challenging and under-addressed psychiatric disorders who are in need of better treatment options,” said Kevin Gorman, Ph.D., Chief Executive Officer at Neurocrine Biosciences. “With our deep understanding in the fields of psychiatry and neurology, we look forward to developing new treatments for schizophrenia, treatment-resistant depression and anhedonia as part of our diverse clinical development pipeline. This strategic partnership enhances our growing pipeline and strengthens our position as a leading neuroscience-focused biopharmaceutical company.”

“With longstanding experience developing and commercializing therapies for serious neurological and psychiatric disorders, Neurocrine Biosciences is the ideal partner to continue to develop our early-to-mid-stage psychiatry portfolio and bring these potential new therapies to patients,” said Sarah Sheikh, M.D., M.Sc., MRCP, Head, Neuroscience Therapeutic Area Unit at Takeda. “Takeda is deeply committed to Neuroscience as one of our core therapeutic areas. The strategic partnership with Neurocrine Biosciences allows us to continue to build on our leadership in psychiatry and deliver future medicines for these patients while advancing our clinical assets for rare neurological diseases, such as narcolepsy, developmental and epileptic encephalopathies and neurodegenerative conditions.”

Collaboration Details

Under the terms of the agreement, Neurocrine Biosciences will be responsible for developing and commercializing all pipeline compounds included in the collaboration. Takeda will receive a total of \$120 million USD in upfront cash. Additionally, Takeda will be entitled to development milestones of up to \$495 million USD, commercial milestones of up to \$1.4 billion USD and up to double-digit royalties on net sales. At certain development events, Takeda may elect to opt in or out of a 50:50 profit share on all clinical programs on an asset-by-asset basis. For any asset in which Takeda is participating in a 50:50 profit share arrangement, Takeda will not be eligible to receive development or commercial milestones.

Conference Call Information

Today, Neurocrine Biosciences will host a conference call and webcast at 8:00 a.m. ET to provide commentary on the collaboration. The live call may be accessed by dialing (866) 831-8711 (U.S.) or (203) 518-9883 (International) using the conference ID: 5022. A live audio webcast of the conference call will be available online on the Neurocrine Bioscience 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 Programs in the Collaboration Agreement

TAK-831

TAK-831 is a potential first-in-class D-Amino Acid Oxidase (DAAO) inhibitor that has completed multiple Phase I studies and is currently in on-going Phase II studies, including the Phase II INTERACT proof-of-concept study in negative symptoms of schizophrenia.

TAK-653

TAK-653 is a potential first-in-class Alpha-Amino-3-Hydroxy-5-Methyl-4-Isloxazole Propionic Acid (AMPA) potentiator. TAK-653 has completed Phase I studies and is a Phase II study-ready compound with the potential to be developed for treatment-resistant depression.

TAK-041

TAK-041 is a potential first-in-class G Protein-Coupled Receptor 139 (GPR139) agonist. TAK-041 has completed multiple Phase I studies and is a Phase II study-ready compound with the potential to be developed for the treatment of anhedonia in depression. Anhedonia is a psychological condition characterized by the inability to experience pleasure.

Preclinical Programs

The collaboration includes the rights to four preclinical programs.

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with 28 years of experience discovering and developing life-changing treatments for people with serious, challenging and under-addressed

neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease endometriosis* and uterine fibroids* and clinical development programs in multiple therapeutic areas including a gene therapy for Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, epilepsy and polycystic ovary syndrome*. Headquartered in San Diego, Neurocrine Biosciences specializes in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit neurocrine.com, and follow the company on [LinkedIn](https://www.linkedin.com/company/neurocrine). (*in collaboration with AbbVie)

Takeda's Commitment to Neuroscience

Takeda's Neuroscience therapeutic area is driven by the immense unmet need of patients suffering from neurological diseases. Our mission is to bring innovative and potentially disease-modifying medicines to these patients. Our commitment to patients extends beyond our research and development efforts by supporting several neuroscience patient and provider organizations to raise awareness, educate and broaden access to therapies.

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited ([TSE:4502](https://www.tse.com/stocks/stocks/4502)/[NYSE:TAK](https://www.nyse.com/quote/TSE:TAK)) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Diseases, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries. For more information, visit <https://www.takeda.com>.

Neurocrine Biosciences 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 transactions with Takeda Pharmaceutical Company Limited; our potential milestone and royalty payments to Takeda; the development of our product candidates and the timing of completion of our clinical, regulatory, 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 the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risks and uncertainties related to any COVID-19 quarantines, shelter-in-place and similar government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our business operations and the business operations of the third parties on which we rely; our future financial and operating performance; risks or uncertainties related to the development of the our product candidates; risks that the FDA or other regulatory authorities may make adverse decisions regarding our

product candidates; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities 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 and uncertainties relating to competitive products and technological changes that may limit demand for a product candidate; risks that the benefits of the agreements with Takeda may never be realized; risks that 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 March 31, 2020. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

Takeda Pharmaceutical Company Limited Forward-Looking Statements

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could" "anticipates", "estimates", "projects" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations; the success of or failure of product development programs; decisions of regulatory authorities and the timing thereof; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda's operations and the timing of any such divestment(s); and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: <https://www.takeda.com/investors/reports/sec-filings/> or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

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Contacts:

Neurocrine Biosciences, Inc.

Takeda Pharmaceuticals

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