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): November 22, 2021

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

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.

On November 22, 2021 (the "Agreement Date"), Neurocrine Biosciences, Inc. (the "Company") entered into a Collaboration and License Agreement (the "License Agreement") with Heptares Therapeutics Limited ("Heptares"), an affiliate of the Sosei Group Corporation, for the development and commercialization of products containing certain sub-type selective muscarinic M1, M4 or dual M1/M4 receptor agonists (collectively, the "Licensed Products").

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"), Heptares has agreed to grant the Company an exclusive, sublicensable license to certain of its intellectual property rights in all fields of use in the Territory to develop, manufacture and commercialize the Licensed Products. "Territory" means worldwide, excluding Japan for Licensed Products comprised of M1 receptor agonists (the "M1 Licensed Products"), subject to the Company's option for M1 Licensed Products in Japan described below. Heptares has also granted the Company a non-exclusive, sublicensable license to its platform intellectual property in all fields of use in the Territory to the extent necessary to develop, commercialize and exploit the Licensed Products under the exclusive license. Heptares has retained the rights to develop, manufacture and commercialize the M1 Licensed Products in Japan, subject to the Company's option in Japan.

Development in the Territory. Under the License Agreement, Heptares is responsible for the completion of any ongoing or future non-clinical activities or other activities as approved by a joint steering committee (the "JSC") for the Licensed Products. The Company has the option to engage Heptares to carry out Phase I clinical trials for certain Licensed Products. The Company is responsible for all development costs and all other development, regulatory, and commercialization activities for the Licensed Products in the Territory. The JSC will monitor and provide strategic oversight of the activities under the License Agreement.

Development in Japan. Heptares is responsible for the development of the M1 Licensed Products in Japan, subject to oversight by the JSC. The Company has the option to fund a portion of the development costs of M1 Licensed Products in Japan incurred after exercise of the option and to receive a portion of the revenues resulting from commercialization of M1 Licensed Products in Japan.

Financial Terms. Under the terms of the License Agreement, the Company has agreed to pay Heptares an upfront payment of $100.0 million within 10 days of the Effective Date. In addition, Heptares is eligible to receive development and regulatory milestones of up to approximately $1.5 billion in the aggregate (for both clinical and non-clinical stage compounds) and commercial milestones of up to approximately $1.1 billion in the aggregate. The Company has also agreed to pay Heptares tiered royalties from the high single digit to mid-teen percentage rates on future net sales of Licensed Products in the Territory. On a country-by-country and Licensed Product-by-Licensed Product basis, royalty payments would commence on the first commercial sale of a Licensed Product and terminate on the later of (i) the expiration of the last patent covering such Licensed Product in such country, (ii) a number of years from the first commercial sale of such Licensed Product in such country and (iii) the expiration of regulatory exclusivity for such Licensed 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 the Royalty Term for such Licensed Product has expired in such country. Prior to the second anniversary of the Effective Date or such other date set by the JSC (the "Research Term"), the Company may terminate the License Agreement for convenience in its entirety or with respect to one or more targets (M1, M4 or dual M1/M4) upon 180 days' written notice to Heptares. After the Research Term, the Company may terminate the License Agreement for convenience in its entirety or with respect to one or more targets upon 90 days' written notice to Heptares. After the Research Term, Heptares may terminate the License Agreement on a target-by-target basis in the event that the Company does not conduct any material development activities in the Territory with respect to Licensed Products within the applicable target class for a continuous period not less than 365 days and does not commence any such activities within 120 days of receiving written notice.

Either party may terminate the License Agreement, subject to specified conditions, (i) in the event of material breach by the other party, subject to a cure period, (ii) if the other party challenges the validity or enforceability of certain intellectual property rights, subject to a cure period, or (iii) if the other party becomes insolvent or takes certain actions related to insolvency. Either party may also terminate the License Agreement if the parties are unable to obtain Antitrust Clearance within 120 days of the Agreement Date.

The foregoing description of the material terms of the License Agreement is qualified in its entirety by reference to the full text of the License Agreement, a copy of which will be filed as an exhibit to a subsequent filing with the Securities and Exchange Commission.

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”, “anticipates”, “believes”, “estimates”, “projects”, “predicts”, “potential” and similar expressions intended to identify forward-looking statements. These statements include, but are not limited to, statements related to the potential benefits of the collaboration with Heptares, the total potential deal value of the collaboration and the ability to obtain Antitrust Clearance. 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. Except as required by law, the Company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Item 9.01. Financial Statements and Exhibits.

Exhibit	Description
99.1	Press Release dated November 22, 2021
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 hereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

Dated: November 22, 2021

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

Exhibit 99.1

Neurocrine Biosciences and Sosei Heptares Announce Collaboration to Develop Novel Muscarinic Receptor Agonists for Schizophrenia and Other Neuropsychiatric Disorders

Neurocrine Biosciences anticipates initiating a Phase 2 study with the selective M4 agonist HTL-0016878 in schizophrenia in 2022 and Phase 1 studies for a dual M1/M4 and selective M1 agonist in 2023

Sosei Heptares receives US$100 million upfront, ongoing R&D funding, and up to US$2.6 billion in potential development, regulatory and commercial milestone payments, plus tiered sales royalties

SAN DIEGO, Calif., USA, TOKYO, Japan and CAMBRIDGE, UK. Nov. 22 2021 - Neurocrine Biosciences, Inc. (Nasdaq: NBIX) and Sosei Group Corporation ("Sosei Heptares"; TSE: 4565) announce the signing of a strategic collaboration and licensing agreement to develop novel muscarinic receptor agonists, which Neurocrine Biosciences intends to study in the treatment for schizophrenia, dementia and other neuropsychiatric disorders.

Under the terms of the agreement, Neurocrine Biosciences gains development and commercialization rights to a broad portfolio of novel clinical and preclinical subtype-selective muscarinic M4, M1 and dual M1/M4 receptor agonists discovered by Sosei Heptares in development for the treatment of major neurological disorders. The most advanced program, HTL-0016878, is a selective M4 agonist. Neurocrine Biosciences plans to submit an Investigational New Drug (IND) application and initiate a placebo-controlled Phase 2 study with HTL-0016878 as a potential treatment for schizophrenia in 2022.

Sosei Heptares retains the rights to develop M1 agonists in Japan in all indications, with Neurocrine Biosciences receiving co-development and profit share options.

Muscarinic receptors are central to brain function and validated as drug targets in psychosis and cognitive disorders. Sosei Heptares has discovered selective muscarinic M4, M1 and M1/M4 dual agonists that offer the potential to deliver therapeutic effects while avoiding both the harmful side effects caused by non-selective agonists and efficacy issues experienced in some older patients caused by positive allosteric modulators that require cooperativity of diminishing levels of acetylcholine. Sosei Heptares achieved this through application of its world leading G protein-coupled receptor (GPCR) stabilized receptor platform (StaR®) and subsequent translational medicine studies.

"Our partnership collaboration with Sosei Heptares to advance their selective muscarinic agonist portfolio leverages the strengths of both our organizations with one goal in mind, to bring important medicines to patients who need better treatment options," said Kevin Gorman, Ph.D., Chief Executive Officer at Neurocrine Biosciences. "We continue to add potential best-in-class compounds to our growing pipeline, which further positions Neurocrine Biosciences as a leading neuroscience-focused biopharmaceutical company."

Shinichi Tamura, President and CEO of Sosei Heptares, added: "We are delighted to partner with Neurocrine Biosciences to advance our selective muscarinic receptor agonist portfolio. The deal highlights the significant potential value within this portfolio and brings to bear the substantial expertise of the Neurocrine team, which is highly experienced in developing and commercializing novel products for patients with neurological and psychiatric diseases globally. It also enables Sosei Heptares to retain rights in Japan, where we are confident that we can make important progress leveraging our own expertise to advance novel candidates that aim to address this major unmet need. Overall, the deal is a great example of our strategy to combine our drug design and early development capabilities with those of later stage development and commercialization partners, while also providing significant funding to expand and advance our own pipeline."

Collaboration Details

Under the terms of the agreement, Neurocrine Biosciences will be responsible for development costs associated with the programs globally, except for M1 agonists being developed in Japan. The agreement will be subject to the following terms:

- **Upfront License Payment**: Sosei Heptares will receive a total of $100 million USD in upfront cash.
- **Development and Regulatory Milestones**: Sosei Heptares is eligible to receive up to approximately $1.5 billion USD related to the successful progression of licensed candidates through to regulatory approval.
- **Commercial Milestones**: Sosei Heptares is eligible to receive up to $1.1 billion USD upon achieving certain global sales milestones of any products developed under the partnership
- **Product Royalties**: Sosei Heptares is eligible to receive tiered royalties ranging from high single digit to mid-teen percentage on future net sales of any products developed under the partnership**.**

- **R&D Collaboration**: The R&D collaboration will be conducted jointly by Neurocrine Biosciences and Sosei Heptares to advance preclinical candidates through Phase 1 clinical studies. The R&D collaboration will be funded by Neurocrine Biosciences.
- **Sosei Heptares M1 Agonist Rights in Japan**: Sosei Heptares retains rights to develop M1 agonists in Japan for any indication, with Neurocrine Biosciences receiving co-development and profit share options.

This transaction is subject to customary clearances under the Hart-Scott-Rodino Antitrust Improvements Act. Assuming this transaction completes by December 31, 2021, the $100 million USD upfront payment will represent a material positive revenue impact to Sosei Heptares, and is expected to be recognized as revenue in the fourth quarter of the financial year ended December 31, 2021, subject to agreement with the Group's auditors.

BofA Securities is acting as financial advisor to Sosei Heptares. Gowling WLG and Orrick Herrington & Sutcliffe LLP are serving as legal counsel to Sosei Heptares.

Conference Call and Webcast Information

On November 23, Sosei Heptares will host a conference call and webinar for Japanese investors on at 8:00 a.m. Japan Standard Time. The live call may be accessed by pre-registration here.

A live audio webcast of the conference call will be available from the Investors section of Sosei Heptares website at www.soseiheptares.com.

A replay of the webcast will be available on Sosei Heptares' website after the conclusion of the event and will be archived for approximately one month.

About Muscarinic Receptors

Muscarinic receptors are G protein-coupled receptors (GPCRs) found in multiple tissues including the brain, cardiovascular system, and gastrointestinal tract. Selective activation of M4 and M1 receptors in the brain is a clinically validated approach to treating cognitive and neuropsychological symptoms of neurological diseases, including Schizophrenia, dementia associated with Alzheimer's disease, Parkinson's disease, and others. Until now, attempts to develop medicines that selectively target M4 and M1 receptors have been unsuccessful because of side effects caused by the activation of M2 and M3 receptors. Highly selective M4 or M1 agonists that do not activate M2 or M3 therefore are highly sought after and expected to have the potential to address major unmet medical needs with blockbuster potential.

About Programs in the Collaboration Agreement

HTL-0016878

HTL-0016878 ("878") is an oral, investigational M4 selective agonist that has completed multiple Phase 1 studies and is preparing for the initiation of Phase 2 studies in schizophrenia. As a selective M4 orthosteric agonist, '878 offers the potential for an improved safety profile without the need of combination therapy to minimize side effects and avoids the need of cooperativity with acetylcholine (ACh) when compared to non-selective muscarinic agonists and positive allosteric modulators in development. Studies completed to date have shown '878 to be generally well tolerated.

Preclinical Programs

The collaboration includes rights to multiple preclinical programs which include selective muscarinic compounds targeting M1, M4 receptors and a dual M1/M4 receptor candidate. In combination with '878, the programs offer the ability to leverage M1 and M4 selectivity to address the unmet need for patients suffering from psychosis and cognitive-related diseases.

After signing a R&D and commercialization partnership in 2016, Allergan returned all program rights to '878 and the preclinical programs to Sosei Heptares in Q1 2021.

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering 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*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, Neurocrine Biosciences has specialized 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. (*in collaboration with AbbVie).

About Sosei Heptares

We are an international biopharmaceutical group focused on the discovery and early development of new medicines originating from our proprietary GPCR-targeted StaR® technology and structure-based drug design platform capabilities. We are advancing a broad and deep pipeline of novel medicines across multiple therapeutic areas, including neurology, immunology, gastroenterology, and inflammatory diseases.

We have established partnerships with some of the world's leading pharmaceutical companies and multiple emerging technology companies, including AbbVie, AstraZeneca, Biohaven, Genentech (Roche), GSK, Neurocrine Biosciences, Pfizer, and Takeda. Sosei Heptares is headquartered in Tokyo, Japan with corporate and R&D facilities in Cambridge, UK.

"Sosei Heptares" is the corporate brand and trademark of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565). Sosei, Heptares, the logo and StaR® are trademarks of Sosei Group companies.

For more information, please visit https://soseiheptares.com/

LinkedIn: @soseiheptaresco | Twitter: @soseiheptaresco | YouTube: @soseiheptaresco

Enquiries:

For Neurocrine Biosciences

Tony Jewell, Media
+1 858-617-7578, media@neurocrine.com

Todd Tushla Investors
+1 858-617-7143, ir@neurocrine.com

For Sosei Heptares

Hironoshin Nomura, SVP Investor Relations and Corporate Strategy
+81 (0)3 6679 2178, Hironoshin.Nomura@SoseiHeptares.com

Shinichiro Nishishita, VP Investor Relations, Head of Regulatory Disclosures
+81 (0)3 5210 3399, IR@SoseiHeptares.com

Citigate Dewe Rogerson (for Japanese Media)

Yas Fukuda
+81 (0)3 4360 9234, Yas.Fukuda@citigatedewerogerson.com

MEDiSTRAVA Consulting (for International Media)

Mark Swallow, David Dible, Eleanor Perkin
+44 (0)20 7638 9571, SoseiHeptares@medistrava.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 Sosei Group Corporation; our potential milestone and royalty payments to Sosei Heptares; 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: the possibility that the transaction with Sosei Heptares is not consummated on the expected timeline or at all or the possibility that regulatory approvals of the proposed transaction will impose conditions or are not obtained; 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 Sosei Heptares 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 our periodic reports filed with the SEC, including without limitation our quarterly report on Form 10-Q for the quarter ended September 30, 2021. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

Sosei Group Corporation Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development, and commercialization of products. Various risks may cause Sosei Group Corporation's actual results to differ materially from those expressed or implied by the forward-looking statements, including: adverse results in clinical development programs; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialize products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialization activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.