# 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): July 13, 2023**

# Acadia Pharmaceuticals Inc.
**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **000-50768** | **06-1376651** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **12830 El Camino Real, Suite 400**<br>**San Diego, California**<br>**(Address of Principal Executive Offices)** | **92130**<br>**(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (858) 558-2871**

**N/A**
**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K 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))

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

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, par value $0.0001 per share | ACAD | The Nasdaq Stock Market LLC |

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 July 13, 2023, Acadia Pharmaceuticals Inc. (the "Company") and Neuren Pharmaceuticals Limited ("Neuren") entered into a joint venture and license agreement (the "License Agreement") for the global commercialization and development of trofinetide and of Neuren's development candidate NNZ-2591. The License Agreement amended and restated the pre-existing license agreement between the Company and Neuren, dated August 6, 2018 (the "Initial License"), pursuant to which Neuren granted to the Company exclusive North American rights to develop and commercialize trofinetide for Rett syndrome and other indications.

Pursuant to the License Agreement, Neuren granted to the Company a worldwide, exclusive license to develop and commercialize any product developed by or on behalf of Neuren or the Company containing a trofinetide compound as an active ingredient (a "Trofinetide Product") for all indications. In addition, pursuant to the License Agreement, Neuren granted to the Company a worldwide, exclusive license to develop and commercialize any product developed by or on behalf of Neuren or the Company containing a NNZ-2591 compound as an active ingredient (a "NNZ-2591 Product") for the treatment of Rett syndrome and Fragile X syndrome (the "Acadia NNZ-2591 Field"). Neuren may conduct development and commercialization of NNZ-2591 outside of the Acadia NNZ-2591 Field. The joint steering committee established under the Initial License will be and become the joint steering committee under the License Agreement, and will oversee efforts by the parties.

Under the License Agreement, the Company will make an upfront payment to Neuren of $100.0 million. This payment is in addition to the upfront payment of $10.0 million previously paid by the Company under the Initial License and the milestone payments in the aggregate of $50.0 million previously paid by the Company upon achieving certain development milestones for trofinetide. Neuren is also eligible to receive future milestone payments of up to $405.0 million for each of trofinetide and NNZ-2591, based on the achievement of certain development and annual net sales milestones in North America. Outside of North America, Neuren is eligible to receive milestone payments based the achievement of certain development and annual net sales milestones for each of trofinetide and NNZ-2591 in certain regions, including payments upon the Company's first commercial sale of each of trofinetide and NNZ-2591 in each region, as follows:

| | | First Commercial Sale | Total Sales Milestones |
|---|---|---|---|
| **Europe** | Rett Syndrome<br>Second Indication | $35.0 million<br>$10.0 million | Up to $170.0 million |
| **Japan** | Rett Syndrome<br>Second Indication | $15.0 million<br>$3.75 million | Up to $110.0 million |
| **Rest of World** | | — | Up to $83.0 million |

Neuren will also be eligible to receive tiered, escalating, double-digit percentage royalties based on net sales of Trofinetide Products and/or NNZ-2591 Products by the Company, its affiliates or sublicensees, subject to reductions in certain circumstances. Royalties will be payable under the License Agreement on a product-by-product and country-by-country basis, commencing on the date of execution of the License Agreement and ending on the last to occur of (a) the expiration date of the last valid claim that would be infringed by an authorized sale of the relevant product in the relevant country, (b) the expiration date of the term of any data exclusivity right in such country, and (c) 10 years after the date of the first commercial sale of the relevant product in such country.

The License Agreement may be terminated by Neuren with respect to a given product by providing 10 business days' prior written notice to the Company if, with respect to such product, (a) the Company challenges the validity of certain Neuren intellectual property or (b) the Company ceases certain commercialization activities with respect to trofinetide in Rett syndrome. The License Agreement may be terminated by the Company at any time in its entirety or on a product-by-product basis by providing 90 business days' prior written notice to Neuren. In addition, either party may terminate the License Agreement upon written notice for the other party's uncured material breach, subject to an extension of the cure period under certain circumstances.

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 (the "SEC") as an exhibit to a subsequent filing with the SEC.

**Item 2.02 Results of Operations and Financial Condition.**

On July 13, 2023, the Company issued a press release announcing the entry into the License Agreement and announcing preliminary net sales for Q2 2023 and updated net sales guidance for Q3 2023 and full year 2023. A copy of the press release is furnished herewith as Exhibit 99.1. Pursuant to the rules and regulations of the SEC, such exhibit and the information set forth therein and in this Item 2.02 have been furnished and 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 liability under that section nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing regardless of any general incorporation language.

**Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "potential" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this Current Report. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this Current Report include, but are not limited to, statements regarding future activities under the License Agreement; approvals of product candidates developed pursuant to the License Agreement; potential future payments that may be become payable by the Company pursuant to the License Agreement; the benefits to be derived from the Company's products and product candidates; the Company's financial and operating performance; expected future clinical and regulatory milestones; and the timing of the initiation and/or completion of the Company's clinical, regulatory, and other development activities. Many factors may cause differences between current expectations and actual results, including the risks and uncertainties inherent in drug development, approval and commercialization. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this Current Report are discussed in the Company's filings with the SEC, including the sections titled "Risk Factors" contained therein. 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.**

**(d) Exhibits**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated July 13, 2023 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**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.

**Acadia Pharmaceuticals Inc.**

Dated: July 18, 2023

By: /s/ Austin D. Kim
Austin D. Kim
Executive Vice President, General Counsel & Secretary

**Exhibit 99.1**

**Acadia Pharmaceuticals Acquires Ex-North American Rights to Trofinetide and Global Rights to Neuren's NNZ-2591 in Rett Syndrome and Fragile X Syndrome**

*— Expanded agreement follows Acadia's April 2023 U.S. launch of DAYBUE™ (trofinetide) as the first and only drug approved for the treatment of Rett syndrome*

*— Acadia provides DAYBUE launch update and announces second quarter preliminary net sales and guidance for third quarter*

*— Company to host conference call and webcast today at 4:30 p.m. Eastern Time*

**San Diego, Calif.** – July 13, 2023 – Acadia Pharmaceuticals Inc. (NASDAQ: ACAD) today announced that it has expanded its current licensing agreement for trofinetide with Neuren Pharmaceuticals to acquire ex-North American rights to the drug as well as global rights in Rett syndrome and Fragile X syndrome to Neuren's development candidate NNZ-2591. In April of this year, Acadia launched trofinetide in the United States under the brand name DAYBUE as the first and only drug approved for the treatment of Rett syndrome.

"This expanded worldwide agreement solidifies Acadia's position as the global leader in addressing the unmet needs of people with Rett syndrome," said Steve Davis, Acadia's President and Chief Executive Officer. "We have successfully delivered DAYBUE, the first FDA-approved therapy that treats the core symptoms of Rett syndrome, and are deeply committed to broadening access to this important therapy for patients worldwide."

In addition to expanding access to trofinetide outside of North America, this agreement gives Acadia exclusive worldwide rights to NNZ-2591 in both Rett syndrome and Fragile X syndrome. NNZ-2591 is an investigational synthetic analogue of cyclo-glycyl-proline (cGP) which results from the breakdown of human insulin-like growth factor 1 (IGF-1). NNZ-2591 is currently under development by Neuren in four other rare neurodevelopmental syndromes.

Execution of this agreement advances Acadia's corporate strategy to expand our rare disease business. This deal also enables Acadia to leverage insights from our successful U.S. launch of DAYBUE in other global territories. In addition, this expansion will further advance the global potential of Acadia's current development portfolio.

Acadia intends to submit a New Drug Submission (NDS) for trofinetide in Canada in the next 18 months with plans for Europe, Asia and other regions to be announced at a later date.

*Financial Terms*

Under the terms of the expanded agreement, Neuren will receive an upfront payment of US $100 million and is eligible to receive additional potential downstream milestone and royalty payments earned separately for trofinetide and NNZ-2591.

Outside of North America, Neuren is eligible to receive additional payments for trofinetide upon the achievement of specified revenue milestones as follows:

| | First Commercial Sales Milestones | Total Sales Milestones(1) |
|---|---|---|
| Europe | $35M (Rett); $10M (2nd indication) | Up to $170M |
| Japan | $15M (Rett); $4M (2nd indication) | Up to $110M |
| Rest of World | -0- | Up to $83M |

(1) Each region's sales milestones are divided into four distinct milestones based upon escalating annual net sales thresholds as defined in the agreement.

Neuren will also receive tiered royalties from the mid-teens to low-twenties percent of trofinetide net sales outside of North America. In North America, all milestones and royalties for trofinetide remain unchanged from Acadia's previously existing North American license agreement with Neuren. Potential future payments to Neuren related to NNZ-2591 in Rett syndrome and Fragile X syndrome are identical to the payments for trofinetide in each of North America and outside North America.

*Preliminary Second Quarter Revenues and Updated Guidance*

DAYBUE

- DAYBUE 2Q 2023 preliminary net sales: $21 to $23 million.
- DAYBUE 3Q 2023 net sales guidance: $45 to $55 million.

NUPLAZID

- NUPLAZID 2Q 2023 preliminary net sales: $140 to $144 million.
- NUPLAZID Full Year 2023 net sales guidance: $530 to $545 million.

*Conference Call and Webcast Information*

Acadia will discuss the exclusive worldwide licensing of trofinetide and NNZ-2591 via conference call and webcast today at 4:30 p.m. Eastern Time. The conference call will be available on Acadia's website, www.acadia.com under the investors section and will be archived there until August 12, 2023. The conference call may also be accessed by registering for the call here. Once registered, participants will receive an email with the dial-in number and unique PIN number to use for accessing the call.

*About Rett Syndrome*

Rett syndrome is a rare, complex, neurodevelopmental disorder that may occur over four stages and affects approximately 6,000 to 9,000 patients in the U.S., with approximately 4,500 patients currently diagnosed according to an analysis of healthcare claims data.[1-4] Worldwide, incidence rates for Rett syndrome are similar in countries across the globe, with prevalence varying according to population size, with the number of patients in Europe estimated to be larger and that of Japan's smaller. A child with Rett syndrome exhibits an early period of apparently normal development until six to 18 months, when their skills seem to slow down or stagnate. This is typically followed by a duration of regression when the child loses acquired communication skills and purposeful hand use. The child may then experience a plateau period in which they show mild recovery in cognitive interests, but body movements remain severely diminished. As they age, those living with Rett may continue to experience a stage of motor deterioration which can last the rest of the patient's life.[3] Rett syndrome is typically caused by a genetic mutation on the MECP2 gene.[5] In preclinical studies, deficiency in MeCP2 function has been shown to lead to impairment in synaptic communication, and the deficits in synaptic function may be associated with Rett manifestations.[5-7]

Symptoms of Rett syndrome may also include development of hand stereotypies, such as hand wringing and clapping, and gait abnormalities.[8] Most Rett patients typically live into adulthood and require round-the-clock care.[2,9]

*About DAYBUE™ (trofinetide)*

Trofinetide is a synthetic version of a naturally occurring molecule known as the tripeptide glycine-proline-glutamate (GPE). The mechanism by which trofinetide exerts therapeutic effects in patients with Rett syndrome is unknown. In animal studies, trofinetide has been shown to increase branching of dendrites and synaptic plasticity signals.[10,11]

**Important Safety Information for DAYBUE™ (trofinetide)**

- **Warnings and Precautions**
  - **Diarrhea**: In a 12-week study and in long-term studies, an aggregate of 85% of patients treated with DAYBUE experienced diarrhea. In those treated with DAYBUE, 49% either had persistent diarrhea or recurrence after resolution despite dose interruptions, reductions, or concomitant antidiarrheal therapy. Diarrhea severity was of mild or moderate severity in 96% of cases. In the 12-week study, antidiarrheal medication was used in 51% of patients treated with DAYBUE. Patients should stop taking laxatives before starting DAYBUE. If diarrhea occurs, patients should notify their healthcare provider, consider starting antidiarrheal treatment, and monitor hydration status and increase oral fluids, if needed. Interrupt, reduce dose, or discontinue DAYBUE if severe diarrhea occurs or if dehydration is suspected.
  - **Weight Loss**: In the 12-week study, 12% of patients treated with DAYBUE experienced weight loss of greater than 7% from baseline, compared to 4% of patients who received placebo. In long-term studies, 2.2% of patients discontinued treatment with DAYBUE due to weight loss. Monitor weight and interrupt, reduce dose, or discontinue DAYBUE if significant weight loss occurs.
- **Adverse Reactions:** The common adverse reactions (≥5% for DAYBUE-treated patients and at least 2% greater than in placebo) reported in the 12-week study were diarrhea (82% vs 20%), vomiting (29% vs 12%), fever (9% vs 4%), seizure (9% vs 6%), anxiety (8% vs 1%), decreased appetite (8% vs 2%), fatigue (8% vs 2%), and nasopharyngitis (5% vs 1%).
- **Drug Interactions: Effect of DAYBUE on other Drugs**
  - DAYBUE is a weak CYP3A4 inhibitor; therefore, plasma concentrations of CYP3A4 substrates may be increased if given concomitantly with DAYBUE. Closely monitor when DAYBUE is used in combination with orally administered CYP3A4 sensitive substrates for which a small change in substrate plasma concentration may lead to serious toxicities.
  - Plasma concentrations of OATP1B1 and OATP1B3 substrates may be increased if given concomitantly with DAYBUE. Avoid the concomitant use of DAYBUE with OATP1B1 and OATP1B3 substrates for which a small change in substrate plasma concentration may lead to serious toxicities.
- **Use in Specific Population: Renal Impairment**
  - DAYBUE is not recommended for patients with moderate or severe renal impairment.

DAYBUE is available as an oral solution (200 mg/mL).

Please read the accompanying full Prescribing Information, also available at DAYBUE.com

*About Fragile X Syndrome*

Fragile X syndrome is the most common inherited cause of intellectual disability and the most common known cause of autism. Fragile X syndrome is due to a gene mutation on the X chromosome that impacts the FMRP protein, which is responsible for regulating the synapses of nerve cells. The full mutation causes Fragile X syndrome. It is estimated that between one in 4,000 and one in 7,000 males and between one in 6,000 and one in 11,000 females have the full mutation. Generally, males are more severely affected, with approximately 50% of the females having some features of the syndrome. Clinically, Fragile X syndrome is characterized by intellectual handicap, hyperactivity and attentional problems, autistic symptoms, anxiety, emotional lability and epilepsy.[12,13] Currently, there are no medicines approved for the treatment of Fragile X syndrome.

*About Acadia Pharmaceuticals*

Acadia is advancing breakthroughs in neuroscience to elevate life. For 30 years we have been working at the forefront of healthcare to bring vital solutions to people who need them most. We developed and commercialized the first and only approved therapies for hallucinations and delusions associated with Parkinson's disease psychosis and for the treatment of Rett syndrome. Our clinical-stage development efforts are focused on treating the negative symptoms of schizophrenia, Prader-Willi syndrome, Alzheimer's disease psychosis and neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at www.acadia.com and follow us on LinkedIn and Twitter.

*Forward-Looking Statements*

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements include but are not limited to statements regarding the timing of future events. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug development, approval and commercialization. For a discussion of these and other factors, please refer to Acadia's annual report on Form 10-K for the year ended December 31, 2022, as well as Acadia's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and Acadia undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

*References*


1 Acadia Pharmaceuticals Inc, Data on file. RTT US Prevalence. March 2022.
2 Fu C, Armstrong D, Marsh E, et al. Consensus guidelines on managing Rett syndrome across the lifespan. *BMJ Paediatrics Open*. 2020; 4: 1-14.
3 Kyle SM, Vashi N, Justice MJ. Rett syndrome: a neurological disorder with metabolic components. *Open Biol*. 2018; 8: 170216.
4 Acadia Pharmaceuticals Inc, Data on file.
5 Amir RE, Van den Veyver IB, Wan M, et al. Rett syndrome is caused by mutations in X-linked MECP2, encoding methyl-CpG-binding protein 2. Nat Genet. 1999; 23(2): 185-188.

6 Fukuda T, Itoh M, Ichikawa T, et al. Delayed maturation of neuronal architecture and synaptogenesis in cerebral cortex of Mecp2-deficient mice. *J Neuropathol Exp Neurol*. 2005; 64(6): 537-544.
7 Asaka Y, Jugloff DG, Zhang L, et al. Hippocampal synaptic plasticity is impaired in the Mecp2-null mouse model of Rett syndrome. *Neurobiol Dis*. 2006; 21(1): 217-227.
8 Neul JL, Kaufmann WE, Glaze DG, et al. Rett syndrome: revised diagnostic criteria and nomenclature. *Ann Neurol*. 2010; 68(6): 944-950.
9 Daniel C, Tarquinio DO, Hou W, et al. The changing face of survival in Rett syndrome and MECP2-related disorders. *Pediatr Neurol*. 2015; 53(5): 402-411.
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12 Neuren Pharmaceuticals. Fragile X Syndrome. Retrieved from https://www.neurenpharma.com/products/trofinetide/fragile-x-syndrome. Accessed July 13, 2023.
13 UpToDate. Fragile X syndrome: Clinical features and diagnosis in children and adolescents. Retrieved from https://www.uptodate.com/contents/fragile-x-syndrome-clinical-features-and-diagnosis-in-children-and-adolescents#H3365848815. Accessed July 13, 2023.

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