# 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 9, 2023**

## ACER THERAPEUTICS INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-33004** | **32-0426967** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| | |
|---|---|
| **One Gateway Center, Suite 356**<br>**300 Washington Street**<br>**Newton, Massachusetts** | **02458** |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: **(844) 902-6100**

**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))

| 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, $0.0001 par value per share** | **ACER** | **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 8.01. Other Events.**

On January 9, 2023, Acer Therapeutics Inc. issued a press release entitled "Acer Therapeutics Highlights Key 2022 Achievements and Pipeline Advancements, and Provides Anticipated 2023 Milestones," a copy of which is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by Acer Therapeutics Inc. dated January 9, 2023, entitled "Acer Therapeutics Highlights Key 2022 Achievements and Pipeline Advancements, and Provides Anticipated 2023 Milestones." |
| 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, thereunto duly authorized.

Dated: January 9, 2023

ACER THERAPEUTICS INC.

By: /s/ Harry S. Palmin
Harry S. Palmin
Chief Financial Officer

**Acer Therapeutics Highlights Key 2022 Achievements and Pipeline Advancements, and Provides Anticipated 2023 Milestones**

**NEWTON, MA – January 09, 2023** – Acer Therapeutics Inc. (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious, rare and life-threatening diseases with significant unmet medical needs, today announced a corporate update and provided anticipated key development milestones for 2023.

"The U.S. approval of OLPRUVA™ (sodium phenylbutyrate) for oral suspension by the U.S. Food and Drug Administration (FDA) is a culmination of Acer's collective efforts and ongoing dedication to develop and provide new treatments to patients suffering from rare diseases. Moreover, OLPRUVA™'s approval marks a significant milestone for patients in need, offering a new, responsibly priced sodium phenylbutyrate treatment option, that will be supported by *Navigator by Acer Therapeutics*, our patient services program designed to support patients and caregivers," stated Chris Schelling, CEO and Founder of Acer. "Our commitment to patients is the cornerstone of our mission, and we are proud to have secured our first FDA approval. We look forward to providing further updates in due course as the commercial launch of OLPRUVA™ progresses."

Mr. Schelling continued, "In addition to the approval of OLPRUVA™, our clinical team has been diligently executing on the clinical trials for ACER-801, being investigated in Vasomotor Symptoms (VMS), Post-traumatic Stress Disorder (PTSD) and now prostate cancer. We are eager to report the topline results from our ongoing Phase 2a trial of ACER-801 in moderate to severe VMS in post-menopausal women in Q1 of 2023. These trial results will provide important insight into ACER-801's therapeutic potential in induced VMS (iVMS). Additionally, our pivotal Phase 3 trial of EDSIVO™ (celiprolol) in COL3A1-positive vascular Ehlers-Danlos Syndrome (vEDS) patients remains ongoing as planned, and we look forward to providing an update on full enrollment later this year."

**Review of Acer's Pipeline**

- OLPRUVA™ (sodium phenylbutyrate) for oral suspension
  - On December 27, 2022, Acer announced that the U.S. Food and Drug Administration (FDA) approved OLPRUVA™ (sodium phenylbutyrate) for the treatment of certain patients with UCDs involving deficiencies of CPS, OTC or AS
  - OLPRUVA™ is a prescription medicine used along with certain therapy, including changes in diet, for the long-term management of adults and children weighing 44 pounds (20 kg) or greater and with a body surface area (BSA) of 1.2 $m^2$ or greater, with UCDs, involving deficiencies of CPS, OTC or AS. OLPRUVA™ is not used to treat rapid increase of ammonia in the blood (acute hyperammonemia), which can be life-threatening and requires emergency medical treatment. For additional Important Safety Information, see full Prescribing Information

(https://www.acertx.com/wp-content/uploads/2022/12/OLPRUVA-Prescribing-Information.pdf), Patient Information and discuss with your doctor
    - Formation of *Navigator by Acer Therapeutics*: Navigator is Acer's patient access program, a suite of integrated patient support services designed to help provide more convenient access to OLPRUVA™. The *Navigator by Acer Therapeutics* support services are intended to facilitate support, education, and treatment adherence to the UCD patient community

- ACER-801 (osanetant)
    - Acer's ongoing Phase 2a randomized, double-blind, placebo-controlled, dose-ranging trial of ACER-801 (osanetant) for the treatment of moderate to severe VMS in post-menopausal women is expected to readout in Q1 2023. The data from the Phase 2a trial will inform Acer's development path for ACER-801 (osanetant) in iVMS
    - In October 2022, Acer announced the expansion of its ACER-801 (osanetant) program into PTSD, a disorder that affects over 12 million adults in the U.S. each year.[1] Related to this program expansion, Acer licensed the worldwide exclusive rights and corresponding intellectual property portfolio from Emory University based on preclinical data that showed osanetant's ability to block fear memory consolidation in mice
    - Concurrent with this expansion, the US Department of Defense (DoD) awarded a $3 million grant to the University of North Carolina Institute for Trauma Recovery to support a proposed investigator-sponsored Phase 2 trial evaluating osanetant in 180 trauma patients. The randomized, placebo-controlled Phase 2 trial is currently expected to begin in Q2 2023
    - In January 2023, Acer announced the initiation of two Phase 2, single-arm investigator-sponsored trials evaluating ACER-801 (osanetant) in men with adenocarcinoma of the prostate. The POSH-MAP (Pilot of Osanetant for Severity of Hot Flashes in Men with Adenocarcinoma of the Prostate) and PORT-MAP (Pilot of Osanetant to Reduce Testosterone in Men with Adenocarcinoma of the Prostate) trials are being sponsored and conducted by The University of Kansas Cancer Center in partnership with Acer

- EDSIVO™ (celiprolol)
    - Acer's ongoing Phase 3 DiSCOVER trial is a randomized, double-blind, placebo-controlled efficacy trial designed to evaluate EDSIVO™ (celiprolol) in patients with genetically confirmed COL3A1-positive vascular Ehlers-Danlos Syndrome (vEDS)

**Expected 2023 Development Milestones (Subject to Available Capital)**

- **Q1 2023:** Acer expects to announce topline results from its ongoing Phase 2a randomized, double-blind, placebo-controlled, dose-ranging trial of ACER-801 (osanetant) for the treatment of moderate to severe VMS in post-menopausal women
- **Q2 2023:** Acer expects initiation of the UNC investigator-sponsored trial to evaluate the potential for ACER-801 (osanetant) to reduce the frequency and severity of PTSD and other trauma related disorders
- **Q4 2023:** Acer anticipates completing enrollment in its ongoing, pivotal Phase 3 DiSCOVER trial of EDSIVO™ (celiprolol) in patients with COL3A1-positive vEDS. The double-blind portion of DiSCOVER trial is intended to end if statistical significance is reached at an interim analysis which occurs at accrual of 28 vEDS-related events, estimated to occur as early as approximately 18 months after completion of full enrollment, or after accrual of 46 vEDS-related clinical events
- Acer intends to explore additional lifecycle opportunities for OLPRUVA™ (sodium phenylbutyrate) in various disorders where proof of concept data exists, including in Maple Syrup Urine Disease (MSUD), Pyruvate Dehydrogenase Complex Deficiency (PCDC), rare pediatric epilepsies and various liver disorders

**About Acer Therapeutics**

Acer is a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs. In the U.S., OLPRUVA™ (sodium phenylbutyrate) is approved for the treatment of urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). Acer is also advancing a pipeline of investigational product candidates for rare and life-threatening diseases, including: OLPRUVA™ (sodium phenylbutyrate) for treatment of various disorders, including Maple Syrup Urine Disease (MSUD); ACER-801 (osanetant) for treatment of induced Vasomotor Symptoms (iVMS), Post-traumatic Stress Disorder (PTSD) and prostate cancer; EDSIVO™ (celiprolol) for treatment of vascular Ehlers-Danlos syndrome (vEDS) in patients with a confirmed type III collagen (COL3A1) mutation; and ACER-2820 (emetine), a host-directed therapy against a variety of viruses, including cytomegalovirus, Zika, dengue, Ebola and COVID-19. For more information, visit www.acertx.com.

**References**

1. National Center for PTSD. How Common is PTSD in Adults?

**Acer Forward-Looking Statements**

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release are forward-looking statements. Examples of such statements include, but are not limited to, statements about the role we believe ACER-

801 could play in reducing the frequency and severity of PTSD, the planned clinical evaluation of ACER-801 for such indication, the continued development of ACER-801 for treatment of iVMS and our expected 2023 milestones. Our pipeline products (including ACER-801) are under investigation and their safety and efficacy have not been established and there is no guarantee that any of our investigational products in development will receive health authority approval or become commercially available for the uses being investigated. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the availability of financing to fund our pipeline product development programs and general corporate operations as well as risks related to drug development and the regulatory approval process, including the timing and requirements of regulatory actions. We disclaim any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made. You should review additional disclosures we make in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. You may access these documents for no charge at http://www.sec.gov.

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