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

October 23, 2024
Date of Report (Date of earliest event reported)

Aprea Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39069**	**84-2246769**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3805 Old Easton Road **Doylestown, PA**	**18902**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 463-9385**

(Former name or former address, if changed since last report): Not applicable

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(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	APRE	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 7.01 Regulation FD Disclosure

On October 23, 2024, Aprea Therapeutics, Inc. (the "Company") issued a press release announcing that preliminary safety results on its WEE1 inhibitor APR-1051 were highlighted in a poster being presented at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, taking place in Barcelona, Spain. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information in this Item 7.01 is being 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 the liabilities of that Section, nor shall it be deemed incorporated by reference into any registration statement or other 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..

Item 8.01 Other Events.

The information set forth in the press release referred to in Item 7.01 above, other than the fourth and seventh paragraphs thereof, each beginning after the "Preliminary Results" section of the press release, is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Aprea Therapeutics, Inc. dated October 23, 2024
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.

Aprea Therapeutics, Inc.

Dated: October 23, 2024

By: /s/ Oren Gilad
Name: Oren Gilad, Ph.D.
Title: President and Chief Executive Officer

Exhibit 99.1

Aprea Therapeutics Presents Preliminary Findings on Oral WEE1 Inhibitor APR-1051 at EORTC-NCI-AACR International Conference on Molecular Targets and Therapeutics

Phase 1 ACESOT-1051 clinical trial is evaluating APR-1051 as monotherapy treatment in patients with significant unmet medical need; active enrollment is ongoing at three sites in the U.S.

Preliminary results to date demonstrate APR-1051 is safe and well-tolerated with no hematologic toxicity

DOYLESTOWN, PA, October 23, 2024 (GLOBE NEWSWIRE) – Aprea Therapeutics, Inc. (Nasdaq: APRE) ("Aprea", or the "Company"), a clinical-stage biopharmaceutical company focused on precision oncology through synthetic lethality, today announced that preliminary safety results on its WEE1 inhibitor APR-1051 are highlighted in a poster being presented today at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, taking place in Barcelona, Spain.

The results are from ACESOT-1051, a first-in-human Phase 1 study assessing the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of single-agent APR-1051 in advanced solid tumors harboring cancer-associated gene alterations.

The dose escalation part of the study (Part 1) is currently ongoing and is expected to include up to 39 patients with advanced solid tumors. Oral APR-1051 is being administered once daily for 28-day cycles. A total of 8 cohorts are planned, evaluating doses of 10 mg to 150 mg once daily. So far, patients have been enrolled in single patient Cohorts 1, 2 and 3, evaluating subtherapeutic doses of 10 mg, 20 mg and 30 mg, respectively.

Preliminary results

Data are available on two of three patients, with a cutoff date of October 7, 2024

- Preliminary results demonstrate that APR-1051 is safe and well-tolerated with no hematologic toxicity
- Hemoglobin, hematocrit, and platelet counts were stable or increased slightly during the first treatment cycle
- There were no signs of neutropenia, with white blood cells and neutrophils trending up for both patients during the first treatment cycle
- All adverse events (AEs) recorded were Grade 1 and 2, with one Grade 1 AE (abdominal distention) possibly related to APR-1051
- No QT prolongation has been observed
- Three patients have been dosed to date with data available on two of these. One had disease progression at 49 days, a second withdrew following 36 days of treatment and dosing is ongoing in the third patient.

"These preliminary data from our ongoing Phase 1 study are encouraging, showing that APR-1051 is safe and well-tolerated," said Philippe Pultar, MD, Senior Medical Advisor and Lead of WEE1 Clinical Development at Aprea. "APR-1051 has been designed to be selective for WEE1, without the off-target inhibition of PLK or QT prolongation reported for other molecules in this class. We expect to confirm this favorable safety profile as we move to higher doses in the ACESTOT-1051 trial. We are excited to explore the full therapeutic benefits of APR-1051, which has best in class potential, and hope to generate preliminary efficacy data from the study during 2025."

APR-1051 targets WEE1 kinase, an enzyme involved in the DNA damage response pathway. Based on preclinical studies, Aprea believes that APR-1051 may solve liabilities associated with other WEE1 inhibitors and is differentiated based on: 1) molecular structure; 2) selectivity for WEE1 versus off-target inhibition of the polo-like kinase, or PLK, family of kinases; 3) potentially improved pharmacokinetic (PK) properties; and 4) potential absence of QT prolongation at doses that significantly inhibit WEE1. No head-to-head studies with APR-1051 have been conducted.

Active enrollment in ACESOT-1051 is ongoing at three sites in the U.S. (NEXT Oncology locations in San Antonio and Dallas, and The University of Texas MD Anderson Cancer Center) with planned additional sites.

Anthony Tolcher M.D., Founder of Next Oncology commented, "The preliminary findings from ACESOT-1051 are promising and we are encouraged by the minimal toxicity in the patients treated so far. WEE1 kinase is a validated oncology target and represents an opportunity for therapeutic intervention in patients who otherwise have poor prognosis and no effective treatments today. We look forward to further exploring APR-1051's potential and are excited to recruit additional patients as the study progresses."

ACESOT-1051 Study Design

ACESOT-1051 (**A** Multi-**C**enter **E**valuation of WEE1 Inhibitor in Patients with Advanced **So**lid **T**umors, APR-1051) is a focused biomarker-driven study designed to assess the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of single-agent APR-1051 in advanced solid tumors harboring cancer-associated gene alterations. Oral APR-1051 will be administered once daily for 28-day cycles. The study consists of two parts: Part 1 is dose escalation and is expected to enroll up to 39 patients with advanced solid tumors. The first three dose levels are using accelerated titration followed by Bayesian Optimal Interval (BOIN) design for the remaining dose levels; Part 2 (up to 40 patients) is designed for dose optimization, with the goal of selecting the Recommended Phase 2 Dose (RP2D). For more information, refer to Clinicaltrials.gov: NCT06260514.

A copy the poster will be available on Aprea's corporate website today. Three additional posters will be available at the conclusion of the EORTC-NCI-AACR Symposium on Friday, October 25, 2024.

About Aprea

Aprea Therapeutics, Inc. is a clinical-stage biopharmaceutical company headquartered in Doylestown, Pennsylvania, focused on precision oncology through synthetic lethality. The Company's lead program is ATRN-119, a clinical-stage small molecule ATR inhibitor in development for solid tumor indications. APR-1051, an oral, small molecule WEE1 inhibitor, recently entered the clinic. For more information, please visit the company website at www.aprea.com.

The Company may use, and intends to use, its investor relations website at https://ir.aprea.com/ as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD.

Forward-Looking Statement

Certain information contained in this press release includes "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 related to our study analyses, clinical trials, regulatory submissions, and projected cash position. We may, in some cases use terms such as "future," "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "targeting," "confidence," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team and on information currently available to management that involve risks, potential changes in circumstances, assumptions, and uncertainties. All statements contained in this press release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize, and achieve market acceptance of our

current and planned products and services, our research and development efforts, including timing considerations and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward-looking statements are subject to risks and uncertainties including, without limitation, risks related to the success, timing, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses, presentations at conferences and data reported in an abstract, and receipt of interim or preliminary results (including, without limitation, any preclinical results or data), which are not necessarily indicative of the final results of our ongoing clinical trials, our understanding of product candidates mechanisms of action and interpretation of preclinical and early clinical results from its clinical development programs, and the other risks, uncertainties, and other factors described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the U.S. Securities and Exchange Commission. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to update such forward-looking statements for any reason, except as required by law.

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