

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 16, 2023  
Date of Report (Date of earliest event reported)

**Aprea Therapeutics, Inc.**  
(Exact name of registrant as specified in its charter)

<p><b>Delaware</b> (State or other jurisdiction of incorporation)</p>	<p><b>001-39069</b> (Commission File Number)</p>	<p><b>84-2246769</b> (IRS Employer Identification No.)</p>
<p><b>3805 Old Easton Road</b> <b>Doylestown, PA</b> (Address of principal executive offices)</p>		<p><b>18902</b> (Zip Code)</p>

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 8.01 Other Events.**

On October 16, 2023, Aprea Therapeutics, Inc. issued a press release announcing initial clinical data on ATRi, ATRN-119, and pre-clinical data on WEE1i, ATRN-1051, presented at AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, supporting highly differentiated synthetic lethality portfolio. A copy of the press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press release dated October 16, 2023.</a>
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

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**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 16, 2023

By: /s/ Oren Gilad

Name: Oren Gilad, Ph.D.

Title: President and Chief Executive Officer

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## **Aprea Unveils Initial Clinical Data on ATRi, ATRN-119, and Pre-Clinical Data on WEE1i, ATRN-1051, at AACR-NCI-EORTC International Conference Supporting Highly Differentiated Synthetic Lethality Portfolio**

**DOYLESTOWN, Pa., October 16, 2023 (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 highlights of two posters presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, October 14, 2023 in Boston, MA. The data in the posters include first-in-human clinical data from the ongoing Phase 1 dose escalation trial of ATR inhibitor, ATRN-119 [LINK to Poster](#), and pre-clinical data from the WEE1 inhibitor, ATRN-1051 [LINK](#) with planned IND submission Q4 2023.

ATRN-119 is in an ongoing Phase 1/2a dose escalation trial in solid tumors to determine the recommended Phase 2 dose, with a daily dosing administration over a 56-day cycle. To date, no hematologic or liver function toxicities in these heavily pretreated solid tumor patients have been observed across the first three cohorts at dose levels of 50mg, 100mg, and 200mg (3 + 3 trial design) [NCT04905914](#). The efficacy findings are still early in the dose escalation portion of the trial and there was one Stable Disease (SD) patient at the 50mg low dose cohort determined at end of cycle 1 (56-day cycle) (September 20, 2023 data cutoff). The company is actively enrolling cohort 4 at 350mg (subsequent 550mg cohort 5 and 800mg cohort 6 are planned) and anticipates dose expansion of the trial in Q2 2024.

The second poster presented focused on ATRN-1051, the WEE1 inhibitor, and highlights the selectivity of ATRN-1051 with low off-target activity against PLK1, PLK2 and PLK3, a family of kinases that promote M phase entry, a critical phase in the cell cycle. The selectivity of ATRN-1051 relative to the WEE1 class is also highlighted by its limited effects on red blood cell counts, hERG inhibition, and body weight loss in the pre-clinical data. PLK off-target activity has been a challenge for other WEE1 inhibitors in this class, as this off-target activity substantially counters the effects of WEE1 inhibition.

“We are excited to share the progress of our encouraging clinical and preclinical programs at this year’s AACR-NCI-EORTC medical meeting,” stated Dr. Oren Gilad, President and CEO of Aprea. “Based on the data to date, daily dosing of our ATR inhibitor, ATRN-119, appears to be well tolerated with a manageable toxicity profile, and no dose-limiting toxicities have been reported to date through data cutoff. We are currently enrolling patients in four US sites with the dose expansion cohort being on track to be initiated in 2Q 2024. The emerging tolerability profile presented in the poster may provide opportunities for potential combinations with multiple anti-cancer agents including our WEE1 inhibitor, ATRN-1051. This preclinical compound exhibits high potency for WEE1 inhibition in vitro and shows low off-target inhibition of the PLK family. The preclinical data findings and sensitivity to our WEE1 asset is guiding our clinical strategy and future patient selection. We look forward to advancing the drug to IND in the fourth quarter of this year.”

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**Poster #1**

**Title:** *First in Human phase 1/2a trial of a macrocyclic ATR inhibitor (ATRN-119) in patients with advanced solid tumors*

**Abstract #:** C034

**Session:** Session C; Level 2, Exhibit Hall D

**Date/Time:** Saturday, October 14 | 12:30pm – 4:00 pm ET

**Presenter:** Nadeem Q Mirza, M.D., M.P.H., Aprea Therapeutics, Inc.

**Poster #2**

**Title:** *The DNA replication checkpoint inhibitors, ATRN-1051 (WEE1i) and ATRN-119 (ATRi), are potentially well-tolerated and effective cancer treatments*

**Abstract #:** C147

**Session:** Session C; Level 2, Exhibit Hall D

**Date/Time:** Saturday, October 14 | 12:30pm – 4:00 pm ET

**Presenter:** Eric J. Brown, Ph.D., Perelman School of Medicine, University of Pennsylvania

\*head-to-head comparisons have not been conducted

**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 being developed for solid tumor indications. Our WEE1 inhibitor is being advanced to IND submission. For more information, please visit the company website at [www.aprea.com](http://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 submits 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, 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, 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 statement for any reason, except as required by law.*

**Investor Contact:**

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