

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 9, 2024

Date of Report (Date of earliest event reported)

Aprea Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39069
(Commission
File Number)

84-2246769
(IRS Employer
Identification No.)

3805 Old Easton Road
Doylestown, PA
(Address of principal executive offices)

18902
(Zip Code)

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

(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(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 2.02 Results of Operations and Financial Condition.

Aprea Therapeutics, Inc. (the “Company”) is currently finalizing its financial quarterly closing process for the three months ended September 30, 2024. While complete financial information and operating data are not yet available, the Company expects cash and cash equivalents to be approximately \$26.2 million as of September 30, 2024, down sequentially as compared to approximately \$28.7 million as of June 30, 2024.

This estimate of cash and cash equivalents is preliminary and subject to completion. As a result, this unaudited preliminary financial information reflects the Company's preliminary estimate with respect to such information, based on information currently available to management, and may vary from the Company's actual financial position as of September 30, 2024. The unaudited preliminary cash and cash equivalents figure included in this Current Report on Form 8-K has been prepared by, and is the responsibility of, the Company's management. The Company's independent registered public accounting firm, EisnerAmper LLP, has not audited, reviewed, compiled or completed its procedures with respect to such unaudited financial information and, accordingly, EisnerAmper LLP does not express an opinion or any other form of assurance with respect thereto. It is possible that the Company or its independent registered public accounting firm may identify items that require the Company to make adjustments to the financial information set forth above.

Item 8.01 Other Events.

On October 9, 2024, the Company issued a press release announcing that the Company engaged Phillippe Pultar, MD to serve as its Senior Medical Advisor and that Dr. Nadeem Mirza will be stepping down as Chief Medical Officer effective as of October 9, 2024, to pursue other professional endeavors but will remain with the Company through a date not later than December 13, 2024, to ensure a smooth leadership transition. The full text of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated October 9, 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.

Date: October 9, 2024

APREA THERAPEUTICS, INC.

By: /s/ Oren Gilad

Oren Gilad, Ph.D., Chief Executive Officer



APrea Therapeutics Engages Philippe Pultar, MD to Serve as Senior Medical Advisor and Lead WEE1 Clinical Development

DOYLESTOWN, PA, October 09, 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 it has engaged Philippe Pultar, MD as its senior medical advisor to support Aprea with developing and advancing APR-1051, Aprea’s potential best in class WEE1 inhibitor.

Dr. Pultar is a seasoned pharmaceutical executive with extensive experience in oncology, including the development of a WEE1 inhibitor (azenosertib) from early to late-stage clinical development. Dr. Pultar has vast experience in clinical development within both large and early-stage pharmaceutical companies. Engaging Dr. Pultar aligns with Aprea’s commitment to provide its WEE1 inhibitor program with all the necessary resources, including the best available professional talent and expertise, to succeed. Dr. Pultar was most recently employed at Zentalis Pharmaceuticals where he played a key role in the strategy and execution of the global clinical development of azenosertib, a WEE1 inhibitor.

Patient enrollment is currently ongoing in the Phase 1 ACESOT-1051 study, designed to assess the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of single-agent APR-1051 in advanced solid tumors harboring certain cancer-associated gene alterations. Aprea intends to provide an update on the progress of this clinical study by year end 2024. The WEE1 program is part of Aprea’s portfolio of DDR-targeted therapeutics aimed to deliver precision medicine solutions that ensure the right patients receive the most effective Aprea treatment, with the goals of improving outcomes and reducing treatment resistance.

“WEE1 inhibition is a promising therapeutic approach in oncology and my prior experience has given me a thorough understanding of biomarker driven clinical studies, the development and regulatory landscape as well as the likely attributes for a successful therapeutic,” said Dr. Pultar. “Aprea has a great opportunity to be a leader in this space. I am quite impressed by the progress the team has made advancing APR-1051, which has a differentiated profile, and is supported by compelling pre-clinical data. I am very excited to be associated with this program and I believe APR-1051 has the potential to be best in class. I look forward to working with the talented scientists at Aprea with the goals of advancing its WEE1 program and bringing new treatments to patients battling difficult-to-treat cancers.”

“Dr. Pultar is a highly capable scientific leader with a track record of successfully leading programs through late-stage development and regulatory approval,” said Oren Gilad, Ph.D., President and CEO of Aprea. “Given the recent initiation of our Phase 1 ACESOT-1051 clinical trial evaluating our promising WEE1 inhibitor, APR-1051, we are excited to bring on a high caliber advisor such as Dr. Pultar. Dr. Pultar’s prior experience in managing multiple clinical trials for a WEE1 inhibitor is particularly relevant and we hope to leverage his expertise as we advance our own program and maximize the therapeutic potential of APR-1051. His addition to the team is part of our broader strategy to bring in exceptional talent with the experience and skills to successfully advance our programs.”

Dr. Nadeem Mirza will be stepping down as Chief Medical Officer effective as of October 9, 2024, to pursue other professional endeavors but will remain with the Company through a date not later than December 13, 2024, to ensure a smooth leadership transition.



About Philippe Pultar, MD

Dr. Pultar brings over 17 years of extensive experience in early and late-stage clinical development. From 2020 to 2023 he was Vice President, Clinical Development at Zentalis Pharmaceuticals where he was responsible for the strategy and execution of the global clinical development of azenosertib, working closely with co-development partners GSK, Pfizer, and Zentara for China. He initiated seven Phase 1 and Phase 2 trials with azenosertib as single agent and in combination with chemotherapy and targeted agents across multiple indications. Prior to Zentalis, he spent seven years at Novartis Oncology (2013 to 2020), including as Senior Clinical Development Medical Director. He was appointed Medical Lead in rare diseases and was assigned to New Drug Application (NDA) activities for Isturisa® (osilodrostat). He led the writing and review of key EU and US NDA documents for Isturisa®, resulting in its approval with broad indication in Cushing's syndrome with limited post-approval commitments. He was also Medical Lead for Phase 2, 3 and 4 trials on Isturisa®, Signifor® (pasireotide) and Odomzo® (sonidegib). Prior to Novartis he was employed in senior clinical development roles at Agennix AG (2011 to 2013) and ImClone Systems (2007 to 2011). Earlier in his career, he held positions at GPC Biotech, ALTANA Pharma, REDEON and MEDICERCLE.

Dr. Pultar earned his medical thesis from Université de Médecine de Poitiers, France and practiced as a physician for several years. His foundational education includes Medical Studies and Residency at Université de Médecine de Poitiers, providing him with a solid academic background to complement his extensive practical experience in clinical development.

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.



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](https://aprea.com) [https://aprea.com/](https://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.

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