**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**August 5, 2021 (August 4, 2021)**
Date of Report (Date of earliest event reported)

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**Aprea Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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

| **535 Boylston Street**<br>**Boston, Massachusetts** | **02116** |
|---|---|
| (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

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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 | NASDAQ Global Select Market |

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 August 4, 2021, Aprea Therapeutics, Inc. (“Aprea”) was notified by the U.S. Food and Drug Administration (FDA) that it had placed a partial clinical hold on its clinical trials of eprenetapopt in combination with azacitidine in its myeloid malignancy programs. The partial clinical hold does not apply to Aprea’s ongoing clinical trials in lymphoid malignancies and solid tumors, or the APR-548 clinical trial. There are approximately 20 patients currently receiving eprenetapopt in combination with azacitidine in Aprea’s myeloid malignancy programs, which includes myelodysplastic syndromes (MDS), acute myeloid leukemia (AML), and post-transplant maintenance trials, all of which have completed enrollment. Patients who are benefiting from treatment can continue to receive study treatment. As part of the clinical hold, no additional patients can be enrolled to these trials until the partial clinical hold is resolved. Aprea intends to work closely with the FDA to analyze the data, address the specific questions raised, and seek to resolve the partial clinical hold as soon as possible.

On August 5, 2021, the Company issued a press release announcing the partial clinical hold. A copy of this press release is filed herewith as Exhibit 99.1 to this Current Report.

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

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release issued by Aprea Therapeutics, Inc. dated August 5, 2021. |

**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: August 5, 2021

By: /s/ Christian S. Schade
Name: Christian S. Schade
Title: Chairman and Chief Executive Officer

**Exhibit 99.1**

**Aprea Therapeutics Announces a Partial Clinical Hold on Myeloid Malignancy Programs**

BOSTON, MA, August 5, 2021 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE), a biopharmaceutical company focused on developing and commercializing novel cancer therapeutics that reactivate mutant tumor suppressor protein, p53, today announced that the U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on its clinical trials of eprenetapopt in combination with azacitidine in its myeloid malignancy programs. The partial clinical hold does not apply to the Company's ongoing clinical trials in lymphoid malignancies and solid tumors, or the APR-548 clinical trial.

There are approximately 20 patients currently receiving eprenetapopt in combination with azacitidine in the Company's myeloid malignancy programs, which includes the MDS, AML and post-transplant maintenance trials, all of which have completed enrollment. Patients who are benefiting from treatment can continue to receive study treatment. As part of the clinical hold, no additional patients can be enrolled to these trials until the partial clinical hold is resolved. Aprea intends to work closely with the FDA to analyze the data, address the specific questions raised, and seek to resolve the partial clinical hold as soon as possible.

"Patient safety is our highest priority," said Christian S. Schade, Chairman and Chief Executive Officer of Aprea. "Based on the totality of the data we have for eprenetapopt, we believe that it continues to be a promising therapeutic option for cancer patients. We are working closely with the FDA to review the data specific to eprenetapopt with azacitidine in our myeloid malignancy trials and will provide an update when we have additional information."

The Company will host a webcast conference call to discuss this announcement on August 6, 2021 at 8:30 AM (ET). Connection details are provided below and are also available on the Events page of Aprea's website.

**Webcast Link:** https://edge.media-server.com/mmc/p/8kjgeas4

**Participant Dial in Number:**

US/CANADA Participant Toll-Free Dial-In Number: (855) 547-3866

US/CANADA Participant International Dial-In Number: (409) 217-8798

**Conference ID:** 3119839

**About Aprea Therapeutics, Inc.**

Aprea Therapeutics, Inc. is a biopharmaceutical company headquartered in Boston, Massachusetts with research facilities in Stockholm, Sweden, focused on developing and commercializing novel cancer therapeutics that reactivate mutant tumor suppressor protein, p53. The Company's lead product candidate is eprenetapopt (APR-246), a small molecule in clinical development for hematologic malignancies and solid tumors. Eprenetapopt has received Breakthrough Therapy, Orphan Drug and Fast Track designations from the FDA for myelodysplastic syndromes (MDS), Orphan Drug and Fast Track designations from the FDA for acute myeloid leukemia (AML), and Orphan Drug designation from the European Commission for MDS and AML. APR-548, a next generation small molecule reactivator of mutant p53, is being developed for oral administration. 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.

**About p53, eprenetapopt and APR-548**

The p53 tumor suppressor gene is the most frequently mutated gene in human cancer, occurring in approximately 50% of all human tumors. These mutations are often associated with resistance to anti-cancer drugs and poor overall survival, representing a major unmet medical need in the treatment of cancer.

Eprenetapopt (APR-246) is a small molecule that has demonstrated reactivation of mutant and inactivated p53 protein – by restoring wild-type p53 conformation and function – thereby inducing programmed cell death in human cancer cells. Pre-clinical anti-tumor activity has been observed with eprenetapopt in a wide variety of solid and hematological cancers, including MDS, AML, and ovarian cancer, among others. Additionally, strong synergy has been seen with both traditional anti-cancer agents, such as chemotherapy, as well as newer mechanism-based anti-cancer drugs and immuno-oncology checkpoint inhibitors.

Aprea's myeloid malignancy program consists of clinical trials in frontline MDS, AML and post-transplant maintenance therapy in MDS/AML. A pivotal Phase 3 clinical trial of eprenetapopt and azacitidine for frontline treatment of *TP53* mutant MDS has been completed and failed to meet the primary statistical endpoint of complete remission. Additional clinical trials, including lymphoid malignancies and solid tumors, are ongoing.

APR-548 is a next-generation small molecule p53 reactivator. APR-548 has demonstrated high oral bioavailability, enhanced potency relative to eprenetapopt in TP53 mutant cancer cell lines and has demonstrated in vivo tumor growth inhibition following oral dosing of tumor-bearing mice.

**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," "seek" 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 that involve risks, potential changes in circumstances, assumptions, and uncertainties. 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 risks related to the success and timing of our clinical trials or other studies, risks associated with the coronavirus pandemic and the other risks set forth in our filings 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 publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Aprea Therapeutics, Inc.

Corporate Contacts:

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