

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

September 16, 2020

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.)

535 Boylston Street
Boston, Massachusetts 02116
(Address of principal executive offices)

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	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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On September 16, 2020, Aprea Therapeutics Inc. (the “Company”) notified Nasdaq that it is not in compliance with the audit committee composition requirement under Nasdaq Listing Rule 5605(c)(2)(A) due to one vacancy on the audit committee, effective September 16, 2020. As set forth in Item 5.02 below, on September 16, 2020, Jonathan Hepple, Ph.D., a member of the audit committee, resigned from the Board of Directors of the Company, effective September 16, 2020. The Company is evaluating the appropriate composition of its board committees and fully intends to regain compliance with Rule 5605(c)(2)(A) within the applicable cure period.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On September 16, 2020, Scott Rocklage, Ph.D. and Jonathan Hepple, Ph.D. resigned from the Board of Directors of the Company, effective September 16, 2020. Such resignations were not the result of any disagreement with the Company on any matter relating to the operations, policies, or practices of the Company.

Item 7.01 Regulation FD Disclosure.

In connection with the departure of Drs. Rocklage and Hepple from the Company’s Board of Directors, Christian S. Schade was appointed Chairman of the Board of Directors and John B. Henneman III was appointed as Lead Independent Director, Richard Peters, M.D., Ph.D, became Chairman of the Company’s Compensation Committee and Fouad Namouni, M.D. became a member of the Company’s Nominating and Corporate Governance Committee, each effective September 16, 2020.

The Company issued a press release discussing the above matters, among other information, which is being furnished and is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
<u>99.1</u>	<u>Press release issued by Aprea Therapeutics, Inc. dated September 18, 2020.</u>

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: September 18, 2020

By: /s/ Christian S. Schade

Name: Christian S. Schade

Title: Chairman and Chief Executive Officer

Aprea Therapeutics Promotes Gregory S. Wessels to Chief Commercial Officer and Announces Governance Changes

BOSTON, MA., September 18, 2020 (GLOBE NEWSWIRE) – Aprea Therapeutics Inc., (NASDAQ: APRE), a clinical-stage biotechnology company focused on developing and commercializing novel cancer therapeutics that reactivate mutant p53 tumor suppressor protein, today announced the promotion of Gregory S. Wessels to the newly created position of Chief Commercial Officer.

“We are excited to have Greg assume the role of Chief Commercial Officer as we approach key milestones in our frontline MDS program and continue to execute on our plans for the future development of eprenetapopt,” said Christian S. Schade, President and Chief Executive Officer of Aprea Therapeutics. “Greg’s leadership and oncology market experience will be essential as we build out our commercial capabilities.”

Mr. Wessels joined Aprea in February 2020 from Bristol-Myers Squibb where he most recently served as Executive Director – US Marketing for Lymphoma and Acute Myeloid Leukemia. Prior to joining Aprea from BMS, Mr. Wessels held global and regional oncology marketing positions of increasing responsibility over more than 11 years at Celgene Corporation.

The Company also announced today that two of its independent directors, Scott Rocklage, Ph.D. and Jonathan Hepple, Ph.D. have decided to step down after nearly a decade of collective service on the Board. In connection with the departure from the Board of Drs. Rocklage and Hepple, Christian S. Schade was appointed Chairman of the Board of Directors, John B. Henneman was named Lead Independent Director, Richard Peters, M.D., Ph.D. became Chairman of the Company’s Compensation Committee and Fouad Namouni, M.D. became a member of the Company’s Nominating and Corporate Governance Committee.

“On behalf of the Board of Directors and all Aprea employees, we are grateful to both Scott Rocklage and Jonathan Hepple for their contributions and years of invaluable service to the Company,” added Christian S. Schade.

“Aprea has made tremendous progress in advancing therapeutics to target *TP53* mutations in oncology,” said Scott Rocklage. “With the addition to the Board of Drs. Namouni and Peters in June, I believe that the Company has the right team in place to transition to the next phase of its development leading with its Phase 3 program in frontline MDS. It has been a pleasure to be a part of the Aprea team.”

About Aprea Therapeutics, Inc.

Aprea Therapeutics, Inc., (NASDAQ: APRE) is a biopharmaceutical company headquartered in Boston, Massachusetts with research facilities in Stockholm, Sweden, focused on developing and commercializing novel cancer therapeutics that reactivate the mutant tumor suppressor protein p53. The Company’s lead product candidate is APR-246 (*eprenetapopt*), a small molecule in clinical development for hematologic malignancies, including myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML). APR-246 has received Breakthrough Therapy, Orphan Drug and Fast Track designations from the FDA for MDS, and Orphan Drug designation from the European Commission for MDS, AML and ovarian cancer. 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 and APR-246 (*eprenetapopt*)

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 – and 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. In addition to pre-clinical testing, a Phase 1/2 clinical program with *eprenetapopt* has been completed, demonstrating a favorable safety profile and both biological and confirmed clinical responses in hematological malignancies and solid tumors with mutations in the *TP53* gene.

A pivotal Phase 3 clinical trial of *eprenetapopt* and azacitidine for frontline treatment of *TP53* mutant MDS is ongoing. *Eprenetapopt* has received Breakthrough Therapy, Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration for MDS, and Orphan Drug designation from the European Medicines Agency for MDS, AML and ovarian cancer.

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 clinical trials and regulatory submissions. We may, in some cases use terms such as “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 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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