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

November 8, 2021
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.)

535 Boylston Street **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 2.02 Results of Operations and Financial Condition

On November 8, 2021, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2021 and an update on the Company's operations for the same period. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed "filed" for the 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 filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Aprea Therapeutics, Inc. dated November 8, 2021.
104	The cover page of this Current Report on Form 8-K, formatted in Inline XBR

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: November 8, 2021

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

Exhibit 99.1

Aprea Therapeutics Reports Third Quarter 2021 Financial Results and Provides Update on Business Operations

BOSTON, MA, November 8, 2021 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE), a biopharmaceutical company focused on developing and commercializing novel cancer therapeutics that reactivate the mutant tumor suppressor protein, p53, today reported financial results for the three and nine months ended September 30, 2021 and provided a business update.

Third Quarter Financial Results

- **Cash and cash equivalents:** As of September 30, 2021, the Company had $61.4 million of cash and cash equivalents compared to $89.0 million of cash and cash equivalents as of December 31, 2020. The Company expects cash burn for the full year 2021 to be between $30.0 million and $35.0 million. The Company believes its cash and cash equivalents as of September 30, 2021, will be sufficient to meet its current projected operating requirements into 2023.

- **Research and Development (R&D) expenses:** R&D expenses were $6.0 million for the quarter ended September 30, 2021, compared to $8.8 million for the comparable period in 2020. The decrease in R&D expenses was primarily due to decreases in clinical trial costs for our pivotal Phase 3 clinical trial of eprenetapopt with azacitidine for the frontline treatment of *TP53* mutant MDS which completed enrollment in Q2 2020 and our Phase 2 post-transplant MDS/AML clinical trial. These decreases were partially offset by increases in clinical trial costs for our other ongoing clinical trials.

- **General and Administrative (G&A) expenses:** G&A expenses were $3.4 million for the quarter ended September 30, 2021, compared to $3.5 million for the comparable period in 2020. The decrease in G&A expenses was primarily due to a decrease in pre-commercialization development activities which was partially offset by increased non-cash stock-based compensation.

- **Net loss:** Net loss was $9.5 million, or $0.45 per share for the quarter ended September 30, 2021, compared to a net loss of $12.3 million, or $0.58 per share for the quarter ended September 30, 2020. The Company had 21,360,140 shares of common stock outstanding as of September 30, 2021.

Business Operations Update:

Myeloid Malignancy Program

On August 4, 2021, the U.S. Food and Drug Administration (FDA) placed a partial clinical hold on the clinical trials of eprenetapopt in combination with azacitidine in our Phase 3 frontline MDS clinical trial, our Phase 2 MDS/AML Post-Transplant clinical trial and our Phase 1/2 AML clinical trial. The FDA's concerns referred to the safety and efficacy data from the Phase 3 frontline MDS clinical trial. In particular, the FDA requested more information related to a potential risk-reward imbalance between the combination of eprenetapopt and azacitidine versus azacitidine alone as it relates to increased serious adverse events in the Company's Phase 3 frontline clinical trial in MDS. There are approximately 9 patients currently receiving eprenetapopt in combination with azacitidine in our 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 partial clinical hold, no additional patients should be enrolled to these clinical trials until the partial clinical hold is resolved, The Company intends to work with the FDA to analyze the data, address the specific questions raised, and seek to resolve the partial clinical hold as soon as possible.

APR-548 Phase 1 Trial -- The Company's second product candidate, APR-548, is a next-generation p53 reactivator that is being developed in an oral dosage form. The Company is currently enrolling a Phase 1 dose-escalation clinical trial evaluating the safety, tolerability, and preliminary efficacy of APR-548 with azacitidine in frontline and relapsed/refractory MDS patients. The trial is open and patients are enrolled in the first dosing cohort.

Lymphoid Malignancy Program

On August 11, 2021, the FDA placed a clinical on the Company's clinical trial evaluating eprenetapopt with acalabrutinib or with venetoclax and rituximab in lymphoid malignancies. The FDA's concerns referred to the safety and efficacy data from the Company's Phase 3 frontline clinical trial in MDS. There are no patients currently receiving study treatment in this trial and no additional patients can be enrolled until the clinical hold is resolved. The Company intends to work with the FDA to address the specific questions raised and seek to resolve the clinical hold as soon as possible.

Solid Tumor Disease Program

Data from the Company's Phase 1/2 clinical trial in relapsed/refractory gastric, bladder and non-small cell lung cancers assessing eprenetapopt with anti-PD-1 therapy was presented at the European Society of Medical Oncology (ESMO) Congress 2021. Results were presented from 31 patients who had initiated treatment, including three gastric/GEJ, three bladder/urothelial cancer and 19 non-small cell lung cancer (NSCLC) patients. In the bladder/urothelial cohort, one patient with localized *TP53* mutant high-grade transitional cell bladder cancer had achieved complete remission (CR) by RECIST criteria at the first response assessment at 9 weeks. In the NSCLC cohort, two patients with *TP53* mutant squamous NSCLC had reductions in target lesions of 26.7% and 8.2%, respectively, from baseline by RECIST criteria at the first response assessment at 9 weeks.

Upcoming Presentations

Investigators will present data from Aprea Therapeutics' clinical trials evaluating eprenetapopt at the upcoming 63rd American Society of Hematology Annual Meeting (ASH).

Title: Long-Term Follow-up and Combined Phase 2 Results of Eprenetapopt (APR-246) and Azacitidine (AZA) in Patients with *TP53* Mutant Myelodysplastic Syndromes (MDS) and Oligoblastic Acute Myeloid Leukemia (AML)

- **Date & Time**: Saturday, December 11, 2021 at 3:15 pm ET
- **Oral Abstract Session**: 637. Myelodysplastic Syndromes—Clinical and Epidemiological: Treatment of High Risk Myelodysplastic Syndrome

Title: Phase II Trial of Eprenetapopt (APR-246) in Combination with Azacitidine (AZA) As Maintenance Therapy for *TP53* Mutated AML or MDS Following Allogeneic Stem Cell Transplantation (SCT)

- **Date & Time**: Sunday, December 12, 2021 at 9:30 am ET
- **Oral Abstract Session**: 723. Allogeneic Transplantation: Long-term Follow-up and Disease Recurrence

Title: Phase I and Expansion Study of Eprenetapopt (APR-246) in Combination with Venetoclax (VEN) and Azacitidine (AZA) in *TP53*-Mutant Acute Myeloid Leukemia (AML)

- **Date & Time**: Monday, December 13, 2021, 6:00 – 8:00 pm ET
- **Poster Abstract Session**: 616. Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster III

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. 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. Eprenetapopt is currently on clinical hold in myeloid and lymphoid malignancies. Eprenetapopt has received 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.

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 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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Aprea Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 61,428,404	$ 89,017,686
Prepaid expenses and other current assets	750,929	3,399,019
Total current assets	62,179,333	92,416,705
Property and equipment, net	27,318	38,515
Right of use lease and other noncurrent assets	278,209	349,999
Total assets	$ 62,484,860	$ 92,805,219
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,548,388	$ 4,503,619
Accrued expenses	6,267,429	10,571,237
Lease liability—current	223,999	256,309
Total current liabilities	9,039,816	15,331,165
Lease liability—noncurrent	29,773	78,847
Total liabilities	9,069,589	15,410,012
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value $0.001; 21,360,140 and 21,186,827 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively.	21,360	21,187
Additional paid-in capital	237,227,804	231,418,356
Accumulated other comprehensive loss	(10,454,699)	(10,037,261)
Accumulated deficit	(173,379,194)	(144,007,075)
Total stockholders' equity	53,415,271	77,395,207
Total liabilities and stockholders' equity	$ 62,484,860	$ 92,805,219

Aprea Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 6,015,616	$ 8,761,095	$ 19,433,721	$ 28,551,246
General and administrative	3,414,795	3,473,210	10,183,953	10,036,564
Total operating expenses	9,430,411	12,234,305	29,617,674	38,587,810
Other income (expense):				
Interest (expense) income	(33)	(9,212)	(1,678)	217,908
Foreign currency (loss) gain	(21,907)	(74,565)	247,233	283,636
Total other (expense) income	(21,940)	(83,777)	245,555	501,544
Net loss	$ (9,452,351)	$ (12,318,082)	$ (29,372,119)	$ (38,086,266)
Other comprehensive income (loss):				
Foreign currency translation	(207,608)	(168,982)	(417,438)	(836,852)
Total comprehensive loss	(9,659,959)	(12,487,064)	(29,789,557)	(38,923,118)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.45)	$ (0.58)	$ (1.39)	$ (1.80)
Weighted-average common shares outstanding, basic and diluted	21,231,584	21,186,827	21,201,910	21,115,797