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

March 15, 2022
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 March 15, 2022, the Company issued a press release announcing its financial results for the fourth quarter and year ended December 31, 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 March 15, 2022.
104	The cover page from this Current Report on Form 8-K, formatted as Inline XBRL

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:March 15, 2022

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

Exhibit 99.1

Aprea Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Update on Business Operations

BOSTON, MA, March 15, 2022 (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 months and year ended December 31, 2021 and provided a business update.

Fourth Quarter Financial Results

- **Cash and cash equivalents:** As of December 31, 2021, the Company had $53.1 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 2022 to be between $25.0 million and $30.0 million. The Company believes its cash and cash equivalents as of December 31, 2021 will be sufficient to meet its current projected operating requirements into 2023.

- **Research and Development (R&D) expenses:** R&D expenses were $4.5 million for the quarter ended December 31, 2021, compared to $9.3 million for the comparable period in 2020. The decrease in R&D expenses was primarily due to decreases in clinical trial costs for the Company's pivotal Phase 3 clinical trial of eprenetapopt with azacitidine for the frontline treatment of *TP53* mutant MDS and the Company's Phase 2 post-transplant MDS/AML clinical trial. These decreases were partially offset by increases in clinical trial costs for other ongoing clinical trials.

- **General and Administrative (G&A) expenses:** G&A expenses were $3.4 million for the quarter ended December 31, 2021, compared to $4.9 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 $7.8 million, or $0.36 per share for the quarter ended December 31, 2021, compared to a net loss of $13.1 million, or $0.73 per share for the quarter ended December 31, 2020. The Company had 21,859,413 shares of common stock outstanding as of December 31, 2021.

Business Operations Update:

Myeloid Malignancy Program

The Company's myeloid malignancy program includes fully enrolled and completed clinical trials in MDS, AML and post-transplant maintenance therapy in MDS/AML. In August 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 the Company's Phase 3 frontline MDS clinical trial, the Company's Phase 2 MDS/AML Post-Transplant clinical trial and the Company's Phase 1/2 AML clinical trial. In December 2021 the Company discussed with FDA the requested data and analyses from the Phase 3 frontline MDS clinical trial and reached agreement on the Company's proposals for new clinical trials in myeloid malignancies. In the first quarter of 2022 the Company received clearance from FDA to proceed under its existing myeloid malignancy IND with a new clinical trial in relapsed/refractory MDS and AML.

Lymphoid Malignancy Program

The Company's lymphoid malignancy program includes a clinical trial evaluating eprenetapopt in patients with non-Hodgkin lymphomas (NHL). In August 2021, FDA placed a clinical hold on this trial. In October 2021, the Company discussed with FDA the requested data and analyses from the Phase 3 frontline MDS clinical trial and proposed amendments for clinical trials to proceed in its lymphoid malignancy program. Following interaction with the FDA, the clinical hold was lifted in December 2021.

The Company is in the planning phase for new clinical trials in both myeloid and lymphoid malignancies and is continuing to evaluate other development opportunities. The Company plans to provide updates on progress on all programs throughout 2022.

APR-548 Phase I 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 initiated a Phase 1 clinical trial testing APR-548 in relapsed/refractory MDS and AML. Enrollment in the first dosing cohort was completed and pharmacokinetic and adverse event data will be collected and analyzed. The Company does not plan to enroll additional patients into the trial.

Solid Tumor Program

The Company's solid tumor program includes its clinical trial evaluating eprenetapopt with anti-PD-1 therapy in advanced solid tumors. The Company completed enrollment in its Phase 1/2 clinical trial in relapsed/refractory gastric, bladder and non-small cell lung cancers assessing eprenetapopt with anti-PD-1 therapy. The Company is in the planning phase for a future clinical trial to further evaluate orally-administered eprenetapopt with immunotherapy checkpoint inhibitors.

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 endpoint of complete remission. Eprenetapopt has received Orphan Drug and Fast Track designations from the FDA for myelodysplastic syndromes (MDS), Orphan Drug and Fast Track designation 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.

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" 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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Sr. Vice President and Chief Business Officer
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Aprea Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 53,076,052	$ 89,017,686
Prepaid expenses and other current assets	3,508,358	3,399,019
Total current assets	56,584,410	92,416,705
Property and equipment, net	23,870	38,515
Right of use lease and other noncurrent assets	215,183	349,999
Total assets	$ 56,823,463	$ 92,805,219
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,773,032	$ 4,503,619
Accrued expenses	5,352,996	10,571,237
Lease liability—current	190,471	256,309
Total current liabilities	7,316,499	15,331,165
Lease liability—noncurrent	--	78,847
Total liabilities	7,316,499	15,410,012
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value $0.001; 21,859,413 and 21,186,827, shares issued and outstanding at December 31, 2021 and 2020, respectively.	21,859	21,187
Additional paid-in capital	240,978,439	231,418,356
Accumulated other comprehensive loss	(10,358,956)	(10,037,261)
Accumulated deficit	(181,134,378)	(144,007,075)
Total stockholders' equity	49,506,964	77,395,207
Total liabilities and stockholders' equity	$ 56,823,463	$ 92,805,219

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 4,462,154	$ 9,328,079	$ 23,895,875	$ 37,879,325
General and administrative	3,366,525	4,895,323	13,550,478	14,931,887
Total operating expenses	7,828,679	14,223,402	37,446,353	52,811,212
Other income (expense):				
Interest income	3,326	4,744	1,648	222,652
Foreign currency gain (loss)	70,169	(1,173,888)	317,402	(890,252)
Total other income (expense)	73,495	(1,169,144)	319,050	(667,600)
Net loss	$ (7,755,184)	$ (15,392,546)	$ (37,127,303)	$ (53,478,812)
Other comprehensive income (loss):				
Foreign currency translation	95,743	2,333,369	(321,695)	1,496,517
Total comprehensive loss	(7,659,441)	(13,059,177)	(37,448,998)	(51,982,295)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.36)	$ (0.73)	$ (1.74)	$ (2.53)
Weighted-average common shares outstanding, basic and diluted	21,538,800	21,186,827	21,286,547	21,133,651