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 26, 2020
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** (Address of principal executive offices)	**02116** (Zip Code)

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 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 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 26, 2020, the Company issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2019 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 26, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aprea Therapeutics, Inc.

Dated: March 26, 2020

By: /s/ Scott M. Coiante
Name: Scott M. Coiante
Title: Sr. Vice President and Chief Financial Officer

Exhibit 99.1

Aprea Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

BOSTON, MA, March 26, 2020 (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 reported financial results for the three months and year ended December 31, 2019 and provided a corporate update.

Corporate Update:

The Company is conducting, supporting and planning multiple clinical trials of APR-246:

- **Pivotal Phase 3 MDS Trial—**The Company is currently enrolling a pivotal Phase 3 randomized, controlled trial evaluating APR-246 with azacitidine as frontline therapy in HMA-naïve *TP53* mutant myelodysplastic syndromes (MDS) patients. The trial has a target enrollment of 154 patients randomized in a 1:1 ratio to either the azacitidine control arm or to the APR-246 + azacitidine experimental arm, with a primary endpoint of CR rate. The Company had anticipated full enrollment in its Phase 3 trial in the first quarter of 2020 and as of March 25, 2020, the Company had enrolled 133 patients. The Company has observed a recent decrease in both patient screening and patient enrollment as a result of the recent coronavirus *(COVID 19)* pandemic. Together with its investigators and clinical sites, the Company is assessing the potential impact of the coronavirus pandemic on enrollment and the ability to maintain patients enrolled in the trial and the corresponding impact on the timing of the completion of the trial and subsequent availability of top-line data. The Company remains confident that it can complete the trial and have top-line data available before year end 2020.

- **Phase 2 MDS/AML Post-Transplant Trial—**The Company is currently enrolling its single-arm, open-label Phase 2 trial evaluating APR-246 with azacitidine as post-transplant maintenance therapy in *TP53* mutant MDS and acute myeloid leukemia (AML) patients who have received an allogeneic stem cell transplant. The primary endpoint is relapse-free survival at 12 months. As of March 25, 2020, the Company had enrolled 11 patients in this trial. Target enrollment is 31 patients and the Company had anticipated full enrollment in the first half of 2020. Together with its investigators and clinical sites, the Company is assessing the potential impact of the coronavirus pandemic on the enrollment and the ability to maintain patients enrolled in this trial.

- **Phase 1 AML Trial—**Based on *in vitro* data evidencing synergistic activity between APR-246 and a Bcl-2 inhibitor, the Company is conducting a Phase 1 clinical trial in frontline and relapsed/refractory *TP53* mutant AML assessing APR-246 with venetoclax with or without azacitidine. The primary endpoint is the composite rate of CR and CR with incomplete hematologic recovery, or CRi. The first patient was enrolled in 1Q 2020 and the Company completed enrollment of the first two safety cohorts of three patients each. Together with its investigators and clinical sites, the Company is assessing the potential impact of the coronavirus pandemic on the enrollment and the ability to maintain patients enrolled in this trial.

- **Phase 1 NHL Trial—**As further assessment of APR-246 in hematological malignancies, the Company has designed and plans to conduct a Phase 1 clinical trial in relapsed/refractory *TP53* mutant chronic lymphoid leukemia (CLL) and mantle cell lymphoma (MCL) assessing APR-246 with venetoclax and rituximab, and APR-246 with ibrutinib. The Company is targeting the first patient to be enrolled in the second half of 2020.

- **Phase 1/2 Solid Tumor Trial—**Based on *in vitro* data evidencing synergistic activity between APR-246 and immuno-therapy agents including anti-PD-1 antibody, the Company has designed and plans to conduct Phase 1/2 clinical trials in relapsed/refractory gastric, bladder and non-small cell lung cancers assessing APR-246 with anti-PD-1 therapy. The Company is targeting the first patient to be enrolled in the second half of 2020.

- **APR-548 --** The Company's second product candidate, APR-548, is a next-generation p53 reactivator with the potential for oral administration. APR-548 is a unique analog of APR-246 and therefore a pro-drug of MQ. APR-548 exhibits high oral bioavailability in preclinical testing and is being developed in an oral dosage form. The Company has completed Investigational New Drug, or IND, enabling preclinical studies of APR-548. Final reports from these studies are pending and the Company is targeting the submission of an IND in the first half of 2020.

- **APR-246 INN** — The Company has secured *eprenetapopt* as the international nonproprietary name (INN) for APR-246.

Fourth Quarter Financial Results

- **Cash and cash equivalents:** As of December 31, 2019, Aprea had $130.1 million of cash and cash equivalents compared to $65.7 million of cash and cash equivalents as of December 31, 2018. In October 2019, the Company completed the sale of 6,516,667 shares of common stock in an initial public offering resulting in net proceeds of approximately $86.9 million. The Company expects cash burn for 2020 to be between $35.0 million $40.0 million. The Company believes its cash and cash equivalents as of December 31, 2019 will be sufficient to meet its current projected operating requirements into 2023.

- **Research and Development (R&D) expenses:** R&D expenses were $8.0 million for the quarter ended December 31, 2019, compared to $4.4 million for the comparable period in 2018. The increase in R&D expenses was primarily related to the advancement of the Company's lead product candidate, APR-246. In Q1 2019 the Company commenced a pivotal Phase 3 clinical trial of APR-246 with azacytidine for frontline treatment of *TP53* mutant MDS which is supported by two ongoing Phase 1b/2 investigator initiated trials, one in the U.S. and one in France, testing APR-246 with azacitidine as frontline treatment in *TP53* mutant MDS and AML patients.

- **General and Administrative (G&A) expenses:** G&A expenses were $3.9 million for the quarter ended December 31, 2019, compared to $0.5 million for the comparable period in 2018. The increase in G&A expenses was primarily due to increased professional fees associated with operating as a public company, as well as increased personnel costs.

- **Net loss:** Net loss was $13.1 million, or $0.64 per share for the quarter ended December 31, 2019, compared to a net loss of $4.7 million, or $4.05 per share for the quarter ended December 31, 2018. Net loss for the year ended December 31, 2019 was $28.1 million, or $4.67 per share, compared to a net loss of $15.5 million, or $13.45 per share for the year ended December 31, 2018.

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 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.

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.

APR-246 (*eprenetapopt)* is a small molecule that has demonstrated reactivation of mutant and inactivated p53 protein – by restoring wild-type p53 conformation and function – and thereby induce programmed cell death in human cancer cells. Pre-clinical anti-tumor activity has been observed with APR-246 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 APR-246 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. 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 clinical trials, regulatory submissions and projected cash position. We may, in some cases use terms such as “predicts,” “believes,” “potential,” “continue,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “targets,” “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, including our Annual Report on Form 10-K. 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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617-463-9385

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Vice President of Business Development
617-463-9385

Aprea Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 130,088,869	$ 65,675,931
Prepaid expenses and other current assets	2,955,878	322,146
Total current assets	133,044,747	65,998,077
Property and equipment, net	41,639	24,450
Right of use lease and other noncurrent assets	521,499	111
Total assets	$ 133,607,885	$ 66,022,638
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,176,852	$ 1,739,337
Accrued expenses	6,642,553	3,128,772
Lease liability—current	242,329	—
Total current liabilities	9,061,734	4,868,109
Lease liability—noncurrent	302,621	—
Total liabilities	9,364,355	4,868,109
Commitments and contingencies		
Convertible preferred stock:		
Series A convertible preferred stock, $0.001 par value; 612,446 shares issued and outstanding at December 31, 2018	—	6,483,044
Series B convertible preferred stock, $0.001 par value; 7,235,969 shares issued and outstanding at December 31, 2018	—	49,742,942
Series C convertible preferred stock, $0.001 par value; 4,712,698 shares issued and outstanding at December 31, 2018	—	56,364,645
Total convertible preferred stock	—	112,590,631
Stockholders' equity (deficit):		
Common stock, par value $0.001 at December 31, 2019 and $0.11 at December 31, 2018; 21,022,752 and 1,155,366, shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively.	21,023	127,091
Additional paid-in capital	226,284,548	19,666,588
Accumulated other comprehensive loss	(11,533,778)	(8,761,325)
Accumulated deficit	(90,528,263)	(62,468,456)
Total stockholders' equity (deficit)	124,243,530	(51,436,102)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 133,607,885	$ 66,022,638

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 8,041,993	$ 4,394,921	$ 20,950,672	$ 14,194,732
General and administrative	3,937,765	504,449	8,593,626	2,294,671
Total operating expenses	11,979,758	4,899,370	29,544,298	16,489,403
Other income (expense):				
Interest income (expense)	169,888	2	156,351	(182)
Foreign currency gain (loss)	(1,262,868)	219,700	1,328,140	961,316
Total other income (expense)	(1,092,980)	219,702	1,484,491	961,134
Net loss	$ (13,072,738)	$ (4,679,668)	$ (28,059,807)	$ (15,528,269)
Other comprehensive loss:				
Foreign currency translation	2,154,388	636,489	(2,772,453)	(473,919)
Total comprehensive loss	(10,918,350)	(4,043,179)	(30,832,260)	(16,002,188)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.64)	$ (4.05)	$ (4.67)	$ (13.45)
Weighted average basic and diluted shares of common stock outstanding	20,318,040	1,154,677	6,002,486	1,154,368