Aprea Therapeutics Reports First Quarter 2025 Financial Results and Provides a Clinical Update

May 14, 2025

ATRN-119, our ATR inhibitor, exhibits early evidence of single agent, anti-tumor activity and is progressing toward the recommended Phase 2 dose (RP2D) in the ongoing ABOYA-119 clinical trial

Three patients in the 550 mg twice daily cohort in the ongoing ABOYA-119 clinical trial demonstrated tumor shrinkage of 7%, 14% and 21%

ACESOT-1051, the Phase 1 trial of WEE1 inhibitor APR-1051, continues to advance, with patients now being dosed at 100 mg once daily

$19.3 million in cash and cash equivalents as of March 31, 2025, providing runway into early Q2 2026

DOYLESTOWN, Pa., May 14, 2025 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) ("Aprea", or the "Company"), a clinical-stage biopharmaceutical company developing innovative treatments that exploit specific cancer cell vulnerabilities while minimizing damage to healthy cells, today reported financial results for the first quarter ended March 31, 2025, and provided a business update.

"2025 is off to a strong start with significant clinical progress across both of our lead therapeutic candidates," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "In our ongoing ATRN-119 clinical program, three patients in the latest twice daily cohort demonstrated stable disease, with tumor shrinkage of 7%, 14% and 21%, marking early evidence of single agent, anti-tumor activity. Notably, these encouraging results were achieved at a dose level below the recommended Phase 2 dose, reinforcing our belief in ATRN-119's potential to address the urgent needs of patients with DDR-deficient cancers. As we progress to a dose level where clinical activity is emerging, our focus is shifting toward RP2D selection. Enrollment also continues in the ACESOT-1051 trial of our WEE1 inhibitor, APR-1051, and we expect to report preliminary efficacy data in the second half of 2025. At Aprea, we aim to redefine what is possible for patients with limited treatment options and we see ATRN-119 and APR-1051 as important clinical assets that may help us achieve this goal."

Key Business Updates and Potential Upcoming Key Milestones

ACESOT-1051: A Biomarker Focused, Phase 1 Trial of Oral WEE1 inhibitor, APR-1051

- APR-1051 is a potent and selective small molecule WEE1 inhibitor designed to potentially solve tolerability challenges of the WEE1 class and may achieve greater clinical activity than other programs currently in development. Aprea is advancing APR-1051 as monotherapy in cancers with well-defined biomarkers that may predict sensitivity to WEE1 inhibition. Among these, cancers over-expressing Cyclin E represent a high unmet medical need. Patients with Cyclin E over-expression have poor prognosis and, currently, lack effective therapies options.
- Patients are now being enrolled into the 100 mg QD dose level in the ACESOT-1051 (A Multi-Center Evaluation of WEE1 Inhibitor in Patients with Advanced Solid Tumors, APR-1051) Phase 1 clinical trial evaluating single-agent APR-1051 in advanced solid tumors harboring cancer-associated gene alterations. Given the encouraging tolerability profile to date, we are in a position to accelerate dose escalation and explore higher doses, potentially improving APR-1051 therapeutic impact. Informed by pharmacokinetic (PK) data, the dose escalation in ACESOT-1051 has been revised to get to potential therapeutic levels of drug earlier. After successfully clearing the 100 mg once-daily dose level, patients in the next cohort are expected to be dosed at 150 mg. The first patient at the 70 mg once-daily dose level had HPV+ head and neck squamous cell carcinoma (HNSCC), in line with a clinical strategy to include populations most likely to benefit from WEEI inhibition.
- The primary objectives of ACESOT-1051 are to assess safety, dose-limiting toxicities (DLTs), maximum tolerated dose or maximum administered dose (MTD/MAD), and determine recommended Phase 2 dose (RP2D); secondary objectives are to evaluate pharmacokinetics and preliminary efficacy according to RECIST or PCWG3 criteria; pharmacodynamic parameters are exploratory objectives.
- Preliminary safety and efficacy data from the ACESOT-1051 study are anticipated in the second half of 2025, with completion of the dose-escalation phase expected in the first half of 2026. Aprea intends to submit an abstract to a major oncology conference.
- For more information, refer to ClinicalTrials.gov NCT06260514.

ABOYA-119: Ongoing Clinical Trial Evaluating ATR inhibitor, ATRN-119

- ATRN-119 is a potent and highly selective first-in-class macrocyclic ATR inhibitor, designed and developed, to be used in patients with mutations in DDR-related genes. Cancers with mutations in DDR-related genes represent a high unmet medical need. These patients often have a poor prognosis and currently lack effective therapeutics options.
- ATRN-119 is being evaluated in the open-label Phase 1/2a clinical trial (ABOYA-119) as monotherapy in patients with advanced solid tumors having at least one mutation in a defined panel of DDR-related genes.
- Six patients have demonstrated stable disease to date, with three patients in the 550 mg twice daily cohort showing tumor shrinkage of 7%, 14% and 21%. The individual results include:
    - A female patient with leiomyosarcoma harboring RB1/ATM mutations achieved a 21% tumor reduction at her first follow-up scan after two months of therapy.
    - A male patient with acinar cell carcinoma of the pancreas harboring ATM mutation experienced a 14% tumor reduction at his first follow-up scan.
    - A female patient with ovarian cancer harboring BRIP1 mutation showed a 7% tumor reduction at her first follow-up scan.

Importantly, these results were observed at a dose level that is below the recommended Phase 2 dose, as dose escalation continues in the trial.

- Preliminary safety and efficacy data from ABOYA-119 are expected in the second half of 2025 and RP2D is expected to be identified in the first half of 2026. For more information on ABOYA-119, please refer to clinicaltrials.gov NCT04905914.

Material Transfer Agreement with MD Anderson Cancer Center

- In March 2025, Aprea entered into a Material Transfer Agreement (MTA) with MD Anderson Cancer Center. Aprea has agreed to supply APR-1051 to support preclinical research aimed at exploring its potential in treating HPV+ and HPV- head and neck squamous cell carcinoma (HNSCC) expressing genomic markers of replication stress.
- The agreement will enable the research group at MD Anderson to conduct a series of pre-clinical experiments designed to generate preliminary efficacy and mechanistic data to support future clinical trials and treatment regimens. The project is being overseen by Professors Jeffrey N. Myers, M.D., Ph.D., F.A.C.S., and Abdullah A. Osman, Ph.D., both from the Department of Head and Neck Surgery, MD Anderson Cancer Center. Prof. Myers is the leading expert on head and neck cancers.

Select Financial Results for the First Quarter Ended March 31, 2025

- As of March 31, 2025, the Company reported cash and cash equivalents of $19.3 million compared to $22.8 million as of December 31, 2024. The Company believes its cash and cash equivalents as of March 31, 2025 will be sufficient to meet its currently projected operating expenses and capital expenditure requirements into early second quarter of 2026.
- For the first quarter ended March 31, 2025, the Company reported an operating loss of $4.1 million, compared to an operating loss of $3.1 million in the first quarter of 2024.
- Research and Development (R&D) expenses were $2.5 million for the quarter ended March 31, 2025, compared to $1.6 million for the first quarter of 2024. The increase in R&D expense was primarily related to the initiation of our second clinical trial program for APR-1051, our small molecule WEE1 inhibitor, and the ABOYA-119 clinical trial to evaluate ATRN-119, our clinical-stage oral small molecule inhibitor of ATR.
- General and Administrative (G&A) expenses were $1.8 million for the quarter ended March 31, 2025, compared to $1.9 million for the first quarter of 2024.
- The Company reported a net loss of $3.9 million ($0.66 per basic share) on approximately 6.0 million weighted-average common shares outstanding for the quarter ended March 31, 2025, compared to a net loss of $2.8 million ($0.67 per basic share) on approximately 4.2 million weighted average common shares outstanding for the comparable period in 2024.

About Aprea
Aprea is pioneering a new approach to treat cancer by exploiting vulnerabilities associated with cancer cell mutations. This approach was developed to kill tumors but to minimize the effect on normal, healthy cells, decreasing the risk of toxicity that is frequently associated with chemotherapy and other treatments. Aprea's technology has potential applications across multiple cancer types, enabling it to target a range of tumors, including ovarian, colorectal, prostate, and breast cancers. The company's lead programs are APR-1051, an oral, small-molecule inhibitor of WEE1 kinase, and ATRN-119, a small molecule ATR inhibitor, both in clinical development for solid tumor indications. 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 and on information currently available to management that involve risks, potential changes in circumstances, assumptions, and uncertainties. All statements contained in this press release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize, and achieve market acceptance of our current and planned products and services, our research and development efforts, including timing considerations and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations. 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, without limitation, risks related to the success, timing, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses, presentations at conferences and data reported in an abstract, and receipt of interim or preliminary results (including, without limitation, any preclinical results or data), which are not necessarily indicative of the final results of our ongoing clinical trials, our understanding of product candidates mechanisms of action and interpretation of preclinical and early clinical results from its clinical development programs, our ability to continue as a going concern, and the other risks, uncertainties, and other factors described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file 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 update such forward-looking statements for any reason, except as required by law.

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Aprea Therapeutics, Inc.
Consolidated Balance Sheets

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 19,275,721	$ 22,849,885
Prepaid expenses and other current assets	558,689	726,254
Total current assets	19,834,410	23,576,139
Property and equipment, net	76,093	81,522
Restricted cash	40,418	40,170
Other noncurrent assets	271,162	281,662
Total assets	$ 20,222,083	$ 23,979,493
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,281,651	$ 1,352,240
Accrued expenses	2,079,447	2,008,735
Total current liabilities	3,361,098	3,360,975
Commitments and contingencies		
Series A convertible preferred stock, $0.001 par value, 40,000,000 shares authorized; 56,227 shares issued and outstanding at March 31, 2025 and December 31, 2024.	1,311,063	1,311,063
Stockholders' equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized, 5,512,656 and 5,481,055 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively.	5,513	5,481
Additional paid-in capital	351,145,676	350,971,225
Accumulated other comprehensive loss	(10,626,736)	(10,627,379)
Accumulated deficit	(324,974,531)	(321,041,872)

Total stockholders' equity	15,549,922	19,307,455
Total liabilities and stockholders' equity	$ 20,222,083	$ 23,979,493

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

	Three Months Ended March 31,	
	2025	**2024**
	(Unaudited)	
Grant revenue	$ 162,463	$ 380,569
Operating expenses:		
Research and development	2,483,066	1,600,373
General and administrative	1,764,979	1,929,866
Total operating expenses	4,248,045	3,530,239
Loss from operations	(4,085,582)	(3,149,670)
Other income (expense):		
Interest income, net	204,726	283,403
Foreign currency (loss) gain	(51,803)	56,176
Total other income	152,923	339,579
Net loss	$ (3,932,659)	$ (2,810,091)
Other comprehensive income (loss) :		
Foreign currency translation	643	(15,083)
Total comprehensive loss	(3,932,016)	(2,825,174)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.66)	$ (0.67)
Weighted-average common shares outstanding, basic and diluted	5,993,866	4,198,326