Aprea Therapeutics Reports Second Quarter 2024 Financial Results and Provides Business Update

August 12, 2024

Enrollment commenced in the ACESOT-1051 Phase 1 trial evaluating APR-1051 – no myelosuppression observed in the first of eight planned cohorts at sub-therapeutic dose

$28.7 million in cash and cash equivalents as of June 30, 2024 with cash runway extended into Q4 2025

DOYLESTOWN, Pa., Aug. 12, 2024 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) ("Aprea", or the "Company"), a clinical-stage biopharmaceutical company focused on precision oncology through synthetic lethality, today reported financial results for the second quarter ended June 30, 2024, and provided a business update.

"Aprea continues to make excellent progress advancing its clinical pipeline of therapeutic candidates," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "We initiated enrollment in the ACESOT-1051 trial, advancing a second clinical asset in our pipeline, APR-1051. APR-1051 is a next-generation inhibitor of WEE1 kinase which has been designed to limit toxicity. Based on its unique characteristics, we believe it could be best in class. We continue to enroll patients in the ABOYA-119 trial evaluating ATRN-119, our ATR inhibitor. We believe that our ongoing progress positions Aprea at the forefront of synthetic lethality drug development. We remain committed to developing new treatments that have a positive impact on the lives of cancer patients while creating value for our shareholders."

Key Business Updates and Potential Upcoming Key Milestones

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

- APR-1051 is a potent and selective small molecule that has been designed to potentially solve liabilities and may achieve greater clinical activity than other WEE1 programs currently in development. Aprea is advancing APR-1051 as monotherapy in cancers with Cyclin E over expression, as well as other biomarkers that are predicted to be sensitive to WEE1 inhibition. Cancers overexpressing Cyclin E represent a high unmet medical need. Patients with Cyclin E overexpression have poor prognosis and, currently, have no effective therapies.
- In June 2024, enrollment commenced 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. The first patient was dosed at NEXT Oncology, San Antonio, Texas, without any dose-limiting toxicities (including myelosuppression) observed to date in the first cohort. A second patient has been enrolled at The University of Texas MD Anderson Cancer Center and has commenced treatment in the second dose cohort.
- The primary objectives of the Phase 1 study are to measure safety, dose-limiting toxicities (DLTs), maximum tolerated dose or maximum administered dose (MTD/MAD), and recommended Phase 2 dose (RP2D); secondary objectives are to evaluate pharmacokinetics, preliminary efficacy according to RECIST or PCWG3 criteria; pharmacodynamics is an exploratory objective.
- The Company will provide an update on the progress of this clinical study by year end. Open-label safety/efficacy data are expected in the first half of 2025.
- In June 2024, Aprea hosted a virtual KOL event to discuss APR-1051. Joseph Vacca, Ph.D., Medicinal Chemistry Expert and Consultant to Aprea, discussed the medicinal chemistry history, strategy-guided selective drug design, and preclinical findings of APR-1051. Eric J. Brown, Ph.D., University of Pennsylvania and Consultant to Aprea, discussed preclinical findings across the WEE1 inhibitor class. A replay of the event (with slides) can be accessed on Aprea's corporate website here.
- APR-1051 was featured in two posters at the American Association of Cancer Research (AACR) annual meeting which took place in April 2024 in San Diego, which summarized the pre-clinical data supporting APR-1051 and the trial design for ACESOT-1051.

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 to be used in patients with mutations in DDR-related genes. Cancers with mutations in DDR-related genes represent a high unmet medical need. Patients with DDR-related gene mutations have a poor prognosis and, currently, have no effective therapies.
- ATRN-119 is currently being evaluated in the open-label Phase 1/2a clinical trial of ABOYA-119 (study AR-276-01) as monotherapy in patients with advanced solid tumors having at least one mutation in a defined panel of DDR-related genes. The first five dose cohorts (50mg to 550mg once daily) have been completed, and patients continue to enroll in additional cohorts in the dose escalation part of the trial.

- The primary endpoint of this Phase 1 trial is the tolerability and pharmacokinetics of ATRN-119 when administered orally on a continuous, once-daily schedule. Aprea is planning to amend the study protocol to add a group of patients who will receive ATRN-119 twice a day and to investigate the effect of food on ATRN-119 absorption and drug exposure in blood. Under the current protocol, the Company anticipates the ABOYA-119 Phase 1 readout to be available in the first half of 2025.
- An update on the ongoing trial was featured in a poster at the AACR Annual Meeting this past April. A copy of the AACR poster can be found here.
- For more information, please refer to clinicaltrials.gov NCT04905914.

Corporate

- Appointed Nadeem Q. Mirza, M.D., M.P.H. as Chief Medical Officer (CMO), effective May 1, 2024. Dr. Mirza had been a consultant to Aprea since February 2023 and has now assumed a more central role in leading the Company's development of its expanding clinical pipeline.

Select Financial Results for the Second Quarter ended June 30, 2024

- As of June 30, 2024, the Company reported cash and cash equivalents of $28.7 million, compared to $21.6 million at December 31, 2023. The Company believes its cash and cash equivalents as of June 30, 2024, will be sufficient to meet its currently projected operating expenses and capital expenditure requirements into the fourth quarter of 2025.
- For the quarter ended June 30, 2024, the Company reported an operating loss of $3.8 million, compared to an operating loss of $3.7 million in the comparable period in 2023.
- Grant revenue, primarily from the National Cancer Institute of the National Institutes of Health (“NIH”) for the three months ended June 30, 2024, and 2023 was approximately $0.6 million and $0.2 million, respectively.
- Research and development expenses were approximately $2.6 million for the quarter ended June 30, 2024, compared to approximately $2.2 million for the comparable period in 2023. The increase was primarily due to an increase in expenses related to the initiation of ACESOT-1051, our Phase 1 dose-escalation study evaluating APR-1051, our small molecule WEE1 inhibitor, in the second quarter of 2024.
- General and administrative expenses were approximately $1.9 million for the quarter ended June 30, 2024, compared to approximately $1.7 million for the comparable period in 2023. The increase was primarily related to an increase in personnel costs primarily related to severance expense.
- The Company reported a net loss of $3.5 million ($0.58 per basic share) on approximately 5.9 million weighted-average common shares outstanding for the quarter ended June 30, 2024, compared to a net loss of $3.3 million ($0.87 per basic share) on approximately 3.7 million weighted average common shares outstanding for the comparable period in 2023.

About Aprea

Aprea Therapeutics, Inc. is a clinical-stage biopharmaceutical company headquartered in Doylestown, Pennsylvania, focused on precision oncology through synthetic lethality. The Company’s lead program is ATRN-119, a clinical-stage small molecule ATR inhibitor in development for solid tumor indications. APR-1051, an oral, small-molecule WEE1 inhibitor, recently entered the clinic. 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, 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.

Investor Contact:

Mike Moyer
LifeSci Advisors
mmoyer@lifesciadvisors.com

Media Contact:

Ignacio Guerrero-Ros, Ph.D., or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310

Aprea Therapeutics, Inc.
Consolidated Balance Sheets

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 28,694,694	$ 21,606,820
Prepaid expenses and other current assets	865,092	914,275
Total current assets	29,559,786	22,521,095
Property and equipment, net	92,379	88,362
Restricted cash	41,260	40,717
Other noncurrent assets	271,162	—
Total assets	$ 29,964,587	$ 22,650,174
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 964,327	$ 1,670,369
Accrued expenses	2,079,163	2,186,262
Deferred revenue	50,739	528,974
Total current liabilities	3,094,229	4,385,605
Total liabilities	3,094,229	4,385,605
Commitments and contingencies		
Series A convertible preferred stock, $0.001 par value, 40,000,000 shares authorized; 56,227 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively.	1,311,063	1,311,063
Stockholders' equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized, 5,430,215 and 3,736,673 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively.	5,430	3,736
Additional paid-in capital	350,566,533	335,644,204
Accumulated other comprehensive loss	(10,649,364)	(10,611,273)
Accumulated deficit	(314,363,304)	(308,083,161)
Total stockholders' equity	25,559,295	16,953,506
Total liabilities and stockholders' equity	$ 29,964,587	$ 22,650,174

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)			
Grant revenue	$ 561,574	$ 249,688	$ 942,143	$ 249,688
Operating expenses:				
Research and development	2,557,679	2,202,657	4,158,052	3,459,199
General and administrative	1,850,819	1,698,712	3,780,685	5,064,673
Total operating expenses	4,408,498	3,901,369	7,938,737	8,523,872
Loss from operations	(3,846,924)	(3,651,681)	(6,996,594)	(8,274,184)
Other income (expense):				
Interest income, net	382,374	336,221	665,777	592,631
Foreign currency gain (loss)	(5,502)	56,363	50,674	42,566
Total other income	376,872	392,584	716,451	635,197
Net loss	$ (3,470,052)	$ (3,259,097)	$ (6,280,143)	$ (7,638,987)

Other comprehensive (loss) gain:				
Foreign currency translation	(23,008)	(73,420)	(38,091)	(11,464)
Total comprehensive loss	(3,493,060)	(3,332,517)	(6,318,234)	(7,650,451)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.58)	$ (0.87)	$ (1.24)	$ (2.18)
Weighted-average common shares outstanding, basic and diluted	5,937,291	3,731,571	5,067,809	3,497,329