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

November 7, 2024

Preliminary results from Phase 1 ACESOT-1051 trial of WEE1 inhibitor, APR-1051, demonstrate the product to be well-tolerated with no unexpected toxicities

Philippe Pultar, MD engaged as senior medical advisor to support the development and advancement of APR-1051

$26.2 million in cash and cash equivalents as of September 30, 2024 with cash runway for at least twelve months

DOYLESTOWN, Pa., Nov. 07, 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 third quarter ended September 30, 2024, and provided a business update.

"We continue to make meaningful progress advancing our pipeline of two clinical stage therapeutic candidates as well as strengthening our clinical team," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "We are ahead of schedule with the enrollment of the Phase 1 ACESOT-1051 trial evaluating our next generation WEE1 inhibitor, APR-1051. Preliminary results at subtherapeutic doses demonstrate the product to be well-tolerated with no unexpected toxicities. APR-1051 has been designed to limit off target toxicity and, based on its unique characteristics, we believe it will be best-in-class. Active enrollment is also ongoing in the Phase 1/2a ABOYA-119 study evaluating ATRN-119, our first-in-class macrocyclic ATR inhibitor. To optimize dosing and scheduling we added a twice-daily dosing regimen."

Key Business Updates and Potential Upcoming Key Milestones

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

- APR-1051 is a potent and selective small molecule that has been designed to potentially solve tolerability challenges of the class 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 may predict sensitivity to WEE1 inhibition. Cancers over-expressing Cyclin E represent a high unmet medical need. Patients with Cyclin E over-expression have poor prognosis and, currently, have no effective therapies available.
- Enrollment is ongoing 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 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; pharmacodynamic parameters are exploratory objectives.
- In October 2024, preliminary findings from the ACESOT-1051 trial were reported in a poster at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, in Barcelona, Spain. As of October 7, 2024, three patients were enrolled (sub-therapeutic doses of 10 mg, 20 mg and 30 mg) in the first three Cohorts with data available on two of these patients. Preliminary results to date have demonstrated that APR-1051 is well-tolerated with no unexpected toxicities. The poster can be viewed on Aprea's corporate website here.
- Cohort 3 has been cleared ahead of schedule, with no safety concerns noted. Accelerated titration is complete and, in November 2024, the trial begun enrolling at Cohort 4 (50 mg) within the BOIN (Bayesian Optimal Interval) design.
- Preliminary efficacy data from ACESOT-1051 are expected in the first half of 2025. 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 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, there are no effective therapies available for them.
- ATRN-119 is currently being evaluated in the open-label Phase 1/2a clinical trial of ABOYA-119 as monotherapy in patients with advanced solid tumors having at least one mutation in a defined panel of DDR-related genes. The primary endpoint of this Phase 1 trial is the tolerability and pharmacokinetics of ATRN-119 when administered orally on a continuous schedule.
- An update from ABOYA-119 was provided in a poster at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics on October 25, 2024. Patients are currently being enrolled at dose level 6 (800mg once daily) in the dose escalation part of the trial. As of October 2, 2024, 14 of 20 patients experienced adverse events (AEs) considered to

be possibly/probably related to ATRN-119. No related SAE or grade 4-5 AEs have been observed. No signs of hematological toxicity have been registered and no DLTs have been observed to date. Preliminary signs of clinical benefit were observed in two patients treated at the 50 mg and 200 mg dose level. A copy of the poster can be viewed here.

- In order to optimize dosing and scheduling early in the development process, a protocol amendment has been submitted to add dose level 9 (1500 mg once daily) and twice-daily (400mg to 750mg) dosing. The addition of twice-daily dosing is supported by the pharmacodynamic properties of the drug and the favorite safety profile observed to date. The dose escalation for the once-daily and the twice-daily schedules will be studied independently. Under the current updated protocol, the Company anticipates the ABOYA-119 Phase 1 readout to be available in the second half of 2025.
- For more information, please refer to clinicaltrials.gov NCT04905914.

Corporate

- In October 2024, the Company engaged Philippe Pultar, MD as senior medical advisor to support the development and advancement of APR-1051. Dr. Pultar is a seasoned pharmaceutical executive with extensive experience in oncology. He was most recently employed at Zentalis Pharmaceuticals where he played a key role in the strategy and execution of the global clinical development of azenosertib, a WEE1 inhibitor.

Select Financial Results for the third quarter ended September 30, 2024

- As of September 30, 2024, the Company reported cash and cash equivalents of $26.2 million, compared to $21.6 million at December 31, 2023. The Company believes its cash and cash equivalents as of September 30, 2024, will be sufficient to fund the Company's operating expenses and capital expenditure requirements through at least twelve months from the date of issuance of the condensed consolidated financial statements on Form 10-Q for the quarter ended September 30, 2024.
- For the quarter ended September 30, 2024, the Company reported an operating loss of $4.1 million, compared to an operating loss of $3.5 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 September 30, 2024 and 2023 was approximately $0.4 million and $0.3 million, respectively.
- Research and development expenses for the three months ended September 30, 2024 were approximately $2.8 million, compared to approximately $2.1 million for the three months ended September 30, 2023. The overall increase was primarily due to an increase in costs related to the ABOYA-119 clinical trial to evaluate ATRN-119 and personnel costs. These were offset in part by a decrease in costs related to IND enabling studies for ATRN-1051.
- General and administrative expenses for the three months ended September 30, 2024 were approximately $1.6 million, compared to approximately $1.7 million for the three months ended September 30, 2023. The decrease was primarily related to a decrease in insurance costs.
- The Company reported a net loss of $3.8 million ($0.64 per basic share) on approximately 5.9 million weighted-average common shares outstanding for the quarter ended September 30, 2024, compared to a net loss of $3.2 million ($0.86 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, is our second clinical program. 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.

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Aprea Therapeutics, Inc.
Consolidated Balance Sheets

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 26,249,625	$ 21,606,820
Prepaid expenses and other current assets	234,195	914,275
Total current assets	26,483,820	22,521,095
Property and equipment, net	86,950	88,362
Restricted cash	41,537	40,717
Other noncurrent assets	281,662	—
Total assets	$ 26,893,969	$ 22,650,174
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,153,880	$ 1,670,369
Accrued expenses	2,482,008	2,186,262
Deferred revenue	—	528,974
Total current liabilities	3,635,888	4,385,605
Total liabilities	3,635,888	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 September 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, 5,434,903 and 3,736,673 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.	5,435	3,736
Additional paid-in capital	350,693,403	335,644,204
Accumulated other comprehensive loss	(10,604,747)	(10,611,273)
Accumulated deficit	(318,147,073)	(308,083,161)
Total stockholders' equity	21,947,018	16,953,506
Total liabilities and stockholders' equity	$ 26,893,969	$ 22,650,174

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
			(Unaudited)	
Grant revenue	$ 354,621	$ 319,468	$ 1,296,764	$ 569,156
Operating expenses:				
Research and development	2,846,399	2,122,603	7,004,451	5,581,802
General and administrative	1,605,238	1,719,715	5,385,923	6,784,388
Total operating expenses	4,451,637	3,842,318	12,390,374	12,366,190
Loss from operations	(4,097,016)	(3,522,850)	(11,093,610)	(11,797,034)

Other income (expense):				
Interest income, net	348,741	321,215	1,014,518	913,846
Foreign currency (loss) gain	(35,494)	(2,880)	15,180	39,686
Total other income	313,247	318,335	1,029,698	953,532
Net loss	$ (3,783,769)	$ (3,204,515)	$ (10,063,912)	$ (10,843,502)
Other comprehensive loss:				
Foreign currency translation	23,557	(1,002)	6,526	(12,466)
Total comprehensive loss	(3,760,212)	(3,205,517)	(10,057,386)	(10,855,968)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.64)	$ (0.86)	$ (1.88)	$ (3.03)
Weighted-average common shares outstanding, basic and diluted	5,939,755	3,735,176	5,360,579	3,577,482