

Aprea Therapeutics Reports First Quarter 2023 Financial Results and Provides Update on Business Operations

May 15, 2023

DOYLESTOWN, Pa., May 15, 2023 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) ("Aprea", or the "Company"), a clinical stage biopharmaceutical company focused on developing novel synthetic lethality-based cancer therapeutics targeting DNA damage response (DDR) pathways, today reported financial results for the three months ended March 31, 2023 and provided a business update.

"We are excited about the strong start for 2023 as we focus on the execution of the pipeline development plan and continue enrollment in our Phase 1/2a dose escalation study of our ATR inhibitor, ATRN-119, in patients with biomarkers related to DDR mutations," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "Our cash position remains strong with a runway to carry us into the third quarter of 2024 and cross meaningful clinical milestones in our two lead inhibitor programs, ATR and WEE1. In February, we closed an underwritten public offering pursuant to which the Company received approximately \$4.9 million in net proceeds. In April, we participated in the American Association of Cancer Research Conference where we had the opportunity to share preclinical results pointing to the potential, groundbreaking benefits of combination therapy with ATRN-119 and ATRN-1051. Our IND-enabling studies continue to progress for our ATRN-1051 inhibitor program and anticipate filing an IND by the end of 2023."

Key Business and Financial Updates

- ATR inhibitor program: ATRN-119 Enrollment continues in the Phase 1/2a trial of Aprea's lead clinical candidate, ATRN-119, a potential best-in-class ATR inhibitor for treatment of advanced solid tumors harboring defined mutations in DDR pathways. ATRN-119 is an orally bioavailable, potent and selective macrocyclic small molecule inhibitor of ATR. ATR is one of several key regulators impacting response to defective DNA replication and DNA damage, which occurs more commonly in cancer cells than in normal cells. Primary endpoints of the Phase 1 dose escalation part of the study include safety, tolerability, pharmacokinetics and a recommended Phase 2 dose. The Company expects to report initial safety, tolerability, and pharmacokinetic data from the ongoing Phase 1 trial of ATRN-119 in the first quarter of 2024.
- WEE1 inhibitor program: ATRN-1051 ATRN-1051 is an orally-bioavailable, highly potent and selective small molecule inhibitor of WEE1, a key regulator of multiple phases of the cell cycle. The Company believes preclinical findings support potentially favorable drug selectivity and exposure. Investigational New Drug (IND) enabling studies with ATRN-1051 are under way, and the Company anticipates filing an IND by the end of 2023.
- Presented Preclinical data on pipeline programs at the American Association for Cancer Research (AACR) 2023 Annual Meeting, held April 14-19, 2023, in Orlando, Florida. In April 2023, the Company presented a poster, titled "ATRN-119 and ATRN-W1051: Novel and potentially well tolerated ATR and WEE1 inhibitors for targeted cancer treatment," highlighting its lead program, ATRN-119, and preclinical WEE1 inhibitor, ATRN-1051. In in vivo models, ATRN-119 demonstrated anti-tumor efficacy, both as a monotherapy and in combination with PARP inhibitors. In xenograft models, ATRN-1051 demonstrated high potency, potentially favorable pharmacokinetic properties, and anti-tumor efficacy.
- Secured non-dilutive funding via a research grant from the National Cancer Institute (NCI) supporting development of DDR inhibitors. In February 2023, the Company announced that it received an award notification from the NCI for the development of a first-in-class combination of DNA damage response inhibitors for the treatment of high-grade serous ovarian cancer (HGSOC). HGSOC is a devastating disease responsible for the deaths of about 125,000 women worldwide each year and has low survival rates.
- Closed an underwritten public offering in February 2023 pursuant to which the Company received approximately \$4.9
 million in net proceeds, after deducting underwriting discounts and offering expenses. Net proceeds from the public offering
 support the continuing development of ATRN-119 and ATRN-1051 as well as general corporate overhead.

 Appointed Gabriela Gruia, M.D., to the Board of Directors, strengthening the Company's leadership. Dr. Gruia brings over 25 years of clinical, regulatory and life science leadership experience to Aprea, having worked for Novartis, Pfizer, Pharmacia, Aventis and Rhone Poulenc. Dr. Gruia received her M.D. from Bucharest Medical School in Romania and a Masters in Breast Pathology and Mammography from Rene Huguenin/Curie Institute Cancer Center in Paris, France.

Select Financial Results for the First Quarter ended March 31, 2023

- As of March 31, 2023, the Company reported cash and cash equivalents of \$31.0 million.
- For the quarter ended March 31, 2023, the Company reported an operating loss of \$4.6 million, compared to an operating loss of \$8.1 million for the same period in 2022.
- Research and Development (R&D) expenses were \$1.3 million for the quarter ended March 31, 2023, compared to \$4.1 million for the same period in 2022. The decrease in R&D expense was related to lower clinical trial expense primarily due to the close out of legacy Aprea clinical trials, lower personnel costs for the former facility in Sweden, and lower non-cash stock-based compensation expense.
- General and Administrative (G&A) expenses were \$3.4 million for the quarter ended March 31, 2023, compared to \$4.0 million for the same period in 2022. The decrease in G&A expenses was due to a lower non-cash stock-based compensation and insurance premium expenses, partially offset by higher personnel costs in the quarter ended March 31, 2023 related to severance expenses for former executives.
- The Company reported a net loss of \$4.4 million (\$1.34 per basic share) on approximately 3.3 million weighted-average common shares outstanding for the quarter ended March 31, 2023, compared to a net loss of \$7.9 million (\$7.25 per basic share) on approximately 1.1 million weighted average common shares outstanding for the same period in 2022.

About Aprea Therapeutics, Inc.

Aprea Therapeutics, Inc. is a clinical stage biopharmaceutical company headquartered in Doylestown, Pennsylvania, focused on developing novel synthetic lethality-based cancer therapeutics that target DNA damage response pathways. The Company's lead program is ATRN-119, a clinical-stage small molecule ATR inhibitor being developed for solid tumor indications. Our WEE1 inhibitor is being advanced to IND submission. 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 forwardlooking 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, 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, 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, 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.

Source: Aprea Therapeutics, Inc.

Investors and Media:

aprea@argotpartners.com 212-600-1902

Aprea Therapeutics, Inc. Condensed Consolidated Balance Sheets

		March 31, 2023		December 31, 2022
Assets				
Current assets:				
Cash and cash equivalents	\$	30,995,714	\$	28,786,647
Prepaid expenses and other current assets		1,022,803		1,366,859
Total current assets		32,018,517		30,153,506
Property and equipment, net		1,912		2,321
Total assets	\$	32,020,429	\$	30,155,827
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	826,027	\$	842,754
Accrued expenses		3,401,361		2,358,332
Total current liabilities		4,227,388		3,201,086
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Commitments and contingencies (Note 8)				
Series A convertible preferred stock, \$0.001 par value, 40,000,000 shares authorized; 56,227 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively.		1,311,063		1,311,063
Stockholders' equity:				
Common stock, \$0.001 par value, 400,000,000 shares authorized, 3,731,562 and 2,655,269 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively.		3.731		2,655
Additional paid-in capital		335,215,994		330,060,836
Accumulated other comprehensive loss		(10,561,452)		(10,623,408)
Accumulated deficit		(298,176,295)		(293,796,405)
		26,481,978		25,643,678
Total stockholders' equity	•		Φ.	
Total liabilities and stockholders' equity	\$	32,020,429	\$	30,155,827

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

	Three Months Ended March 31,			
		2023		2022
Operating expenses:				
Research and development	\$	1,256,542	\$	4,089,577
General and administrative		3,365,961		3,985,298
Acquired in-process research and development				
Total operating expenses		4,622,503		8,074,875
Other income (expense):				
Interest income, net		256,410		1,971
Foreign currency (loss) gain		(13,797)		136,211
Total other income		242,613		138,182
Net loss	\$	(4,379,890)	\$	(7,936,693)
Other comprehensive loss:				
Foreign currency translation		61,956		(65,505)
Total comprehensive loss		(4,317,934)		(8,002,198)
Net loss per share attributable to common stockholders, basic and diluted	\$	(1.34)	\$	(7.25)
Weighted-average common shares outstanding, basic and diluted		3,260,484		1,095,076



Source: Aprea Therapeutics