Aprea Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides a Business Update

March 26, 2024

First-in-class macrocyclic ATR inhibitor, ATRN-119, on track to complete dose escalation and potentially generate human efficacy data in H2 2024

U.S. FDA cleared IND for APR-1051, a highly selective and potentially best-in-class oral WEE1 inhibitor; Company plans to initiate Phase 1 ACESOT-1051 clinical trial in H1 2024.

$21.6 million in cash and cash equivalents as of December 31, 2023

Private placement financing in March 2024 raised upfront gross proceeds of approximately $16 million

DOYLESTOWN, Pa., March 26, 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 fourth quarter and full year ended December 31, 2023, and provided a business update.

"Aprea had a very productive 2023 with significant progress across our diversified pipeline of synthetic lethality-based cancer therapeutics. We are pleased to continue this positive momentum in 2024 and focus on the execution on our programs towards successfully delivering potentially safer and more effective therapies for cancer patients," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "We continue to enroll and treat patients in the ongoing Phase 1/2a study of our novel macrocyclic ATR inhibitor, ATRN-119. ATRN-119 appears to be well tolerated with a manageable toxicity profile. Dose escalation will proceed throughout 2024 with potential for human efficacy data in the second half of the year. We are preparing to enter the clinic with our next generation inhibitor of WEE1 kinase, APR-1051, having received clearance from the FDA on our IND. Based on the unique characteristics of APR-1051 we believe it will be best in class."

Dr. Gilad continued "the closing of our recent private placement financing provides us with the capital to fund both of these lead programs through meaningful clinical milestones. I would like to thank our dedicated team, our academic collaborators, as well as existing and new investors who have supported our recent advancements. Our mission is to be a global leader in synthetic lethality and we see a great opportunity to help cancer patients in need and create value for our shareholders."

Key Business Updates and Potential Upcoming Key Milestones

ATR inhibitor, ATRN-119, on track to complete monotherapy dose escalation end of the year; initial efficacy data expected in second half of 2024

- 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 mutation in DDR-related genes represent a high unmet medical need. Patients with DDR-related gene mutations have poor prognosis and, currently, have no effective therapies.
- In January 2023, enrollment commenced in an open-label Phase 1/2a clinical trial of ATRN-119 (study AR-276-010) as monotherapy in patients with advanced solid tumors having at least one mutation in a defined panel of DDR-related genes. In the ongoing monotherapy dose escalation phase (Part 1) of the trial, the primary endpoint is evaluating the tolerability and pharmacokinetics of continuous daily oral dosing of ATRN-119 using a 3+3 trial design in up to approximately 30 patients. A secondary endpoint is evaluating potential initial efficacy.
- An update from Part 1 of the trial was featured in a poster presentation at the AACR-NCI-EORTC International Conference in October 2023.
- As of January 2, 2024, 12 patients were enrolled to the first four cohorts of the Phase 1 escalation stage (50mg/day, 100mg/daily, 200mg/daily and 350mg/daily). ATRN-119 was found to be safe and well tolerated in all four cohorts, with no related adverse effects > grade 2. The most recent efficacy analysis conducted at that date shows that two patients achieved stable disease – one each in the 50 mg and 200 mg cohorts. Both these patients' tumors have mutations that have been predicted to confer sensitivity to ATR inhibition.
- As of March 26, 2024 four clinical sites have been activated in the US. At completion of Part 1 of the study, the company anticipates identification of a recommended Phase 2 dose (RP2D) that will be used in a Phase 2a cohort expansion (Part 2) to test the tolerability and potential efficacy of ATRN-119 monotherapy in approximately 30 additional patients. The Phase 1 dose escalation is expected to be completed in 4Q 2024, and RP2D is to be determined in 1Q 2025. Enrollment in the Phase 2a cohort is expected to begin in 1Q 2025 with additional efficacy data expected in 3Q 2025.
- A more comprehensive dataset from Part 1 of the study has been accepted for presentation at the American Association of Cancer Research (AACR) annual meeting in April 2024.

- For more information, please refer to clinicaltrials.gov NCT04905914.

Oral WEE1 inhibitor, APR-1051, expected to enter Phase 1 clinical trial in the first half of 2024

- APR-1051 is a potent and selective small molecule that has the potential to avoid off target toxicity and achieve greater clinical activity than other WEE1 programs currently in development. Aprea is advancing APR-1051 as monotherapy in ovarian cancer with Cyclin E over expression. 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.
- In March 2024, the U.S. FDA cleared the Investigational New Drug (IND) application (IND 169359) for APR-1051. Clearance of this IND will allow Aprea to initiate the Phase 1 ACESOT-1051 (**A** Multi-**C**enter **E**valuation of WEE1 Inhibitor in Patients with Advanced **S**olid **T**umors, APR-1051) trial. This dose escalation trial will evaluate the safety, tolerability, and preliminary efficacy of APR-1051. Enrollment of the first patient is expected in H1 2024 with an update expected in the Q4 2024.
- Preclinical data on APR-1051 were presented in a poster at the AACR-NCI-EORTC International Conference in October 2023. The data highlighted the selectivity of APR-1051 with low off-target activity against PLK1, PLK2 and PLK3, a family of kinases that promote M phase entry, a critical phase in the cell cycle. APR-1051 showed potentially favorable PK properties and appears to cause lower inhibition of hERG, a potential indication of low cardiotoxicity. At doses and scheduling that suppress tumor growth, APR-1051 causes little anemia. The selectivity of APR-1051 may solve a long-standing problem with other WEE1 inhibitors. Recent studies indicate that PLK1 off-targeting partially counters the intracellular effects of WEE1 inhibition and could potentially contribute to the myelosuppression observed with other WEE1 inhibitors.

Pipeline – lead candidate for a third synthetic lethality program to be selected in 2024

- Aprea's research and development team has identified a new target in synthetic lethality. Our discovery team is developing a series of molecules that are selective and potent against it.
- A lead molecule is expected to be declared in 2Q 2024.
- This program may provide clinically meaningful differences for cancer patients that currently have limited therapies.

KOL Event

- Hosted a Key Opinion Leader (KOL) event on October 31, 2023, highlighting the Company's portfolio of small molecules focused on Synthetic Lethality (SL) by targeting the DNA Damage Response (DDR) Pathways. The event featured Key Opinion Leaders Dr. Fiona Simpkins, Professor in the Division of Gynecology Oncology and Department of OB-GYN at the University of Pennsylvania, Dr. Timothy Yap, medical oncology physician-scientist and Professor at the University of Texas MD Anderson Cancer Center, Dr. Eric Brown, a consultant to Aprea and a Professor at the University of Pennsylvania and a member of the Abramson Family Cancer Research Institute, and Aprea's Dr. Nadeem Mirza, Senior Medical Advisor. The speakers, along with the management team, provided an overview of the Company's lead ATR inhibitor candidate, ATRN-119, and its WEE1 inhibitor candidate, APR-1051, and highlighted the addressable unmet clinical need and potential combination therapies using these programs. A replay of the event can be access on the Aprea corporate website here.

Select Financial Results for the Fourth Quarter ended December 31, 2023

- As of December 31, 2023, Aprea reported cash and cash equivalents of $21.6 million.
- For the quarter ended December 31, 2023, the Company reported an operating loss of $3.7 million, compared to an operating loss of $2.7 million in the fourth quarter of 2022.
- Research and Development (R&D) expenses were $2.0 million for the quarter ended December 31, 2023, compared to $0.5 million for the fourth quarter of 2022. The increase in R&D expense was primarily related to the Phase 1/2a clinical trial evaluating ATRN-119 which enrolled its first subject in Q1 2023 and IND enabling studies for APR-1051, the Company's small molecule WEE1 inhibitor.
- General and Administrative (G&A) expenses were $1.6 million for the quarter ended December 31, 2023, compared to $2.1 million for the comparable period in 2022. The decrease in G&A expenses was primarily due to a decrease in personnel costs and insurance premiums.

- The Company reported a net loss of $3.4 million ($0.92 per basic share) on approximately 3.7 million weighted-average common shares outstanding for the quarter ended December 31, 2023, compared to a net loss of $2.4 million ($0.92 per basic share) on approximately 2.6 million weighted average common shares outstanding for the comparable period in 2022.

Select Financial Results for the Year ended December 31, 2023

- As of December 31, 2023, the Company reported cash and cash equivalents of $21.6 million compared to $28.8 million as of December 31, 2022. The Company believes its cash and cash equivalents as of December 31, 2023, combined with the upfront gross proceeds of approximately $16.0 million received from the Company's private placement of common stock and warrants in March 2024, before deducting placement agent fees and offering costs of approximately $1.4 million, will be sufficient to meet its currently projected operating expenses and capital expenditure requirements into the third quarter of 2025.
- For the year ended December 31, 2023, the Company reported an operating loss of $15.5 million, compared to an operating loss of $113.4 million, which include $76.0 million for acquired in-process research and development, for the year ended December 31, 2022.
- Research and Development (R&D) expenses were $7.6 million for the year ended December 31, 2023, compared to $16.4 million for the year ended December 31, 2022. The decrease in R&D expense was primarily related to the close out of our clinical trials of eprenetapopt and APR-246, non-cash stock-based compensation from the acceleration of vesting of all outstanding stock options and restricted stock units in connection with the acquisition of Atrin Pharmaceuticals Inc. in 2022 and personnel costs primarily related to the close out of our research facility in Sweden during 2022.
- General and Administrative (G&A) expenses were $8.4 million for the year ended December 31, 2023, compared to $21.0 million for the year ended December 31, 2022. The decrease in G&A expenses was primarily due to a decrease in non-cash stock-based compensation from the acceleration of vesting of all outstanding stock options and restricted stock units in connection with the acquisition of Atrin Pharmaceuticals Inc. in 2022 and insurance premiums.
- The Company reported a net loss of $14.3 million ($3.95 per basic share) on approximately 3.6 million weighted-average common shares outstanding for the year ended December 31, 2023, compared to a net loss of $112.7 million ($67.99 per basic share) on approximately 1.7 million weighted average common shares outstanding for the comparable period in 2022.

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. Aprea has completed all IND enabling studies for its oral, small molecule WEE1 inhibitor, APR-1051, and recently received FDA clearance of its IND. 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

Aprea Therapeutics, Inc.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 21,606,820	$ 28,786,647
Prepaid expenses and other current assets	914,275	1,366,859
Total current assets	22,521,095	30,153,506
Property and equipment, net	88,362	2,321
Restricted cash	40,717	—
Total assets	$ 22,650,174	$ 30,155,827
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,670,369	$ 842,754
Accrued expenses	2,186,262	2,358,332
Deferred revenue	528,974	—
Total current liabilities	4,385,605	3,201,086
Total liabilities	4,385,605	3,201,086
Commitments and contingencies		
Series A convertible preferred stock, $0.001 par value, 40,000,000 shares authorized; 56,227 shares issued and outstanding at December 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, 3,736,673 and 2,655,269 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively.	3,736	2,655
Additional paid-in capital	335,644,204	330,060,836
Accumulated other comprehensive loss	(10,611,273)	(10,623,408)
Accumulated deficit	(308,083,161)	(293,796,405)
Total stockholders' equity	16,953,506	25,643,678
Total liabilities and stockholders' equity	$ 22,650,174	$ 30,155,827

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(Unaudited)			
Grant revenue	$ 14,075	$ —	$ 583,231	$ —
Operating expenses:				
Research and development	2,045,689	531,406	7,627,491	16,402,273

General and administrative	1,643,315	2,120,222	8,427,703	20,969,771
Acquired in-process research and development	—	—	—	76,020,184
Total operating expenses	3,689,004	2,651,628	16,055,194	113,392,228
Loss from operations	(3,674,929)	(2,651,628)	(15,471,963)	(113,392,228)
Other income:				
Interest income, net	310,287	243,082	1,224,133	448,667
Foreign currency gain (loss)	(78,612)	(33,596)	(38,926)	281,534
Total other income	231,675	209,486	1,185,207	730,201
Net loss	$ (3,443,254)	$ (2,442,142)	$ (14,286,756)	$ (112,662,027)
Other comprehensive gain (loss):				
Foreign currency translation	24,601	(382,763)	12,135	(264,452)
Total comprehensive loss	(3,418,653)	(2,824,905)	(14,274,621)	(112,926,479)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.92)	$ (0.92)	$ (3.95)	$ (67.99)
Weighted-average common shares outstanding, basic and diluted	3,736,673	2,649,349	3,617,607	1,657,055

APREA THERAPEUTICS

Source: Aprea Therapeutics