Aprea Therapeutics Reports First quarter 2024 Financial Results and Provides a Business Update

May 14, 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 June 2024

First-in-class macrocyclic ATR inhibitor, ATRN-119, on track to complete dose escalation in ABOYA-119 clinical trial and potentially generate initial human efficacy data in 2H 2024

Company had four poster presentations at the AACR Annual Meeting, including updates on APR-1051 and ATRN-119

$32.4 million in cash and cash equivalents as of March 31, 2024

DOYLESTOWN, Pa., May 14, 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 first quarter ended March 31, 2024, and provided a business update.

"During the first quarter of 2024, Aprea had a number of noteworthy achievements across clinical, regulatory and corporate fronts," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "FDA clearance of the IND for APR-1051, our next-generation inhibitor of WEE1 kinase, was an important milestone and allows us to commence clinical trials with this exciting, differentiated and potentially best in class molecule. We look forward to evaluating its therapeutic activity in patients, focusing on Cyclin E overexpressing cancers, including ovarian and breast cancers amongst others. Enrollment continues in the dose escalation portion of our ABOYA-119 clinical trial evaluating ATRN-119 in patients with advanced solid tumors having mutations in defined DDR-related genes. We are encouraged by correlations of the preliminary signs of clinical benefit and genetic mutations. Importantly, Aprea has a strong balance sheet, and the closing of our successful private placement in March of this year provides us with the capital to fund both our lead programs through meaningful clinical milestones. As we progress, we are committed to leveraging our expertise in synthetic lethality in order to provide hope and new treatment options to cancer patients who urgently need them. We believe that our strategic initiatives and pipeline expansion have the potential to drive substantial value for shareholders."

Key Business Updates and Potential Upcoming Key Milestones

ABOYA-119: ATR inhibitor, ATRN-119, on track to complete monotherapy dose escalation end of the year

- 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.
- Enrollment continues 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.
- An update on the ongoing trial was featured in a poster at the AACR Annual Meeting this past April. As of March 12, 2024, 16 patients were enrolled in the first five cohorts of the dose escalation stage (50 mg/day, 100 mg/daily, 200 mg/daily, 350 mg/daily, and 550 mg/daily). Based on data to date, ATRN-119 has been found to be safe and well tolerated. PK studies show ATRN-119 serum concentrations are entering the expected therapeutic range at the current highest dose level (550 mg). We have clearance up to 800 mg/daily and, on March 12, submitted an amendment to the FDA for the additional cohorts. Preliminary signs of clinical benefit have been observed with two patients achieving stable disease (SD) – one in the 50 mg/day cohort and a second patient who showed longer duration when treated at 200 mg/day. The latter patient at 200 mg/day had SD at Days 55, 112, and 168. For further details, including the status of all 16 patients enrolled to date, refer to the AACR poster here.
- Initial efficacy data from Part 1 of the study may potentially be announced in 2H 2024. At completion of Part 1, 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.
- For more information, please refer to clinicaltrials.gov NCT04905914.

ACESOT-1051: Oral WEE1 inhibitor, APR-1051, expected to enter Phase 1 clinical trial in June, 2024

- APR-1051 is a potent and selective small molecule that has been designed to potentially solve liabilities and achieve greater clinical activity than other WEE1 programs currently in development. Aprea is advancing APR-1051 as monotherapy in ovarian and breast cancers with Cyclin E over expression, amongst others. 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 is allowing Aprea to initiate the Phase 1 ACESOT-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 2Q 2024 with an update expected in 4Q 2024.
- 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 ASECOT-1051.

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 chemists and discovery team are developing a series of molecules that are selective and potent against it.
- A lead molecule is expected to be declared in 3Q 2024. This program may provide clinically meaningful differences for cancer patients that currently have limited therapies.
- An additional poster at AACR described a combination approach using Aprea's next-generation macrocyclic ATR inhibitor, ATRN-333, to sensitize glioblastoma (GBM) tumors to lomustine, an oral DNA alkylating agent. The results support further investigation and potential clinical implementation of ATRN-333 and other macrocyclic ATR inhibitors as chemosensitizers for glioblastoma.

Corporate

- In March 2024, Aprea announced a securities purchase agreement with new and existing healthcare institutional investors and certain Company insiders to raise up to $34.0 million in gross proceeds, including initial upfront gross funding of $16.0 million and up to an additional $18.0 million upon cash exercise of accompanying warrants at the election of the investors. The financing was led by Sphera Healthcare with participation from new and existing healthcare focused investors including Nantahala Capital, DAFNA Capital Management, Exome Asset Management and Stonepine Capital Management, among others, as well as certain Company insiders. The capital is being deployed for general working capital purposes and to fund the Phase 1 ACESOT-1051 clinical trial, as well as, continuation of patient enrollment in the dose expansion portion of the ABOYA-119 clinical trial evaluating ATRN-119.
- 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 First Quarter ended March 31, 2024

- As of March 31, 2024, the Company reported cash and cash equivalents of $32.4 million, compared to $21.6 million at December 31, 2023. The Company believes its cash and cash equivalents as of March 31, 2024 will be sufficient to meet its currently projected operating expenses and capital expenditure requirements into the third quarter of 2025.
- For the quarter ended March 31, 2024, the Company reported an operating loss of $3.1 million, compared to an operating loss of $4.6 million in the comparable period in 2023.
- Research and Development (R&D) expenses were $1.6 million for the quarter ended March 31, 2024, compared to $1.3 million for the comparable period in 2023. The increase in R&D expense was primarily related to IND enabling studies for APR-1051, the Company's small molecule WEE1 inhibitor, in preparation for enrollment of first patient into Phase 1 dose-escalation in the second quarter of 2024.
- General and Administrative (G&A) expenses were $1.9 million for the quarter ended March 31, 2024, compared to $3.4 million for the comparable period in 2023. The decrease in G&A expenses was primarily due to a decrease in personnel costs.
- The Company reported a net loss of $2.8 million ($0.67 per basic share) on approximately 4.2 million weighted-average common shares outstanding for the quarter ended March 31, 2024, compared to a net loss of $4.4 million ($1.34 per basic share) on approximately 3.3 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. 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.

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Aprea Therapeutics, Inc.
Consolidated Balance Sheets

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 32,369,973	$ 21,606,820
Prepaid expenses and other current assets	698,864	914,275
Total current assets	33,068,837	22,521,095
Property and equipment, net	90,183	88,362
Restricted cash	40,986	40,717
Total assets	$ 33,200,006	$ 22,650,174
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,318,385	$ 1,670,369
Accrued expenses	1,498,286	2,186,262
Deferred revenue	148,405	528,974
Total current liabilities	2,965,076	4,385,605
Total liabilities	2,965,076	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 March 31, 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 March 31, 2024 and December 31, 2023, respectively.	5,430	3,736
Additional paid-in capital	350,438,045	335,644,204
Accumulated other comprehensive loss	(10,626,356)	(10,611,273)
Accumulated deficit	(310,893,252)	(308,083,161)
Total stockholders' equity	28,923,867	16,953,506
Total liabilities and stockholders' equity	$ 33,200,006	$ 22,650,174

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

	Three Months Ended March 31,	
	2024	2023
Grant revenue	$ 380,569	$ —
Operating expenses:		
Research and development	1,600,373	1,256,542
General and administrative	1,929,866	3,365,961

Total operating expenses	3,530,239	4,622,503
Loss from operations	(3,149,670)	(4,622,503)
Other income (expense):		
Interest income, net	283,403	256,410
Foreign currency gain (loss)	56,176	(13,797)
Total other income	339,579	242,613
Net loss	$ (2,810,091)	$ (4,379,890)
Other comprehensive (loss) gain:		
Foreign currency translation	(15,083)	61,956
Total comprehensive loss	(2,825,174)	(4,317,934)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.67)	$ (1.34)
Weighted-average common shares outstanding, basic and diluted	4,198,326	3,260,484

Source: Aprea Therapeutics