Aprea Therapeutics Reports Third Quarter 2023 Financial Results and Provides a Business Update

DOYLESTOWN, PA, Nov. 9, 2023 (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 three and nine months ended September 30, 2023, and provided a business update.

"We are very pleased by the progress of our diversified programs this past quarter. Importantly, we presented initial clinical data from our Phase 1/2a study of our ATR inhibitor, ATRN-119, in solid tumors in a poster at the recent AACR-NCI-EORTC International Conference. To date, ATRN-119 has demonstrated an ability to be a very compelling molecule, appearing to be well tolerated with no reports of dose-limiting toxicities and ongoing daily dosing may result in persistent tumor-reducing effect," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "We are continuing with patients in the dose escalation portion of the study, and the dose expansion cohort is on track to be initiated in 2Q 2024. In our WEE1 inhibitor, ATRN-1051, program we are on track to file an IND with the FDA by the end of 2023, and plan to begin clinical testing in the first half of 2024. Our strong balance sheet continues to support our strategy and plans through our near-term milestones in both our ATR and WEE1 programs, with a cash runway through the end of the fourth quarter of 2024. We look forward to providing more updates as we make progress and reach important milestones in the coming weeks and months."

Key Business and Financial Updates

- 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, ATRN-1051, and highlighted the addressable unmet clinical need and potential combination therapies using these programs.

- Presented initial clinical data on the Company's ATR inhibitor, ATRN-119, and preclinical data on its WEE1 inhibitor, ATRN-1051, at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on October 14, 2023. The first poster included initial data from the Company's first-in-human Phase 1/2a dose escalation trial of ATRN-119 in solid tumors. The trial is being conducted to determine the recommended Phase 2 dose, with a daily dosing administration over a 56-day cycle. The Company is actively enrolling cohort 4 at 350mg, with subsequent 550mg cohort 5 and 800mg cohort 6 planned. The Company anticipates enrolling the first patient in the dose expansion portion of the study in Q2 2024.

- The second poster presented preclinical data from the Company's WEE1 inhibitor program that demonstrated the potential safety and efficacy of its highly differentiated WEE1 inhibitor, ATRN-1051, in the treatment of ovarian cancer. The data showed ATRN-1051 to be a highly potent and selective inhibitor of WEE1 that does not significantly affect the off-target PLK1, PLK2, and PLK3 family of kinases. ATRN-1051 shows potentially favorable PK properties and appears to cause lower inhibition of hERG, a potential indication of low cardiotoxicity. Importantly, at doses and scheduling that suppress tumor growth, ATRN-1051 causes little anemia. These findings have justified IND-enabling studies for clinical development of ATRN-1051. Evidence generated by Aprea suggests such off-targeting of the PLK family, which has been a challenge for other WEE1 inhibitors in the class, substantially limits the ability of WEE1 inhibitors to cause cell death.

- Appointed Dr. Jean-Pierre Bizzari to its Board of Directors. Dr. Bizzari has been responsible for numerous global approvals of several billion-dollar therapies, has been involved in acquisition and licensing agreements with several major pharmaceutical companies, and is a member and leader on many scientific committees. The Company also named Dr. Richard Peters as Chairman of the Board; Dr. Peters has served as a member of the Board since June 2020 bringing over 2 decades of experience in developing new therapies for difficult-to-treat diseases.

Potential Upcoming Key Milestones

ATR Inhibitor Clinical Program (ATRN-119)

- Phase 1/2a Monotherapy Dose Escalation study
  - 1Q 2024 Complete dose escalation

- Phase 1/2a Monotherapy Dose Expansion study
  - 2Q 2024 First patient enrolled

WEE1 Inhibitor Program (ATRN-1051)

- IND
  - 4Q 2023 IND Submission
  - 1Q 2024 IND Clearance

- Phase 1/2a Monotherapy Dose Escalation Study
  - 1H 2024 First patient enrolled

Select Financial Results for the Third Quarter ended September 30, 2023

- As of September 30, 2023, the Company reported cash and cash equivalents of $25.4 million.

- For the quarter ended September 30, 2023, the Company reported an operating loss of $3.5 million, compared to an operating loss of $4.2 million for the same period in 2022.

- Research and Development (R&D) expenses were $2.1 million for the quarter ended September 30, 2023, compared to $1.1 million for the same period in 2022. The increase in R&D expense was related to IND enabling studies for ATRN-1051, the Company's small molecule WEE1 inhibitor, offset in part by a decrease in personnel costs related to the former facility in Sweden.

- General and Administrative (G&A) expenses were $1.7 million for the quarter ended September 30, 2023, compared to $3.1 million for the same period in 2022. The decrease in G&A expenses was due to a decrease in professional fees primarily associated with post-acquisition activities during 2022, a decrease in insurance premiums, and a decrease in personnel costs related to the former facility in Sweden.

- The Company reported a net loss of $3.2 million ($0.86 per basic share) on approximately 3.7 million weighted-average common shares outstanding for the quarter ended September 30, 2023, compared to a net loss of $4.0 million ($2.32 per basic share) on approximately 1.7 million weighted average common shares outstanding for the same 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. Its oral, small molecule WEE1 inhibitor, ATRN-1051, 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 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, 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.

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+++ Tables to Follow +++

Aprea Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 25,353,513	$ 28,786,647
Prepaid expenses and other current assets	286,263	1,366,859
Total current assets	25,639,776	30,153,506
Property and equipment, net	86,198	2,321
Restricted cash	40,449	—
Total assets	$ 25,766,423	$ 30,155,827
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 862,552	$ 842,754
Accrued expenses	3,303,510	2,358,332
Total current liabilities	4,166,062	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 September 30, 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 September 30, 2023 and December 31, 2022, respectively.	3,736	2,655
Additional paid-in capital	335,561,343	330,060,836
Accumulated other comprehensive loss	(10,635,874)	(10,623,408)
Accumulated deficit	(304,639,907)	(293,796,405)
Total stockholders' equity	20,289,298	25,643,678
Total liabilities and stockholders' equity	$ 25,766,423	$ 30,155,827

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Grant revenue	$ 319,468	$ —	$ 569,156	$ —
Operating expenses:				
Research and development	2,122,603	1,117,576	5,581,802	15,870,867
General and administrative	1,719,715	3,082,618	6,784,388	18,849,549
Acquired in-process research and development	—	—	—	76,020,184
Total operating expenses	3,842,318	4,200,194	12,366,190	110,740,600
Loss from operations	(3,522,850)	(4,200,194)	(11,797,034)	(110,740,600)
Other income:				
Interest income, net	321,215	151,123	913,846	205,585
Foreign currency gain	(2,880)	24,353	39,686	315,130
Total other income	318,335	175,476	953,532	520,715
Net loss	$ (3,204,515)	$ (4,024,718)	$ (10,843,502)	$ (110,219,885)
Other comprehensive loss:				
Foreign currency translation	(1,002)	26,161	(12,466)	118,311
Total comprehensive loss	(3,205,517)	(3,998,557)	(10,855,968)	(110,101,574)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.86)	$ (2.32)	$ (3.03)	$ (83.33)
Weighted-average common shares outstanding, basic and diluted	3,735,176	1,732,783	3,577,482	1,322,652