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

DOYLESTOWN, PA, August 10, 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 six months ended June 30, 2023 and provided a business update.

"We continue to execute across all our programs, with notable progress in enrollment in our lead Phase 1/2a dose escalation study with ATRN-119, our ATR inhibitor for the treatment of advanced solid tumors and anticipate initial preliminary data in the fourth quarter 2023," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "Our IND enabling studies for ATRN-1051, our WEE1 inhibitor, continue to be on track, and we continue to anticipate filing an IND by the end of the year. 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 into the fourth quarter 2024. We look forward to providing more updates as we make progress throughout the rest of the year."

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 the 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 interim safety, tolerability, and pharmacokinetic data from the ongoing Phase 1 trial of ATRN-119 in the fourth quarter of 2023.

- *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.

- 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 René Huguenin/Curie Institute Cancer Center in Paris, France.

Select Financial Results for the Second Quarter ended June 30, 2023

- As of June 30, 2023, the Company reported cash and cash equivalents of $27.7 million.

- For the quarter ended June 30, 2023, the Company reported an operating loss of $3.7 million, compared to an operating loss of $98.5 million for the same period in 2022.

- Research and Development (R&D) expenses were $2.2 million for the quarter ended June 30, 2023, compared to $6.8 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 $1.7 million for the quarter ended June 30, 2023, compared to $15.6 million for the same period in 2022. The decrease in G&A expenses was due to lower non-cash stock-based compensation expense, lower insurance premium expenses and lower personnel costs for the former facility in Sweden.

- Acquired in-process research and development (IPR&D) expenses were $0 million for the quarter ended June 30, 2023, compared to $76.0 million for the same period in 2022. The decrease in IPR&D was related to the 2022 acquisition of Atrin, which was accounted for as an asset acquisition. The acquisition cost allocated to acquired IPR&D with no alternative future use was recorded as an expense as of the closing date in May 2022.

- The Company reported a net loss of $3.3 million ($0.87 per basic share) on approximately 3.7 million weighted-average common shares outstanding for the quarter ended June 30, 2023, compared to a net loss of $98.3 million ($86.72 per basic share) on approximately 1.1 million weighted average common shares outstanding for the same period in 2022. The decrease in net loss was primarily attributable to the acquired IPR&D associated with the Atrin acquisition in May 2022 described above.

About Aprea Therapeutics, Inc.

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 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 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.

Source: Aprea Therapeutics, Inc.

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+++ Tables to Follow +++

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 27,685,131	$ 28,786,647
Prepaid expenses and other current assets	953,670	1,366,859
Total current assets	28,638,801	30,153,506
Property and equipment, net	1,687	2,321
Restricted cash	40,180	—
Total assets	$ 28,680,668	$ 30,155,827
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,131,197	$ 842,754
Accrued expenses	2,819,624	2,358,332
Total current liabilities	3,950,821	3,201,086
Total liabilities	3,950,821	3,201,086
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 June 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, 3,731,571 and 2,655,269 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively.	3,731	2,655
Additional paid-in capital	335,485,317	330,060,836
Accumulated other comprehensive loss	(10,634,872)	(10,623,408)
Accumulated deficit	(301,435,392)	(293,796,405)
Total stockholders' equity	23,418,784	25,643,678
Total liabilities and stockholders' equity	$ 28,680,668	$ 30,155,827

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Grant revenue	$ 249,688	$ —	$ 249,688	$ —
Operating expenses:				
Research and development	2,202,657	6,811,609	3,459,199	10,901,186
General and administrative	1,698,712	15,633,738	5,064,673	19,619,036
Acquired in-process research and development	—	76,020,184	—	76,020,184
Total operating expenses	3,901,369	98,465,531	8,523,872	106,540,406
Loss from operations	(3,651,681)	(98,465,531)	(8,274,184)	(106,540,406)
Other income:				
Interest income, net	336,221	52,491	592,631	54,462
Foreign currency gain	56,363	154,566	42,566	290,777
Total other income	392,584	207,057	635,197	345,239
Net loss	$ (3,259,097)	$ (98,258,474)	$ (7,638,987)	$ (106,195,167)
Other comprehensive loss:				
Foreign currency translation	(73,420)	157,655	(11,464)	92,150
Total comprehensive loss	(3,332,517)	(98,100,819)	(7,650,451)	(106,103,017)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (86.72)	$ (2.18)	$ (95.31)
Weighted-average common shares outstanding, basic and diluted	3,731,571	1,133,092	3,497,329	1,114,189

See accompanying notes to unaudited condensed consolidated financial statements.