UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

August 11, 2022
Date of Report (Date of earliest event reported)

Aprea Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39069**	**84-2246769**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

535 Boylston Street **Boston, Massachusetts**	**02116**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 463-9385**

(Former name or former address, if changed since last report): Not applicable

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	APRE	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition

On August 11, 2022, the Company issued a press release announcing its financial results for the second quarter ended June 30, 2022 and an update on the Company's operations for the same period. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Aprea Therapeutics, Inc. dated August 11, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aprea Therapeutics, Inc.

Dated: August 11, 2022

By: /s/ Oren Gilad
Name: Oren Gilad
Title: President and Chief Executive Officer

Exhibit 99.1

Aprea Therapeutics Reports Second Quarter 2022 Financial Results and Provides Update on Business Operations

BOSTON, MA, August 11, 2022 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE), a biopharmaceutical company focused on developing and commercializing novel synthetic lethality-based cancer therapeutics targeting DNA damage response (DDR) pathways today reported financial results for the three and six months ended June 30, 2022 and provided a business update.

“This is an exciting time for Aprea as we advance our ATR program into clinical development this year, continue to progress our WEE1 program toward IND submission and leverage our unique discovery platform capabilities to build for future success,” said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. “We believe our current cash resources will last through the end of 2023 and enable us to execute on our development plan to reach near term clinical milestones.”

Second Quarter Financial Results

- **Cash and cash equivalents:** As of June 30, 2022, the Company had $39.1 million of cash and cash equivalents compared to $53.1 million of cash and cash equivalents as of December 31, 2021. The Company believes its cash and cash equivalents as of June 30, 2022 will be sufficient to meet its current projected operating requirements through the end of 2023.

- **Research and Development (R&D) expenses:** R&D expenses were $6.8 million for the quarter ended June 30, 2022, compared to $6.7 million for the comparable period in 2021. R&D expenses for the quarter ended June 30, 2022 primarily represented close out costs for (i) the Company’s pivotal Phase 3 clinical trial of eprenetapopt with azacitidine for the frontline treatment of *TP53* mutant MDS, (ii) the Company’s Phase 2 post-transplant MDS/AML clinical trial, (iii) the Company’s Phase 1 AML trial, and (iv) the Company’s Phase 1/2 solid tumor trial and the Company’s Phase 1 dose-escalation trial of APR-548.

- **General and Administrative (G&A) expenses:** G&A expenses were $15.6 million for the quarter ended June 30, 2022, compared to $3.3 million for the comparable period in 2021. The increase in G&A expenses was primarily due to an increase in non-cash stock-based compensation expense resulting from the acceleration of vesting of all outstanding stock options and restricted stock units in connection with the acquisition of Atrin in May 2022.

- **Acquired In-Process Research and Development (IPR&D) expenses:** Acquired IPR&D expense was $76.0 million for the quarter ended June 30, 2022. Acquired IPR&D resulted from the Atrin Acquisition in May 2022 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.

- **Net loss:** Net loss was $98.3 million, or $4.34 per share for the quarter ended June 30, 2022, compared to a net loss of $10.3 million, or $0.48 per share for the quarter ended June 30, 2021. The increase in net loss was primarily attributable to the acquired in process research and development of $76.0 million associated with the Atrin acquisition. The Company had 23,401,846 shares of common stock outstanding as of June 30, 2022.

Business Operations Update:

On May 16, 2022 the Company completed the acquisition of Atrin Pharmaceuticals, Inc. (“Atrin”), a privately held biotechnology company focused on the discovery and development of novel therapeutics targeting proteins in the DDR, pathway in oncology through synthetic lethality. Following the Company’s Annual Meeting of Stockholders on July 28, 2022, Christian S. Schade transitioned to the role of Executive Chairman of the Board of Directors and Oren Gilad, Ph.D., assumed the role of Chief Executive Officer.

DDR Programs

ATRN-119 – ATRN-119 is an orally-bioavailable, highly potent and selective macrocyclic small molecule inhibitor of ATR, a protein with key roles in response to DNA damage. ATRN-119 has received FDA IND approval for a first-in-human clinical trial for cancer patients and this trial is expected to begin in the third quarter of 2022.

ATRN-W1051 – ATRN-W1051 is an orally-bioavailable, highly potent and selective small molecule inhibitor of WEE1, a key regulator of multiple phases of the cell cycle. ATRN-W1051 is currently in preclinical development and we anticipate commencing IND-enabling studies in the second half of 2022.

p53 Reactivator Programs

Eprenetapopt - APR-246, or eprenetapopt, is a small molecule p53 reactivator that has been tested in clinical trials for solid tumors and for hematologic malignancies. A manuscript describing the results of a Phase 2 clinical trial of eprenetapopt with azacitidine after allogeneic stem-cell transplantation in *TP53* mutant acute myeloid leukemia and myelodyspastic syndromes has recently been published online in the *Journal of Clinical Oncology* and a manuscript describing results of a Phase 1b clinical trial of eprenetapopt with pembrolizumab in advanced solid tumors has been accepted for publication in *ESMO Open*. We currently have no ongoing clinical trials of eprenetapopt.

APR-548 - APR-548 is a second generation p53 reactivator that is a unique analog of eprenetapopt. APR-548 exhibits high oral bioavailability in preclinical testing and is being developed in an oral dosage form. We initiated a Phase 1 clinical trial testing APR-548 in relapsed/refractory MDS and AML. Enrollment in the first dosing cohort was completed. There are currently no patients receiving APR-548 in this trial and enrollment into the trial has been closed.

About Aprea Therapeutics, Inc.

Aprea Therapeutics, Inc. is a biopharmaceutical company headquartered in Boston, Massachusetts with research facilities in Doylestown, Pennsylvania, focused on developing and commercializing novel cancer therapeutics that target DNA damage response pathways. The Company's lead program is ATRN-119, a Phase 1-ready small molecule ATR inhibitor being developed for solid tumor indications. 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 that involve risks, potential changes in circumstances, assumptions, and uncertainties. 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 risks related to the success and timing of our clinical trials or other studies, risks associated with the coronavirus pandemic and the other risks set forth in our filings 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 publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Aprea Therapeutics, Inc.

Corporate Contacts:

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Sr. Vice President and Chief Financial Officer
617-463-9385

Gregory A. Korbel
Sr. Vice President and Chief Operating Officer
617-463-9385

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 39,062,415	$ 53,076,052
Prepaid expenses and other current assets	1,400,837	3,508,358
Total current assets	40,463,252	56,584,410
Property and equipment, net	20,258	23,870
Right of use lease and other noncurrent assets	200,326	215,183
Total assets	$ 40,683,836	$ 56,823,463
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,989,794	$ 1,773,032
Accrued expenses	3,505,287	5,352,996
Lease liability—current	189,116	190,471
Total current liabilities	7,684,197	7,316,499
Lease liability—noncurrent	--	--
Total liabilities	7,684,197	7,316,499
Commitments and contingencies		
Preferred stock, par value $0.001; 2,949,630 and 0 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	68,777,468	--
Stockholders' equity (deficit):		
Common stock, par value $0.001; 23,401,846 and 21,859,413 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively.	23,401	21,859
Additional paid-in capital	261,795,121	240,978,439
Accumulated other comprehensive loss	(10,266,806)	(10,358,956)
Accumulated deficit	(287,329,545)	(181,134,378)
Total stockholders' equity	(35,777,829)	49,506,964
Total liabilities and stockholders' equity (deficit)	$ 40,683,836	$ 56,823,463

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 6,811,609	$ 6,654,257	$ 10,901,186	$ 13,418,105
General and administrative	15,633,738	3,343,325	19,619,036	6,769,158
Acquired in-process research and development	76,020,184	--	76,020,184	--
Total operating expenses	98,465,531	9,997,582	106,540,406	20,187,263
Other income (expense):				
Interest income (expense)	52,491	(588)	54,462	(1,645)
Foreign currency (loss) gain	154,566	(252,843)	290,777	269,140
Total other income (expense)	207,057	(253,431)	345,239	267,495
Net loss	$ (98,258,474)	$ (10,251,013)	$ (106,195,167)	$ (19,919,768)
Other comprehensive income (loss):				
Foreign currency translation	157,655	193,020	92,150	(209,830)
Total comprehensive loss	(98,100,819)	(10,057,993)	(106,103,017)	(20,129,598)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.34)	$ (0.48)	$ (4.77)	$ (0.94)
Weighted-average common shares outstanding, basic and diluted	22,661,835	21,186,827	22,283,783	21,186,827