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

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

Aravive, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36361**	**26-4106690**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

River Oaks Tower
3730 Kirby Drive, Suite 1200
Houston, Texas 77098
(Address of principal executive offices)

(936) 355-1910
(Registrant's telephone number, including area code)

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 (*see* General Instruction A.2. below):

☐ 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 $0.0001 per share	**ARAV**	**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 Operation and Financial Condition.

On August 11, 2022, Aravive, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for its quarter ended June 30, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in the press release is being furnished to the Securities and Exchange Commission (the "Commission") and shall not be deemed incorporated by reference into any of the Registrant's registration statements or other filings with the Commission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished with this Current Report on Form 8-K:

Exhibit	Description
99.1	Press Release issued by Aravive , 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, as amended, the registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 11, 2022

ARAVIVE, INC.
(Registrant)

By: /s/ Gail McIntyre
Name: Gail McIntyre
Title: Chief Executive Officer

aravive

Aravive Reports Second Quarter 2022 Financial Results and Provides Corporate Updates

- *Hosted Key Opinion Leader (KOL) Symposium; KOLs Presented Positive Updated Batiraxcept Phase 1b Clear Cell Renal Cell Carcinoma (ccRCC) and Phase 1b Pancreatic Adenocarcinoma Data.*
- *Presented Updated Clinical Data at ASCO Showing Continued Best-In-Class Potential of Batiraxcept in Advanced or Metastatic Clear Cell Renal Cell Carcinoma (ccRCC); Abstract Selected for Oral Discussion.*
- *Continued to Strengthen the Senior Management Team with the Addition of Rudy Howard as Chief Financial Officer and Dr. Robert Geller as Chief Medical Officer.*
- *Continued to Advance Clinical Trials in Platinum Resistant Ovarian Cancer, Clear Cell Renal Cell Carcinoma and Pancreatic Adenocarcinoma.*

HOUSTON, TX, August 11, 2022 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV, "the Company"), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today reported financial results for the second quarter ended June 30, 2022 and provided corporate updates.

"We continued to achieve great progress for Aravive in the second quarter of 2022. All of our batiraxcept clinical trials for the treatment of ovarian, kidney and pancreatic cancers continued to advance at a strong pace," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "We remain on track with our lead Phase 3 registrational study in ovarian cancer to complete enrollment around year-end 2022, which would enable us to read out topline data mid-2023 and potentially file a BLA with the FDA by year-end 2023."

"We continue to successfully enroll patients in our Phase 2 trial of batiraxcept in clear cell renal cancer and will have updates throughout the remainder of this year. Our Phase 1b trial in pancreatic cancer has completed enrollment and updated results are anticipated later this year. We remain confident in the execution of our clinical trials and encouraged by the continued signals of the potential therapeutic success of batiraxcept."

"Finally, we hired two industry seasoned veterans to round out our senior management team. Rudy Howard and Dr. Robert Geller will not only add tremendous support as we continue our trials, but also as we potentially move towards and beyond regulatory approval of a commercially viable portfolio."

Recent Corporate Highlights

- **Batiraxcept in Platinum Resistant Ovarian Cancer (PROC)**: The registration-directed Phase 3 program of batiraxcept in combination with paclitaxel in PROC remains on track to complete enrollment around year-end 2022. The Company expects to report topline data from the trial by mid-2023. CMC work remains on track with the goal of filing a BLA by year-end 2023. The global, randomized, double-blind, placebo-controlled Phase 3 trial is evaluating efficacy and tolerability of batiraxcept at a dose of 15 mg/kg in combination with paclitaxel versus placebo in combination with paclitaxel. The trial aims to enroll 350 patients with platinum resistant, high-grade serous ovarian cancer who have received 1-4 prior lines of therapy.

- **Batiraxcept in Clear Cell Renal Cell Carcinoma (ccRCC) and Serum-Based Biomarker**: As of April 30, 2022 and as presented during the KOL symposium, 26 previously treated (2L+) patients with ccRCC were treated with batiraxcept in the Phase 1b portion of the trial at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily. There were no dose limiting toxicities observed at either dose and 14 of the 26 patients remained on study. The best overall response rate (ORR, confirmed + unconfirmed) in the ITT population was 46% and 50% in patients dosed with 15 mg/kg (the recommended Phase 2 dose). One of the objectives of the ongoing Phase 1b/2 ccRCC trial is to evaluate the correlation of baseline serum soluble AXL (sAXL)/GAS6 (biomarker) with radiographic response in patients with ccRCC treated with batiraxcept plus cabozantinib. The best ORR in the biomarker high population was 60%, and 67% in the biomarker high population dosed at 15 mg/kg. The 7-month progression-free survival (PFS) rate was 71% in the ITT population, 83% in the biomarker high population, and 91% in the 15 mg/kg biomarker high group. Eight patients experienced resolution of one or more target lesions. The Company has discussed a registrational path with the US FDA that includes use of the sAXL/Gas6 ratio as a basis for an accelerated approval. The Company is on track to report updated results from the Phase 1b and Phase 2 portions of the trial in the second half of 2022.

- **Batiraxcept in Pancreatic Adenocarcinoma**: As of May 3, 2022 and as discussed at the KOL symposium, 21 patients with advanced or metastatic pancreatic adenocarcinoma have been treated with 15 mg/kg batiraxcept in combination with gemcitabine and nab-paclitaxel as a first-line treatment. Batiraxcept has been generally well-tolerated with no unexpected safety signals. The best ORR (confirmed + unconfirmed) was 29%. As noted with the other programs, an observable correlation of baseline levels of serum soluble AXL (sAXL)/GAS6 (biomarker) to clinical activity was noted in this trial and the best ORR in the biomarker high population was 40%. Five patients experienced resolution of one or more target lesions; however, two of these patients have since progressed. The Company is on track to report additional updated data from the Phase 1b portion of the trial in the second half of 2022.

Second Quarter 2022 Financial Results
Revenues for the three months ended June 30, 2022 were $1.6 million, compared to $1.1 million for the three months ended March 31, 2022. Revenues were derived solely from the Company's collaboration and license agreement with 3D Medicines, executed in November 2020 to develop and commercialize batiraxcept in oncology indications in Greater China. Revenues represent 1) a portion of initial signing and milestone payments received from 3D Medicines that is recognized at the time of the receipt and 2) a portion of the payments that is deferred and recognized over the PROC trial period. The increase in revenues is attributable to increased expenditures related to the PROC trial which drives the recognition of deferred payments over the PROC trial period.

Total operating expenses for the three months ended June 30, 2022 were $21.0 million, compared to $16.1 million for the three months ended March 31, 2022. Research and development expense for the three months ended June 30, 2022 was $17.3 million, compared to $13.0 million for the three months ended March 31, 2022. The increase in research and development expense is attributable to the continued progression of the Company's PROC and ccRCC clinical trials, as well as increases in related CMC costs. General and administrative expense for the three months ended June 30, 2022 was $3.7 million, compared to $3.1 million for the three months ended March 31, 2022. The increase in general and administrative expense is attributable to increased stock-based compensation, increased consulting fees, and severance expense.

Aravive reported a net loss of $18.5 million, or $0.61 per share, for the three months ended June 30, 2022, compared to a net loss of $13.1 million, or $0.62 per share, for the three months ended March 31, 2022.

Cash Position
As of June 30, 2022, cash and cash equivalents were $46.8 million, compared to $65.8 million as of March 31, 2022 and $59.4 million as of December 31, 2021. The Company anticipates that its current cash and cash equivalents will fund its operating plans into the first quarter of 2023.

About Aravive

Aravive, Inc. is a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease. Our lead product candidate, batiraxcept (formerly AVB-500), is an ultra-high affinity decoy protein that binds to GAS6, the sole ligand that activates AXL, thereby inhibiting metastasis and tumor growth, and restoring sensitivity to anti-cancer agents. Batiraxcept has been granted Fast Track Designation by the U.S. FDA and Orphan Drug Designation by the European Commission in platinum-resistant recurrent ovarian cancer. Batiraxcept is in an active registrational Phase 3 trial in platinum resistant ovarian cancer (NCT04729608), a Phase 1b/2 trial in clear cell renal cell carcinoma (NCT04300140), and a Phase 1b/2 trial in pancreatic adenocarcinoma (NCT04983407). The Company is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. Additional information at www.aravive.com.

Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 on our current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “potential,” “continue,” “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates,” and similar expressions and include statements regarding the registration-directed Phase 3 program of batiraxcept in combination with paclitaxel in PROC remaining on track to complete enrollment by year end 2022, topline data from the trial being available in mid-2023, CMC work remaining on track with the goal of filing a BLA in late 2023 and the trial enrolling 350 patients with platinum resistant, high-grade serous ovarian cancer who have received 1-4 prior lines of therapy; the open-label Phase 2 portion of the ccRCC clinical trial enrolling 55 patients across three parts, Part A enrolling approximately 25 patients and investigating batiraxcept 15 mg/kg in combination with cabozantinib in 2L+ ccRCC patients, Part B enrolling approximately 20 patients and evaluating batiraxcept 15 mg/kg in combination with nivolumab and cabozantinib as a potential front-line treatment for ccRCC, Part C evaluating batiraxcept 15 mg/kg monotherapy in approximately 10 patients with ccRCC who are not eligible for curative intent therapies and being on track to report additional updated results from the Phase 1b portion of the ccRCC trial in the second half of 2022; being on track to report additional updated data from the Phase 1b portion of the pancreatic adenocarcinoma trial in the second half of 2022 and current cash and cash equivalents funding operating plans into the first quarter of 2023. Forward-looking statements are based on current beliefs and assumptions, are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those contained in any forward-looking statement as a result of various factors, including, but not limited to, risks and uncertainties related to: the ability to report data from the current clinical trials in accordance with current timelines, the data from patients treated in the future with batiraxcept being consistent with the results reported, the ability to enroll the expected number of patients, the impact of COVID-19 on the Company's clinical strategy, clinical trials, supply chain and fundraising, the Company's ability to expand development into additional indications, the Company's dependence upon batiraxcept, batiraxcept’s ability to have favorable results in clinical trials and ISTs, the clinical trials of batiraxcept having results that are as favorable as those of preclinical and clinical trials, the ability to receive regulatory approval, potential delays in the Company's clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients; the risk that batiraxcept may cause serious side effects or have properties that delay or prevent regulatory approval or limit its commercial potential; the risk that the Company may encounter difficulties in manufacturing batiraxcept; if batiraxcept is approved, risks associated with its market acceptance, including pricing and reimbursement; potential difficulties enforcing the Company's intellectual property rights; the Company's reliance on its licensor of intellectual property and financing needs. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, recent Current Reports on Form 8-K and subsequent filings with the SEC. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Aravive, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended June 30, 2022	Three Months Ended March 31, 2022
	(unaudited)	(unaudited)
Revenue		
Collaboration revenue	$ 1,615	$ 1,092
Total revenue	1,615	1,092
Operating expenses		
Research and development	17,315	13,002
General and administrative	3,727	3,088
Total operating expenses	21,042	16,090
Loss from operations	(19,427)	(14,998)
Other income, net	950	1,941
Net loss	$ (18,477)	$ (13,057)
Net loss per share- basic and diluted	$ (0.61)	$ (0.62)
Weighted-average common shares used to compute basic and diluted net loss per share	30,505	21,130

Aravive, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Revenue				
Collaboration revenue	$ 1,615	$ 3,789	$ 2,707	$ 4,045
Total revenue	1,615	3,789	2,707	4,045
Operating expenses				
Research and development	17,315	8,120	30,317	14,004
General and administrative	3,727	3,080	6,815	5,460
Total operating expenses	21,042	11,200	37,132	19,464
Loss from operations	(19,427)	(7,411)	(34,425)	(15,419)
Other income, net	950	306	2,891	310
Net loss	$ (18,477)	$ (7,105)	$ (31,534)	$ (15,109)
Net loss per share- basic and diluted	$ (0.61)	$ (0.35)	$ (1.22)	$ (0.78)
Weighted-average common shares used to compute basic and diluted net loss per share	30,505	20,414	25,844	19,247

Aravive, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2022	March 31, 2022
	(unaudited)	(unaudited)
Assets:		
Cash and cash equivalents	$ 46,833	$ 65,825
Restricted cash	2,431	2,431
Other assets	4,793	3,595
Operating lease right-of-use assets	1,834	2,020
Total assets	**$ 55,891**	**$ 73,871**
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 15,202	$ 13,086
Deferred revenue	5,412	7,027
Operating lease obligation	5,211	5,787
Warrant liability	—	8,772
Total liabilities	25,825	34,672
Total stockholders' equity	30,066	39,199
Total liabilities and stockholders' equity	**$ 55,891**	**$ 73,871**

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