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): May 25, 2023

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 7.01. Regulation FD Disclosure.

On May 25, 2022, Aravive, Inc. (the "Company") issued a press release announcing the presentation of updated results from its ongoing Phase 2 trial of batiraxcept in clear cell renal cell carcinoma (ccRCC) at the 2023 American Society of Clinical Oncology (ASCO) annual meeting, taking place June 2-6, 2023 in Chicago, IL and virtually.

Safety and clinical activity of batiraxcept as monotherapy in heavily pretreated patients with no curative intent, in combination with cabozantinib (cabo) in patients who had failed first line and subsequent therapies, and in combination with cabo and nivolumab (nivo) as first line therapy were evaluated.

The abstract was released by ASCO today and contains data available as of January 17, 2023. The poster will be presented at ASCO on June 3, 2023 and will have more mature data as of April 21, 2023 and will include:

- Batiraxcept monotherapy and batiraxcept plus cabo or cabo/nivo demonstrated a manageable safety profile, consistent with cabo and nivo prescribing information.
- Batiraxcept plus cabo showed promising results in previously IO and VEGF-TKI-treated ccRCC patients, with an objective response rate (ORR) of 50% in this population (n=12), compared to 38% (n=13) in patients with no prior VEGF-TKI.
- Batiraxcept plus cabo and nivo showed an ORR of 55% (n=11) in first-line treatment, consistent with combination first line therapies.
- In the batiraxcept monotherapy cohort (n=10), one patient attained stable disease, suggesting that batiraxcept achieves greatest activity in combination therapies, supporting the intended combination approach in the planned registrational Phase 3 trial.
- The combination of batiraxcept and cabo appears to improve median progression-free survival (mPFS) in patients previously treated with IO and VEGF-TKI treatments compared to those without prior VEGF-TKI exposure, consistent with the P1b data and supporting the intended target population of the planned Phase 3 trial.

A copy of the abstract titled "Phase 2 study of batiraxcept (AVB-S6-500, an AXL inhibitor) as monotherapy, in combination with cabozantinib (cabo), and in combination with cabo and nivolumab (nivo) in patients with advanced clear cell renal cell carcinoma (ccRCC)" is filed as an exhibit to this Current Report on Form 8-K.

The information in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release furnished as Exhibit 99. to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

Item 8.01. Other Events.

The Company presented updated results from its ongoing Phase 2 trial of batiraxcept in clear cell renal cell carcinoma (ccRCC) at the 2023 American Society of Clinical Oncology (ASCO) annual meeting, taking place June 2-6, 2023 in Chicago, IL and virtually. Safety and clinical activity of batiraxcept as monotherapy in heavily pretreated patients with no curative intent, in combination with cabozantinib (cabo) in patients who had failed first line and subsequent therapies, and in combination with cabo and nivolumab (nivo) as first line therapy were evaluated.

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Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press Release of Aravive, Inc.
99.2	Abstract titled "Phase 2 Study of Batiraxcept (AVB-S6-500, an AXL inhibitor) as Monotherapy, in combination with Cabozantinib (Cabo), and in combination with Cabo and Nivolumab (Nivo) in Patients with Advanced Clear Cell Renal Cell Carcinoma (ccRCC)"
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 report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 25, 2023

ARAVIVE, INC.
(Registrant)

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

Aravive to Present Promising Updated Data from Phase 2 Trial of Batiraxcept in Combination with Cabozantinib in Clear Cell Renal Cell Carcinoma at ASCO 2023

HOUSTON, TX, May 25, 2023 (GLOBE NEWSWIRE) - Aravive, Inc. (Nasdaq: ARAV, "the Company"), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced the presentation of updated results from its ongoing Phase 2 trial of batiraxcept in clear cell renal cell carcinoma (ccRCC) at the 2023 American Society of Clinical Oncology (ASCO) annual meeting, taking place June 2-6, 2023 in Chicago, IL and virtually. The poster presentation will highlight updated results from the Phase 2 portion of the trial in patients with advanced or metastatic ccRCC with or without prior line(s) of therapy, including immuno-oncology (IO)- and vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)-based therapies. In addition, an abstract highlighting batiraxcept data in pancreatic adenocarcinoma (PDAC) will be published in the 2023 ASCO Annual Meeting Proceedings.

"We are excited to present updated results from our Phase 2 trial in ccRCC, demonstrating the promise of batiraxcept plus cabozantinib combination therapy in this high unmet need population," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "These results continue to support our belief that the highest potential impact of batiraxcept in ccRCC is combined batiraxcept plus cabozantinib treatment in patients treated with prior IO and VEGF-TKI therapies. Importantly, this therapeutic combination and patient population will be the focus of our planned pivotal Phase 3 trial, which is anticipated to initiate the second half of 2023."

Poster Presentation Details:

Title:	Phase 2 study of batiraxcept (AVB-S6-500, an AXL inhibitor) as monotherapy, in combination with cabozantinib (cabo), and in combination with cabo and nivolumab (nivo) in patients with advanced clear cell renal cell carcinoma (ccRCC)
Presenter:	Kathryn Beckermann, MD, PhD
Abstract Number:	4534
Format/Session:	Poster; Genitourinary Cancer—Kidney and Bladder
Session Date/Time:	Saturday, June 3, 2023, 8:00 AM – 11:00 AM CDT

Safety and clinical activity of batiraxcept as monotherapy in heavily pretreated patients with no curative intent, in combination with cabozantinib (cabo) in patients who had failed first line and subsequent therapies, and in combination with cabo and nivolumab (nivo) as first line therapy were evaluated.

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- The combination of batiraxcept and cabo appears to improve median progression-free survival (mPFS) in patients previously treated with IO and VEGF-TKI treatments compared to those without prior VEGF-TKI exposure, consistent with the P1b data and supporting the intended target population of the planned Phase 3 trial.

Batiraxcept was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of systemic therapy, including both IO-based and VEGF-TKI-based therapies (either in combination or sequentially). Fast Track Designation was based on data submitted to the agency from 26 patients treated with 15 mg/kg or 20 mg/kg batiraxcept plus 60 mg cabozantinib in the Phase 1b ccRCC study as of September 26, 2022. Results showed no dose limiting toxicities at either dose of batiraxcept and demonstrated clinical activity of batiraxcept plus cabozantinib in patients with metastatic ccRCC. Following an End-of-Phase 2 meeting with the FDA, the Company anticipates initiating a registrational Phase 3 trial of batiraxcept in combination with cabozantinib in patients previously treated with IO and VEGF-TKI therapies in the second half of 2023.

Publication-only Abstract Details:

Title: Phase 1b Batiraxcept (AVB-S6-500, BT) plus Gemcitabine (G) and Nab-paclitaxel (NP) as first-line treatment (1L) for pancreatic adenocarcinoma (PDAC)
Abstract Number: e16258

As of January 17, 2023, safety, pharmacokinetics and clinical activity of batiraxcept plus gemcitabine and nab-paclitaxel as first-line treatment were evaluated in 21 patients with PDAC. Combination treatment was well-tolerated, with batiraxcept safety profiles consistent with prior trials. Patients who achieved trough concentrations greater than the model-informed minimum effective concentration (MEC) demonstrated significantly longer mPFS. As of May 2023, median overall survival (OS) for patients with trough levels above the minimal batiraxcept efficacious concentration is greater than 15 months, which is longer than historical data of 8.5 months. One patient who achieved >MEC by C2D1 has demonstrated a complete response from 10 months to 20 months and is still on study. Additional dose levels of batiraxcept in combination with gemcitabine and nab-paclitaxel are under study to see if higher doses will increase the proportion of patients with longer OS.

About Aravive
Aravive, Inc. is a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease. 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 for both clear cell renal cell carcinoma and platinum-resistant ovarian cancer 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 communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 includes statements regarding results continuing to support our belief that the highest potential impact of batiraxcept in ccRCC is combined batiraxcept plus cabozantinib treatment in patients treated with prior IO and VEGF-TKI therapies, the therapeutic combination and patient population being the focus of the planned pivotal Phase 3 trial Phase 3 trial initiation of a registrational Phase 3 trial of batiraxcept plus cabozantinib in patients previously treated with IO and VEGF-TKI therapies in 2H 2023following an End-of-Phase 2 meeting with the FDA . 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 enroll patients as anticipated at the planned sites, the ability to initiate the trial when anticipated and to provide data when anticipated; the Company's dependence upon batiraxcept; batiraxcept's ability to have favorable results in clinical trials; 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 especially in light of the COVID-19 pandemic; 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; and the Company's reliance on its licensor of intellectual property and financing needs and the cash runway being sufficient to sustain operations into the fourth quarter of 2023 and beyond the readout on the Company’s Phase 3 Ovarian cancer trial. 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, 2022, the Company’s Quarterly Reports on Form 10-Q for the fiscal quarter ended March 31, 2023, 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.

Investor Relations Contact:
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[i] Van Hoff, D.D., et al., 2013, Increased Survival in Pancreatic Cancer with nab-Paclitaxel plus Gemcitabine N Engl J Med 369;18

Phase 2 Study of Batiraxcept (AVB-S6-500, an AXL inhibitor) as Monotherapy, in combination with Cabozantinib (Cabo), and in combination with Cabo and Nivolumab (Nivo) in Patients with Advanced Clear Cell Renal Cell Carcinoma (ccRCC).

Katy Beckermann, Matthew T Campbell, Naomi B. Haas, Moshe Chaim Ornstein, Xin Gao, Shifeng S. Mao, Hans J. Hammers, Saby George, Ariel Ann Nelson, Theodore Stewart Gourdin, Holavanahalli Keshava-Prasad, Arif Hussain, Christopher J. Hoimes, Hongxia Yan, Vanessa Esquibel, Gail McIntyre, Robert B. Geller, Martin H Voss, Brian I. Rini, Neil J. Shah; Vanderbilt-Ingram Cancer Center, Nashville, TN; University of Texas MD Anderson Cancer Center, Houston, TX; University of Pennsylvania, Abramson Cancer Center, Philadelphia, PA; Cleveland Clinic, Cleveland, OH; Massachusetts General Hospital Cancer Center and Harvard Medical School, Boston, MA; Allegheny Health Network Cancer Institute - AGH, Pittsburgh, PA; UT Southwestern Medical Center, Dallas, TX; Roswell Park Comprehensive Cancer Center, Buffalo, NY; The Medical College of Wisconsin, Department of Medicine, Division of Hematology and Oncology, Milwaukee, WI; Medical University of South Carolina, Charleston, SC; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; University of Maryland Medical Center, Baltimore, MD; Duke Cancer Institute, Duke University, Durham, NC; Aravive, Inc., Houston, TX; Aravive Inc, Houston, TX; Aravive Inc, Lansdale, PA; Memorial Sloan Kettering Cancer Center and Weill Medical College, New York, NY; Department of Medicine, Vanderbilt University Medical Center, Nashville, TN; Memorial Sloan Kettering Cancer Center, New York, NY

Background: AXL is up-regulated by hypoxia-inducible factor-1 signaling in VHL- deficient tumor cells, playing a critical role in metastasis and resistance to VEGF- targeted therapies. Batiraxcept is a recombinant fusion protein containing an extracellular region of AXL combined with the human immunoglobulin G1 heavy chain (Fc), demonstrating potent and specific AXL inhibition through competitive binding of its ligand GAS6. A prior Phase 1b study showed promising outcomes for batiraxcept + cabo combination in patients who had failed first line (1L) therapy.

Methods: This trial tested batiraxcept 15 mg/kg every 2 weeks (q2w) in 3 cohorts of ccRCC patients: 1) batiraxcept monotherapy (n = 10) in patients with relapsing disease and no curative options; 2) batiraxcept + cabo 60 mg daily (QD) in patients with at least 1 prior therapy (n = 25); and 3) batiraxcept + cabo 40 mg QD and nivo 240 q2w or 480 mg q4w in 1L (n = 11). Primary endpoint was investigator assessed objective response rate (ORR) by RECIST v1.1, and key secondary endpoints were safety, progression free survival (PFS), and overall survival.

Results: Enrollment has completed as of 17-January-2023. In the 3 cohorts, IMDC intermediate + poor risk was 80%, 76%, and 27%, and median prior lines of therapy were 4, 2, 0. Prior immunotherapy (IO) was received by 100%, 88%, and 0% patients. One hundred percent of patients receiving monotherapy and 40% of 2L patients receiving batiraxcept + cabo had received prior VEGF-TKIs. Table 1 describes efficacy and safety across the 3 cohorts.

Conclusions: Batiraxcept monotherapy was well tolerated but had limited clinical activity. Batiraxcept-based combinations demonstrated efficacy and tolerability. Given encouraging safety and efficacy signals, batiraxcept + cabo will be further studied in a phase 3 trial of 2L+ ccRCC patients whose disease has progressed on prior IO and VEGF-TKI treatment. Exploratory analysis for a baseline serum soluble AXL/GAS6 ratio biomarker was found to have predictability for clinical activity in the phase 1b study evaluating batiraxcept + cabo in patients who had failed 1L therapies; a similar analysis using the biomarker is ongoing for this patient population.

Table 1	Batiraxcept monotherapy N = 10	Batiraxcept + Cabo N = 25	Batiraxcept Cabo + Niv N = 11
ORR (CR + PR confirmed), n (%) (95% CI)	0 0, 30.8	9 (36) 18.0, 57.5	6 (55) 16.7, 76.6
Clinical Benefit Rate (ORR+stable disease), n (%), (95% CI)	1 (10) 0.3, 44.5	18 (72) 50.6, 87.9	7 (64) 30.8, 89.1
mPFS months (95% CI) Censor (n), Events (n)	1.8 (0.5, 3.7) 1, 9	7.2 (4.9, NE) 17, 8	7.6 (2.0, NE 6, 5
All batiraxcept related AEs*, n (%)	8 (80)	17 (68)	10 (91)
Grade ≥ 3 batiraxcept related AEs, n (%)	1 (10)	7 (28)	5 (46)

*All cohorts ≥ 20%: Diarrhea, fatigue, and infusion-related reaction