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 26, 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 7.01. Regulation FD Disclosure.

On May 26, 2022, Aravive, Inc. (the "Company") issued a press release announcing the presentation of updated Phase 1b/2 ccRCC data at the 2022 American Society of Clinical Oncology (ASCO) annual meeting, taking place June 3-7 in Chicago (the "2022 ASCO Annual Meeting").

A summary of the interim Phase 1b results include (as of April 30, 2022, the cut-off date):
- Batiraxcept 15 mg/kg in combination with cabozantinib 60 mg has a manageable safety profile in previously treated ccRCC; no dose-limiting toxicities have been observed; a similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts.
- Batiraxcept given every 2 weeks suppressed serum GAS6 to below the level of quantitation in 25/26 patients (1 patient did not have an assessment), showing a clear pharmacokinetic (PK)/pharmacodynamic (PD) relationship; 23/26 patients had batiraxcept trough levels above the minimally efficacious concentration of 13.8 mg/L by Cycle 2.
- The confirmed + unconfirmed response rate in the total population was 46% with a 50% confirmed response rate in the 15mg/kg (RP2D) batiraxcept group.
- The proportion of patients in the total population who were progression free at 7 months was 71%.
- The proportion of patients in the total population who had a duration of response of at least 7 months was 75%.
- A baseline biomarker enriched the confirmed response rate in the RP2D (15mg/kg) biomarker high population to 67%, increased the proportion of patients progression free at 7 months to 91% and increased the proportion of patients who had a duration of response of at least 7 months to 80%.
- 58% (15/26) of total population achieved a better response on the batiraxcept trial than they did with their therapy prior to study entry, which was only 23%.
- The safety and clinical activity of this combination together with PK/PD data support a RP2D of 15 mg/kg.

A copy of the abstract titled "A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell (ccRCC) carcinoma who have received front-line treatment (NCT04300140)" and "A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib, cabozantinib and nivolumab, and as monotherapy in patients with advanced or metastatic clear cell renal cell carcinoma (NCT04300140)" are filed as exhibits 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 99.1 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 Phase 1b/2 ccRCC data at the 2022 ASCOAnnual Meeting.

A summary of the interim Phase 1b results include (as of April 30, 2022, the cut-off date):
- Batiraxcept 15 mg/kg in combination with cabozantinib 60 mg has a manageable safety profile in previously treated ccRCC; no dose-limiting toxicities have been observed; a similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts.
- Batiraxcept given every 2 weeks suppressed serum GAS6 to below the level of quantitation in 25/26 patients (1 patient did not have an assessment), showing a clear pharmacokinetic (PK)/pharmacodynamic (PD) relationship; 23/26 patients had batiraxcept trough levels above the minimally efficacious concentration of 13.8 mg/L by Cycle 2.
- The confirmed + unconfirmed response rate in the total population was 46% with a 50% confirmed response rate in the 15mg/kg (RP2D) batiraxcept group.
- The proportion of patients in the total population who were progression free at 7 months was 71%.
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- A baseline biomarker enriched the confirmed response rate in the RP2D (15mg/kg) biomarker high population to 67%, increased the proportion of patients progression free at 7 months to 91% and increased the proportion of patients who had a duration of response of at least 7 months to 80%.
- 58% (15/26) of total population achieved a better response on the batiraxcept trial than they did with their therapy prior to study entry, which was only 23%.
- The safety and clinical activity of this combination together with PK/PD data support a RP2D of 15 mg/kg.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press Release of Aravive, Inc.
99.2	Abstract titled "A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell (ccRCC) carcinoma who have received front-line treatment (NCT04300140)"
99.3	Abstract titled "A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib, cabozantinib and nivolumab, and as monotherapy in patients with advanced or metastatic clear cell renal cell carcinoma (NCT04300140)"
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 26, 2022

ARAVIVE, INC.
(Registrant)

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

aravive

Aravive Presents 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 on Genitourinary Cancer on Saturday June 4, 2022
- Development of biomarker offers the potential of a first in class targeted therapy in renal cancer
- Company has a registrational path for potential accelerated approval as well as full approval of batiraxcept in 2L+ ccRCC

Houston, TX, May 26, 2022 - 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 Phase 1b/2 ccRCC data at the 2022 American Society of Clinical Oncology (ASCO) annual meeting, taking place June 3-7, 2022 in Chicago. The abstract presents the updated response rate, landmark progression-free-survival data, and biomarker data.

"We are jubilant about the selection of the poster on the use of batiraxcept in 2L+ ccRCC for oral discussion at this year's ASCO annual meeting," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "This is a rare opportunity provided only to select abstracts at this meeting. Batiraxcept continues to show best-in-class potential in advanced or metastatic clear cell renal carcinoma, platinum resistant ovarian cancer, and pancreatic cancer. Enrollment in the registration directed Phase 3 program in PROC remains on pace to complete this year and we look forward to providing updates on the renal and pancreatic cancer programs throughout 2022."

Abstract Title:	*A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC) who have received front-line treatment (NCT04300140)*
Abstract Number:	4511 (Poster Discussion Session – Data will be presented)
Poster Session:	Genitourinary Cancer—Kidney and Bladder
Session Date:	Poster Presentation: Saturday, June 4, 2022,1:15 PM - 4:15 PM CDT Discussion: Saturday, June 4, 2022, 4:30 PM CDT (5:30 PM EDT)

Abstract Title:	*A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib, cabozantinib and nivolumab, and as monotherapy in patients with advanced or metastatic clear cell renal cell carcinoma (NCT04300140)*
Abstract Number:	TPS4599 (Trials in Progress poster – No data presented)
Poster Session:	Genitourinary Cancer—Kidney and Bladder
Session Date:	Saturday, June 4, 2022, 1:15 PM-4:15 PM CDT

Of note, 100% of patients had received a prior immunotherapy, 77% of the patients were in the IMDC (International Metastatic RCC Database Consortium) Risk Score of intermediate or poor, and 39% of the patients had received 2 or more prior lines of therapy prior to study entry.

A summary of the interim Phase 1b results include (as of April 30, 2022, the cut-off date):
- Batiraxcept 15 mg/kg in combination with cabozantinib 60 mg has a manageable safety profile in previously treated ccRCC; no dose-limiting toxicities have been observed; a similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts.
- Batiraxcept given every 2 weeks suppressed serum GAS6 to below the level of quantitation in 25/26 patients (1 patient did not have an assessment), showing a clear pharmacokinetic (PK)/pharmacodynamic (PD) relationship; 23/26 patients had batiraxcept trough levels above the minimally efficacious concentration of 13.8 mg/L by Cycle 2.
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- The proportion of patients in the total population who had a duration of response of at least 7 months was 75%.
- A baseline biomarker enriched the confirmed response rate in the RP2D (15mg/kg) biomarker high population to 67%, increased the proportion of patients progression free at 7 months to 91% and increased the proportion of patients who had a duration of response of at least 7 months to 80%.
- 58% (15/26) of total population achieved a better response on the batiraxcept trial than they did with their therapy prior to study entry, which was only 23%.
- The safety and clinical activity of this combination together with PK/PD data support a RP2D of 15 mg/kg.

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, inhibiting metastasis, 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 European Commission in PROC. 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 development of the biomarker offering the potential of a first in class targeted therapy in renal cancer, having a registrational path for potential accelerated approval as well as full approval of batiraxcept in 2L+ ccRCC, enrollment in the registration directed Phase 3 program in PROC remaining on pace to

complete this year and providing updates on the renal and pancreatic cancer programs throughout 2022. 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 of the biomarker to offer the potential of a first in class targeted therapy in renal cancer, the ability to obtain accelerated approval as well as full approval of batiraxcept in 2L+ ccRCC ; 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, 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.

Contact:
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Exhibit 99.2

A Phase 1b/2 study of Batiraxcept (AVB-S6-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC) received front-line treatment (NCT04300140)

Background: AXL is up-regulated by hypoxia-inducible factor-1 signaling in both VHL-deficient and hypoxic tumor cells and plays a critical role in the metastatic phenotype of ccRCC. Batiraxcept is a recombinant fusion protein containing an extracellular region of human AXL combined with the human immunoglobulin G1 heavy chain (Fc), demonstrating highly potent, specific AXL inhibition.

Methods: Batiraxcept at doses of 15 and 20 mg/kg, plus cabozantinib 60 mg daily, was evaluated using a 3+3 dose escalation study design. The primary objective was safety; secondary and exploratory objectives included identification of the recommended phase 2 dose (RP2D), overall response rate (ORR), and duration of response (DOR). Correlation of serum soluble AXL (sAXL)/GAS6 with ORR was evaluated. Key eligibility criteria include previously treated (2L+) ccRCC patients; prior treatment with cabozantanib was not allowed. sAXL/GAS6 was evaluated at baseline.

Results: Data as of 4-February-2022, Phase 1b enrolled 26 patients, 16 patients treated with 15 mg/kg and 10 patients with 20 mg/kg dose of batiraxcept. Baseline characteristics: median age 60 (40-81); male 22 (85%); median prior line of therapy 1 (1-5); IMDC risk group of favorable 6 (23%); prior VEGF inhibitor 15 (58%); 100% with prior immunotherapy.

At median follow up of 4.9 months, 92% (n=24) patients remained on the study. No dose limiting toxicities were observed at either 15 mg/kg or 20 mg/kg dose. Batiraxcept and cabozantinib related adverse events (AEs) occurred in 17 subjects (65%). Most common related AE include decreased appetite 31% (n=8), diarrhea and fatigue 23% (n=6). Grade 3 related AEs occurred in 4 patients (15%) including diarrhea, thromboembolism, hypertension, small bowel obstruction, and thrombocytopenia (n=1, 4% each) being most common. No grade 4 or 5 related AEs were observed.

The ORR was 46% (n=12, partial response [PR], Table 1). No patients had progressive disease as a best response. Among the patients who had baseline sAXL/GAS6 ratio of ≥ 2.3, the ORR was 67% (12/18). Regardless of baseline sAXL/GAS6 ratio, 3-month DOR was 100%; and 6-month progression free survival was 79%. Batiraxcept PK levels were similar across both doses and GAS6 levels suppressed through the dosing period.

Conclusions: Batiraxcept plus cabozantinib is well tolerated. The RP2D of batiraxcept was identified as 15 mg/kg. Early efficacy signals were observed including 100% DOR at 3 months. Baseline sAXL/GAS6 may serve as a potential biomarker to enrich the population.

Table 1	Entire Cohort N=26 (%)	Batiraxcept 15 mg/kg Cohort N=16 (%)	Batiraxcept 20 mg/kg Cohort N=10 (%)
ORR (confirmed + unconfirmed)	12 PR (46)	9 PR (56)	3 PR (30)
DOR (3-month)	26 (100)	26 (100)	Not reached
Any Grade related AEs	17 (65)	11 (69)	6 (60)
Grade ≥3 related AEs	4 (15)	2 (13)	2 (20)

Exhibit 99.3

A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib, cabozantinib and nivolumab, and as monotherapy in patients with advanced or metastatic clear cell renal cell carcinoma (NCT04300140)

Background:

In clear cell renal cell carcinoma (ccRCC) the constitutive expression of hypoxia induced factor 1-α leads to increased expression of AXL. AXL overexpression has been associated with the development of resistance to VEGF inhibitors and suppression of the innate immune response through inhibition of macrophage-driven inflammation. Batiraxcept is a recombinant fusion protein dimer containing an extracellular region of human AXL combined with the human immunoglobulin G1 heavy chain (Fc), which demonstrates highly potent, specific AXL inhibition. In preclinical studies using the 786-O, M62, and SN12L1 tumors, batiraxcept monotherapy resulted in a significant reduction of tumor growth compared to control. In healthy volunteer and ovarian cancer clinical studies, batiraxcept was well tolerated with no dose-related adverse events, and a maximum tolerated dose was not reached. Therefore, batiraxcept could be tested as either a monotherapy or in combination with standard of care drugs in patients with metastatic ccRCC.

The Phase 1b dose-escalation portion of this study evaluated batiraxcept in combination with standard of care cabozantanib in patients who progressed on or after first line therapy. No DLT was observed at either of two batiraxcept doses evaluated. The recommended Phase 2 dose of batiraxcept has been identified as 15 mg/kg every 2 weeks (q2w) with cabozantinib 60 mg based upon safety, PK/PD, and preliminary efficacy data.

Methods:

This Phase 2, multi-center, open-label study includes three parts: Part A) batiraxcept 15 mg/kg q2w in combination with cabozantinib 60 mg daily for ccRCC subjects who have progressed on or after one line of therapy, n=25. Part B) batiraxcept 15 mg/kg q2w with cabozantinib 40 mg daily and nivolumab at the investigator’s choice (240 mg q2w or 480 mg q4w) for first line treatment of advanced or metastatic ccRCC subjects, n=20. If no safety signals are observed in the first 6 subjects enrolled, 10 subjects will be enrolled in the first stage of a Simon 2-stage minmax statistical design. If ≥ 6/10 subjects achieve PR or CR, stage 2 will open to enroll up to 20 total subjects. Part C) batiraxcept 15 mg/kg q2w monotherapy for subjects with advanced/metastatic ccRCC ineligible for curative intent therapies, n=10.

The primary objective for each arm is objective response rate by RECIST v1.1. Secondary objectives include safety, duration of response, clinical benefit rate, progression free survival by RECIST v1.1, and overall survival. Exploratory objectives include pharmacokinetic and pharmacodynamic assessments.

The Phase 2 portion of this Ph1b/2 study is currently enrolling. Clinical trial information: NCT04300140