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): November 9, 2021

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 Instructions 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 November 9, 2021, Aravive, Inc. (the "Company") issued a press release announcing that an abstract titled "A Phase 1b/2 randomized study of AVB-S6-500 in combination with cabozantinib versus cabozantinib alone in patients with advanced clear cell renal cell carcinoma who have received front-line treatment" that it had submitted to the Society for Immunotherapy of Cancer (SITC) in connection with its 36th Annual Meeting was published.

As of July 21, 2021, seven patients received at least one dose of batiraxcept (AVB-500) 15 mg/kg in combination with cabozantinib, six patients were ongoing treatment, and five patients were evaluable for efficacy. No dose-limiting toxicities were observed in the first three evaluable patients. Trough levels at cycle 1 day 15 were above the minimal efficacious concentration identified from the Company's model informed drug development approach, and serum GAS6 levels were suppressed prior to cycle 2 day 1. A best overall response of partial response was observed in 3 of 5 patients (60%, unconfirmed as of July 21, 2021), based on investigator assessment, RECIST v 1.1 criteria. In addition, all patients demonstrated tumor decrease from baseline.

A copy of the Abstract is furnished to this Current Report on Form 8-K as Exhibit 99.2. The press release and Abstract are being furnished and 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 such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference 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.

The furnishing of the attached Abstract is not an admission as to the materiality of any information therein. The information contained in the Abstract is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

Item 8.01 Other Information

On November 9, 2021, the Company issued a press release announcing that an abstract titled "A Phase 1b/2 randomized study of AVB-S6-500 in combination with cabozantinib versus cabozantinib alone in patients with advanced clear cell renal cell carcinoma who have received front-line treatment" that it had submitted to the Society for Immunotherapy of Cancer (SITC) in connection with its 36th Annual Meeting was published.

As of July 21, 2021, seven patients received at least one dose of batiraxcept (AVB-500) 15 mg/kg in combination with cabozantinib, six patients were ongoing treatment, and five patients were evaluable for efficacy. No dose-limiting toxicities were observed in the first three evaluable patients. Trough levels at cycle 1 day 15 were above the minimal efficacious concentration identified from the Company's model informed drug development approach, and serum GAS6 levels were suppressed prior to cycle 2 day 1. A best overall response of partial response was observed in 3 of 5 patients (60%, unconfirmed as of July 21, 2021), based on investigator assessment, RECIST v 1.1 criteria. In addition, all patients demonstrated tumor decrease from baseline.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit Number	Description
99.1	Press Release dated November 9, 2021
99.2	Abstract titled "A Phase 1b/2 randomized study of AVB-S6-500 in combination with cabozantinib versus cabozantinib alone in patients with advanced clear cell renal cell carcinoma who have received front-line treatment"
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: November 9, 2021

ARAVIVE, INC.
(Registrant)

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

Aravive Announces Positive Preliminary Data from Phase 1b Trial Evaluating Batiraxcept (AVB-500) in Combination with Cabozantinib in Clear Cell Renal Cell Carcinoma to be Presented at 2021 Society for Immunotherapy of Cancer Annual Meeting

3 of 5 (60%) patients achieved a partial response
All 5 patients treated demonstrated tumor decrease from baseline
Batirxcept has been generally well-tolerated with no dose-limiting toxicities
Aravive to host conference call and webcast on November 12 at 8:30 a.m. ET to discuss updated data

Houston, TX, November 9, 2021 – Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative, targeted therapeutics to treat life-threatening cancers, today announced that positive new data from the Phase 1b portion of its open-label Phase 1b/2 trial evaluating batiraxcept (AVB-500) in combination with cabozantinib in patients with clear cell renal cell carcinoma (ccRCC) will be presented at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting on November 13, 2021. The presentation will highlight interim safety, pharmacokinetic (PK), pharmacodynamic (PD), and clinical activity data.

"We are encouraged by the preliminary performance of batiraxcept in combination with cabozantinib in patients with clear cell renal cell carcinoma," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "These results highlight the potential of batiraxcept to improve outcomes for patients with advanced kidney cancer. We look forward to sharing these new clinical data with the research and medical community at this year's SITC Annual Meeting."

As of July 21, 2021, seven patients received at least one dose of batiraxcept 15 mg/kg in combination with cabozantinib, six patients were ongoing treatment, and five patients were evaluable for efficacy. No dose-limiting toxicities were observed. Trough levels at cycle 1 day 15 were above the minimal efficacious concentration identified from the Company's model informed drug development approach, and serum GAS6 levels were suppressed prior to cycle 2 day 1. A best overall response of partial response was observed in 3 of 5 patients (60%, unconfirmed as of July 21, 2021), based on investigator assessment, RECIST v 1.1 criteria. In addition, all patients demonstrated tumor decrease from baseline.

Aravive's presentation at the SITC Annual Meeting will include updated safety, PK, PD, and clinical activity data from a larger set of patients treated with batiraxcept 15 mg/kg in combination with cabozantinib as of October 16, 2021.

Poster Presentation Details

Title: A Phase 1b/2 randomized study of AVB-S6-500 in combination with cabozantinib versus cabozantinib alone in patients with advanced clear cell renal cell carcinoma who have received front-line treatment

Presenter: Reshma Rangwala, M.D., Ph.D., Chief Medical Officer of Aravive

Date: November 13, 2021

Time: 7:00 AM – 8:30 PM ET

Location: Hall E

For additional information, please visit the SITC 36th Annual Meeting website: https://www.sitcancer.org/2021/home.

Conference Call Information
Aravive will host a conference call and webcast on November 12, 2021 at 8:30 a.m. ET to discuss these clinical data. The conference call may be accessed by dialing (877) 423-9813 (domestic) and (201) 689-8573 (international) and referring to conference ID 13724115. A webcast of the conference call will be available in the Investors section of the Aravive website at https://ir.aravive.com/. The archived webcast will be available on Aravive's website after the conference call.

About the Batiraxcept (AVB-500) Phase 1b/2 ccRCC Trial
Aravive initiated the Phase 1b portion of the Phase 1b/2 trial of batiraxcept in ccRCC in March 2021. The Phase 1b portion of the clinical trial, a dose escalation study, is expected to enroll approximately 18 patients in three dosing arms (15 mg/kg, 20 mg/kg and 25 mg/kg) to evaluate tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of batiraxcept in combination with cabozantinib. The controlled, randomized, open-label Phase 2 portion of the clinical trial is expected to enroll approximately 45 patients and investigate the recommended batiraxcept dose identified during the Phase 1b portion of the clinical trial in combination with cabozantinib versus cabozantinib alone. The primary endpoint is progression-free survival. The trial is enrolling patients with advanced ccRCC who have progressed on front-line treatment. The Phase 1b/2 trial is listed on clinicaltrials.gov NCT04300140.

About Batiraxcept (AVB-500)
Batiraxcept is a therapeutic recombinant fusion protein that has been shown to neutralize GAS6 activity by binding to GAS6 with very high affinity in preclinical models. In doing so, batiraxcept selectively inhibits the GAS6-AXL signaling pathway, which is upregulated in multiple cancer types including ovarian, renal and pancreatic cancer. In preclinical studies, GAS6-AXL inhibition has shown anti-tumor activity in combination with a variety of anticancer therapies, including radiation therapy, immuno-oncology agents, and chemotherapeutic drugs that affect DNA replication and repair. Increased expression of AXL and GAS6 in tumors has been correlated with poor prognosis and decreased survival and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies. Batiraxcept is currently being evaluated in multiple clinical trials and has been granted Fast Track designation by the U.S. Food and Drug Administration and orphan drug designation by the European Commission in platinum resistant recurrent ovarian cancer.

About Aravive
Aravive, Inc. is a clinical-stage oncology company developing transformative, targeted therapeutics to treat life-threatening cancers. The Company is currently evaluating its lead therapeutic, batiraxcept (AVB-500), in a registrational Phase 3 trial in platinum resistant ovarian cancer, a Phase 1b/2 trial in second line plus, clear cell renal cell carcinoma, and a Phase 1b/2 trial in first-line treatment of pancreatic adenocarcinoma. The Company is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. For more information, please visit 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 the potential of batiraxcept (AVB-500) to improve outcomes for patients with advanced kidney cancer. 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 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 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; 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, 2020, 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.

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A Phase 1b/2 randomized study of AVB-S6-500 in combination with cabozantinib versus cabozantinib alone in patients with advanced clear cell renal cell carcinoma who have received front-line treatment (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. AVB-S6-500 (AVB-500) is 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 a mouse ccRCC xenograft model, AVB-500 showed significantly more tumor reduction in combination with pazopanib versus pazopanib alone. In a Ph1b study of AVB-500 plus chemotherapy in platinum-resistant ovarian cancer (NCT03639246), no dose limiting toxicity (DLT) or treatment discontinuation due to adverse events was observed. The recommended phase 2 dose (RP2D) of 15 mg/kg was established by a model-informed drug development (MIDD) approach.

Trial design

The P1b portion of this trial is a 3+3 dose escalation study to evaluate safety, pharmacokinetics, and pharmacodynamics of AVB-500 in combination with cabozantinib 60 mg daily in patients with advanced ccRCC. Dose levels of AVB-500 evaluated include 15, 20, and 25 mg/kg every two weeks. The primary objective is to evaluate safety and tolerability. Secondary objectives include identification of the RP2D of AVB-500 and clinical activity. Key eligibility criteria include clear cell histology RCC and at least one prior line of therapy administered in the advanced or metastatic setting.

Results

As of July 21, 2021, seven patients have received at least one dose of AVB-500 15 mg/kg and cabozantinib, with six patients ongoing treatment. No DLTs were observed. Trough levels at C1D15 were above the minimally efficacious concentration (MEC) identified from MIDD and serum GAS6 (AXL ligand) levels were suppressed prior to C2D1. Partial responses were observed in 3 of 5 patients (Table 1); all patients demonstrated tumor decrease from baseline.

Table 1: Preliminary Clinical Activity in NCT04300140

	Prior lines of therapy in the advanced/metastatic setting	# Cycles completed	Best overall response
102-001	1) Nivolumab/ipilimumab 2) Axitinib 3)	1.5, discontinued study	SD
102-002	1) Pazopanib 2) Pembrolizumab/axitinib	3, ongoing	SD
103-001	1) Nivolumab/ipilimumab	4, ongoing	PR, unconfirmed
105-002	1) Sunitinib 2) Nivolumab	2, ongoing	PR, unconfirmed
107-002	1) Pazopanib 2) Everolimus 3) Axitinib 4) Nivolumab/ipilimumab 5) Pembrolizumab/axitinib (Best response to therapy PD)	2, ongoing	PR, unconfirmed

Summary:

AVB-500 in combination with cabozantanib demonstrates promising preliminary clinical activity and tolerability in patients with ccRCC. AVB-500 15 mg/kg is the presumptive RP2D with C1D15 AVB-500 troughs consistently above MECs observed in the Ph1b OC trial. Safety, PK/ PD and clinical activity will be updated at the time of presentation.