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): March 8, 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 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 March 8, 2020, Aravive, Inc. (the "Company") issued a press release announcing that the Company has dosed its first patient in an open label Phase 1b/2 clinical trial to evaluate the safety, pharmacokinetic, and preliminary clinical activity of AVB-500, including progression free survival. The trial will enroll patients with advanced clear cell renal cell carcinoma (ccRCC) that have progressed on front-line treatment. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and in the press release attached 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. The information contained in this Item 7.01 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K 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 attached 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 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 if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

Item 8.01. Other Events.

On March 8, 2021, the Company issued a press release announcing that the Company has dosed its first patient in an open label Phase 1b/2 clinical trial to evaluate the safety, pharmacokinetic, and preliminary clinical activity of AVB-500, including progression free survival. The trial will enroll patients with advanced clear cell renal cell carcinoma (ccRCC) that have progressed on front-line treatment.

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 March 8, 2021

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.

March 8, 2021

ARAVIVE, INC.
(Registrant)

By: /s/ Vinay Shah
Name: Vinay Shah
Title: Chief Financial Officer

Aravive Announces First Patient Dosed in Phase 1b/2 Clinical Trial of AVB-500 in Patients with Clear Cell Renal Cell Carcinoma

Lead Compound AVB-500 Now Being Evaluated in Broad Range of Cancers

Houston, TX, March 8, 2021 – Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative therapeutics, today announced that the Company has dosed its first patient in an open label Phase 1b/2 clinical trial to evaluate the safety, pharmacokinetic, and preliminary clinical activity of AVB-500, including progression free survival. The trial will enroll patients with advanced clear cell renal cell carcinoma (ccRCC) that have progressed on front-line treatment.

AVB-500 is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway associated with tumor cell growth and is currently being evaluated in clinical trials for the treatment of ovarian, kidney and urothelial cancer.

“The preclinical data of AVB-500 in ccRCC suggest a great potential in treating this cancer without adding toxicity,” said Gail McIntyre, Ph.D., Chief Executive Officer of Aravive. “Given that there is a large unmet need for effective treatments in renal cell carcinoma, we look forward to advancing the development of AVB-500 to potentially improve outcomes for patients with renal cancer.”

Kidney cancer is a leading cause of cancer-related deaths in the United States and is among the 10 most common cancers in both men and women. ccRCC is a cancer of the kidney and accounts for more than 75% of malignant kidney tumors. Metastasis to distant organs including the lung, bone, liver and brain is the primary cause of death in kidney cancer patients, and only 12% of people with metastatic kidney cancer will survive past 5 years. According to the American Cancer Society, it is estimated that there will be approximately 76,080 new cases of kidney cancer and 13,780 people will die from this disease in the United States during 2021.

“AXL/GAS6 is associated with poor prognosis and resistance mechanisms in renal cell carcinoma. This trial will focus on safety and early efficacy signals of AVB-500 in combination with cabozantinib in patients who have progressed after front-line treatment of kidney cancer. This trial presents a unique opportunity to study a new therapeutic target in combination with cabozantinib,” said Kathryn Beckermann, M.D., Ph.D., Assistant Professor, Division of Hematology and Oncology, Vanderbilt University Medical Center and lead investigator for the trial.

The Phase 1b portion of the trial will evaluate AVB-500 in combination with cabozantinib, a small molecule inhibitor of the tyrosine kinases c-Met and VEGFR2. The trial will enroll up to 18 patients in three dosing arms (15 mg/kg, 20 mg/kg and 25 mg/kg) to evaluate tolerability, pharmacokinetics, pharmacodynamics, and clinical activity. The controlled, randomized, open-label Phase 2 portion of the trial will enroll up to 45 patients and investigate the recommended AVB-500 dose identified during the Phase 1b portion of the trial in combination with cabozantinib versus cabozantinib alone. The primary endpoint of the Phase 2 portion of the trial is progression-free survival and the secondary endpoints are objective response rate, duration of response, clinical benefit rate and overall survival. The Phase 1b/2 trial is listed on clinicaltrials.gov NCT04300140.

About AVB-500
AVB-500 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, AVB-500 selectively inhibits the GAS6-AXL signaling pathway, which is upregulated in multiple cancer types including ovarian cancer and clear cell renal 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. AVB-500 is currently being evaluated in clinical trials and has been granted Fast Track Designation by the U.S. Food and Drug Administration in platinum resistant recurrent ovarian cancer. Analysis of all safety data to date showed that AVB-500 has been generally well-tolerated with no dose-limiting toxicities or unexpected safety signals.

About Aravive
Aravive, Inc. is a clinical-stage oncology company developing transformative therapeutics designed to halt the progression of life-threatening diseases. Aravive is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. Aravive's lead product candidate, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway associated with tumor cell growth. Aravive successfully completed a Phase 1b trial of AVB-500 in platinum resistant ovarian cancer and is in the process of initiating a registrational Phase 3 trial of AVB-500 at a dose of 15 mg/kg. While the Phase 1b trial of AVB-500 in platinum resistant ovarian cancer was a safety trial and not powered to demonstrate efficacy, all 5 patients in the 15 mg/kg cohort experienced clinical benefit, with 1 complete response, 2 partial responses, and 2 stable disease. For more information, please visit www.aravive.com.

Forward-Looking Statements
This communication contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended), express or implied, such statements regarding the potential for AVB-500 to treat clear cell renal cell carcinoma without adding toxicity and advancing the development of AVB-500 to potentially improve outcomes for patients with renal 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: our ability to show the potential for AVB-500 to treat clear cell renal cell carcinoma without adding toxicity, our ability to advance the development of AVB-500 to potentially improve outcomes for patients with renal cancer, the Company's dependence upon AVB-500, AVB-500's ability to have favorable results in clinical trials and ISTs, the clinical trials of AVB-500 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 AVB-500 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 AVB-500, if AVB-500 is approved, risks associated with its market acceptance, including pricing and reimbursement, potential difficulties enforcing the Company's intellectual property rights, the

Company's ability to expand development into additional oncology indications, and 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, 2019, 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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