
**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): December 20, 2019

Aravive, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36361
(Commission
File Number)

26-4106690
(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 December 20, 2019, Aravive, Inc. (the “Company”) issued a press release announcing that it has begun enrolling patients in the Phase 2a clinical trial of AVB-500 in patients with kidney fibrosis, specifically IgA Nephropathy (IgAN) (NCT04042623). A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 attached to this Current Report on Form 8-K are being furnished under Item 7.01 of Form 8-K. Such information shall not be deemed “filed” for 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 it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

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 or the press release attached to this Current Report on Form 8-K as Exhibit 99.1, 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 December 20, 2019, the Company announced that it has begun enrolling patients in the Phase 2a clinical trial of AVB-500 in patients with kidney fibrosis, specifically IgA Nephropathy (IgAN) (NCT04042623).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit Number	Description
99.1	Press Release of Aravive, Inc. dated December 20, 2019

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: December 20, 2019

ARAVIVE, INC.
(Registrant)

By: /s/ Jay P. Shepard
Name: Jay P. Shepard
Title: Chief Executive Officer

Aravive Initiates a Phase 2a Clinical Trial of AVB-500 in Patients with Kidney Fibrosis

HOUSTON, Dec. 20, 2019 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage biopharmaceutical company, today announced that the company has begun enrolling patients in the Phase 2a clinical trial of AVB-500 in patients with kidney fibrosis, specifically IgA Nephropathy (IgAN) (NCT04042623).

“We are very pleased to initiate this first trial of AVB500 in patients with renal fibrosis,” said Gail McIntyre Ph.D., DABT, CSO at Aravive. “GAS6 is more highly expressed in human IgAN tissues than normal kidney tissue, GAS6 levels correlate with severity of the disease and inhibition of the pathway preclinically has demonstrated a positive effect.”

This is an open-label Phase 2a clinical study designed to evaluate the safety and efficacy of AVB500 in patients with biopsy-proven IgAN and excreting 1-3 grams of protein daily in their urine. The primary endpoints will be safety of AVB500 in the population and efficacy of AVB500 treatment on decreasing the amount of protein in the urine.

IgAN, also known as Berger's disease, is a kidney disease that occurs when an antibody called immunoglobulin A builds up in the kidneys. This results in local inflammation that, over time, damages the kidneys. Preclinical studies have demonstrated that GAS6 acts as a mitogen, stimulating mesangial cell proliferation through binding to its cell-surface receptor AXL and an AXL decoy protein can inhibit mesangial cell proliferation by interfering with the GAS6/AXL pathway. IgA nephropathy usually progresses slowly over years and patients can develop end-stage kidney failure, requiring dialysis. No cure exists for IgAN, but certain medications can slow its course.

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 doing so, AVB-500 selectively inhibits the GAS6-AXL signaling pathway. In preclinical studies, GAS6-AXL inhibition has shown anti-tumor activity, both

as a single agent and 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 is correlated to poor prognosis and survival, and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies.

Aravive reported positive data from the expansion cohort in the Phase 1b portion of a Phase 1b/2 clinical trial of AVB-500 in platinum-resistant recurrent ovarian cancer. AVB-500 continues to be well tolerated with no dose limiting toxicities. An investigator-sponsored Phase I study of AVB-500, in combination with durvalumab in patients with platinum-resistant recurrent epithelial ovarian cancer, is also ongoing. Based on AVB-500's safety profile and specifically targeted mechanism of action, this drug candidate has the potential to be used both in combination with existing therapies, as well as a maintenance drug. The U.S. Food and Drug Administration granted Fast Track Designation to AVB-500 in platinum-resistant recurrent ovarian cancer.

About Aravive

Aravive, Inc. (Nasdaq: ARAV) is a clinical-stage biopharmaceutical company developing treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis. Aravive's lead product candidate, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling

pathway. By capturing serum GAS6, AVB-500 starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression. The GAS6-AXL signaling pathway also plays a significant role in fibrogenesis. Aravive is evaluating AVB-500 in platinum-resistant ovarian cancer and kidney fibrosis and intends to expand development into additional oncology and fibrotic indications. Aravive 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 (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, concerning the potential of AVB-500 to be used both in combination with existing therapies, as well as a maintenance drug, the potential of AVB-500 to halt the biological programming that promotes disease progression and the expansion of the development of AVB-500 into additional oncology and fibrotic indications. 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 Company's ability to expand development in 2019 into additional oncology and fibrotic indications, the Company's dependence upon AVB-500, AVB-500's ability to have favorable results in clinical trials or 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 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 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 and Form 10-K/A for the fiscal year ended December 31, 2018, 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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