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): July 31, 2019

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.)

LyondellBasell Tower
1221 McKinney Street, Suite 3200
Houston, Texas 77010
(Address of principal executive offices, including zip code)

(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 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 8.01. Other Events.

On July 31, 2019, Aravive, Inc. (the "Company") issued a press release announcing that the preliminary efficacy data from their ongoing clinical trial with AVB-500 showed compelling anti-tumor activity in the 12 patients treated from the first cohort of the ongoing Phase 1b portion of the Phase 1b/2 trial of AVB-500 in patients with platinum-resistant recurrent ovarian cancer where response to standard of care chemotherapy alone in patients is typically 10-15 percent.

The open-label, Phase 1b safety lead-in portion of the efficacy and safety study of AVB-500 in patients with platinum-resistant recurrent ovarian cancer enrolled patients into two cohorts, one investigating a combination of AVB-500 with pegylated liposomal doxorubicin (PLD) and the other, a combination of AVB-500 with paclitaxel (PAC). The overall best response rate (ORR) in the AVB-500 combination cohorts to date by investigator determined RECIST v1.1 criteria was greater than response rates observed historically with standard of care chemotherapy alone in this clinical setting. The Company therefore has decided to expand enrollment in the Phase 1b portion of the study, to validate the unanticipated early positive efficacy signal.

The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 issued by Aravive, Inc. on July 31, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 31, 2019

ARAVIVE, INC.
(Registrant)

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

Exhibit 99.1

Aravive Reports Preliminary Results of AVB-500 from the First Cohort of the Phase 1b/Phase 2 Recurrent Platinum Resistant Ovarian Cancer Trial

AVB-500 in combination with standard of care demonstrates early proof of concept for anti-tumor activity in platinum-resistant ovarian cancer

Aravive to expand enrollment in Phase 1b Trial of AVB-500 in platinum-resistant ovarian cancer

HOUSTON—July 31, 2019—Aravive, Inc. (Nasdaq: ARAV) today announced that preliminary efficacy data from their ongoing clinical trial with AVB-500 showed compelling anti-tumor activity in the 12 patients treated from the first cohort of the ongoing Phase 1b portion of the Phase 1b/2 trial of AVB-500 in patients with platinum-resistant recurrent ovarian cancer where response to standard of care chemotherapy alone in patients is typically 10-15 percent.

The open-label, Phase 1b safety lead-in portion of the efficacy and safety study of AVB-500 in patients with platinum-resistant recurrent ovarian cancer enrolled patients into two cohorts, one investigating a combination of AVB-500 with pegylated liposomal doxorubicin (PLD) and the other, a combination of AVB-500 with paclitaxel (PAC). The overall best response rate (ORR) in the AVB-500 combination cohorts to date by investigator determined RECIST v1.1 criteria was greater than response rates observed historically with standard of care chemotherapy alone in this clinical setting.

The company plans to present the detailed safety, pharmacokinetic, pharmacodynamic and preliminary efficacy results for this cohort at an upcoming scientific meeting.

“We have decided to expand the clinical trial to validate that early positive efficacy signal,” said Laura Bonifacio, PharmD, Ph.D, Vice President of Aravive. “If we continue to see a robust efficacy signal, we plan to work with FDA to explore the most efficient regulatory pathway to bring this drug to the patients in need. We continue to pursue our other pipeline programs, including renal cell carcinoma and renal fibrosis” added Bonifacio.

About Ovarian Cancer

Each year in the United States, more than 22,000 women develop ovarian cancer and there are approximately 14,240 attributed deaths annually, making ovarian cancer the deadliest of gynecologic malignancies. Clinical studies over time have shown little response to treatment, especially for platinum-resistant ovarian cancer. In fact, on average, only 10-15 percent of patients with platinum-resistant ovarian cancer have an objective response to currently approved therapies (Davis et al. Gynecologic Oncology 133 (2014) 624–631). Clearly, there is a need to develop new therapeutic strategies to improve the overall survival of patients who face less than optimal outcomes due to metastasis and treatment resistant ovarian cancer.

About AVB-500

AVB-500 (previously called AVB-S6-500) 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 or 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.

A Phase 1 clinical trial in healthy volunteers (NCT03401528) investigating the safety, pharmacokinetics, and pharmacodynamics was completed last year. The study met the safety and tolerability endpoints and demonstrated clinical proof-of-mechanism for AVB-500 in neutralizing GAS6. Based on AVB-500's favorable safety profile, coupled with its specifically targeted mechanism of action, the protein has the potential to be used both in combination with existing therapies, as well as a maintenance drug. U.S. FDA granted Fast Track Designation to Aravive Biologics' AVB-S6-500 in platinum-resistant recurrent ovarian cancer in 2018.

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 has initiated the Phase 1b portion of a Phase 1b/2 clinical trial of AVB-500 combined with standard of care therapies in patients with platinum-resistant ovarian cancer, 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. Aravive was one of FierceBiotech's Fierce 15 in 2017. For more information, please visit www.aravive.com.

Forward Looking Statements

This press release 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 Company's goals, intentions and expectations as to future plans or events, including statements regarding the plans to present the detailed safety, pharmacokinetic, pharmacodynamic and preliminary efficacy results for the first cohort at an upcoming scientific meeting, the potential for AVB-500 to be used both in combination with existing therapies, as well as a maintenance drug, plans to work with FDA to explore the most efficient regulatory pathway to bring this drug to the patients in need, the continued pursuit of the Company's other pipeline programs, including renal cell carcinoma and renal fibrosis. 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 Quarterly Reports on Form 10-Q, 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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