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): January 4, 2023

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 January 4, 2023, Aravive, Inc. (the "Company") issued a press release attached hereto as Exhibit 99.1 announcing that the Company had achieved full enrollment in its registrational Phase 3 trial of batiraxcept plus paclitaxel for platinum-resistant ovarian cancer ("PROC"). The global, randomized, double-blind, placebo-controlled Phase 3 AXLerate-OC trial is evaluating efficacy and tolerability of 15 mg/kg batiraxcept in combination with weekly paclitaxel versus placebo in combination with weekly paclitaxel. The Company also announced that public reporting of topline Phase 3 PROC data remained on track for mid-2023 and, if successful, would support a potential biologics license application (BLA) submission for PROC at the end of 2023.

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 Company's 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.

On January 4, 2023, the Company issued a press release announcing that the Company had achieved full enrollment in its registrational Phase 3 trial of batiraxcept plus paclitaxel for PROC. The global, randomized, double-blind, placebo-controlled Phase 3 AXLerate-OC trial is evaluating efficacy and tolerability of 15 mg/kg batiraxcept in combination with weekly paclitaxel versus placebo in combination with weekly paclitaxel. The Company also announced that public reporting of topline Phase 3 PROC data remained on track for mid-2023 and, if successful, would support a potential biologics license application (BLA) submission for PROC at the end of 2023.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release of Aravive, Inc., dated January 4, 2023
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: January 4, 2023

ARAVIVE, INC.
(Registrant)

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

Aravive Announces Complete Enrollment in the Global Registrational Phase 3 AXLerate-OC Trial for Platinum-Resistant Ovarian Cancer

- Topline data expected mid-2023
- Potential Biologics License Application (BLA) submission end of 2023

HOUSTON, TX, January 4, 2023 (GLOBE NEWSWIRE) - Aravive, Inc. (Nasdaq: ARAV, the "Company"), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced the achievement of full enrollment in the registrational Phase 3 trial of batiraxcept plus paclitaxel for platinum-resistant ovarian cancer (PROC). The global, randomized, double-blind, placebo-controlled Phase 3 AXLerate-OC trial is evaluating efficacy and tolerability of 15 mg/kg batiraxcept in combination with weekly paclitaxel versus placebo in combination with weekly paclitaxel. The trial was planned to enroll approximately 350 patients with platinum resistant, high grade serous ovarian cancer who received 1-4 prior lines of therapy at approximately 165 sites in the U.S. and Europe.

"Completing enrollment of this pivotal study brings us closer to the day when batiraxcept potentially is available to patients," said Scott Dove, Ph.D., Chief Operating Officer of Aravive. "Public reporting of topline data remains on track for mid-2023 and, if successful, are expected to support a Biologics License Application for PROC at the end of 2023. I would like to thank the patients enrolled in the trial, the clinical investigators, our CRO partners, and the Aravive team who worked tirelessly to advance the trial to this stage."

"The majority of patients with ovarian cancer will develop platinum resistance and have residual side effects from previous treatments," said Katherine Fuh, MD, PhD, John A. Kerner Chair in Gynecologic Oncology, Associate Professor, Department of OB/GYN, Director of Basic and Translational Research, Division of Gynecologic Oncology, University of California, San Francisco. "There is a need to develop effective novel agents with little to no side effects. As overall response rates for current treatments in platinum-resistant ovarian cancer range from 4% to 30%, we anticipate that batiraxcept and paclitaxel could be an option for our patients."

About the Phase 3 PROC Trial

The global, randomized, double-blind, placebo-controlled adaptive trial (GOG-3059/ENGOT OV-66) is designed to evaluate efficacy and safety of batiraxcept at a dose of 15 mg/kg in combination with paclitaxel. The trial is expected to enroll approximately 350 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy at approximately 165 sites in the U.S. and Europe. The primary endpoint for the trial is progression free survival and the secondary endpoint is overall survival. Exploratory endpoints include objective response rate, duration of response, quality of life, clinical benefit rate, pharmacokinetic and pharmacodynamic profile, and sAXL/GAS6 ratio. This trial is being conducted in partnership with The GOG Foundation, Inc. (GOG-F), through the GOG Partners program in the USA and in partnership with the European Network for Gynaecological Oncological Trial (ENGOT) groups in Europe. The Phase 3 trial is listed on clinicaltrials.gov NCT04729608.

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, thereby inhibiting metastasis and tumor growth, and restoring sensitivity to anti-cancer agents. Batiraxcept has been granted Fast Track Designation by the U.S. Food and Drug Administration for both the platinum-resistant ovarian cancer and clear cell renal cell cancer programs and Orphan Drug Designation by the European Commission in platinum-resistant recurrent ovarian cancer. 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 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 achievement of full enrollment in the registrational Phase 3 trial of batiraxcept plus paclitaxel for platinum-resistant ovarian cancer, the timing for reporting topline Phase 3 PROC data and the proposed BLA submission for PROC at the end of 2023. 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 potential of batiraxcept as a treatment for advanced or metastatic clear cell renal cell carcinoma (ccRCC), the ability to provide data when anticipated; 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 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; 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, 2021, the Company's Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2022, June 30, 2022 and September 30, 2022, respectively, recent Current Reports on Form 8-K and subsequent filings with the Securities and Exchange Commission. 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.

Investor Relations Contact:
Corey Davis, Ph.D.
LifeSci Advisors, LLC
212-915-2577
cdavis@lifesciadvisors.com