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): February 28, 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 February 28, 2023, Aravive, Inc. (the "Company") issued a press release attached hereto as Exhibit 99.1 announcing that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to batiraxcept for the treatment of pancreatic ductal adenocarcinoma cancer (PDAC).

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 February 28, 2023, the Company issued a press release announcing that the FDA has granted Orphan Drug Designation to batiraxcept for the treatment of pancreatic ductal adenocarcinoma cancer (PDAC).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press release of Aravive, Inc. dated February 28, 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: February 28, 2023

ARAVIVE, INC.
(Registrant)
By: /s/ Gail McIntyre
Name: Gail McIntyre
Title: Chief Executive Officer

Aravive Announces FDA Orphan Drug Designation Granted to Batiraxcept for the Treatment of Pancreatic Cancer

- Dose escalation portion of ongoing Phase 1b/2 pancreatic adenocarcinoma trial initiated, with preliminary results expected in 2H 2023

HOUSTON, TX, February 28, 2023 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV, "the Company"), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to batiraxcept for the treatment of pancreatic ductal adenocarcinoma cancer (PDAC).

The FDA's Office of Orphan Products Development grants ODD status to a drug or biological product to prevent, diagnose or treat a rare disease or condition affecting fewer than 200,000 people in the USA. Companies that are granted ODD are eligible for incentives, including tax credits for qualified clinical trials, exemption from user fees and up to seven years of market exclusivity after approval.

"Receiving Orphan Drug Designation is another important milestone for batiraxcept, and it underscores the significant unmet medical need in patients with pancreatic cancer, typically diagnosed at an incurable advanced stage with a 5-year survival rate of 11%[1]" said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "Three patients from our P1b trial are still responding to treatment with 15mg/kg batiraxcept, gemcitabine and nab-paclitaxel after 1 year and one patient has a confirmed complete response. Consistent with our other clinical trials, we noted a relationship between clinical activity and batiraxcept drug levels, however highly fibrotic tumors like PDAC may require more batiraxcept than platinum-resistant ovarian cancer and clear cell renal cell cancer patients to reach the appropriate batiraxcept drug levels. Due to this characteristic of pancreatic cancer, we are testing higher doses of batiraxcept to see if we can increase the proportion of patients who benefit from the triplet regimen."

Batiraxcept (15mg/kg on Days 1 & 15) is currently being evaluated in a Phase 1b/2 trial (NCT04983407) as first-line treatment in combination with gemcitabine (1000 mg/m2 on Days 1, 8, & 15) and nab-paclitaxel (125 mg/m2 on Days 1, 8, & 15) in patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) pancreatic adenocarcinoma. The Phase 1b portion of the trial is ongoing and the dose escalation phase was initiated this month. Preliminary results from the 20mg/kg batiraxcept plus gemcitabine and nab-paclitaxel cohort are anticipated in the second half of 2023. In addition to ODD granted by the FDA in pancreatic cancer, batiraxcept was previously granted ODD by the European Commission in platinum resistant recurrent ovarian cancer (PROC) and was granted Fast Track Designation by the FDA in PROC and clear cell renal cell carcinoma (ccRCC).

About Aravive
Aravive, Inc. is a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease. 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. FDA for both clear cell renal cell carcinoma and platinum-resistant ovarian cancer 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.

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[1] The Surveillance, Epidemiology, and End Results (SEER) website:
https://seer.cancer.gov/statfacts/html/pancreas.html

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 benefitting from the ODD incentives, including tax credits for qualified clinical trials, exemption from user fees and up to seven years of market exclusivity after approval and PDAC requiring more batiraxcept than platinum-resistant ovarian cancer and clear cell renal cell cancer patients to reach the appropriate batiraxcept drug levels. 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 ability to benefit from the incentives from ODD status, the ability to enroll patients as anticipated, 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 and the cash runway being sufficient to sustain operations into the fourth quarter of 2023 and beyond the readout on the Company’s Phase 3 Ovarian cancer trial. 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 and June 30, 2022, respectively, 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.

Investor Relations Contact:

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