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 15, 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 2.02. Results of Operation and Financial Condition.

On March 15, 2023, Aravive, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for its fourth quarter and year ended December 31, 2022. 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 2.02 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 2.02 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit	Description
99.1	Press Release issued by Aravive , Inc. dated March 15, 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 Current Report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 15, 2023

ARAVIVE, INC.
(Registrant)

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

aravive

Aravive Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Updates

Company on Track for PROC Phase 3, Pivotal Trial Readout in Mid 2023; Ends Year with Strengthened Cash Position

HOUSTON, TX, March 15, 2023 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV, "the Company"), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today reported fourth quarter and full year ended December 31, 2022 financial results and provided corporate updates.

"As we reflect on a productive 2022, Aravive remains committed to driving progress across all aspects of our business," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "We are on track with development activities around our PROC Phase 3 program, and we anticipate delivering topline results in mid-2023. Our trials in both clear cell renal cell carcinoma and pancreatic cancer continue to yield meaningful and encouraging data, further underscoring the potential of batiraxcept in multiple indications. Furthermore, we are pleased to have secured the funding needed to advance all of our programs beyond the PROC readout and progressing our clinical activities, with strong support from a respected syndicate of leading biotech investors. With a strengthened management team and a continued focus on scientific excellence, we are excited to build on our momentum and make significant strides in the year ahead. We look forward to updating you on our progress throughout the year as our clinical programs advance."

Recent Corporate Highlights

- ***The Phase 3 AXLerate-OC Trial in PROC Completed Enrollment***
  The registration-directed Phase 3 trial of batiraxcept plus paclitaxel for PROC completed enrollment in January 2023. The trial planned to enroll 350 patients with platinum resistant, high-grade serous ovarian cancer who have received 1-4 prior lines of therapy. CMC work remains on track and the Company expects to report topline data from the trial by mid-2023. If those results are positive, the Company plans on submitting a Biologics License Application (BLA) to FDA by year-end 2023. The global, randomized, double-blind, placebo-controlled Phase 3 trial is evaluating efficacy and tolerability of 15 mg/kg batiraxcept in combination with paclitaxel versus placebo in combination with paclitaxel.

- ***Advancement of PROC trial in China Results in Milestone Payment***
  The Company's partner in China, 3D Medicines enrolled patients into the Phase 3 PROC trial, which effectively begins their Phase 3 clinical activity towards their goal of ultimate approval in China. The Company received the $6 million payment related to achievement of this milestone in October 2022, the third milestone payment received since the Company entered into an agreement with 3D Medicines in November 2020.

- ***Batrixacept Granted Fast Track Designation for ccRCC Program***
  In November 2022, FDA granted Fast Track designation to batiraxcept for treatment of patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of systemic therapy that include both IO-based and VEGF-TKI-based therapies (either in combination or sequentially). FDA's designation was based on new Phase 1b data showing an Objective Response Rate (ORR) of 57% and median Progression-Free Survival (PFS) of 11.4 months in patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of immuno-oncology (IO)- and vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)-based therapies.

- ***Updated ccRCC Data Presented at the 2023 ASCO Genitourinary (GU) Cancers Symposium***
  The Company presented a poster at the 2023 ASCO GU Cancers Symposium in February 2023 featuring updated results from its ongoing Phase 1b/2 trial of batiraxcept in ccRCC. As of January 17, 2023, safety, pharmacokinetics (PK), pharmacodynamics (PD), and clinical activity of 15 mg/kg and 20 mg/kg batiraxcept in combination with 60 mg cabozantinib were evaluated in 26 patients with 2L+ ccRCC. In addition, one of the objectives of the ongoing Phase 1b/2 ccRCC trial is to evaluate the correlation of baseline serum soluble AXL (sAXL)/GAS6 (biomarker) with radiographic response in patients with ccRCC treated with batiraxcept plus cabozantinib. There were no dose limiting toxicities observed at either dose of batiraxcept. The best response of partial response was observed in 42% (11/26) of the overall population 57% (8/14) of the prior VEGF-TKI-treated group and 55% (11/20) of the biomarker high (sAXL/GAS6) group. The 9-month progression-free survival (PFS) rate was 65% in the overall population, 69% in the biomarker high group (n=20) and 75% in the prior VEGF-TKI, biomarker high group (n=11). Eighty-five percent of patients (22/26) had a reduction in target lesions at the 8-week response assessment, and 58% (15/26) of the total population achieved a better response on batiraxcept plus cabozantinib than they did on prior therapy. The Company has discussed a registrational path with the US FDA that includes use of the sAXL/GAS6 ratio as a potential basis for an accelerated approval.

  The open-label Phase 2 portion of the clinical trial initiated January 31, 2022 and is expected to enroll 55 patients across three parts. Part A is expected to enroll approximately 25 patients and investigate 15 mg/kg batiraxcept in combination with cabozantinib in 2L+ ccRCC patients. Part B is expected to enroll approximately 20 patients and evaluate 15 mg/kg batiraxcept in combination with nivolumab and cabozantinib as a potential front-line treatment for ccRCC. Part C is expected to evaluate 15 mg/kg batiraxcept monotherapy in approximately 10 patients with ccRCC who are not eligible for curative intent therapies.

  The Company expects to report additional data from the P1b portion and preliminary data from the P2 portion of the ccRCC trial mid-2023.

- ***Batiraxcept Granted FDA Orphan Drug Designation in Pancreatic Cancer; Phase 1b/2 Trial in PDAC is Advancing***
  In February 2023, the Company announced that the U.S. Food and Drug Administration (FDA) granted batiraxcept Orphan Drug Designation (ODD) for the treatment of pancreatic cancer. The Company provided an update on the Phase 1b pancreatic study on September 27, 2022 for 18 patients who had been treated with 15 mg/kg batiraxcept (Days 1 & 15) plus nab-paclitaxel (125 mg/m^2 on Days 1, 8, & 15) and gemcitabine (1000 mg/m^2 on Days 1, 8, & 15) and have pharmacokinetic data. Consistent with other Phase 1b cancer studies with batiraxcept, there is a relationship between batiraxcept exposures and clinical activity such that 5 of 9 patients in the PDAC study whose batiraxcept levels exceeded the minimum efficacious concentration (MEC) of batiraxcept had a response versus 1 of 9 patients in the low MEC group. Similarly, the mPFS in the high MEC group was 5.6 months (95% CI 2.1, not evaluable) versus 2.7 months (95% CI 1.1, 5.4) in the low MEC group. In May 2022, the Company had reported that batiraxcept was generally well-tolerated in combination with gemcitabine and nab-paclitaxel with no unexpected safety signals. Based on these data, the Company intends to dose an additional 6-18 patients at higher doses (20 mg/kg and potentially 25 mg/kg) to assess whether a higher dose will increase the proportion of patients who will achieve high MEC and increase the clinical activity of batiraxcept in combination with gemcitabine plus nab-paclitaxel. Preliminary data from the 20 mg/kg cohort is expected in the second half of 2023.

- ***Strengthened Balance Sheet, Adding Funding to Support Operations Beyond PROC Readout***
  In January 2022, Aravive raised approximately $9.9 million in net proceeds from the sale of a pre-funded warrant to purchase 4,545,455 shares of the company's common stock to Eshelman Ventures, LLC at a price of $2.20 per share, which was the consolidated closing bid price of the company's common stock on The Nasdaq Global Select Market on December 31, 2021, the date of execution of the stock purchase agreement. Additionally, Fred Eshelman, Pharm.D., was appointed the Executive Chairman of Aravive, having served as the Non-Executive Chairman of the board since April 2020. In March 2022, the Company raised an additional approximately $9.3 million in net proceeds from the sale of common stock and a pre-funded warrant for an aggregate of a combination of 4,850,241 shares of the company's common stock and pre-funded warrants to a single healthcare-focused institutional investor and Eshelman Ventures, LLC and issued warrants to purchase an additional aggregate of 4,850,241 shares of common stock in a registered direct offering priced at-the-market under Nasdaq rules. In October 2022, the Company raised approximately $40 million in net proceeds from a private placement offering from new biotechnology investors, existing investors and certain of the Company's management and directors. Combined, the additional capital infusions strengthen the Company's financial position and fund operations as currently planned into the fourth quarter of 2023, beyond the readout on our Phase 3 PROC trial.

- ***Strengthened Leadership Team with Experienced Industry Experts***
  Throughout 2022, the Company built upon its strong leadership with the appointments of Scott Dove, Ph.D. as Chief Operating Officer, Rudy Howard as Chief Financial Officer and Robert B. Geller, M.D. as Chief Medical Officer.

Fourth Quarter and Full Year 2022 Financial Results
Revenues for the three and twelve months ended December 31, 2022 were approximately $1.5 million and $9.1 million, respectively, compared with approximately $1.0 million and $7.4 million, respectively, for the three and twelve months ended December 31, 2021. Revenues for 2022 and 2021 were derived solely from the Company's collaboration and license agreement with 3D Medicines, executed in November 2020, to develop and commercialize batiraxcept in oncology indications in China. Revenues represent 1) a portion of initial signing and milestone recorded from 3D Medicines that is recognized at the time it is probable the milestone will be met and 2) a portion of the milestone that is deferred and recognized over the PROC trial period. The increase in revenue for fiscal year 2022 compared to 2021 was driven primarily by increased expenditures related to the PROC trial, which drives the recognition of deferred revenue over the PROC trial period.

Total operating expenses for the three and twelve months ended December 31, 2022 were approximately $21.3 million and $80.0 million, respectively, compared with approximately $14.6 million and $48.1 million, respectively, for the three and twelve months ended December 31, 2021. Research and development expenses for the three and twelve months ended December 31, 2022 were approximately $18.0 million and $66.9 million, respectively, compared with approximately $12.2 million and $37.5 million, respectively, for the three and twelve months ended December 31, 2021. The increase in research and development expense in 2022 compared to the same periods in 2021 is driven by the continued advancement of our clinical trials and increases in CMC-related costs. General and administrative expenses for the three and twelve months ended December 31, 2022 were approximately $3.4 million and $13.0 million, respectively, compared with approximately $2.4 million and $10.6 million, respectively, for the three and twelve months ended December 31, 2021. The increase in general and administrative expense was primarily driven by higher salary expense, higher stock-based compensation expense, higher severance expense, and increased consulting fees.

For the three and twelve months ended December 31, 2022, Aravive reported a net loss of approximately $29.1 million and $76.3 million, or $0.46 per share and $2.10 per share, respectively compared to a net loss of approximately $13.0 million and $39.2 million, or $0.62 per share and $1.95 per share, respectively, for the three and twelve months ended December 31, 2021.

Cash Position
As of December 31, 2022, cash and cash equivalents were approximately $53.7 million, compared to approximately $27.9 million as of September 30, 2022. During October 2022, the Company received a $6 million milestone payment from the Company's licensee, 3D Medicines, Inc. and raised approximately $40 million in net proceeds from a private placement offering. The Company believes that its existing cash and cash equivalents will be sufficient to sustain operations into the fourth quarter of 2023.

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.

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 remaining on track with development activities around the PROC Phase 3 program, the Company reporting topline data from the PROC trial by mid-2023, the potential of batiraxcept in multiple indications, making significant strides in the year ahead, providing updates on progress throughout the year, CMC work remaining on track with the goal of filing a BLA by year-end 2023, the trial enrolling 350 patients with platinum resistant, high-grade serous ovarian cancer who have received 1-4 prior lines of therapy, 3D Medicines obtaining approval in China the open-label Phase 2 portion of the ccRCC enrolling 55 patients across three parts (part A enrolling approximately 25 patients and investigating batiraxcept 15 mg/kg in combination with cabozantinib in 2L+ ccRCC patients; part B enrolling approximately 20 patients and evaluating batiraxcept 15 mg/kg in combination with nivolumab and cabozantinib as a potential front-line treatment for ccRCC and part C evaluating batiraxcept 15 mg/kg monotherapy in approximately 10 patients with ccRCC who are not eligible for curative intent therapies), use of the sAXL/GAS6 ratio as a potential basis for an accelerated approval, the Company reporting additional data from the P1b portion and preliminary data from the P2 portion of the ccRCC trial mid-2023, the Company dosing an additional 6-18 patients at higher doses in the Phase 1b pancreatic study, providing preliminary data from the 20gm/kg cohort in the second half of 2023 and cash and cash equivalents being sufficient to sustain operations into the fourth quarter 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 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 file a BLA by year-end 2023 and 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 PROC 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, 2022, 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.

Aravive, Inc.
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended December 31, 2022 (unaudited)	Three Months Ended September 30, 2022 (unaudited)
Revenue		
Collaboration revenue	$ 1,474	$ 4,956
Total revenue	1,474	4,956
Operating expenses		
Research and development	17,952	18,668
General and administrative	3,385	2,836
Total operating expenses	21,337	21,504
Loss from operations	(19,863)	(16,548)
Total other income (expense), net	(9,262)	885
Net loss	$ (29,125)	$ (15,663)
Net loss per share - basic and diluted	$ (0.46)	$ (0.51)
Weighted-average common shares used to compute basic and diluted net loss per share	62,938	30,518

Aravive, Inc.
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
	(unaudited)			
Revenue				
Collaboration revenue	$ 1,474	$ 985	$ 9,137	$ 7,442
Total revenue	1,474	985	9,137	7,442
Operating expenses				
Research and development	17,952	12,194	66,938	37,541
General and administrative	3,385	2,448	13,036	10,550
Total operating expenses	21,337	14,642	79,974	48,091
Loss from operations	(19,863)	(13,657)	(70,837)	(40,649)
Total other income (expense), net	(9,262)	701	(5,485)	1,498
Net loss	$ (29,125)	$ (12,956)	$ (76,322)	$ (39,151)
Net loss per share - basic and diluted	$ (0.46)	$ (0.62)	$ (2.10)	$ (1.95)
Weighted-average common shares used to compute basic and diluted net loss per share	62,938	20,998	36,372	20,070

Aravive, Inc.
Consolidated Balance Sheets
(in thousands)

	December 31, 2022	September 30, 2022 (unaudited)
Assets:		
Cash and cash equivalents	$ 53,689	$ 27,896
Accounts receivable	—	6,000
Restricted cash	2,445	2,436
Other assets	4,557	4,242
Operating lease right-of-use assets	1,462	1,648
Total assets	**$ 62,153**	**$ 42,222**
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 15,503	$ 16,078
Deferred revenue	5,035	6,456
Operating lease obligation	4,077	4,646
Warrant liability	26,881	—
Total liabilities	51,496	27,180
Total stockholders' equity	10,657	15,042
Total liabilities and stockholders' equity	**$ 62,153**	**$ 42,222**

Investor Relations Contact:

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