

**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): May 10, 2023

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 2.02. Results of Operation and Financial Condition.

On May 10, 2023, Aravive, Inc., a Delaware corporation (the “Registrant”), issued a press release that included financial information for its quarter ended March 31, 2023. 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 May 10, 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: May 10, 2023

ARAVIVE, INC.
(Registrant)

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

Aravive Reports First Quarter 2023 Financial Results and Provides Corporate Updates

- **On Track for PROC Pivotal Phase 3 Trial Readout Mid-2023**
- **Promising ccRCC Phase 1b/2 Results to Date; Update to be Presented at ASCO 2023**
- **Strengthened Management Team with Appointment of Carolina Petrini as Chief Commercial Officer**
- **Company hosting Key Opinion Leader (KOL) webinar featuring batiraxcept in PROC and ccRCC on May 24, 2023 at 1pm ET; Go to the Company website to register**

HOUSTON, TX, May 10, 2023 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV, “the Company”), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today reported first quarter 2023 financial results and provided corporate updates.

“During the first quarter, we continued to make progress in the development of batiraxcept in ovarian, kidney and pancreatic cancer as well as strengthened our management team,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “We remain on track to deliver topline results from our platinum-resistant ovarian cancer (PROC) Phase 3 trial in mid-2023 and, if successful, plan to submit a Biologics License Application (BLA) by the end of 2023. We are also looking forward to presenting updated data from our clear cell renal cell carcinoma (ccRCC) trial at ASCO in June. Finally, we were excited to welcome Carolina Petrini as our Chief Commercial Officer and are already leveraging her expertise ahead of the PROC Phase 3 data readout.”

Recent Corporate Highlights

- **The Phase 3 AXLerate-OC Trial in PROC Completed Enrollment; On Track for Topline Data Mid-2023**
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 successful, the Company plans to submit a BLA 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.
- **Advancing Commercial Readiness with Appointment of Carolina Petrini as Chief Commercial Officer**
On April 11, 2023, the Company announced the appointment of Carolina Petrini as Chief Commercial Officer. Ms. Petrini brings over two decades of experience in developing pre-commercial, launch readiness and commercial strategies, building and leading high-performing commercial teams.
- **Presented Promising ccRCC Data at the 2023 ASCO Genitourinary (GU) Cancers Symposium; Updated Data to be Presented at ASCO 2023**
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. To date, batiraxcept demonstrates a favorable safety profile in previously treated ccRCC patients. Efficacy results suggest that batiraxcept has a greater impact on patients previously treated with IO and VEGF-TKI.

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 will present updated data from the P1b portion and preliminary data from the P2 portion of the ccRCC trial in a poster presentation at the 2023 ASCO Annual Meeting.

- **Batiraxcept Granted FDA Orphan Drug Designation in Pancreatic Cancer**
In February 2023, the Company announced that the FDA granted batiraxcept Orphan Drug Designation (ODD) for the treatment of pancreatic cancer. Based on the favorable safety and tolerability data reported to date, 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 whose batiraxcept blood levels will be above the model-informed minimal efficacious concentration 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.
- **Preclinical Batiraxcept Data in Bile Duct Cancer Published in the Peer-reviewed Journal Cancers**
In March 2023, preclinical results from a study of batiraxcept in bile duct cancer were published in the peer-reviewed journal *Cancers*. In the study, data showed that tumor tissues from bile duct cancer patients had significantly higher AXL expression compared to normal liver tissues, which correlated with metastasis and poor survival rates, suggesting that AXL is a potential therapeutic target in biliary cancer. In *in vitro* and *in vivo* models of bile duct cancer, batiraxcept demonstrated a significant anti-tumor effect, reducing tumor growth, invasion and metastatic burden, highlighting its potential for clinical development in high AXL-expressing bile duct cancers. The article entitled, “Targeting AXL Using the AVB-500 Soluble Receptor and through Genetic Knockdown Inhibits Bile Duct Cancer Growth and Metastasis” the article can be found at the Company website.

First Quarter 2023 Financial Results

Revenue for the three months ended March 31, 2023 was \$1.5 million, compared with \$1.1 million for the same period in 2022. Revenues were derived solely from our 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.

Total operating expenses for the three months ended March 31, 2023 were \$19.4 million, compared with \$16.1 million for the same period in 2022. Research and development expenses for the three months ended March 31, 2023 were \$15.9 million, compared with \$13.0 million for the same period in 2022. Non-cash stock-based compensation for the three months ended March 31, 2023 was \$0.7 million, compared with \$0.6 million for the same period in 2022.

For the three months ended March 31, 2023 the Company recognized an expense for the increase in the fair value of the warrant liability in the amount of \$33.2 million, compared to a gain of \$1.2 million for the same period a year ago.

For the three months ended March 31, 2023, Aravive reported a net loss of \$50.0 million, or \$0.66 per share, compared to a net loss of \$13.1 million, or \$0.62 per share, for the same period in 2022. The majority of the net loss for the three months ended March 31, 2023 is attributable to the change in fair value of the warrant liability of \$33.2 million. Operating loss for the three months ended March 31, 2023 was \$17.9 million, compared to the operating loss from operations of \$15.0 million for the same period in 2022.

Cash Position

As of March 31, 2023, cash and cash equivalents were \$35.9 million, compared to \$53.7 million as of December 31, 2022. The Company anticipates that its current cash and cash equivalents will fund operating plans 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 being on track for PROC Pivotal Phase 3 Trial Readout mid-2023, the Company hosting key opinion leader webinar featuring batiraxcept in PROC and ccRCC, continuing to make progress in the development of batiraxcept in ovarian, kidney and pancreatic cancer as well as strengthened our management team, remaining on track to deliver topline results from our platinum-resistant ovarian cancer (PROC) Phase 3 trial in mid-2023, planning to file a Biologics License Application (BLA) by the end of 2023, presenting updated data from our clear cell renal cell carcinoma (ccRCC) trial at ASCO in June, leveraging her expertise ahead of the PROC Phase 3 data readout, continuing to discuss the registrational path with the FDA, dosing an additional 6-18 patients in the pancreatic cancer trial at higher doses (20 mg/kg and potentially 25 mg/kg), preliminary data from the 20 mg/kg cohort in the in the pancreatic cancer trial in the second half of 2023, the PROC trial enrolling 350 patients with platinum resistant, high-grade serous ovarian cancer who have received 1-4 prior lines the open-label Phase 2 portion of the clinical trial enrolling 55 patients across three parts: Part A approximately 25 patients and investigating 15 mg/kg batiraxcept in combination with cabozantinib in 2L+ ccRCC patients, Part B approximately 20 patients and evaluating 15 mg/kg batiraxcept in combination with nivolumab and cabozantinib as a potential front-line treatment for ccRCC and Part C evaluating 15 mg/kg batiraxcept monotherapy in approximately 10 patients with ccRCC who are not eligible for curative intent therapies batiraxcept's potential as a therapeutic option for the treatment of high AXL-expressing bile duct cancers and cash and cash equivalents funding operating plans 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 and to file a BLA 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; 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, 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.
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended March 31, 2023 (unaudited)	Three Months Ended December 31, 2022 (unaudited)
Revenue		
Collaboration revenue	\$ 1,491	\$ 1,474
Total revenue	1,491	1,474
Operating expenses		
Research and development	15,915	17,952
General and administrative	3,489	3,385
Total operating expenses	19,404	21,337
Loss from operations	(17,913)	(19,863)
Other income (expense), net:		
Interest income	467	432
Change in fair value of warrant liability	(33,207)	(10,391)
Other income, net	697	697
Total other income (expense), net	(32,043)	(9,262)
Net loss	\$ (49,956)	\$ (29,125)
Net loss per share - basic and diluted	\$ (0.66)	\$ (0.46)
Weighted-average common shares used to compute basic and diluted net loss per share	75,715	62,938

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

	Three Months Ended March 31, 2023 2022 (unaudited)	
Revenue		
Collaboration revenue	\$ 1,491	\$ 1,092
Total revenue	1,491	1,092
Operating expenses		
Research and development	15,915	13,002
General and administrative	3,489	3,088
Total operating expenses	19,404	16,090
Loss from operations	(17,913)	(14,998)
Other income (expense), net:		
Interest income	467	10
Change in fair value of warrant liability	(33,207)	1,228
Other income, net	697	703
Total other income (expense), net	(32,043)	1,941
Net loss	\$ (49,956)	\$ (13,057)
Net loss per share - basic and diluted	\$ (0.66)	\$ (0.62)
Weighted-average common shares used to compute basic and diluted net loss per share	75,715	21,130

Aravive, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2023	December 31, 2022
	(unaudited)	
Assets:		
Cash and cash equivalents	\$ 35,924	\$ 53,689
Restricted cash	2,458	2,445
Other assets	3,385	4,557
Operating lease right-of-use assets	1,277	1,462
Total assets	\$ 43,044	\$ 62,153
Liabilities and stockholders' (deficit) equity:		
Accounts payable and accrued liabilities	\$ 14,440	\$ 15,503
Deferred revenue	3,610	5,035
Operating lease obligation	3,517	4,077
Warrant liability	60,088	26,881
Total liabilities	81,655	51,496
Total stockholders' (deficit) equity	(38,611)	10,657
Total liabilities and stockholders' (deficit) equity	\$ 43,044	\$ 62,153

Investor Relations Contact:

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