

**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 12, 2022

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 12, 2022, Aravive, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 12, 2022
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 12, 2022

ARAVIVE, INC.
(Registrant)

By: /s/ Vinay Shah
Name: Vinay Shah
Title: Chief Financial Officer

Aravive Reports First Quarter 2022 Financial Results and Provides Corporate Updates

- *Reported positive updated data and new biomarker data from Phase 1b Study of Batiraxcept in ccRCC*
- *Presented updated modeling data from batiraxcept clinical trials at the AACR annual meeting*
- *Dosed first patient in Phase 2 study of batiraxcept in clear cell Renal Cell Carcinoma*
- *Provided positive clinical updates on ongoing clinical programs at company's KOL Symposium*
- *Appointed Scott Dove, Ph.D. as Chief Operating Officer*
- *Strengthened balance sheet with approximately \$20 million from two separate transactions*

Houston, TX, May 12, 2022 - Aravive, Inc. (Nasdaq: ARAV, "the Company"), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today reported financial results for the first quarter ended March 31, 2022 and provided corporate updates.

"During the first quarter we continued to advance the development of batiraxcept for the potential treatment of ovarian, kidney and pancreatic cancer, successfully raised additional capital and strengthened the management team," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "Our registrational Phase 3 trial of batiraxcept in ovarian cancer continues on pace to complete enrollment in 2022, with top line data anticipated in 2Q'23 and a potential BLA filing with the FDA in 4Q'23. Our ongoing Phase 2 trial of batiraxcept in clear cell renal cell carcinoma also continues to successfully enroll patients across three cohorts and the Phase 1b trial of batiraxcept in pancreatic cancer completed enrollment in 1Q'22. Updated results are anticipated throughout 2022. We remain encouraged by the continued signals of best-in-class potential of batiraxcept and look forward to providing continued clinical updates on each of our three active programs throughout 2022."

Recent Corporate Highlights

- **Batiraxcept in Platinum Resistant Ovarian Cancer (PROC):** The registration-directed Phase 3 program of batiraxcept in combination with paclitaxel in PROC remains on track to complete enrollment in 2H'22. Topline data from the trial is anticipated to be available in 2Q'23. CMC work related to the PROC program remains on track with the goal of filing a BLA in 4Q'23. The global, randomized, double-blind, placebo-controlled Phase 3 trial is evaluating efficacy and tolerability of batiraxcept at a dose of 15 mg/kg in combination with paclitaxel versus placebo in combination with paclitaxel. The trial aims to enroll 350 platinum resistant, high-grade serous ovarian cancer patients who have received 1-4 prior lines of therapy.
- **Batiraxcept in Clear Cell Renal Cell Carcinoma (ccRCC) and Serum-Based Biomarker:** The Company dosed first patient in the Phase 2 study of batiraxcept in combination with cabozantinib in 2L+ ccRCC trial in January 2022. Enrollment across the three patient cohorts of the Phase 2 study continues on pace for planned completion and updated data releases during 2Q'22. The Company anticipates providing clinical updates on the Phase 2 study throughout 2022. In March 2022, the Company announced new biomarker data from the Phase 1b portion of the trial in patients with ccRCC. Aravive had previously reported an observable correlation of baseline levels of serum soluble AXL (sAXL)/GAS6 to clinical activity in its Phase 1b PROC trial. As such, one of the objectives of the ongoing Phase 1b/2 ccRCC trial is to evaluate the correlation of baseline sAXL/GAS6 with radiographic response in patients with ccRCC treated with batiraxcept plus cabozantinib. The Company continues to engage the US FDA about utilizing the biomarker as a basis for an accelerated development strategy. Updated biomarker data is anticipated in 2022.

As of April 30, 2022, 26 patients with ccRCC were treated with batiraxcept in the Phase 1b portion of the trial at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily in previously treated (2L+) patients with ccRCC. There were no dose limiting toxicities observed at either dose and 14 of the 26 patients remain on study. The best overall response rate (ORR, confirmed + unconfirmed) in the ITT population was 46% and 50% in patients dosed with 15 mg/kg (the recommended Phase 2 dose). The best ORR in the biomarker high population was 60%, and 67% in the biomarker high population dosed at 15 mg/kg. The 7-month progression-free survival (PFS) rate was 71% in the ITT population, 83% in the biomarker high population, and 91% in the 15 mg/kg biomarker high group. Eight patients experienced resolution of one or more target lesions. The company is on track to report additional updated results from the Phase 1b portion of the trial in the second quarter of 2022.

- **Batiraxcept in Pancreatic Adenocarcinoma:** In January 2022, Aravive completed enrollment of the Phase 1b portion of its Phase 1b/2 trial of batiraxcept in combination with gemcitabine and nab-paclitaxel as a first-line treatment in patients with advanced or metastatic pancreatic adenocarcinoma who are eligible to receive gemcitabine and nab-paclitaxel combination therapy. As of May 3, 2022, 21 patients have been treated with 15 mg/kg batiraxcept in combination with gemcitabine and nab-paclitaxel as a first-line treatment. Batiraxcept has been generally well-tolerated with no unexpected safety signals. The best ORR (confirmed + unconfirmed) was 29%. As noted with the other programs, an observable correlation of baseline levels of serum soluble AXL (sAXL)/GAS6 to clinical activity was noted in this trial as well and the best ORR in the biomarker high population was 40%. Five patients experienced resolution of one or more target lesions; however, 2 of these patients have since progressed. The company is on track to report additional updated data from the Phase 1b portion of the trial in the second quarter of 2022.

- **Strengthened Balance Sheet:** In January 2022, Aravive raised approximately \$10.0 million 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. 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 \$10.0 million 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. Combined, the additional capital infusions strengthen the Company's financial position and fund operations as currently planned into 1Q'23.

First Quarter 2022 Financial Results

Revenue for the three months ended March 31, 2022 was \$1.1 million compared with \$0.3 million for the same period in 2021. Revenues 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 Greater China. Revenues represent a portion of initial signing and milestone payments received from 3D Medicines that is recognized at the time of the receipt and a portion of the payments that is deferred and recognized over the PROC trial period.

Total operating expenses for the three months ended March 31, 2022 were \$16.1 million compared with \$8.3 million for the same period in 2021. Total operating expenses for the three months ended March 31, 2022 included non-cash stock-based compensation expense of \$0.6 million, compared to \$0.5 million for the same period in 2021.

For the three months ended March 31, 2022, Aravive reported a net loss of \$13.1 million, or \$0.62 per share compared to a net loss of \$8.0 million, or \$0.44 per share for the same period in 2021.

Cash Position

As of March 31, 2022, cash and cash equivalents were \$65.8 million, compared to \$59.4 million as of December 31, 2021. In January 2022, Aravive announced an approximately \$10.0 million investment by Eshelman Ventures and in March 2022, Aravive announced an additional approximately \$10 million investment by a healthcare-focused institutional investor and Eshelman Ventures, LLC. The company anticipates that its current cash and cash equivalents will fund operating plans into 1Q'23.

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. FDA 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 press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 on our current expectations and projections about future events. 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 include statements regarding the registrational Phase 3 trial of batiraxcept in ovarian cancer continuing on pace to complete enrollment in 2022, with top line data anticipated in 2Q’23 and a potential BLA filing with the FDA in 4Q’23, the ongoing Phase 2 trial of batiraxcept in clear cell renal cell carcinoma also continuing to successfully enroll patients across three cohorts; updated results are anticipated throughout 2022, providing continued clinical updates on each of our three active programs throughout 2022, the Phase 3 trial enrolling 350 platinum resistant, high-grade serous ovarian cancer patients who have received 1-4 prior lines of therapy, the potential of utilizing the biomarker as a basis for an accelerated development strategy for clear cell renal cell carcinoma; updated biomarker data in 2022, being on track to report additional updated results from the Phase 1b portion of the clear cell renal cell carcinoma trial in the second quarter of 2022, being on track to report additional updated data from the Phase 1b portion of the pancreatic adenocarcinoma trial in the second quarter of 2022 and current cash and cash equivalents funding operating plans into 1Q’23. 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 report data from the current clinical trials in accordance with current timelines, the data from patients treated in the future with batiraxcept being consistent with the results reported, the ability to enroll the expected number of patients, the impact of COVID-19 on the Company's clinical strategy, clinical trials, supply chain and fundraising, the Company's ability to expand development into additional indications, the Company's dependence upon batiraxcept, batiraxcept's ability to have favorable results in clinical trials and ISTs, 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; 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, 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	
	2022	2021
	March 31,	
	(unaudited)	
Revenue		
Collaboration revenue	\$ 1,092	\$ 256
Total revenue	<u>1,092</u>	<u>256</u>
Operating expenses		
Research and development	13,002	5,884
General and administrative	3,088	2,380
Total operating expenses	<u>16,090</u>	<u>8,264</u>
Loss from operations	(14,998)	(8,008)
Other income (expense), net	1,941	4
Net loss	<u>\$ (13,057)</u>	<u>\$ (8,004)</u>
Net loss per share- basic and diluted	<u>\$ (0.62)</u>	<u>\$ (0.44)</u>
Weighted-average common shares used to compute basic and diluted net loss per share	<u>21,130</u>	<u>18,067</u>

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

	March 31, 2022	December 31, 2021
	(unaudited)	
Assets:		
Cash and cash equivalents	\$ 65,825	\$ 59,424
Restricted cash	2,431	2,431
Other assets	3,595	3,725
Operating lease right-of-use assets	2,020	2,207
Total assets	\$ 73,871	\$ 67,787
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 13,086	\$ 11,073
Deferred revenue	7,027	8,119
Operating lease obligation	5,787	6,373
Warrant liability	8,772	—
Total liabilities	34,672	25,565
Total stockholders' equity	39,199	42,222
Total liabilities and stockholders' equity	\$ 73,871	\$ 67,787

Contact:

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