

**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): November 5, 2020

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 Instructions 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 Operations and Financial Condition.

On November 5, 2020, Aravive, Inc., a Delaware corporation (the “Registrant”), issued a press release that included financial information for its quarter ended September 30, 2020. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in the press release is being furnished to the Securities and Exchange Commission (the “Commission”) and shall not be deemed incorporated by reference into any of the Registrant’s registration statements or other filings with the Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit Number	Exhibit Description
99.1	Press Release, issued by Aravive, Inc. dated November 5, 2020

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: November 5, 2020

ARAVIVE, INC.
(Registrant)

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



Aravive Reports Third Quarter 2020 Financial Results and Provides Corporate Updates

- Company expects to initiate pivotal trial of AVB-500 in Platinum Resistant Ovarian Cancer during fourth quarter 2020/first quarter 2021, based on Phase 1b results
- On-track to initiate Phase 1b/2 trial of AVB-500 in Clear Cell Renal Cell Carcinoma during fourth quarter 2020
- Expanded Board of Directors and strengthened leadership team with industry veterans
- Current cash and cash equivalents expected to fund operations into 2022

HOUSTON, TX, November 5, 2020 – Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative therapeutics, today announced recent corporate updates and financial results for the third quarter ended September 30, 2020.

“Aravive has made continued progress executing on our strategic initiatives in the third quarter of 2020, including strengthening our leadership team, expanding our Board of Directors and advancing our development plans for AVB-500,” said Gail McIntyre, Ph.D., chief executive officer of Aravive. “We expect to initiate a pivotal trial of AVB-500 in platinum resistant ovarian cancer during the fourth quarter of 2020 or in the first quarter of 2021 and are on-track to initiate a Phase 1b/2 trial of AVB-500 in clear cell renal cell carcinoma this year. We are very encouraged by the AVB-500 clinical trial results to date, and are well-positioned to continue to advance both the ovarian cancer and renal cancer programs.”

Recent Corporate Highlights

- **AVB-500 in Platinum Resistant Ovarian Cancer (PROC):** Aravive expects to initiate a pivotal trial for AVB-500 in PROC during the fourth quarter of 2020/first quarter of 2021. The study is expected to be a global, randomized, double-blind, placebo-controlled trial to evaluate efficacy and tolerability of AVB-500 at a dose of 15 mg/kg in combination with paclitaxel.
- **AVB-500 in Clear Cell Renal Cell Carcinoma (ccRCC):** Aravive is on-track to initiate a Phase 1b/2 trial of AVB-500 in ccRCC during the fourth quarter of 2020. This is an open-label study which is expected to provide safety, pharmacokinetic, and preliminary clinical activity in 2021.
- **Strengthened Leadership Team:** The Company enhanced its clinical development and oncology expertise with the appointments of Reshma Rangwala, M.D., Ph.D., as Chief Medical Officer, Randy Anderson, Ph.D., as Senior Vice President of Data Sciences, Elisabeth Gardiner, Ph.D., as Vice President of Translational Medicine, and Patrick Simms, as Vice President of Clinical Operations.
- **Expanded Board of Directors:** Aravive appointed Michael W. Rogers, a biopharmaceutical veteran and healthcare leader with more than 20 years of public company financial experience, to the Company’s Board of Directors. Mr. Rogers serves as Chair of Aravive’s Audit Committee.

Third Quarter 2020 Financial Results

Revenue for the three and nine months ended September 30, 2020 were \$0 for both periods, compared to \$0 and \$4.8 million for the same periods in 2019. Revenue for 2019 was derived solely from the Cancer Prevention Research Institute of Texas (CPRIT) grant.

Total operating expenses for the three and nine months ended September 30, 2020 were \$10.7 million and \$26.7 million, respectively, compared to \$7.0 million and \$21.4 million for the same periods in 2019.

Total operating expenses for the three and nine months ended September 30, 2020 included non-cash stock-based compensation expense of \$0.4 million and \$1.6 million, respectively, compared to \$0.8 million and \$2.8 million for the same periods in 2019. In addition, during the three and nine months

ended September 30, 2020, there was a non-recurring non-cash charge for impairment of the Company's right-of-use asset and leasehold improvements of \$2.9 million and \$5.8 million, respectively.

For the three and nine months ended September 30, 2020, Aravive reported a net loss of \$10.7 million and \$26.5 million, or \$0.66 per share and \$1.69 per share, respectively, compared to a net loss of \$6.1 million and \$13.9 million, or \$0.54 per share and \$1.23 per share, for the same periods in 2019.

Cash Position

As of September 30, 2020, cash and cash equivalents was \$54.0 million, compared to \$65.1 million as of December 31, 2019. The Company expects that its current cash and cash equivalents will be sufficient to fund its operating plans into 2022.

About Aravive

Aravive, Inc. is a clinical-stage oncology company developing transformative therapeutics designed to halt the progression of life-threatening diseases. Aravive's lead therapeutic, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway associated with tumor cell growth. Aravive recently successfully completed a Phase 1b trial of AVB-500 in platinum resistant ovarian cancer and selected 15 mg/kg as the dose for the pivotal trial. Analysis of all safety data to date showed that AVB-500 has been generally well-tolerated with no dose-limiting toxicities or unexpected safety signals. While the Phase 1b trial of AVB-500 in platinum resistant ovarian cancer was a safety trial and not powered to demonstrate efficacy, all 5 patients in the 15 mg/kg cohort experienced clinical benefit, with 1 complete response, 2 partial responses, and 2 stable disease. The Company also intends to initiate a Phase 1b/Phase 2 trial of AVB-500 in clear cell renal cell carcinoma later this year. For more information, please visit www.aravive.com.

Forward-Looking Statements

This communication contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended), express or implied, such as initiation of a pivotal trial of AVB-500 in platinum resistant ovarian cancer during the fourth quarter 2020/first quarter 2021, initiation of Phase 1b/2 trial of AVB-500 in clear cell renal cell carcinoma during fourth quarter of 2020, the pivotal trial of AVB-500 in platinum resistant ovarian cancer being a global, randomized, double-blind, placebo-controlled trial to evaluate efficacy and tolerability of AVB-500 at a dose of 15 mg/kg in combination with paclitaxel, the Phase 1b/2 trial of AVB-500 in clear cell renal cell carcinoma providing safety, pharmacokinetic, and preliminary clinical activity in 2021 and current cash and cash equivalents expected to fund operations into 2022. 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 Company's ability to design and obtain approval for a randomized, double-blind, placebo-controlled trial to evaluate efficacy and tolerability of AVB-500 at a dose of 15 mg/kg in combination with paclitaxel, the ability to properly fund the Company, the ability to initiate the open-label ccRCC study and expected pivotal PROC study within the expected timelines, the ability to provide preliminary safety, pharmacokinetic and preliminary clinical activity from the ccRCC study in 2021, the ability to fund operations into 2022 with current cash and cash equivalents, the ability of the new directors and management team to deliver on the Company's strategic vision and execute on its business plan, 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 oncology indications, the Company's dependence upon AVB-500, AVB-500's ability to have favorable results in clinical trials and ISTs, the clinical trials of AVB-500 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 AVB-500 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 AVB-500; if AVB-500 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, 2019, 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)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue				
Grant revenue	\$ —	\$ —	\$ —	\$ 4,753
Operating expenses				
Research and development	5,070	3,840	11,085	10,325
General and administrative	2,715	3,158	9,866	11,039
Loss on impairment of long-lived assets	2,914	—	5,784	—
Total operating expenses	<u>10,699</u>	<u>6,998</u>	<u>26,735</u>	<u>21,364</u>
Loss from operations	(10,699)	(6,998)	(26,735)	(16,611)
Interest income	8	232	251	811
Other income (expense), net	31	624	(13)	1,910
Net loss	<u>\$ (10,660)</u>	<u>\$ (6,142)</u>	<u>\$ (26,497)</u>	<u>\$ (13,890)</u>
Net loss per share- basic and diluted	<u>\$ (0.66)</u>	<u>\$ (0.54)</u>	<u>\$ (1.69)</u>	<u>\$ (1.23)</u>
Weighted-average common shares used to compute basic and diluted net loss per share	<u>16,055</u>	<u>11,285</u>	<u>15,658</u>	<u>11,280</u>

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

	September 30, 2020 (unaudited)	December 31, 2019
Assets:		
Cash and cash equivalents	\$ 53,967	\$ 65,134
Restricted cash	2,430	2,423
Other assets	2,182	5,867
Operating lease right-of-use assets	2,651	8,697
Total assets	\$ 61,230	\$ 82,121
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 3,162	\$ 2,575
Operating lease obligation	8,407	10,233
Contingent payable	295	264
Total liabilities	11,864	13,072
Total stockholders' equity	49,366	69,049
Total liabilities and stockholders' equity	\$ 61,230	\$ 82,121

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