



Aravive Reports Third Quarter 2022 Financial Results and Provides Corporate Updates

November 10, 2022

- ***Continued Advancement of Clinical Trials in Platinum Resistant Ovarian Cancer (PROC), Clear Cell Renal Cell Carcinoma and Pancreatic Adenocarcinoma***
- ***Secured Funding to Take the Company Beyond the PROC Readout in Mid-2023***
- ***Advanced Development of Batiraxcept in China and Received Significant Milestone Payment***

HOUSTON, Nov. 10, 2022 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2022 and provided corporate updates.

"Aravive continues to make tremendous progress on all fronts," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "All development activities around our PROC Phase 3 trial, including patient enrollment and CMC, remain on track to deliver topline data in mid-2023. Our trials in clear cell renal cancer and pancreatic cancer continue to provide encouraging data. Importantly, we have been able to secure the proper funding to advance all programs beyond the PROC readout, allowing us to focus on the critical clinical activities around our trials, particularly the PROC registrational study. In addition to the funding itself, we have added new support from a strong and respected syndicate of leading biotech investors. We are grateful for their confidence in both our science and our ability to move it ahead."

Recent Corporate Highlights

- ***The Company Completes PIPE Offering Adding Funding to Support Operations Beyond PROC Readout***
In October, the Company raised approximately \$41.5 million in gross proceeds from a private placement offering with new biotechnology investors, existing investors and certain of the Company's management and directors. This funding, along with the receipt of the Company's milestone payment (see below), takes our cash runway into late 2023, beyond the readout on our Phase 3 ovarian cancer trial. Pro forma cash at September 30, 2022, giving effect to the capital raise (after transaction expenses), milestone payment and cash balances on that date is approximately \$73 million. Current common shares outstanding after the offering are 59,826,881 in addition to 15,870,199 prefunded warrants, for a total of 75,697,080 basic shares outstanding.
- ***Continued Progress with the Company's Partner in China Results in Milestone Payment***
Our partner in China, 3D Medicines enrolled patients into its Phase 3 PROC trial, which begins their Phase 3 clinical activity towards ultimate approval in China. The Company received the \$6 million payment related to achievement of this milestone in October.
- ***The Phase 3 Platinum Resistant Ovarian Cancer (PROC) Trial Remains On Track***
The registration-directed Phase 3 program of batiraxcept in combination with paclitaxel in PROC remains on track to complete enrollment around year-end 2022. The Company continues to expect to report topline data from the trial by mid-2023. CMC work remains on track with the goal of filing a Biologics License Application (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. The trial aims to enroll 350 patients with platinum resistant, high-grade serous ovarian cancer who have received 1-4 prior lines of therapy.
- ***Updated Clear Cell Renal Cell Cancer (ccRCC) Data Continues to Be Encouraging***
As of August 8, 2022, 26 previously treated (2L+) patients with ccRCC have been treated with batiraxcept in the Phase 1b portion of a Phase 1b/2 trial at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily. There were no dose limiting toxicities observed at either dose. The best overall response rate (ORR, confirmed) in the ITT population was 42%. 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. The best ORR in the biomarker high population was 55%. The 9-month progression-free survival (PFS) rate was 65% in the ITT population and 72% in the biomarker high population. The Company has discussed a registrational path with the US FDA that includes use of the sAXL/Gas6 ratio as a 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.

- ***Expansion of Phase 1b Pancreatic Adenocarcinoma Study***

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/m² on Days 1, 8, & 15) and gemcitabine (1000 mg/m² 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 see if a higher dose will increase the proportion of patients who will achieve high MEC of batiraxcept 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.

Third Quarter 2022 Financial Results

Revenues for the three months ended September 30, 2022, were approximately \$4.9 million, compared to approximately \$1.6 million for the three months ended June 30, 2022. 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 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 was driven primarily by the achievement during the third quarter of 2022 of a development milestone from the Company's licensee, 3D Medicines, based on the initiation of the global Phase 3 PROC clinical trial in China as part of the collaboration and license agreement.

Total operating expenses for the three months ended September 30, 2022, were \$21.5 million, compared to \$21.0 million for the three months ended June 30, 2022. Research and development expense for the three months ended September 30, 2022, was \$18.7 million, compared to \$17.3 million for the three months ended June 30, 2022. The increase in research and development expense is primarily attributable to increases in CMC-related costs. General and administrative expense for the three months ended September 30, 2022 was \$2.8 million, compared to \$3.7 million for the three months ended June 30, 2022. The decrease in general and administrative expense is primarily attributable to decreased stock-based compensation, consulting expense, and severance expense.

Aravive reported a net loss of \$15.7 million, or \$0.51 per share, for the three months ended September 30, 2022, compared to a net loss of \$18.5 million, or \$0.61 per share, for the three months ended June 30, 2022.

Cash Position

As of September 30, 2022, cash and cash equivalents were \$27.9 million, compared to \$46.8 million as of June 30, 2022 and \$59.4 million as of December 31, 2021. During October 2022, the Company received a \$6 million milestone payment from the Company's licensee, 3D Medicines, Inc. (recorded as an account receivable on the consolidated balance sheet as of September 30, 2022) and raised approximately \$41.5 million in gross 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. 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 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 continuing to make tremendous progress on a fronts, all aspects of the development activities around the Company's PROC Phase 3 trial, including patient enrollment and CMC, remaining on track to deliver topline data in mid-2023, the Company's trial in clear cell renal cancer and pancreatic cancer continuing to provide the Company with meaningful and encouraging data, the cash runway extending into late next year, beyond the readout on the Company's Phase 3 Ovarian cancer trial, the registration-directed Phase 3 program of batiraxcept in combination with paclitaxel in PROC remaining on track to complete enrollment around year-end 2022, the Company reporting topline data from the trial by mid-2023. 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, 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), 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 and providing preliminary data from the 20 mg/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 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.

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

	Three Months Ended September 30, 2022	Three Months Ended June 30, 2022
	(unaudited)	(unaudited)
Revenue		
Collaboration revenue	\$ 4,956	\$ 1,615
Total revenue	4,956	1,615
Operating expenses		
Research and development	18,668	17,315
General and administrative	2,836	3,727
Total operating expenses	21,504	21,042
Loss from operations	(16,548)	(19,427)
Other income, net	885	950
Net loss	\$ (15,663)	\$ (18,477)
Net loss per share- basic and diluted	\$ (0.51)	\$ (0.61)
Weighted-average common shares used to compute basic and diluted net loss per share	30,518	30,505

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Revenue				
Collaboration revenue	\$ 4,956	\$ 2,412	\$ 7,663	\$ 6,457
Total revenue	4,956	2,412	7,663	6,457
Operating expenses				
Research and development	18,668	11,343	48,985	25,347
General and administrative	2,836	2,643	9,651	8,102
Total operating expenses	21,504	13,986	58,636	33,449
Loss from operations	(16,548)	(11,574)	(50,973)	(26,992)
Other income, net	885	488	3,776	797
Net loss	\$ (15,663)	\$ (11,086)	\$ (47,197)	\$ (26,195)
Net loss per share- basic and diluted	\$ (0.51)	\$ (0.53)	\$ (1.72)	\$ (1.33)
Weighted-average common shares used to compute basic and diluted net loss per share	30,518	20,763	27,419	19,758

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

	September 30, 2022	June 30, 2022
	(unaudited)	(unaudited)
Assets:		
Cash and cash equivalents	\$ 27,896	\$ 46,833
Accounts receivable	6,000	—
Restricted cash	2,436	2,431
Other assets	4,242	4,793
Operating lease right-of-use assets	1,648	1,834
Total assets	\$ 42,222	\$ 55,891
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 16,078	\$ 15,202
Deferred revenue	6,456	5,412
Operating lease obligation	4,646	5,211
Total liabilities	27,180	25,825
Total stockholders' equity	15,042	30,066
Total liabilities and stockholders' equity	\$ 42,222	\$ 55,891

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