



## Aravive Reports Fourth Quarter and Twelve Months Ended December 31, 2019 Financial Results and Provides Recent Corporate Updates

March 27, 2020

- *AVB-500 Phase 1b dose escalation ongoing at 20 mg/kg dose in platinum resistant ovarian cancer with potential for topline data in summer 2020*
- *Company announces clinical trial updates for clear cell renal cell carcinoma and IgA Nephropathy studies*
- *Current cash runway expected to fund company into 2022*

HOUSTON, March 27, 2020 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage biopharmaceutical company developing treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis, announced recent corporate updates and financial results for the fourth quarter and twelve months ended December 31, 2019.

With the recent and rapidly evolving impact of COVID-19 on patient recruitment in clinical trials and considering patient safety and trial integrity, Aravive has decided to make certain changes to its clinical plans:

- The company has decided to amend its clear cell renal cell carcinoma (ccRCC) trial to initiate treatment at 15 mg/kg or 20 mg/kg given the positive safety profile seen with the 15 mg/kg dosing cohort of the platinum resistant ovarian cancer (PROC) trial and the recent initiation of the 20 mg/kg dosing cohort in the PROC population. While this may delay first patient dosing, the overall timelines for top line data may not be significantly impacted given the higher starting dose, assuming the COVID-19 situation does not interfere with ongoing clinical studies.
- To reduce the risk of unnecessary exposure of patients to COVID-19 that may be caused by patients coming to health centers for their AVB-500 intravenous infusion, the company will pause new enrollment in its IgA nephropathy (IgAN) trial as this is a relatively healthy patient population with a chronic disease.

Aravive plans to continue enrollment in its ongoing Ph 1b dose escalation cohort at the 20 mg/kg dose in patients with PROC with the goal of targeting up to twelve patients in the trial, subject to the impact of COVID-19.

Based on updated clinical plans, Aravive anticipates that its cash and cash equivalents will be sufficient to fund operations into 2022.

"We are encouraged with the safety and efficacy profile of AVB-500 seen in the small number of patients in the 15 mg/kg dose cohort in our ongoing Phase 1b trial in platinum resistant ovarian cancer that is consistent with the hypothesis generated from the 10 mg/kg dose cohort. The 20 mg/kg dose cohort is ongoing and we anticipate topline data later this summer, assuming the COVID-19 situation doesn't interfere with ongoing clinical studies," said Rekha Hemrajani, president and chief executive officer of Aravive, "2019 was a transformative year for Aravive with several clinical and financial achievements that have set us up well for 2020 and beyond despite the short-term challenges we may face due to COVID-19."

### Recent Corporate Updates

- In March 2020, Aravive announced that the first patient has been dosed in an investigator-sponsored Phase 1/2 clinical trial of AVB-500 in combination with PD-L1 inhibitor avelumab in patients with advanced urothelial carcinoma (UC). The trial is being led by Abhishek Tripathi, M.D., Assistant Professor of Medicine, Section of hematology/oncology at the University of Oklahoma Stephenson Cancer Center.
- In February 2020, Aravive announced that the independent Data Monitoring Committee (DMC) has reviewed the open-label data following the first 28-day treatment cycle for the three patients in each of the two 15 mg/kg dosing cohorts of the Phase 1b portion of the Phase 1b/Phase 2 clinical trial of AVB-500 in patients with PROC and unanimously recommended the trial continue as planned with enrollment of patients into the 20mg/kg dose cohorts.
- In January 2020, Aravive announced that the company received IND Clearance for Phase 1b/Phase 2 clinical trial of AVB-500 in Patients with ccRCC.
- In January 2020, Aravive announced the appointment of Rekha Hemrajani as president, chief executive officer and director of the company and the transition of Jay Shepard's role from president and chief executive officer of the company to the chairman of the board of directors.
- In December 2019, Aravive announced that the company had begun enrolling patients in the Phase 2a clinical trial of AVB-500 in patients with kidney fibrosis, specifically IgAN (NCT04042623). This is an open-label Phase 2a clinical trial designed to evaluate the safety and efficacy of AVB-500 in patients with biopsy-proven IgAN and excreting 1-3 grams of

protein daily in their urine. The primary endpoints will be safety as well as measuring the effects of AVB-500 treatment on protein levels in patient's urine.

- In December 2019, Aravive raised net proceeds of approximately \$25 million in a public offering. A total of 3,633,334 shares of its common stock were issued at a price of \$7.50 per share.
- In November 2019, Aravive announced positive data from the Phase 1b portion of the Phase 1b/2 clinical trial of AVB-500 in PROC patients. The data from the first 31 patients treated at the 10 mg/kg dose affirmed earlier findings on the relationship between AVB-500 levels in the blood and clinical benefit. In this data analysis, high serum drug levels of AVB-500 were strongly predictive of anti-tumor activity with statistically significant correlation with progression-free survival.
- In November 2019, Aravive and AstraZeneca announced that an investigator-sponsored Phase 1/2 clinical trial of AVB-500 in combination with durvalumab, a PD-L1 inhibitor, in patients with platinum-resistant, recurrent epithelial ovarian cancer had initiated and was recruiting patients (NCT04019288).
- In October 2019, Aravive reported publication of data from a non-clinical trial where AVB-500 reduced tumor size and blood vessel density in animal models of ccRCC, highlighting the role of GAS6/AXL signaling in promoting tumor angiogenesis through control of plasminogen receptor S100A10. This data was published in the peer-reviewed journal [Cancer Research](#) and supports the Company's development plans for AVB-500 in this indication .

### Financial Results

The consolidated statements of operations for the three and twelve months ended December 31, 2019 include the operations of Aravive Biologics, Inc. for a full twelve months, which were not included for the full twelve months in the consolidated statements of operations for the twelve months ended December 31, 2018, due to the fact that the merger with Aravive Biologics, Inc. was consummated in October 2018.

Revenue for the three and twelve months ended December 31, 2019 were \$0 and \$4.8 million, respectively, compared to \$1.4 million for both periods in 2018. Revenue was derived solely from the Cancer Prevention Research Institute of Texas (CPRIT) grant.

Total operating expenses for the three and twelve months ended December 31, 2019 were \$5.2 million and \$26.5 million, respectively, compared to \$52.6 million and \$76.8 million for the same periods in 2018.

Total operating expenses for the three and twelve months ended December 31, 2019 include non-cash stock-based compensation expense of \$0.6 million and \$3.4 million, respectively, compared to \$9.9 million and \$16.1 million for the same periods in 2018. In addition, for the year ended December 31, 2018, there was a one-time non-cash charge for acquired in process research and development of \$38.3 million incurred in connection with the completion of the merger in the fourth quarter of 2018.

Net loss for the three and twelve months ended December 31, 2019 was \$4.3 million and \$18.2 million, or \$0.35 per share and \$1.57 per share, respectively, compared to a net loss of \$51.0 million and \$76.3 million, or \$4.82 per share and \$10.64 per share, respectively for the same periods in 2018.

### Cash Position

At December 31, 2019, cash and cash equivalents were \$65.1 million. Based on the updated clinical plans, Aravive anticipates that its cash and cash equivalents will be sufficient to fund operations into 2022.

### About AVB-500

AVB-500 is a therapeutic recombinant fusion protein that has been shown to neutralize GAS6 activity by binding to GAS6 with very high affinity. In doing so, AVB-500 selectively inhibits the GAS6-AXL signaling pathway. In preclinical studies, GAS6-AXL inhibition has shown anti-tumor activity, both as a single agent and in combination with a variety of anticancer therapies including radiation therapy, immuno-oncology agents and chemotherapeutic drugs that affect DNA replication and repair. Increased expression of AXL and GAS6 in tumors is correlated to poor prognosis and survival, and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies.

Aravive reported positive data from the first 31 patients enrolled in the Phase 1b portion of a Phase 1b/2 clinical trial of AVB-500 in platinum-resistant recurrent ovarian cancer. AVB-500 continues to be well tolerated with no dose limiting toxicities. An investigator-sponsored Phase 1/2 trial of AVB-500, in combination with durvalumab in patients with platinum-resistant recurrent epithelial ovarian cancer, is also ongoing. Based on AVB-500's safety profile and specifically targeted mechanism of action, this drug candidate has the potential to be used both in combination with existing therapies, as well as a maintenance drug. The U.S. Food and Drug Administration granted Fast Track Designation to AVB-500 in platinum-resistant recurrent ovarian cancer.

### About Aravive

Aravive, Inc. (Nasdaq: ARAV) is a clinical-stage biopharmaceutical company developing treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis. Aravive's lead product candidate, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway. By capturing serum GAS6, AVB-500 starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression. The GAS6-AXL signaling pathway also plays a significant role in fibrogenesis. Aravive is evaluating AVB-500 in platinum-resistant ovarian cancer, clear cell renal cell carcinoma and kidney fibrosis and intends to expand development into additional oncology and fibrotic indications. Aravive is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. For more information, please visit [www.aravive.com](http://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, including the overall timelines for the ccRCC trial not being significantly impacted by the amendment given the higher starting dose, assuming the COVID-19 situation does not interfere with ongoing clinical studies, the planned continued enrollment in the Phase 1b dose escalation cohort at the 20 mg/kg dose in patients with PROC with the goal of targeting up to 12 patients in the trial, subject to the impact of COVID-19, cash and cash equivalents will be sufficient to fund operations into 2022, early topline data later this summer from the 20mg/kg dosing cohort assuming the COVID-19 situation doesn't interfere with ongoing clinical studies, the potential of AVB-500 to be used both in combination with existing therapies, as well as a maintenance drug, the potential of AVB-500 to halt the biological programming that promotes disease progression and the expansion of the development of AVB-500 into additional oncology and fibrotic indications. 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 expand development into additional oncology and fibrotic indications, the Company's dependence upon AVB-500, AVB-500's ability to have favorable results in clinical trials and results that are as favorable as those of preclinical studies and the Phase 1b portion of the Phase 1b/2 trial, the ability to continue enrollment in the Phase 1b/2 trial, especially in light of COVID-19, 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 corona virus; 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 most recent Annual Report on Form 10-K, our 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.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
	(unaudited)			
<b>Revenue</b>				
Grant revenue	\$ —	\$ 1,371	\$ 4,753	\$ 1,371
<b>Operating expenses</b>				
Research and development	2,511	3,010	12,836	11,075
Write-off of acquired in-process research and development	—	38,313	—	38,313
General and administrative	2,652	11,284	13,691	27,395
Total operating expenses	<u>5,163</u>	<u>52,607</u>	<u>26,527</u>	<u>76,783</u>
Loss from operations	(5,163)	(51,236)	(21,774)	(75,412)
Interest income	211	286	1,022	989
Interest expense	—	(604)	—	(2,429)
Other income (expense), net	624	600	2,534	519
Net loss	<u>\$ (4,328)</u>	<u>\$ (50,954)</u>	<u>\$ (18,218)</u>	<u>\$ (76,333)</u>
Net loss per share- basic and diluted	\$ (0.35)	\$ (4.82)	\$ (1.57)	\$ (10.64)
Weighted-average common shares used to compute net loss per share- basic and diluted	12,506	10,580	11,589	7,171

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

December 31, 2019	December 31, 2018
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Assets:

Cash and cash equivalents	\$ 65,134	\$ 56,992
Restricted cash	2,423	2,396
Other assets	5,867	1,431
Operating lease right-of-use assets	8,697	—
Build-to-suit lease asset	—	8,651
<b>Total assets</b>	<b>\$ 82,121</b>	<b>\$ 69,470</b>
Liabilities and stockholders' equity:		
Accounts payable and other current liabilities	\$ 2,574	\$ 1,791
Deferred revenue	—	146
Build-to-suit lease obligation	—	7,324
Operating lease obligation	10,234	—
Contingent liabilities	264	264
Total liabilities	13,072	9,525
Total stockholders' equity	69,049	59,945
<b>Total liabilities and stockholders' equity</b>	<b>\$ 82,121</b>	<b>\$ 69,470</b>



Source: Aravive, Inc.