Aravive Reports Second Quarter 2020 Financial Results and Provides Recent Corporate Updates

August 3, 2020

- Successfully completed Phase 1b trial of AVB-500 in Platinum Resistant Ovarian Cancer with encouraging clinical data showing 60% ORR in the subpopulation that has not previously been treated with bevacizumab
- On-track to discuss the potential pivotal trial of AVB-500 with FDA this year
- On-track to initiate Phase 1b/2 trial of AVB-500 in Clear Cell Renal Cell Carcinoma in 2H 2020
- Current cash and cash equivalents expected to fund operations into 2022

HOUSTON, Aug. 03, 2020 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative therapeutics, today announced recent corporate updates and financial results for the second quarter ended June 30, 2020.

“Aravive has made significant progress in the second quarter of 2020, highlighted by the successful completion of our Phase 1b trial evaluating AVB-500 in platinum resistant ovarian cancer with encouraging clinical data setting us up to move into what could be a pivotal study with our lead program,” said Gail McIntyre, Ph.D., chief executive officer of Aravive. “A preliminary discussion with the FDA suggests an adaptive, randomized, controlled trial with biomarker-based stratification and an interim analysis to drop the control arm could potentially be an efficient pathway to approval. We are very encouraged by the Phase 1b trial results and look forward to formally discussing the data and our development plans with the FDA in the coming months. The Aravive team is also looking forward to advancing both the ovarian cancer and renal cancer programs over the next few months.”

Second Quarter 2020 Financial Results
Revenue for the three and six months ended June 30, 2020 were $0 for both periods, compared to $3.1 million 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 six months ended June 30, 2020 were $5.7 million and $16.0 million, respectively, compared to $6.9 million and $14.4 million for the same periods in 2019.

Total operating expenses for the three and six months ended June 30, 2020 included non-cash stock-based compensation expense of $0.5 million and $1.2 million, respectively, compared to $0.9 million and $2.0 million for the same periods in 2019. In addition, as previously reported, during the three months ended March 31, 2020, there was a one-time non-cash charge for impairment of the Company’s right-of-use asset and leasehold improvements of $2.9 million.

For the three and six months ended June 30, 2020, Aravive reported a net loss of $5.0 million and $15.8 million, or $0.32 per share and $1.02 per share, respectively, compared to a net loss of $3.0 million and $7.7 million, or $0.27 per share and $0.69 per share, for the same periods in 2019.

Cash Position
As of June 30, 2020, cash and cash equivalents was $60.1 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.

Recent Corporate Highlights

- **AVB-500 in Platinum Resistant Ovarian Cancer (PROC)**: On July 23, 2020, the Company announced the successful completion of its Phase 1b trial of AVB-500 in PROC and selection of the recommended Phase 2 dose.
    - AVB-500 plus paclitaxel showed an overall Investigator-assessed best response rate (per RECIST V1.1) of 35% (95% CI of 16% to 57%) across all dosing cohorts with 2 complete responses (CR) and 6 partial responses (PR). These data compare favorably to the average response rate in platinum-resistant ovarian cancer patients of 10-15%.1
    - The Company is encouraged with 60% ORR in the sub population that has not been previously treated with bevacizumab and 71% among those with high plasma sAXL/GAS6 ratio, a potential biomarker of response.
    - Analysis of all safety data to date showed that AVB-500 has been well-tolerated with no dose-limiting toxicities or unexpected safety signals.
    - While the Phase 1b trial was a safety trial and not powered to demonstrate efficacy, all 5 patients in the 15 mg/kg cohort experienced clinical benefit, with 1 CR (patient continues to maintain CR for 3 months on AVB-500 alone following discontinuation of paclitaxel), 2 partial responses, and 2 stable disease.
    - The safety, pharmacokinetic and clinical activity at the 15 mg/kg dose support advancing 15 mg/kg AVB-500 into the next, potentially registrational enabling PROC trial. An interim analysis of this study is expected in 2021.
- **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 in the second half of 2020. This is an open-label study which is expected to provide safety, pharmacokinetic, and preliminary clinical activity during the upcoming year. This study will also explore the biomarkers that have been identified during the PROC study.

- **Investigator-Sponsored Trials (ISTs)**: The Company expects to provide an update on the ongoing ISTs within the next 12 months (assuming COVID-19 and other unforeseen circumstances do not interfere).
- **Strategic Decision to Focus on Oncology Assets and Pipeline Expansion:** The Company announced a new strategic focus for AVB-500 in oncology. Following the positive results from the AVB-500 Phase 1 trial in PROC, Aravive plans to focus its resources on advancing the development of AVB-500 in PROC, ccRCC and potentially additional oncology indications.
    - Recent preclinical data with AVB-500 has highlighted its promise to be combined with various oncology compounds (e.g., PARP inhibitors, bevacizumab, immunotherapy as well as cytotoxic agents) to support the Company's pipeline expansion in oncology indications.
    - Specifically, in addition to Aravive's focus on PROC, the Company is also considering moving AVB-500 into frontline therapy in Ovarian cancer in combination with PAC/Platinum/Bevacizumab, all of which have biological rationale and supportive data for potential synergy/additive anti-tumor effects. Importantly, the safety profile of AVB-500 suggests there may not be added toxicity to the first line cocktails used in frontline metastatic ovarian cancer.
    - The Company expects to announce expansion plans during 2021.

"I am delighted at the achievements that Gail and her team have made with AVB-500 and we strongly support moving the program forward. With a renewed focus on oncology assets, AVB-500 offers a first-and potentially best-in-class opportunity in oncology," said Fred Eshelman, Pharm.D., chairman of the board of directors. "On behalf of the Aravive Board, we look forward to continuing to grow our business, add talent to our management team and Board and assess business development opportunities around our pipeline and ex-U.S."

About Aravive

Aravive, Inc. (Nasdaq: ARAV) is a clinical-stage oncology company developing transformative treatments designed to halt the progression of life-threatening diseases. Aravive's lead product candidate, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway. On July 23, 2020, Aravive announced the successful completion of a Phase 1b trial of AVB-500 in platinum resistant ovarian cancer and selection of the recommended Phase 2 dose, 15 mg/kg. 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 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 (CR), 2 partial responses, and 2 stable disease. Across all cohorts, AVB-500 plus paclitaxel data showed an ORR of 35% (8/23 patients, including 2 CRs) and a 60% ORR in paclitaxel patients who had not previously been given bevacizumab. 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 advancing both the ovarian cancer and renal cancer programs over the next few months, being on-track to discuss the potentially pivotal study with FDA this year and initiation of Phase 1b/2 trial of AVB-500 in clear cell renal cell carcinoma in second half of 2020, moving into what could be a pivotal trial, expanding the pipeline in oncology and announcement of expansion plans in 2021, an adaptive, randomized, controlled trial with biomarker-based stratification and an interim analysis to drop the control arm potentially being an efficient pathway to approval, an interim analysis of the PROC trial in 2021, current cash and cash equivalents expected to fund operations into 2022, ISTs providing information within the next twelve months, moving AVB-500 into frontline therapy in ovarian cancer and the suggestion that AVB-500 may not be added toxicity to the first line cocktails used in frontline metastatic ovarian cancer and continuing to grow the business, add talent to the management and Board and assess business development opportunities around the pipeline and ex-U.S. 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, controlled trial with an interim analysis and drop the control arm that potentially could be a pathway to approval, the ability to properly fund the Company, the ability to initiate the open-label ccRCC study and potentially pivotal PROC study, the ability to provide preliminary safety, pharmacokinetic and tumor response data from the ccRCC study, interim analysis data on the potentially pivotal study by the end of 2021 and announcement of pipeline expansion plans in 2021, providing information from ISTs within the next twelve months, the ability to move AVB-500 into frontline therapy, 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.

Contacts:

Media:
Sheryl Seapy, W2O
sseapy@w2ogroup.com
(949) 903-4750

Investors:
Luke Heagle, W2O
lheagle@w2ogroup.com
(910) 726-1372

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenue				
Grant revenue	$ —	$ 3,054	$ —	$ 4,753
Operating expenses				
Research and development	2,522	3,637	6,014	6,485
General and administrative	3,201	3,291	7,151	7,881
Loss on impairment of long-lived assets	—	—	2,870	—
Total operating expenses	5,723	6,928	16,035	14,366
Loss from operations	(5,723)	(3,874)	(16,035)	(9,613)
Interest income	26	233	243	579
Other income (expense), net	656	597	(45)	1,286
Net loss	$ (5,041)	$ (3,044)	$ (15,837)	$ (7,748)
Net loss per share- basic and diluted	$ (0.32)	$ (0.27)	$ (1.02)	$ (0.69)
Weighted-average common shares used to compute basic and diluted net loss per share	15,902	11,280	15,457	11,277

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

	June 30, 2020	**December 31, 2019**
	(unaudited)	
Assets:		
Cash and cash equivalents	$ 60,062	$ 65,134
Restricted cash	2,429	2,423
Other assets	3,128	5,867
Operating lease right-of-use assets	5,394	8,697
Total assets	**$ 71,013**	**$ 82,121**
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 2,276	$ 2,575
Operating lease obligation	8,995	10,233
Contingent payable	295	264
Total liabilities	11,566	13,072
Total stockholders' equity	59,447	69,049
Total liabilities and stockholders' equity	**$ 71,013**	**$ 82,121**

[1] A Davis et al., Gynecologic Oncology 133 (2014) 624–631

Source: Aravive, Inc.