Aravive Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Recent Corporate Updates

March 7, 2019

HOUSTON, March 07, 2019 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage biopharmaceutical company focused on developing innovative therapies that target important survival pathways for cancer, announced recent corporate updates and financial results for the fourth quarter and full year ended December 31, 2018.

“2019 will be an important year for Aravive, with several data readouts expected along with the initiation of two additional studies. Enrollment in the Phase 1b portion of the Phase 1b/2 clinical trial of AVB-S6-500 in patients with platinum-resistant recurrent ovarian cancer is on-track and we are eager to report preliminary data in the third quarter of this year,” said Jay Shepard, president and chief executive officer. “At our KOL event in February, we announced the planned expansion of our pipeline with two additional indications, clear cell renal cell carcinoma and IgA nephropathy. We remain committed to further exploring the potential of our platform in the treatment for both oncology and fibrotic indications.”

Recent Corporate Updates

AVB-S6-500

AVB-S6-500 is a novel, high-affinity, soluble Fc-fusion protein designed to block the activation of the GAS6-AXL signaling pathway by intercepting the binding of GAS6 to its receptor AXL. 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. Below are some recent highlights from the program:

- Presented detailed results from the Phase 1 clinical trial of AVB-S6-500 at the 2018 EORTC-NCI-AACR Symposium. A copy of the poster presentation is available at www.aravive.com.
- Initiated Phase 1b portion of Phase 1b/2 clinical trial of AVB-S6-500 in platinum-resistant recurrent ovarian cancer.
- Highlighted AVB-S6-500 and GAS6/AXL pathway and announced indications for additional clinical trials at Key Opinion Leader Breakfast Symposium in New York on February 5, 2019.
    - Announced first indication for a clinical trial outside of oncology is expected to be a Phase 1b trial of AVB-S6-500 in patients with IgA nephropathy. The company expects to initiate a clinical trial in the second half of 2019.
    - Announced next oncology study is expected to be a Phase 1b/2 clinical trial of AVB-S6-500 in patients with clear cell renal cell carcinoma. The company expects to initiate a Phase 1b/2 clinical trial in the second half of 2019.
- Findings from a preclinical study of AVB-S6-500 will be presented at the Society of Gynecologic Oncology’s 50 th Annual Meeting on Women’s Cancer to be held March 16-19, 2019, in Honolulu, Hawaii. The data will be presented by Maggie Mullen, MD and Katherine Fuh, MD, PhD, both from the Center for Reproductive Health Sciences, Department of Obstetrics & Gynecology, Washington University School of Medicine.
  Date & Time: Monday, March 18, 2019 6:00 – 7:00 PM HST
  Session Title: Oral Featured Poster Session II: Trials, Basic Science, and Translational Science
  Abstract & Poster Number: Abstract 68
  Poster Title: *Therapeutic AXL/GAS6 inhibition of tumor and tumor microenvironment stromal cells improves response to chemotherapy in ovarian cancer*

Company

- Completed the merger of Aravive Biologics and Versartis to form Aravive, Inc. in October 2018 (the “Merger”).
- Expanded executive team with promotion of Gail McIntyre, PhD, DABT to chief scientific officer. Dr. McIntyre has over 25 years of experience in the biopharmaceutical industry, having focused much of her time moving compounds through lead optimization and preclinical development and onto the market. She has worked closely with Aravive Biologics since August 2016, most recently serving as the company’s senior vice president of research and development.

Anticipated Milestones

- Report interim safety, pharmacodynamic, and pharmacokinetic data for the Phase 1b portion of the Phase 1b/2 clinical trial of AVB-S6-500 in patients with platinum-resistant recurrent ovarian cancer in the third quarter of 2019.
- Initiate Phase 1b clinical trial in patients with IgA nephropathy in the second half of 2019.
- Initiate the Phase 2 portion of the Phase 1b/2 clinical trial of AVB-S6-500 in patients with platinum-resistant recurrent ovarian cancer in the second half of 2019.
- Initiate Phase 1b/2 clinical trial in patients with clear cell renal cell carcinoma in the second half of 2019.

Fourth Quarter and Full Year 2018 Financial Results

The following commentary and condensed consolidated statements of operations and balance sheets include the results of Aravive, Inc. (formerly Versartis, Inc.), which include the results of Aravive Biologics from October 12, 2018 onward, the effective date of the Merger. The condensed consolidated statements of operations for the comparative periods in 2017 and the December 31, 2017 condensed consolidated balance sheet include only those of Aravive, Inc. (formerly Versartis, Inc.). All share and per share figures for all periods presented reflect the 1-for-6 reverse stock split effective on October 16, 2018.

For the fourth quarter ended December 31, 2018, Aravive reported a net loss of approximately $51.0 million, or $4.82 per share, basic and diluted, compared to net income for the same period in 2017 of $31.1 million, or $5.20 per share on a diluted basis.

Total operating expenses for the quarter ended December 31, 2018 were $52.6 million compared to $8.9 million for the same period in 2017. Research and development (R&D) expenses for the quarter ended December 31, 2018 were $3.0 million, compared to $1.3 million for the same period in 2017. General and administrative (G&A) expenses were $11.3 million for the quarter ended December 31, 2018 compared to $7.6 million for the same period in 2017.

Also included in fourth quarter 2018 operating expenses is 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.

Total operating expenses for the quarter ended December 31, 2018 include non-cash stock-based compensation expense of $9.9 million, of which $8.2 million relates to the assumption of options in connection with the Merger, compared to $2.2 million of non-cash stock-based compensation expense for the same period in 2017.

For the year ended December 31, 2018, Aravive reported a net loss of $76.3 million, or $10.64 per share, compared to a net loss for the same period in 2017 of $85.0 million, or $14.47 per share.

Total operating expenses for the year ended December 31, 2018 were $76.8 million, compared to $124.5 million for the same period in 2017. R&D expenses for the year ended December 31, 2018 were $11.1 million, compared to $94.6 million for the same period in 2017. G&A expenses for the year ended December 31, 2018 were $27.4 million, compared to $29.9 million for the same period in 2017.

Total operating expenses for the year ended December 31, 2018 include non-cash stock-based compensation expense of $16.1 million, of which $8.2 million relates to the assumption of options in connection with the Merger, compared to $13.3 million of non-cash stock-based compensation expense for the same period in 2017.

Cash Position and Guidance

Cash and cash equivalents were $57.0 million as of December 31, 2018. Aravive expects current cash and cash equivalents will enable the company to fund its operating plans into the end of 2020.

About Aravive

Aravive, Inc. (Nasdaq: ARAV) is a clinical-stage biopharmaceutical company focused on developing innovative therapies that target important survival pathways for cancer. Aravive's lead candidate, AVB-S6-500, is a novel, high-affinity, soluble Fc-fusion protein designed to block the activation of the GAS6-AXL signaling pathway by intercepting the binding of GAS6 to its receptor AXL. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression. Aravive has initiated the phase 1b portion of a phase 1b/2 clinical trial of AVB-S6-500 combined with standard of care therapies in patients with platinum-resistant recurrent ovarian cancer, and intends to expand development into additional oncology and fibrotic indications. 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, concerning the Company's goals, intentions and expectations as to future plans or events, including statements regarding the following anticipated milestones: the reporting of interim safety, pharmacodynamic, and pharmacokinetic data for the Phase 1b portion of the Phase 1b/2 clinical trial of AVB-S6-500 in patients with platinum-resistant recurrent ovarian cancer in the third quarter of 2019, initiation of a Phase 1b clinical trial in patients with IgA Nephropathy in the second half of 2019, initiation of the Phase 2 portion of the Phase 1b/2 clinical trial of AVB-S6-500 in patients with platinum-resistant recurrent ovarian cancer in the second half of 2019, and initiation of a Phase 1b/2 clinical trial in patients with clear cell renal cell carcinoma in the second half of 2019. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could 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 in 2019 into additional oncology and fibrotic indications, the anticipated development strategy for AVB-S6-500 being successful, AVB-S6-500's ability to have favorable results in clinical trials or receive regulatory approval, including its ability to meet the primary and secondary endpoint for the Phase 1b portion of the clinical trial and show a clinical benefit; potential delays in the Company's clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients; the risk that AVB-S6-500 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-S6-500; if AVB-S6-500 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 proxy statement/prospectus/information statement filed with the SEC on September 6, 2018, the Company's Form S-4 filed with the SEC on August 3, 2018, as subsequently amended, Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended December 31, 2017, Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, recent Current Reports on Form 8-K and subsequent filings with the SEC. Additional information will also be set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. 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.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenue				
Contract revenue	$ -	$ 40,000	$ -	$ 40,000
Grant revenue	1,371		1,371	
Total revenue	1,371	40,000	1,371	40,000
Operating expenses				
Research and development	3,010	1,317	11,075	94,612
Acquired in-process research and development	38,313	—	38,313	—
General and administrative	11,284	7,569	27,395	29,870
Total operating expenses	52,607	8,886	76,783	124,482
Income (loss) from operations	(51,236)	31,114	(75,412)	(84,482)
Interest income	286	186	989	847
Interest expense	(604)	(528)	(2,429)	(528)
Other income (expense), net	600	(19)	519	(1,063)
Net income (loss) before provision for income taxes	(50,954)	30,753	(76,333)	(85,226)
Benefit from income taxes	-	(375)	-	(247)
Net income (loss)	$ (50,954)	$ 31,128	$ (76,333)	$ (84,979)
Net income (loss) per share- basic (1)	$ (4.82)	$ 5.21	$ (10.64)	$ (14.47)
Net income (loss) per share- diluted (1)	$ (4.82)	$ 5.20	$ (10.64)	$ (14.47)
Weighted-average common shares used to compute basic net income (loss) per share (1)	10,580	5,979	7,171	5,871
Weighted-average common shares used to compute diluted net income (loss) per share (1)	10,580	5,984	7,171	5,871

(1) All share and per share figures for all periods presented reflect the 1-for-6 reverse stock split effective on October 16, 2018.

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

	December 31, 2018	December 31, 2017
Assets:		
Cash and cash equivalents	$ 56,992	$ 81,146
Other assets	3,827	3,743
Build-to-suit lease asset	8,651	8,888
Total assets	**$ 69,470**	**$ 93,777**
Liabilities and stockholders' equity:		
Accounts payable and other current liabilities	$ 1,937	$ 5,593
Build-to-suit lease obligation	7,324	5,428
Contingent payables	264	—
Total liabilities	9,525	11,021

Total stockholders' equity	59,945	82,756
Total liabilities and stockholders' equity	**$ 69,470**	**$ 93,777**

Source: Aravive, Inc.