
**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 8, 2019

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 Instruction 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 8, 2019, Aravive, Inc., a Delaware corporation (the “Registrant”) issued a corrective press release that included financial information for its quarter ended September 30, 2019. 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 7.01 Regulation FD Disclosure.

See “Item 2.02 Results of Operations and Financial Condition” above.

The information in this Current Report on Form 8-K under Items 2.02 and 7.01, including the information contained in Exhibit 99.1, is being furnished to the Commission, and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

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 8, 2019 |

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 8, 2019

ARAVIVE, INC.
(Registrant)

By: /s/ Jay P. Shepard

Name: Jay P. Shepard

Title: Chief Executive Officer



CORRECTION – Aravive Reports Third Quarter 2019 Financial Results and Provides Recent Corporate Updates

HOUSTON – Nov. 8, 2019-- In a release issued under the same headline on Thursday, November 7th by Aravive, Inc. (Nasdaq: ARAV), please note that in the last sentence of the second paragraph, the year for the IgA Nephropathy study should be 2019, not 2020. The corrected release follows:

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 quarter ended September 30, 2019.

"We are encouraged by the positive data we reported in our clinical program for AVB-500, an ultrahigh-affinity decoy protein that targets the GAS6-AXL signaling pathway, being evaluated in platinum-resistant recurrent ovarian cancer and we are focused on advancing further clinical development," said Jay Shepard, president and CEO of Aravive. "Additionally, we remain on track to initiate clinical development in renal cell carcinoma in 4Q2019/1Q2020, and we are making progress toward initiating additional programs including our IgA Nephropathy study in 2019."

Recent Corporate Updates

- In October 2019, Aravive reported publication of data from a non-clinical study where AVB-500 reduced tumor size and blood vessel density in animal models of clear cell renal cell carcinoma, 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
 - In September 2019, the Company reported positive data from the initial 12 patients of the ongoing Phase 1b portion of the Company's Phase 1b/2 study of AVB-500 in ovarian cancer patients treated with 10mg/kg AVB-500. The study showed AVB-500 treatment led to early proof of concept with overall best response rate (ORR) by investigator determined RECIST v1.1 criteria and durable response in responders. AVB-500 was well tolerated with no dose limiting toxicities (DLT). These data were presented at the European Society for Medical Oncology Congress (ESMO).
 - In September 2019, the Company also reported data on the initial 28 evaluable patients treated with the 10mg/kg AVB-500 dose in the same study in ovarian cancer patients demonstrating that the patients' current response rates in the clinical study correlate with drug exposure. As a result, higher doses of AVB-500 will be tested in the Phase 1b study to investigate the potential to increase the proportion of patients who achieve the higher drug exposures. AVB-500 continues to be well tolerated and the clinical benefit rate in the initial 28 patients is currently at 61 percent with 25 percent partial response. Once these data mature and the best response rates are confirmed for each patient, we may see different response and clinical benefit rates.
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- In August 2019, Aravive announced Jay Shepard intends to step down as president, chief executive officer (CEO) and member of the Board of Directors for family medical reasons. The Board of Directors continues to search for his successor, and Mr. Shepard plans to serve in his current role until a successor is appointed.

Financial Results

The condensed consolidated statements of operations for the three and nine months ended September 30, 2019 include the operations of Aravive Biologics, Inc., which were not included in the three and nine months ended September 30, 2018, due to the fact that the merger with Aravive Biologics, Inc. was consummated in October 2018.

Revenue for the nine months ended September 30, 2019 was \$4.8 million derived solely from the Cancer Prevention Research Institute of Texas (CPRIT) grant.

Total operating expenses for the three and nine months ended September 30, 2019 were \$7.0 million and \$21.4 million, respectively, compared to \$6.2 million and \$24.2 million for the same periods in 2018.

Total operating expenses for the three and nine months ended September 30, 2019 includes non-cash stock-based compensation expense of \$0.8 million and \$2.8 million, respectively, compared to \$1.3 million and \$6.3 million for the same periods in 2018.

Net loss for the three and nine months ended September 30, 2019 were \$6.1 million and \$13.9 million, or \$0.54 per share and \$1.23 per share, respectively, compared to a net loss of \$6.6 million and \$25.4 million, or \$1.08 per share and \$4.23 per share, for the same periods in 2018.

Cash Position

At September 30, 2019, cash and cash equivalents was \$45.0 million.

About AVB-500

AVB-500 is an ultrahigh-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.

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 ultrahigh-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, 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. Aravive was one of FierceBiotech's Fierce 15 in 2017. 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 making progress toward initiating additional clinical programs including an IgA Nephropathy study in 2019, remaining on track to initiate clinical development in renal cell carcinoma in 4Q2019/1Q2020, the potential to increase the proportion of patients who achieve the higher drug exposures and the potential of AVB-500 halting the biological programming that promotes disease progression. 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 or receive regulatory approval, potential delays in the Company's clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients; 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 and Form 10-K/A for the fiscal year ended December 31, 2018, 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.
Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands, except per share amounts)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|------------|------------------------------------|-------------|
| | 2019 | 2018 | 2019 | 2018 |
| Revenue | | | | |
| Grant revenue | \$ — | \$ — | \$ 4,753 | \$ — |
| Operating expenses | | | | |
| Research and development | 3,840 | 1,027 | 10,325 | 8,065 |
| General and administrative | 3,158 | 5,191 | 11,039 | 16,111 |
| Total operating expenses | 6,998 | 6,218 | 21,364 | 24,176 |
| Loss from operations | (6,998) | (6,218) | (16,611) | (24,176) |
| Interest income | 232 | 261 | 811 | 703 |
| Other income (expense), net | 624 | (593) | 1,910 | (1,906) |
| Net loss | \$ (6,142) | \$ (6,550) | \$ (13,890) | \$ (25,379) |
| Net loss per share- basic and diluted | \$ (0.54) | \$ (1.08) | \$ (1.23) | \$ (4.23) |
| Weighted-average common shares used to compute basic and diluted net loss per share | 11,285 | 6,040 | 11,280 | 5,998 |

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

| | September 30, 2019 (unaudited) | December 31, 2018 |
|---|--------------------------------------|----------------------|
| Assets: | | |
| Cash and cash equivalents | \$ 44,975 | \$ 56,992 |
| Restricted cash | 2,418 | 2,396 |
| Other assets | 6,101 | 1,431 |
| Build-to-suit lease asset | — | 8,651 |
| Operating lease right-of-use assets | 9,092 | — |
| Total assets | \$ 62,586 | \$ 69,470 |
| Liabilities and stockholders' equity: | | |
| Accounts payable and accrued liabilities | \$ 3,921 | \$ 1,791 |
| Deferred revenue | — | 146 |
| Build-to-suit lease obligation | — | 7,324 |
| Operating lease obligation | 10,871 | — |
| Contingent payable | 264 | 264 |
| Total liabilities | 15,056 | 9,525 |
| Total stockholders' equity | 47,530 | 59,945 |
| Total liabilities and stockholders' equity | \$ 62,586 | \$ 69,470 |