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 12, 2019

AVEO Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-34655**	**04-3581650**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One Broadway, 14th Floor **Cambridge, Massachusetts** **(Address of Principal Executive Offices)**	**02142** **(Zip Code)**

Registrant's telephone number, including area code: (617) 588-1960

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:

☐ 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, $0.001 par value	AVEO	Nasdaq Capital 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 12, 2019, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Form 8-K and Exhibit 99.1 shall not be deemed "filed" for 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Q3 2019 earnings press release issued by the Company on November 12, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVEO Pharmaceuticals, Inc.

Date: November 12, 2019

By: /s/ Michael Bailey
Michael Bailey
President and Chief Executive Officer

Exhibit 99.1

AVEO Reports Third Quarter 2019 Financial Results and Provides Business Update

CAMBRIDGE, Mass. – November 12, 2019 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the third quarter ended September 30, 2019 and provided a business update.

"This quarter we have made meaningful progress toward our goal of bringing effective and better tolerated therapies to patients battling kidney and other cancers," said Michael Bailey, president and chief executive officer of AVEO. "We are working to submit our New Drug Application (NDA) in the first quarter of 2020 for tivozanib as a treatment for relapsed/refractory renal cell carcinoma (RCC) and to provide a final overall survival (OS) update for the TIVO-3 study in June 2020. We also continue to make progress in evaluating tivozanib-immunotherapy combinations, with recently reported positive results from the TiNivo study of tivozanib and OPDIVO® (nivolumab) in RCC and the initiation of the Phase 1b/2 DEDUCTIVE study with IMFINZI® (durvalumab) in hepatocellular carcinoma. Ficlatuzumab also continues to advance in the clinic, with the initiation of CyFi-2, a Phase 2 randomized study in patients with relapsed and refractory acute myeloid leukemia (AML). Critical to this progress, we continue to maintain a strong balance sheet that we believe provides us with a cash runway into the second quarter of 2021."

Tivozanib North America Regulatory and Phase 3 TIVO-3 Study Updates

- **Announced Plans for TIVO-3 Final OS Analysis and NDA Submission for Tivozanib**. Last week, AVEO provided a regulatory update following a meeting with the U.S. Food and Drug Administration (FDA) to discuss results from the August 2019 OS analysis of the TIVO-3 trial and the Company's proposal to proceed with an NDA for tivozanib in relapsed/refractory RCC.

  The Company intends to submit an update to the TIVO-3 statistical analysis plan to the FDA allowing for the final OS analysis to be conducted, followed by an NDA submission in the first quarter of 2020, and expects to report results from the final OS analysis of the TIVO-3 trial in June 2020. The FDA and the Company agreed that if, during the review, the final analysis yields an OS hazard ratio (HR) above 1.00, the Company will withdraw its NDA application. The FDA informed the Company that an Oncologic Drugs Advisory Committee panel would likely be convened to review the final tivozanib data package.

  TIVO-3 is the Company's Phase 3 randomized, controlled, multi-center, open-label study to compare tivozanib, the Company's vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR-TKI), to sorafenib in 350 subjects with highly refractory metastatic RCC.

- **Announced Updated Overall Survival HR of 0.99 in Phase 3 TIVO-3 Trial of Tivozanib in RCC.** In September 2019, AVEO announced results from the second prespecified analysis of OS in the TIVO-3 trial. These results included an OS HR, which

assesses the relative risk of death for the entirety of the dataset, that was below 1.00 (HR=0.99; 95% CI: 0.76-1.29; p=0.95).

The data cutoff date for the second prespecified analysis was August 15, 2019, two years from the last patient enrolled and approximately ten months from the data cutoff date for the first prespecified analysis. Between the two data cutoff dates, 16 additional OS events were reported on the tivozanib arm and 28 on the sorafenib arm, resulting in a total of 114 OS events on the tivozanib arm and 113 on the sorafenib arm. Median OS, a point in time value of the OS when half of the patients within each arm are still alive, was 16.4 months for tivozanib (95% CI: 13.4-22.2) and 19.7 months for sorafenib (95% CI: 15.0-24.2). As of the second data cutoff date, twenty patients remained progression free on the tivozanib arm and two on the sorafenib arm, with a median duration on study of 32.5 months.

- **Updated Data from TIVO-3 Trial to be Presented at the 18th International Kidney Cancer Symposium.** Updated data from the TIVO-3 trial will be presented during an oral session at the 18th International Kidney Cancer Symposium being held November 15-16, 2019 in Miami. The presentation, titled "Overall Survival from Phase 3 TIVO-3 Study in Advanced Renal Cell Carcinoma", will be presented on Saturday, November 16 at 9:42 a.m. Eastern Time. The presentation will include the recently announced OS data, as well as new data from important subgroups. A copy of the slides will be available in the Publications & Presentations Section of AVEO's website following the presentation.

Additional Tivozanib Updates

- **Announced Initiation of Enrollment in Phase 1b/2 DEDUCTIVE Study of Tivozanib in Combination with IMFINZI® (durvalumab) in Previously Untreated Metastatic HCC.** In September 2019, AVEO announced the initiation of enrollment in the DEDUCTIVE trial, an open-label, multi-center Phase 1b/2 clinical trial evaluating tivozanib in combination with IMFINZI® (durvalumab), AstraZeneca's human monoclonal antibody directed against programmed death-ligand 1 (PD-L1), in patients with HCC who have not received prior systemic therapy. The trial is being conducted as part of a clinical collaboration between AVEO and AstraZeneca. AVEO is serving as the study sponsor, with study costs shared equally by both parties and clinical drug supplied by each respective company.

- **Presented Final PFS Results from Phase 2 Portion of the TiNivo Study of Tivozanib and OPDIVO® (nivolumab) in Advanced or Metastatic RCC.** In September 2019, AVEO and EUSA Pharma announced the presentation of final progression free survival (PFS) results from the Phase 2 portion of the TiNivo study, a Phase 1b/2 multicenter trial of tivozanib in combination with OPDIVO® (nivolumab), Bristol-Myers Squibb's immune checkpoint, or PD-1, inhibitor, for the treatment of advanced or metastatic RCC. The data were presented at the European Society of Medical Oncology (ESMO) 2019 Annual Congress in Barcelona, Spain.

  The combination required few dose reductions and showed additive or synergistic activity for objective response rate and PFS in both treatment naïve and previously treated patients

with metastatic RCC. Overall median PFS for the 25 patients treated at the study's full dose and schedule was 18.9 months (95% CI: 16.4; NR). Median PFS for previously untreated patients (n=12) was 18.5 months, while median PFS for previously treated patients (n=13) had not yet been reached as of the August 27, 2019 data cutoff date. An objective response rate was observed in 56% of patients (complete responses + partial responses), including one treatment naïve patient (1/12) achieving a complete response, and disease control (complete response + partial response + stable disease) was observed in 96% of patients. The most common treatment-related Grade 3/4 adverse event was hypertension, and only 17% of patients required a dose reduction.

A copy of the presentation is available in the Publications & Presentations Section of AVEO's website.

- **Announced Kyowa Kirin Buy Back of Tivozanib Non-Oncology Rights from AVEO.** In August 2019, AVEO and Kyowa Kirin Co., Ltd. announced that the companies' license agreement for tivozanib has been amended to allow Kyowa Kirin to buy back the non-oncology rights of tivozanib in AVEO's territories, which includes the U.S. and EU. Under the terms of the amended license agreement, AVEO received a $25 million upfront payment and a waiver of the $18 million milestone payment due to Kyowa Kirin upon AVEO obtaining U.S. market approval for tivozanib. In addition, AVEO will be eligible to receive up to $391 million in milestone payments upon the successful achievement of certain development and commercial objectives related to tivozanib formulations for the treatment of non-oncology indications. AVEO is also eligible to receive tiered royalty payments on net sales in these indications, which range from a high single-digit to low double-digit percent.

Ficlatuzumab Update

- **Initiation of the CyFi-2 Study of Ficlatuzumab in Relapsed and Refractory AML.** Last week, AVEO and Biodesix, Inc. announced the initiation of the CyFi-2 study, a randomized Phase 2 clinical study evaluating ficlatuzumab, AVEO's potent hepatocyte growth factor (HGF) inhibitory antibody product candidate, in combination with high-dose cytarabine vs. high-dose cytarabine alone in patients with relapsed and refractory AML.

  AVEO will sponsor the CyFi-2 study, which is expected to enroll approximately 60 patients with AML who failed induction chemotherapy or who achieved a complete response but relapsed within one year. The CyFi-2 study is being conducted as part of the companies' worldwide partnership to develop and commercialize ficlatuzumab. Under the terms of this agreement, AVEO and Biodesix equally share all development costs.

Recent Corporate Update

Appointment of Key Regulatory, Commercial and Medical Affairs Leadership Roles. AVEO announced today the appointment of three individuals to key leadership roles during the fourth quarter:

- **Darlene Noci, Interim Head of Regulatory Affairs.** Ms. Noci brings to AVEO over 20 years of leadership experience in global regulatory affairs and strategic drug development. She received a Bachelor's degree in Political Science from Adelphi University and a Master's degree in Government from Harvard University.
- **Kevin Peacock, Vice President of Marketing.** Mr. Peacock brings over 15 years of commercial leadership experience in oncology marketing, strategic planning, and business analytics. He received his Bachelor's degree in Business Administration from Temple University.
- **Daniel Powers, D.O., Vice President of Medical Affairs.** Dr. Powers brings to AVEO over 20 years of clinical, academic, and biopharmaceutical medical affairs experience. He received his Bachelor's degree in Chemistry from the University of Massachusetts Boston and a Doctor of Osteopathic Medicine degree from Rowan University. He completed his internship and residency in Internal Medicine at Yale-New Haven Hospital and National Navy Medical Center.

Third Quarter 2019 Financial Results

- AVEO ended Q3 2019 with approximately $57.7 million in cash, cash equivalents and marketable securities as compared with $24.4 million at December 31, 2018.
- Total revenue for Q3 2019 was approximately $25.7 million compared with $2.5 million for Q3 2018.
- Research and development expense for Q3 2019 was $4.0 million compared with $5.2 million for Q3 2018.
- General and administrative expense for Q3 2019 was $2.9 million compared with $2.7 million for Q3 2018.
- Net income for Q3 2019 was $16.4 million, or net income of $0.10 per basic and diluted share, respectively, compared with a net loss of $22.2 million for Q3 2018, or a loss of $0.18 per basic and diluted share, respectively.
- On August 1, 2019, as scheduled and included in the Company's cash guidance below, the Company resumed principal payments of approximately $0.8 million per month on the $20.0 million Hercules loan that matures on July 1, 2021.

Financial Guidance

AVEO believes that its cash, cash equivalents and marketable securities of approximately $57.7 million at September 30, 2019 would allow the Company to fund its planned operations into the second quarter of 2021. This estimate is a change from the Company's prior quarter guidance as a result of the Company's plan to file an NDA for tivozanib, reflecting additional costs related to the NDA filing, as well as limited commercial launch-readiness activities.

About Tivozanib (FOTIVDA®)

Tivozanib (FOTIVDA®) is an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) discovered by Kyowa Kirin and approved for the treatment of adult

patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway, New Zealand and Iceland. It is a potent, selective and long half-life inhibitor of all three VEGF receptors and is designed to optimize VEGF blockade while minimizing off-target toxicities, potentially resulting in improved efficacy and minimal dose modifications.[1,2] Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models[3] and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC[4]. Tivozanib has been investigated in several tumor types, including renal cell, hepatocellular, colorectal, ovarian and breast cancers.

About Ficlatuzumab

Ficlatuzumab (formerly known as AV-299) is a potent hepatocyte growth factor (HGF) inhibitory antibody that binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities. AVEO and Biodesix, Inc. have a worldwide agreement to develop and commercialize ficlatuzumab. Ficlatuzumab is currently being evaluated in squamous cell carcinoma of the head and neck (SCCHN), metastatic pancreatic ductal cancer (PDAC), and acute myeloid leukemia (AML).

About AVEO

AVEO Pharmaceuticals is a biopharmaceutical company seeking to advance targeted medicines for oncology and other unmet medical needs. The Company's lead candidate is tivozanib, a potent, selective, long half-life inhibitor of vascular endothelial growth factor 1, 2 and 3 receptors, which AVEO is seeking to develop and commercialize in North America as a treatment for renal cell carcinoma (RCC), hepatocellular carcinoma (HCC) and other cancers. Tivozanib (FOTIVDA®) is approved by the European Commission for the treatment of adult patients with advanced RCC in the European Union plus Norway, New Zealand and Iceland. AVEO is leveraging or seeks to leverage partnerships to develop and commercialize its pipeline of products and product candidates, including tivozanib in oncology and other indications in various geographies, and ficlatuzumab (HGF MAb) in head and neck cancer, pancreatic cancer and acute myeloid leukemia. AVEO's earlier-stage pipeline includes AV-203 (anti-ErbB3 MAb), AV-380 (GDF15 MAb) and AV-353 (Notch 3 MAb) drug candidates being developed for various oncology indications.

For more information, please visit the Company's website at www.aveooncology.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of AVEO within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. The words "anticipate," "believe," "expect," "intend," "may," "plan," "potential," "could," "should," "would," "seek," "look forward," "advance," "goal," "strategy," or the negative of these terms or other similar expressions, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: AVEO's plans to submit an NDA for tivozanib, including the submission of an updated statistical analysis plan and additional data to the FDA; the potential for tivozanib as a treatment option for patients with relapsed/refractory or advanced RCC; the advancement of AVEO's pipeline, including AVEO's plans with respect to advancement of the DEDUCTIVE trial and the CyFi-2 trial; the potential

efficacy, safety, and tolerability of tivozanib and ficlatuzumab, both as stand-alone drug candidates and in combination with other therapies in several indications, including without limitation, AVEO's expectations regarding the potential of tivozanib to successfully meet endpoints in the TIVO-3 trial in RCC and the potential for outcomes from studies of ficlatuzumab to provide AVEO with opportunities to pursue regulatory strategies; expected costs of AVEO's clinical studies; AVEO's cash runway; AVEO's plans and strategies for commercialization of tivozanib in the United States and Europe; and AVEO's strategy, prospects, plans and objectives for its product candidates and for the Company generally. AVEO has based its expectations and estimates on assumptions that may prove to be incorrect. As a result, readers are cautioned not to place undue reliance on these expectations and estimates. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors, including risks relating to: AVEO's ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA the safety, efficacy and clinically meaningful benefit of AVEO's product candidates, including, in particular, tivozanib and ficlatuzumab; AVEO's ability to successfully file an NDA for tivozanib; and AVEO's ability to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its strategic partners, to achieve development and commercialization objectives under these arrangements. AVEO faces other risks relating to its business as well, including risks relating to the timing and costs of seeking and obtaining regulatory approval; AVEO's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with regulatory requirements applicable to its product candidates; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates; AVEO's ability to successfully implement its strategic plans; AVEO's ability to raise the substantial additional funds required to achieve its goals, including those goals pertaining to the development and commercialization of tivozanib; unplanned capital requirements; adverse general economic and industry conditions; competitive factors; and those risks discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" included in AVEO's quarterly and annual reports on file with the Securities and Exchange Commission (SEC) and in other filings that AVEO makes with the SEC. The forward-looking statements in this press release represent AVEO's views as of the date of this press release, and subsequent events and developments may cause its views to change. While AVEO may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing AVEO's views as of any date other than the date of this press release. Any reference to AVEO's website address in this press release is intended to be an inactive textual reference only and not an active hyperlink.

References

1. Fotivda (Tivozanib) SmPC August 2017
2. Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9.
3. Pawlowski N et al. AACR 2013. Poster 3971.
4. Barthelemy et al. ESMO 2018. Poster 878P

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AVEO PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Collaboration and licensing revenue	$ 25,494	$ 2,335	$ 27,441	$ 3,651
Partnership royalties	223	132	590	275
	25,717	2,467	28,031	3,926
Operating expenses:				
Research and development	3,983	5,160	13,446	15,451
General and administrative	2,884	2,719	8,325	8,156
Settlement costs	—	—	—	(667)
	6,867	7,879	21,771	22,940
Income (loss) from operations	18,850	(5,412)	6,260	(19,014)
Other income (expense), net:				
Interest expense, net	(467)	(579)	(1,482)	(1,621)
Change in fair value of PIPE Warrant liability	(1,954)	(16,172)	9,071	(6,512)
Other income (expense), net	(2,421)	(16,751)	7,589	(8,133)
Net income (loss)	$ 16,429	$ (22,163)	$ 13,849	$ (27,147)
Basic net income (loss) per share				
Net income (loss) per share	$ 0.10	$ (0.18)	$ 0.09	$ (0.23)
Weighted average number of common shares outstanding	160,744	120,138	150,794	119,311
Diluted net income (loss) per share				
Net income (loss) per share	$ 0.10	$ (0.18)	$ 0.09	$ (0.23)
Weighted average number of common shares and dilutive common share equivalents outstanding	160,826	120,138	151,294	119,311

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 57,654	$ 24,427
Accounts receivable	1,090	3,026
Prepaid expenses and other current assets	1,016	482
Other assets	—	—
Total assets	$ 59,760	$ 27,935
Liabilities and stockholders' equity (deficit)		
Accounts payable and accrued expenses	$ 9,087	$ 12,451
Loans payable, net of discount	17,971	19,033
Deferred revenue and research and development reimbursements	5,252	5,914
PIPE Warrant liability	7,603	16,674
Other liabilities	1,090	1,090
Stockholder's equity (deficit)	18,757	(27,227)
Total liabilities and stockholders' equity (deficit)	$ 59,760	$ 27,935