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): March 16, 2020

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**	**02142**
(Address of Principal Executive Offices)	**(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 March 16, 2020, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 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 Fiscal year 2019 earnings press release issued by the Company on March 16, 2020

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: March 16, 2020

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

Exhibit 99.1

AVEO Oncology Reports Full Year 2019 Financial Results and Provides Business Update

CAMBRIDGE, Mass.– March 16, 2020 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the full year ended December 31, 2019 and provided a business update.

"The coming months will be an important period for AVEO, with filing of a New Drug Application (NDA) for tivozanib as a treatment for relapsed or refractory renal cell carcinoma (RCC) planned for the end of this quarter, and reporting of the final overall survival (OS) update for the TIVO-3 trial expected by June," said Michael Bailey, president and chief executive officer of AVEO. "As we work toward the potential FDA marketing approval of tivozanib, our attention will turn increasingly to commercialization and potential expanded clinical opportunities, while further advancing the balance of our pipeline. We continue to believe that our tivozanib dataset in RCC, which provides insights into the sequencing of therapies, notably, following immunotherapy, positions tivozanib well within this meaningful and growing relapsed or refractory RCC patient population."

Mr. Bailey added: "In addition, we look forward to continuing to build on the clinical evaluation of tivozanib-immunotherapy (IO) combinations, such as those studied in the TiNivo trial of tivozanib and OPDIVO® (nivolumab) in RCC, for which we reported encouraging final PFS data at last year's ESMO Conference, and the DEDUCTIVE trial of tivozanib and IMFINZI® (durvalumab) in hepatocellular carcinoma (HCC). With a favorable tolerability profile and results suggesting additive or synergistic activity in both treatment naïve and previously treated RCC patients, our early data support the potential for tivozanib to serve as a TKI companion in combination with IO therapy. Beyond tivozanib, building on promising results seen to date, we look forward to continued progress in the evaluation of ficlatuzumab in multiple clinical trials, including two ongoing randomized Phase 2 trials, one in acute myeloid leukemia (AML) and one in head and neck cancer, with the goal of identifying a pivotal trial design for registration, assuming favorable trial outcomes."

Phase 3 TIVO-3 Trial and North America Regulatory Highlights

- **Published Data from Phase 3 TIVO-3 Trial in Lancet Oncology.** In December 2019, AVEO announced that previously reported data from its positive Phase 3 TIVO-3 trial were published in *The Lancet Oncology*. The article, titled "Tivozanib versus sorafenib in patients with advanced renal cell carcinoma (TIVO-3): a phase 3, multicentre, randomised, controlled, open-label study", is available online via this link."
- **Presented Updated OS and Subgroup Data from TIVO-3 Trial at the 18th International Kidney Cancer Symposium.** In November 2019, AVEO announced updated data from the Phase 3 TIVO-3 trial, including two prespecified subgroup analyses of patients previously treated with a checkpoint inhibitor and a VEGFR TKI, or two VEGFR TKIs. Each of the prespecified subgroups showed superior progression free survival (PFS) and overall response rate, as well as an OS HR below 1, favoring tivozanib.

Tivozanib was shown to have lower overall rates of adverse events and fewer dose interruptions and reductions versus sorafenib, indicating better patient tolerability. A copy of the presentation, which was presented at the 18th International Kidney Cancer Symposium, is available in the Publications & Presentations section of AVEO's website.

- **NDA Submission Expected This Month and Final OS Analysis Report Expected by June.** The Company continues to expect to submit an NDA to the U.S. FDA in relapsed/refractory RCC by the end of this month. As previously announced, a final OS analysis of the study will be conducted in the second quarter based on a May 1, 2020 data cutoff date, at which point the Company estimates that the study will have reached approximately 263 OS events. AVEO expects to report results from the final OS analysis by June 2020. The FDA and the Company agreed that if, during the review, the final analysis yields an OS HR above 1.00, the Company will withdraw its NDA. The FDA informed the Company that an Oncologic Drugs Advisory Committee panel would likely be convened to review the final tivozanib data package.

Additional Tivozanib Updates

- **Announced Publication of Phase 1b/2 Trial of Tivozanib in Advanced, Inoperable HCC in the British Journal of Cancer.** In February 2020, AVEO announced the publication of results from a monotherapy trial of tivozanib in patients with advanced, inoperable HCC in the British Journal of Cancer. 27 patients were enrolled in the trial that sought to evaluate the safety, dosing, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity of tivozanib in patients with advanced HCC. The recommended Phase 2 dose (RP2D) was determined to be 1.0 mg once daily for 21 days followed by 7 days off treatment on a 28-day cycle. Median PFS and OS were 24 weeks and 9 months, respectively, for patients treated at the RP2D, with an overall response rate of 21%. A significant decrease in soluble plasma VEGFR-2 was also observed, suggesting adequate target engagement. The link to this publication is available on the Publications & Presentations section of AVEO's website.

- **Announced Initiation of Enrollment in Phase 1b/2 DEDUCTIVE Trial 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.

- **Announced Kyowa Kirin Buy Back of Tivozanib Non-Oncology Rights from AVEO.** In August 2019, AVEO and Kyowa Kirin Co., Ltd. amended the companies' license agreement for tivozanib 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 that would have been due to Kyowa Kirin upon AVEO obtaining U.S. marketing 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 percentage of net sales.

Ficlatuzumab Update

- **Presented Results from Phase 1b Trial of Ficlatuzumab, Gemcitabine and Nab-Paclitaxel in Advanced Pancreatic Cancer.** In January 2020, AVEO and Biodesix, Inc. announced the presentation of results from an investigator-sponsored Phase 1b trial of ficlatuzumab, AVEO's potent hepatocyte growth factor inhibitory antibody product candidate, in combination with nab-paclitaxel and gemcitabine in patients with previously untreated metastatic pancreatic ductal adenocarcinoma. The results were presented during a poster session at the 2020 American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium.

  A total of 24 patients were enrolled. The average number of 28-day cycles received was 7.5 (range 1-15), with 3 patients remaining on active treatment at the end of the trial. The combination was associated with a promising durable response rate relative to data observed for gemcitabine and nab-paclitaxel alone. This included a 29% partial response (PR) rate and 92% rate of disease control (PR + stable disease). Treatment with this regimen was associated with significant hypoalbuminemia and edema, and therefore a follow up safety study is under consideration of ficlatuzumab in combination with an alternate cytotoxic regimen. A copy of the presentation is available in the Publications & Presentations section of AVEO's website.

- **Initiated CyFi-2 Trial of Ficlatuzumab in Relapsed and Refractory AML.** In November 2019, AVEO and Biodesix, Inc. announced the initiation of the CyFi-2 study, a randomized Phase 2 clinical trial 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 for 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 Updates

- **Effected 1-for-10 Reverse Stock Split.** In February 2020, the holders of a majority of AVEO's outstanding shares of common stock approved a reverse stock split and gave AVEO's Board of Directors authority to select a ratio for the split ranging from 1-for-5 to 1-for-15. The Board of Directors approved the reverse stock split at a ratio of 1-for-10, and

it became effective on February 19, 2020. AVEO's common stock began trading on the Nasdaq Capital Market on a split-adjusted basis on February 20, 2020.

- **Appointed Erick J. Lucera as Chief Financial Officer.** In January 2020, AVEO announced the appointment of Erick Lucera as chief financial officer. Mr. Lucera brings to AVEO over twenty years of financial, operational, and investment experience in the biotechnology and medical device industries and will be responsible for managing all aspects of the Company's financial and accounting functions.
- **Added Scarlett Spring to Board of Directors.** In November 2019, AVEO announced the appointment of Scarlett Spring to its Board of Directors. Ms. Spring brings to AVEO extensive sales, commercial, and leadership experience in the biopharmaceutical and life sciences industries.
- **Key Commercial and Medical Affairs Leadership Appointments.** AVEO appointed Jason Noto, Vice President of Market Access; Kevin Peacock, Vice President of Marketing; and Daniel Powers, D.O., Vice President of Medical Affairs.

Full Year 2019 Financial Highlights

- AVEO ended 2019 with $47.7 million in cash, cash equivalents and marketable securities as compared with $24.4 million at December 31, 2018.
- Total revenue for 2019 was approximately $28.8 million compared with $5.4 million for 2018. In August 2019, AVEO earned a $25 million upfront payment in connection with Kyowa Kirin's buy back of tivozanib non-oncology rights.
- Research and development expense for 2019 was $18.0 million compared with $20.7 million for 2018.
- General and administrative expense for 2019 was $11.2 million compared with $10.8 million for 2018.
- Net income for 2019 was $9.4 million, or net income of $0.61 per basic and diluted share, compared with a net loss of $5.3 million for 2018, or a loss of $0.44 and $1.93 per basic and diluted share, respectively (adjusted to reflect the 1-for-10 reverse stock split described above).
    - Net income in 2019 reflects an approximate $11.6 million non-cash gain attributable to the decrease in the fair value of the 2016 private placement warrant liability that principally resulted from the decrease in the stock price that occurred within the fiscal year. The net loss in 2018 was partially offset by an approximate $19.9 million non-cash gain attributable to the decrease in the fair value of such warrant liability.
- On August 1, 2019, as scheduled and included in AVEO's cash guidance below, AVEO 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 $47.7 million at December 31, 2019, along with anticipated partnership payments from cost sharing obligations and royalty revenues from sales of FOTIVDA® by EUSA, would allow the Company to fund its planned operations into the second quarter of 2021.

About Tivozanib (FOTIVDA®)

Tivozanib (FOTIVDA®) is an oral, once-daily, vascular endothelial growth factor receptor (VEGFR) 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, the United Kingdom, 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 is being studied in the TIVO-3 trial, which is intended to support a regulatory submission of tivozanib in the U.S. seeking marketing approval as a treatment for relapsed/refractory RCC. 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 is developing an oncology pipeline designed to provide a better life for patients with cancer. AVEO's strategy is to focus its resources toward development and commercialization of its product candidates in North America, while leveraging partnerships to support development and commercialization in other geographies. AVEO's lead candidate, tivozanib (FOTIVDA®) is approved in the European Union, the United Kingdom, Norway, New Zealand and Iceland for the treatment of adult patients with advanced renal cell carcinoma. AVEO is working to develop and commercialize tivozanib in North America as a treatment for renal cell carcinoma, hepatocellular carcinoma and other cancers. Ficlatuzumab (HGF MAb) is in Phase 2 clinical trials in head and neck cancer and acute myeloid leukemia and has reported early clinical data in pancreatic cancer. AVEO's earlier-stage pipeline includes several monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 MAb), AV-380 (GDF15 MAb) and AV-353 (Notch 3 MAb). 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,” “designed to,” “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 at the end of the first quarter of 2020; AVEO’s plans to report the final OS data of the TIVO-3 trial by June 2020; the potential marketing approval of tivozanib by the FDA; the commercial and clinical opportunities of tivozanib; the advancement of AVEO’s pipeline; the potential for tivozanib as a treatment option for patients with relapsed/refractory or advanced RCC; the growth of the relapsed/refractory RCC patient population; the potential efficacy, safety, and tolerability of tivozanib, both as a stand-alone drug candidate and in combination with other therapies in several indications; AVEO’s plans to expand its tivozanib-immunotherapy combination clinical strategy; the clinical development of ficlatuzumab in multiple clinical studies to identify a pivotal strategy, including two ongoing phase 2 studies for the treatment of AML and HNSCC; 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 impact of the novel coronavirus (COVID-19) outbreak on AVEO’s clinical trials and other business operations; 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; the outcome of litigation; 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 or a third-party 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.
Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Collaboration and licensing revenue	$ 493	$ 1,296	$ 27,934	$ 4,947
Partnership royalties	271	187	861	462
	764	1,483	28,795	5,409
Operating expenses:				
Research and development	4,512	5,201	17,958	20,652
General and administrative	2,886	2,625	11,211	10,781
Settlement costs	—	—	—	(667)
	7,398	7,826	29,169	30,766
Loss from operations	(6,634)	(6,343)	(374)	(25,357)
Other income (expense), net:				
Interest expense, net	(333)	(570)	(1,815)	(2,191)
Change in fair value of PIPE Warrant liability	2,506	26,431	11,577	19,919
Other income	—	2,300	—	2,300
Other income (expense), net	2,173	28,161	9,762	20,028
Net income (loss)	$ (4,461)	$ 21,818	$ 9,388	$ (5,329)
Basic net income (loss) per share				
Net income (loss) per share (1)	$ (0.28)	$ 1.75	$ 0.61	$ (0.44)
Weighted average number of common shares outstanding (1)	16,077	12,439	15,331	12,059
Diluted net income (loss) per share				
Net income (loss) per share (1)	$ (0.28)	$ (0.35)	$ 0.61	$ (1.93)
Weighted average number of common shares and dilutive common share equivalents outstanding (1)	16,077	13,358	15,376	13,073

(1)All share amounts and per share amounts have been restated to reflect the 1-for-10 reverse stock split on a retroactive basis.

Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	December 31, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 47,745	$ 24,427
Accounts receivable	1,631	3,026
Prepaid expenses and other current assets	1,224	482
Other assets	—	—
Total assets	$ 50,600	$ 27,935
Liabilities and stockholders' equity (deficit)		
Accounts payable and accrued expenses	$ 9,482	$ 12,451
Loans payable, net of discount	15,766	19,033
Deferred revenue and research and development reimbursements	4,619	5,914
PIPE Warrant liability	5,097	16,674
Other liabilities	790	1,090
Stockholder's equity (deficit)	14,846	(27,227)
Total liabilities and stockholders' equity (deficit)	$ 50,600	$ 27,935