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): April 30, 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.)**

30 Winter Street **Boston, Massachusetts**	**02108**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 400-0101

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 April 30, 2020, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2020. 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 Q1 2020 earnings press release issued by the Company on April 30, 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: April 30, 2020

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

Exhibit 99.1

AVEO Oncology Reports First Quarter 2020 Financial Results and Provides Business Update

BOSTON, Mass. – April 30, 2020 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the first quarter ended March 31, 2020 and provided a business update.

"Our recent submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for tivozanib as a treatment for relapsed or refractory renal cell carcinoma (R/R RCC) is both an important milestone and a significant achievement for AVEO," said Michael Bailey, president and chief executive officer of AVEO. "There is no current standard of care for the third+ line R/R RCC population and, prior to TIVO-3, there was no robust clinical dataset to support treatment choice. If approved, we believe tivozanib has the opportunity to address this meaningful and growing segment of treatment. We look forward to the presentation of results from the final TIVO-3 overall survival (OS) analysis as we continue to build on our foundation for commercial readiness."

"In addition, our clinical and business development teams' attention is turning toward opportunities to expand tivozanib-immunotherapy combination studies that build on the TiNivo and DEDUCTIVE trials in RCC and HCC, where we believe tivozanib's safety and activity profile could make it a companion TKI of choice. We also remain committed to advancing the balance of our pipeline, which includes ficlatuzumab, currently in an ongoing randomized Phase 2 trial in head and neck cancer (HNSCC) which, with a favorable outcome, could characterize a potential registration path, and AV-380, for which we look forward to filing an IND in the second half of 2020," continued Mr. Bailey.

Tivozanib Updates

- **Final Overall Survival Analysis from the Phase 3 TIVO-3 Trial of Tivozanib in RCC to be Presented at the ASCO 2020 Virtual Scientific Program.** Data from the final OS analysis from AVEO's pivotal Phase 3 TIVO-3 trial comparing tivozanib, the Company's vascular endothelial growth factor receptor tyrosine kinase inhibitor, to sorafenib in 3rd and 4th line renal cell carcinoma, will be presented at the ASCO 2020 Virtual Scientific Program. The presentation, titled, "TIVO-3: Final OS analysis of a phase III, randomized, controlled, multicenter, open-label study to compare tivozanib to sorafenib in subjects with metastatic renal cell carcinoma (RCC)" (abstract 5062) will be featured during a poster session (Genitourinary Cancer – Kidney and Bladder). A copy of the poster will be available at the ASCO virtual meeting and on the AVEO website Friday, May 29, 2020, at 8:00 AM ET.

- **Submitted an NDA to U.S. FDA for Tivozanib in Patients with Relapsed or Refractory RCC and Results of Final TIVO-3 OS Analysis Expected by June.** In March 2020, AVEO announced the submission of an NDA to the U.S. FDA seeking marketing approval for tivozanib as a treatment for relapsed or refractory RCC. 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. 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.

- **Announced Publication of Phase 1b/2 Trial of Tivozanib in Advanced, Inoperable Hepatocellular Carcinoma (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.

Ficlatuzumab Updates

- **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.

- **CyFi-2 Study of Ficlatuzumab in Relapsed and Refractory AML Discontinued.** In March 2020, AVEO and Biodesix, Inc. announced the discontinuation of their Phase 2 CyFi-2 study of ficlatuzumab in combination with high-dose cytarabine in relapsed and refractory AML. The decision was made due to the urgent shift among clinical sites toward efforts to combat the COVID-19 pandemic, which has impacted the feasibility of completing the study within the shelf-life of the current ficlatuzumab clinical trial supply.

Recent Corporate Updates

- **Announced New Corporate Headquarters.** AVEO today announced that it recently relocated its headquarters from Cambridge, Massachusetts to Boston. The new headquarters will lower overall costs and support further growth as the Company continues to execute on its tivozanib development strategy and advance the balance of its pipeline.

- **Building out Foundation for Commercial Readiness.** As part of the build-out of its commercial organization ahead of the potential launch of tivozanib in R/R RCC, AVEO recently announced the appointment of key commercial and medical affairs leadership, including Jason Noto, Vice President of Market Access; Kevin Peacock, Vice President of Marketing; and Daniel Powers, D.O., Vice President of Medical Affairs. The commercial organization has begun additional recruitment efforts in medical affairs, market access and patient access contingent on the near-term OS update from the TIVO-3 trial.

First Quarter 2020 Financial Results

- AVEO ended Q1 2020 with $33.6 million in cash, cash equivalents and marketable securities as compared with $47.7 million at December 31, 2019.
- Total revenue for Q1 2020 was approximately $0.8 million compared with $1.6 million for Q1 2019.
- Research and development expense for Q1 2020 was $7.8 million compared with $6.8 million for Q1 2019. Research and development expense in Q1 2020 includes the $2.9 million application user fee pursuant to the FDA's Prescription Drug User Fee Act that was paid upon the submission of the tivozanib NDA to the U.S. FDA in March 2020.
- General and administrative expense for Q1 2020 was $3.7 million compared with $2.5 million for Q1 2019.
- Net loss for Q1 2020 was $8.4 million, or net loss of $0.52 per basic and diluted share, compared with net income of $0.6 million for Q1 2019, or net income of $0.04 and net loss of $0.62 per basic and diluted share, respectively.
    - The Company recognized approximately $2.6 million and $8.8 million in non-cash gains in Q1 2020 and Q1 2019, respectively, that were attributable to the decrease in fair value of the 2016 private placement warrant liability that principally resulted from decreases in the stock price that occurred within each of the periods.

Financial Guidance

AVEO believes that its cash, cash equivalents and marketable securities of approximately $33.6 million at March 31, 2020, 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 supporting a regulatory submission of tivozanib in the U.S. seeking marketing approval as a treatment for relapsed or 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 a clinical study of patients with squamous cell carcinoma of the head and neck (HNSCC).

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 a Phase 2 clinical trial in head and neck cancer 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," "expect," "hope," "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: the potential for tivozanib as a treatment option for patients with advanced HCC or relapsed/refractory or advanced RCC, and following earlier TKI and immunotherapy treatment; AVEO's plan to conduct a final OS analysis in the second quarter based on a May 1, 2020 data cutoff date and to report results by June 2020; 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 execution of its clinical and regulatory strategy for tivozanib; 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: the potential for unfavorable final OS data from the TIVO-3 trial; the potential for the FDA to not accept AVEO's NDA for filing; whether the results of TIVO-3 are sufficient to obtain marketing approval for tivozanib in the U.S., which turns on the ability of AVEO to demonstrate to the satisfaction of the FDA the safety and efficacy of tivozanib based upon the findings of TIVO-3, including its data with respect to PFS, the rate of adverse events, OS and other information that the FDA may determine to be relevant to approvability; 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; 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, including its ability to successfully launch and commercialize tivozanib if it may be approved for commercialization by the FDA; 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; the potential adverse effects of the COVID-19 pandemic on AVEO's business continuity, financial

condition, results of operations, liquidity and ability to successfully and timely enroll, complete and read-out data from its clinical trials; 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 March 31,	
	2020	2019
Revenues:		
Collaboration and licensing revenue	$ 493	$ 1,454
Partnership royalties	291	157
	784	1,611
Operating expenses:		
Research and development	7,826	6,852
General and administrative	3,672	2,455
	11,498	9,307
Loss from operations	(10,714)	(7,696)
Other income, net:		
Interest expense, net	(315)	(564)
Change in fair value of PIPE Warrant liability	2,648	8,815
Other income, net	2,333	8,251
Net income (loss)	$ (8,381)	$ 555
Basic net income (loss) per share		
Net income (loss) per share	$ (0.52)	$ 0.04
Weighted average number of common shares outstanding	16,081	13,230
Diluted net income (loss) per share		
Net income (loss) per share	$ (0.52)	$ (0.62)
Weighted average number of common shares and dilutive common share equivalents outstanding	16,081	13,283

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	March 31, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	$ 33,620	$ 47,745
Accounts receivable	2,779	1,631
Prepaid expenses and other current assets	665	1,224
Property and equipment, net	100	—
Operating lease right-of-use asset	1,225	—
Other assets	158	—
Total assets	$ 38,547	$ 50,600
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 9,541	$ 9,482
Loans payable, net of discount	13,486	15,766
Deferred revenue and research and development reimbursements	4,243	4,619
PIPE Warrant liability	2,449	5,097
Operating lease liability	1,030	—
Other liabilities	790	790
Stockholder's equity	7,008	14,846
Total liabilities and stockholders' equity	$ 38,547	$ 50,600