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): August 8, 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 August 8, 2019, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 Q2 2019 earnings press release issued by the Company on August 8, 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: August 8, 2019

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

Exhibit 99.1

AVEO Reports Second Quarter 2019 Financial Results and Provides Business Update

CAMBRIDGE, Mass. – August 8, 2019 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the second quarter ended June 30, 2019 and provided a business update.

"As we move toward reporting more mature interim overall survival (OS) results from our TIVO-3 study of tivozanib in advanced kidney cancer, AVEO continues to make meaningful clinical, regulatory and strategic progress across our pipeline," said Michael Bailey, president and chief executive officer of AVEO. "Notably, since the beginning of the second quarter, we presented encouraging data from ongoing clinical studies of ficlatuzumab, our HGF inhibitory antibody, closed a public offering in April, and saw the approval of FOTIVDA® in New Zealand. In addition to these events, we recently announced the amendment to our license agreement with Kyowa Kirin for tivozanib non-oncology rights, which is consistent with our strategy to develop and commercialize our oncology-focused pipeline while retaining meaningful economic interest and advancing our non-oncology pipeline through partnerships. As a result of the license amendment with Kyowa Kirin and the April financing, the Company's cash runway is now anticipated to extend into the third quarter of 2021. We expect this progress will continue to build momentum as we look forward to the next interim OS readout from our TIVO-3 study in the fourth quarter of this year."

Recent Highlights

- **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 will receive 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.
- **FOTIVDA® (tivozanib) Approval in New Zealand for the Treatment of Advanced RCC received by AVEO's Partner, EUSA Pharma**. In July 2019, the New Zealand Medicines and Medical Devices Safety Authority approved FOTIVDA® (tivozanib) for the first line treatment of adult patients with advanced renal cell carcinoma (RCC) and for adult patients who are vascular endothelial growth factor receptor (VEGFR) and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for advanced RCC.

- **Presented Tivozanib Studies at the 2019 ASCO Annual Meeting.** In June 2019, two tivozanib poster presentations reported encouraging data at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois. The presentations, titled "Efficacy and safety of tivozanib in recurrent, platinum-resistant ovarian, fallopian tube or primary peritoneal cancer" (abstract 361) and "TIVO-3: Subgroup analysis of progression-free survival of tivozanib compared to sorafenib in subjects with refractory advanced renal cell carcinoma (RCC)" (abstract 4572), are available in the Publications & Presentations section of AVEO's website.

- **$2 Million Milestone Payment from EUSA Pharma Triggered.** In April 2019, AVEO announced the triggering of a $2 million milestone payment from EUSA Pharma related to the reimbursement approval and commercial launch of FOTIVDA® (tivozanib) in Spain as a first-line treatment of adult patients with RCC.

- **Closed Public Offering of Common Stock and Warrants.** In April 2019, AVEO completed an underwritten public offering of 21,739,131 shares of common stock and warrants to purchase 25,000,000 shares of common stock at the public offering price of $1.14 per share and $0.01 per warrant. The warrants have a two-year term and a strike price of $1.25 per share. Gross proceeds of the offering were approximately $25.0 million and are expected to be used for clinical and preclinical development of AVEO's product candidates, as well as for working capital and other general corporate purposes.

- **Announced Results from Phase 1b Ficlatuzumab-Cytarabine Trial (CyFi) in Patients with Relapsed and Refractory AML.** In April 2019, AVEO announced the presentation of encouraging data from an investigator-sponsored Phase 1b expansion cohort of ficlatuzumab, AVEO's potent hepatocyte growth factor (HGF) inhibitory antibody in combination with cytarabine in patients with relapsed and refractory acute myeloid leukemia (AML), at the American Association for Cancer Research (AACR) Annual Meeting, held March 29 - Apr 3, 2019 in Atlanta. Of 18 AML patients enrolled in the study, all had disease that was refractory to initial treatment, 17 were evaluable and 9 achieved a complete response. The most frequent grade 3/4 treatment emergent adverse events observed were febrile neutropenia, liver function test abnormalities, and electrolyte disturbance. There was one death from sepsis and multi-organ failure that was determined to be disease related, and one patient withdrew from the study due to grade 4 gastrointestinal bleed, determined to be likely ficlatuzumab related. A copy of the presentation is currently available in the Publications & Presentations section of AVEO's website.

  Based on these encouraging results, the Company is planning potential next steps for this program in collaboration with its ficlatuzumab development and commercialization partner, Biodesix, Inc.

Second Quarter 2019 Financial Results

- AVEO ended Q2 2019 with $40.2 million in cash, cash equivalents and marketable securities as compared with $24.4 million at December 31, 2018.

- Total revenue for Q2 2019 was approximately $0.7 million compared with $0.4 million for Q2 2018.
- Research and development expense for Q2 2019 was $2.6 million compared with $4.9 million for Q2 2018.
- General and administrative expense for Q2 2019 was $3.0 million compared with $2.8 million for Q2 2018.
- Net loss for Q2 2019 was $3.1 million, or net loss of $0.02 per basic and diluted share, respectively, compared with net income of $4.0 million for Q2 2018, or income of $0.03 per basic share and a loss of $0.06 per diluted share.

Financial Guidance

AVEO believes that our approximate $40.2 million in cash, cash equivalents and marketable securities at June 30, 2019 together with the $25 million upfront payment from the Kyowa Kirin license amendment to be received in the third quarter would allow us to fund our planned operations into the third quarter of 2021. This estimate excludes, subject to our decision whether to submit an New Drug Application (NDA) for tivozanib to the U.S. Food and Drug Administration (FDA) following the availability of more mature OS results, remaining costs to prepare and filing fees in connection with a possible NDA submission, and pre-commercialization activities that we may undertake. This estimate also assumes no receipt of additional milestone payments from our partners, no funding from new partnership agreements, no additional equity financings, no debt financings, no additional sales of equity under our sales agreement with SVB Leerink and no additional sales of equity through the exercise of our outstanding warrants. Accordingly, the timing and nature of activities contemplated for the remainder of 2019 and thereafter will be conducted subject to the availability of sufficient financial resources.

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, ovarian, colorectal 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 investigator-sponsored

trials 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 working 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) 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: the potential commercial opportunity of tivozanib; AVEO's plans to report the results of an interim OS analysis for the TIVO-3 trial in the fourth quarter and make a NDA filing decision following such analysis; AVEO's expectation that the OS outcome will be more mature; the potential efficacy, safety, and tolerability of tivozanib, as a single agent and in combination with other therapies in several indications, such as RCC and liver cancer; 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; 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

AVEO Contact:
David Pitts, Argot Partners
(212) 600-1902
aveo@argotpartners.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Collaboration and licensing revenue	$ 493	$ 336	$ 1,947	$ 1,316
Partnership royalties	210	97	367	143
	703	433	2,314	1,459
Operating expenses:				
Research and development	2,611	4,887	9,463	10,291
General and administrative	2,986	2,827	5,441	5,437
Settlement costs	—	(709)	—	(667)
	5,597	7,005	14,904	15,061
Loss from operations	(4,894)	(6,572)	(12,590)	(13,602)
Other income (expense), net:				
Interest expense, net	(451)	(549)	(1,015)	(1,042)
Change in fair value of PIPE Warrant liability	2,210	11,125	11,025	9,660
Other income, net	1,759	10,576	10,010	8,618
Net income (loss)	$ (3,135)	$ 4,004	$ (2,580)	$ (4,984)
Basic net income (loss) per share				
Net income (loss) per share	$ (0.02)	$ 0.03	$ (0.02)	$ (0.04)
Weighted average number of common shares outstanding	159,020	118,940	145,736	118,891
Diluted net income (loss) per share				
Net income (loss) per share	$ (0.02)	$ (0.06)	$ (0.02)	$ (0.11)
Weighted average number of common shares and dilutive common share equivalents outstanding	159,020	128,692	145,736	129,372

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 40,232	$ 24,427
Accounts receivable	611	3,026
Prepaid expenses and other current assets	819	482
Other assets	—	—
Total assets	$ 41,662	$ 27,935
Liabilities and stockholders' equity (deficit)		
Accounts payable and accrued expenses	$ 8,226	$ 12,451
Loans payable, net of discount	19,344	19,033
Deferred revenue and research and development reimbursements	5,720	5,914
PIPE Warrant liability	5,649	16,674
Other liabilities	1,090	1,090
Stockholder's equity (deficit)	1,633	(27,227)
Total liabilities and stockholders' equity (deficit)	$ 41,662	$ 27,935