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 9, 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 November 9, 2020, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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	Q3 2020 earnings press release issued by the Company on November 9, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 9, 2020

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

Exhibit 99.1

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

- U.S. Commercial Launch Preparations Underway Supporting the Tivozanib PDUFA Target Action Date of March 31, 2021 –

- Ficlatuzumab Worldwide Rights Regained; Final Results from Open Label Randomized Phase 2 HNSCC Study and Plans for Pivotal Program Expected in the Middle of 2021 –

- AV-380 IND Submission Expected by Year-end; Phase 1 Clinical Study Planned for the First Quarter of 2021 –

BOSTON, Mass. – November 9, 2020 – AVEO Oncology (Nasdaq: AVEO) today reported financial results for the third quarter ended September 30, 2020 and provided a business update.

"In advance of the Food and Drug Administration's (FDA) March 31, 2021 Prescription Drug User Fee Act (PDUFA) target action date for our tivozanib New Drug Application, we are actively building out AVEO's U.S. commercial infrastructure to support the FDA-pending U.S. launch of tivozanib in relapsed or refractory renal cell carcinoma (RCC)," said Michael Bailey, president and chief executive officer of AVEO. "Market data suggests that a significant and growing demand exists for effective and better tolerated treatment options for these patients. These data also suggest that roughly half of patients currently forego treatment in the third- and fourth-line of treatment.[1] We believe tivozanib has the potential to help address some of these challenges and provide patients with a new option for continuing their fight against cancer."

Mr. Bailey added, "Beyond our ongoing development of tivozanib as a potential monotherapy treatment, we are continuing our work in the immunotherapy combination setting as a key area of focus, given tivozanib's tolerability profile and effects on reducing regulatory T-cells[2] to potentially enhance activity of the immune system. In addition, we further enhanced our pipeline by regaining full global rights to our second late-stage asset, ficlatuzumab, and have secured additional manufacturing capacity to enable a potential registrational Phase 3 trial in head and neck squamous cell cancer (HNSCC) in 2022. Finally, we remain on track to file an Investigational New Drug (IND) application by the end of the year for AV-380 for the treatment of cancer cachexia, with a potential Phase 1 study in the first quarter of 2021, following the IND safe to proceed letter."

Tivozanib Updates

- **Announced Publication of Results from Phase 1b/2 TiNivo Study of Tivozanib in Combination with OPDIVO® (nivolumab) in RCC in Annals of Oncology.** In November 2020, AVEO announced that previously reported results from the Phase 1b/2 TiNivo study of oral (PO) tivozanib (FOTIVDA®), AVEO's next-generation vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor (TKI) drug candidate,

in combination with intravenous (IV) nivolumab (OPDIVO®, Bristol-Myers Squibb), an immune checkpoint, or PD-1, inhibitor, for the treatment of advanced RCC, were published in *Annals of Oncology*. The article, titled "TiNivo: Safety and Efficacy of Tivozanib-Nivolumab Combination Therapy in Patients with Metastatic Renal Cell Carcinoma", is available online first via this link.

AVEO is also studying tivozanib in combination with IMFINZI® (durvalumab), AstraZeneca's human monoclonal antibody directed against programmed death-ligand 1 (PD-L1), in patients with first-line metastatic hepatocellular carcinoma (HCC) in the Phase 1b/2 DEDUCTIVE clinical trial, which is currently in Phase 2.

- **Published Final Overall Survival Results from Phase 3 TIVO-3 Study of Tivozanib in RCC in European Urology.** In September 2020, AVEO announced that final overall survival (OS) results from its pivotal Phase 3 TIVO-3 study comparing tivozanib to sorafenib in third- and fourth-line RCC were published in the journal *European Urology*. The article, titled "Final Overall Survival Results from a Phase 3 Study to Compare Tivozanib to Sorafenib as Third- or Fourth-line Therapy in Subjects with Metastatic Renal Cell Carcinoma," is available online via this link.

- **Preparations Ongoing to Support Commercial Launch of Tivozanib in the U.S. Following the PDUFA Date (March 31, 2021).** In preparation for the potential commercial launch of tivozanib in the U.S., the Company continues to expand its sales, marketing, market access and medical affairs teams, and is working to put in place its U.S. distribution capabilities by the end of the year. In connection with these preparations, in October 2020, AVEO announced the appointment of David W. Crist as vice president of sales. Mr. Crist, who brings to AVEO over twenty years of oncology sales experience in both launch-stage and late-stage companies, will be responsible for building out AVEO's sales force in anticipation of the potential marketing approval and launch of tivozanib in the U.S.

Tivozanib Non-Oncology Partnership Update

- **$2.8 Million Development Milestone from Kyowa Kirin Co., Ltd.** In August 2020, the Company announced that it earned a $2.8 million development milestone payment from partner Kyowa Kirin. The milestone relates to acceptance by the Japanese Pharmaceuticals and Medical Devices Agency of an IND application for a new formulation of tivozanib in a non-oncology indication being developed by Kyowa Kirin.

  Under the terms of AVEO's agreement with Kyowa Kirin, in addition to the 2019 upfront payment of $25 million to AVEO, waiver of AVEO's obligation to make an $18 million milestone payment upon AVEO gaining U.S. marketing approval of tivozanib for RCC, and the $2.8 million IND development milestone, Kyowa Kirin has also agreed to pay AVEO up to an additional $388 million in potential milestone payments upon the successful achievement of certain development, regulatory, and commercial objectives in non-oncology indications of tivozanib. Kyowa Kirin will also be obligated to make tiered

royalty payments on the net sales of a product for these indications, ranging from a high single-digit to low double-digit percent.

Ficlatuzumab Update

- **Regained Full Global Rights to Ficlatuzumab.** In September 2020, AVEO regained full global rights to ficlatuzumab, the Company's potent hepatocyte growth factor (HGF) inhibitor antibody which binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities. The Company announced plans to fund the clinical manufacture of ficlatuzumab to enable a potential registrational Phase 3 clinical trial in HNSCC, as well as additional potential development in Phase 2 studies in pancreatic cancer and acute myeloid leukemia. Ficlatuzumab is being studied in an ongoing randomized confirmatory Phase 2 study in combination with cetuximab, an EGFR-targeted antibody, in metastatic HNSCC, which is expected to conclude enrollment in the fourth quarter of 2020, with results from the study expected in the middle of 2021. In that timeframe, the Company plans to provide an update on its pivotal program for ficlatuzumab.

AV-380 Update

- **Company on Track for IND Application Submission by Year-end, with Phase 1 Clinical Study Planned for the First Quarter of 2021.** AVEO plans to submit an IND application to the FDA for AV-380, its first-in-class, potent, humanized inhibitory antibody targeting GDF15, for the treatment of cancer cachexia by year-end. Cachexia, a common complication in patients with advanced cancer and other chronic diseases, is a complex metabolic syndrome characterized by malnutrition and severe involuntary weight loss due to the loss of muscle and fat tissue, as well as the clinical manifestation of anemia, inflammation and suppression of immune functions. Preparations for a Phase 1 trial are currently underway.

Corporate Updates

- **Announced Restructuring of Existing Term Loan with Closing of New Tranched, $35 Million Debt Facility, Potentially Providing for Working Capital into 2022.** In August 2020, The Company announced the closing of a tranched, $35 million debt facility with Hercules Capital, Inc. and its affiliates. Under the terms of the agreement, the initial tranche of $15 million fully refinanced AVEO's existing Hercules term loan facility, which had an outstanding principal amount of approximately $9.7 million, providing net new proceeds of $5.3 million. A second $10 million tranche is contingent upon the approval of the tivozanib New Drug Application by the FDA as a treatment for RCC, and certain other terms and conditions. An additional two $5 million tranches would potentially become available after that time – one if net product revenues of tivozanib reach $20.0 million within a specified time frame, and the other upon the lender's consent.

A current summary of the Company's activities and corporate updates is available in AVEO's corporate presentation available on the investor relations portion of the Company's website at investor.aveooncology.com.

Third Quarter 2020 Financial Results

- AVEO ended Q3 2020 with $68.8 million in cash, cash equivalents and marketable securities as compared with $47.7 million at December 31, 2019.
- Total revenue was approximately $3.6 million for Q3 2020 compared with $25.7 million for Q3 2019. The third quarter of 2019 included the $25.0 million upfront payment pursuant to AVEO's agreement with Kyowa Kirin for non-oncology indications of tivozanib.
- Research and development expense for Q3 2020 was $5.9 million compared with $4.0 million for Q3 2019.
- General and administrative expense for Q3 2020 was $5.8 million compared with $2.9 million for Q3 2019.
- Net loss for Q3 2020 was $8.4 million, or net loss of $0.33 per basic and diluted share, compared with net income of $16.4 million for Q3 2019, or net income of $1.02 per basic and diluted share, respectively.

Financial Guidance

AVEO believes that its $68.8 million in cash, cash equivalents and marketable securities as of September 30, 2020, along with anticipated partnership cost sharing reimbursements, royalties from EUSA's FOTIVDA sales and, if the pending marketing application for FOTIVDA is approved by the FDA, resulting product revenues upon commercial launch and the potential additional $20 million in credit under the Hercules loan, would allow the Company to fund planned operations into 2022.

In accordance with Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Accounting Standards Codification Subtopic 205-40), cash flows that are contingent on FDA approval, such as product revenues, cannot be reflected in the going concern assessment. As a result, Hercules loan funding contingent on such approval and revenue is also excluded from the Company's going concern assessment. Accordingly, the Company continues to have a going concern opinion.

About Tivozanib (FOTIVDA®)

Tivozanib is an oral, once-daily, next-generation vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) discovered by Kyowa Kirin and approved as FOTIVDA® for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union and other countries in the EUSA territory. 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.[3,4] 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 adult patients with relapsed or refractory advanced RCC. Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models[2] and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC.[5] Tivozanib has been investigated in several tumor types,

including renal cell, hepatocellular, colorectal, ovarian and breast cancers. Tivozanib is also being studied by partner Kyowa Kirin in non-oncology indications.

About AVEO Pharmaceuticals, Inc.

AVEO is an oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for cancer patients. 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, is approved as FOTIVDA® in the European Union and other countries in the EUSA territory for the treatment of adult patients with advanced renal cell carcinoma. AVEO is working to develop and potentially commercialize tivozanib in the U.S. as a treatment for renal cell carcinoma and hepatocellular carcinoma. AVEO has previously reported promising early clinical data on ficlatuzumab (anti-HGF mAb) in head and neck cancer, acute myeloid leukemia and pancreatic cancer and is conducting a randomized Phase 2 confirmatory clinical trial of ficlatuzumab in head and neck cancer. AVEO's earlier-stage pipeline includes several monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 mAb), AV-380 (anti-GDF15 mAb) and AV-353 (anti-Notch 3 mAb). AVEO is committed to creating an environment of diversity and inclusion as a foundation for innovation.

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 advancement of AVEO's pipeline, including the advancement of ficlatuzumab in multiple clinical studies; the potential efficacy, safety and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies; the potential outcomes from studies of ficlatuzumab to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab in areas of unmet need; the potential for tivozanib as a treatment option for patients with advanced HCC or relapsed/refractory or advanced RCC; 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 current and future clinical trials of tivozanib, ficlatuzumab and AV-380 and for commercialization of tivozanib in the United States; AVEO's expectations about its cash runway and its cash runway guidance; 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: 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 consider to be relevant to an approval determination; 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; 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; AVEO's ability to access future borrowings under the Hercules loan facility, which turns on the achievement of milestones related to the approval and commercialization of tivozanib in the U.S., which milestones may not be achieved; 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. Decision Resources, 2019
2. Pawlowski N et al. AACR 2013. Poster 3971
3. Fotivda (Tivozanib) SmPC August 2017
4. Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9
5. 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,	
	2020	2019	2020	2019
Revenues:				
Collaboration and licensing revenue	$ 3,293	$ 25,494	$ 4,280	$ 27,441
Partnership royalties	307	223	853	590
	3,600	25,717	5,133	28,031
Operating expenses:				
Research and development	5,860	3,983	18,105	13,446
Selling, general and administrative	5,800	2,884	13,209	8,325
	11,660	6,867	31,314	21,771
Income (loss) from operations	(8,060)	18,850	(26,181)	6,260
Other income (expense), net:				
Interest expense, net	(419)	(467)	(1,083)	(1,482)
Change in fair value of PIPE Warrant liability	86	(1,954)	3,184	9,071
Other income (expense), net	(333)	(2,421)	2,101	7,589
Net income (loss)	$ (8,393)	$ 16,429	$ (24,080)	$ 13,849
Basic net income (loss) per share				
Net income (loss) per share	$ (0.33)	$ 1.02	$ (1.22)	$ 0.92
Weighted average number of common shares outstanding	25,808	16,074	19,773	15,079
Diluted net income (loss) per share				
Net income (loss) per share	$ (0.33)	$ 1.02	$ (1.22)	$ 0.92
Weighted average number of common shares and dilutive common share equivalents outstanding	25,808	16,083	19,773	15,129

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	$ 68,844	$ 47,745
Accounts receivable	1,052	1,631
Prepaid expenses and other current assets	1,746	1,224
Property and equipment, net	210	—
Operating lease right-of-use asset	1,012	—
Other assets	158	—
Total assets	$ 73,022	$ 50,600
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 11,335	$ 9,482
Loans payable, net of discount	13,617	15,766
Deferred revenue and research and development reimbursements	3,286	4,619
PIPE Warrant liability	1,913	5,097
Operating lease liability	815	—
Other liabilities	1,833	790
Stockholder's equity	40,223	14,846
Total liabilities and stockholders' equity	$ 73,022	$ 50,600