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 10, 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 August 10, 2020, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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	Q2 2020 earnings press release issued by the Company on August 10, 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: August 10, 2020

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

Exhibit 99.1

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

- NDA Filing Accepted by U.S. FDA for Tivozanib as a Treatment of Relapsed or Refractory Renal Cell Carcinoma; Assigned PDUFA Target Action Date of March 31, 2021 –

- Preparations Underway to Support Potential Commercial Launch of Tivozanib in the U.S.; New Debt and Equity Financings, Partnership Milestones Potentially Provide for Working Capital into 2022 -

- Company Evaluating Registrational Opportunities for Ficlatuzumab and Tivozanib Immunotherapy Combination Programs –

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

BOSTON, Mass. – August 10, 2020 – AVEO Oncology (Nasdaq: AVEO) today reported financial results for the second quarter ended June 30, 2020 and provided a business update.

“The first half of 2020 was one of the most important periods in AVEO’s history to date, with the successful completion of the TIVO-3 study and the acceptance for filing and substantive review of a New Drug Application (NDA) for tivozanib as a treatment for relapsed or refractory renal cell carcinoma (RCC),” said Michael Bailey, president and chief executive officer of AVEO. “Through successful debt and equity financings, we now expect to have access to the capital to ensure a robust launch of FOTIVDA® (tivozanib) into 2022 to potentially address what we believe is a significant unmet need for an effective, better tolerated drug. Currently, more than half of patients are opting to forego third or later lines of therapy, largely due to issues of tolerability and a lack of evidence-based studies in this setting.[1] Supported by positive results from TIVO-3, we believe tivozanib could address these challenges and allow patients to continue their fight against cancer, and therefore has the potential to become a standard of care in this large and growing segment of the market.”

Mr. Bailey added, “With TIVO-3 complete, we are now evaluating several opportunities to initiate new pivotal studies for both tivozanib and ficlatuzumab. Building on the TiNivo and DEDUCTIVE trials in RCC and hepatocellular carcinoma (HCC) respectively, we believe tivozanib’s activity, favorable safety profile, and ability to significantly reduce regulatory T cells[2] all have the potential to make tivozanib a companion tyrosine kinase inhibitor of choice in these settings. In addition, the early data we have seen in the randomized head and neck cancer (HNSCC) study with ficlatuzumab combined with cetuximab (ERBITUX®), which could serve as the basis for pursuing a pivotal study in this tumor type, has led us to initiate the process to evaluate securing additional clinical manufacturing capacity. Finally, we expect AV-380 to enter into a Phase 1 study

in the first quarter of 2021, if an Investigational New Drug (IND) application which we expect to file by year end 2020, is accepted by the U.S. Food and Drug Administration (FDA)."

Tivozanib Updates

- **Announced FDA Acceptance for Filing of an NDA for Tivozanib as a Treatment of Relapsed or Refractory RCC.** In June 2020, AVEO announced that the FDA accepted for filing its NDA seeking approval for tivozanib, the Company's next-generation vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR-TKI), as a treatment for relapsed or refractory RCC. The FDA has assigned the application standard review and a Prescription Drug User Fee Act target action date of March 31, 2021. The FDA also indicated that they do not currently plan on convening an Oncologic Drug Advisory Committee (ODAC) to discuss the application.

  The NDA submission is based on AVEO's pivotal Phase 3 study, TIVO-3, comparing tivozanib to sorafenib in 3rd and 4th line RCC. The application is also supported by three additional trials in RCC and includes safety data from over 1,000 clinical trial subjects.

- **Preparations Underway to Support Potential Commercial Launch of Tivozanib in the U.S.** In preparation for the potential commercial launch of tivozanib in the U.S., the Company is actively engaged in the expansion of its sales, marketing, market access and medical affairs teams, as well as working to enable distribution capabilities by the end of the year. The Company also today announced that the FDA has conditionally accepted "FOTIVDA®" as the proprietary brand name for tivozanib in the U.S.

- **Presented TIVO-3 Final Overall Survival Results at ASCO 2020 Virtual Scientific Program.** In May 2020, the Company presented data from the final overall survival (OS) analysis of the pivotal Phase 3 TIVO-3 trial at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program. The final OS hazard ratio (HR) of 0.97 was similar to those observed with prior approved VEGFR TKI vs. VEGFR TKI pivotal studies in RCC.[3-6] TIVO-3 represents the first positive Phase 3 superiority study designed to help guide treatment decisions in third and fourth line RCC, a growing patient population with a high unmet medical need for effective and better tolerated therapies.

  A copy of the presentation is available on the Publications & Presentations section of AVEO's website.

- **Announced Advancement to the Phase 2 Portion of Phase 1b/2 DEDUCTIVE Study of Tivozanib in Combination with IMFINZI® (durvalumab) in Previously Untreated HCC After No Dose-Limiting Toxicities Observed in Phase 1 Portion.** In May 2020, AVEO announced that the Phase 1b/2 DEDUCTIVE 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 first line metastatic HCC has progressed to the Phase 2 portion of the trial. Advancement of the study into the Phase 2 portion, for which enrollment is currently underway, was based on findings from

the recently completed Phase 1 portion of the combination in which no dose limiting toxicities were observed.

Taken together with positive results from the TiNivo study, a Phase 1b/2 multicenter trial of tivozanib in combination with PD-1 inhibitor nivolumab (OPDIVO®, Bristol-Myers Squibb) in first or second line metastatic RCC, AVEO is currently evaluating opportunities to initiate potential registrational immunotherapy combination studies.

Tivozanib Non-Oncology Partnership Update

- **$2.8 Million Development Milestone from Kyowa Kirin Co., Ltd.** The Company recently announced that it earned a $2.8 million development milestone payment from partner Kyowa Kirin Co., Ltd. (Kyowa Kirin). The milestone relates to acceptance by the Japanese Pharmaceuticals and Medical Devices Agency of an IND application for 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 previously-paid 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

- **Based on Early Data from Randomized Phase 2 Study of Ficlatuzumab in Combination with Erbitux in Head and Neck Cancer, AVEO Currently Evaluating Phase 3 Study Opportunities.** AVEO's potent hepatocyte growth factor (HGF) inhibitory antibody, ficlatuzumab, which binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities, is being studied in an ongoing randomized confirmatory Phase 2 study in combination with cetuximab, an EGFR-targeted antibody, in metastatic HNSCC. The study was designed to confirm findings from a Phase 1 study of ficlatuzumab and cetuximab where the combination was well tolerated and resulted in a disease control rate of 67%, as well as prolonged progression free and OS compared to historical controls. The Phase 2 multi-center study is being conducted under the direction of Julie E. Bauman, MD, MPH, Professor of Medicine, Chief, Division of Hematology/Oncology, Associate Director of Translational Research, University of Arizona Cancer Center. Enrollment is expected to conclude in the fourth quarter of 2020, and results from the study are expected to be presented at a scientific meeting in the first half of 2021. AVEO and its partner Biodesix are evaluating the process to secure additional clinical manufacturing of ficlatuzumab to potentially enable a Phase 3 clinical trial of ficlatuzumab for the treatment of HNSCC in 2022.

- **Data from Phase 1 Study of Ficlatuzumab and Cetuximab in HNSCC Published in *Cancers.*** Data from the Phase 1 study of ficlatuzumab and cetuximab in patients with HNSCC were recently published in the journal *Cancers*. The combination of ficlatuzumab and cetuximab demonstrated an acceptable safety profile and showed promising antitumor activity in a refractory HNSCC patient population. A link to the publication, titled, "Phase I Study of Ficlatuzumab and Cetuximab in Cetuximab-Resistant, Recurrent/Metastatic Head and Neck Cancer", is available on the Publications & Presentations section of AVEO's website.

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 growth differentiation factor 15 (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

- **Raised Gross Proceeds of $51.1M in Oversubscribed Public Offering.** In June 2020, AVEO announced the closing of an oversubscribed underwritten public offering yielding aggregate gross proceeds of approximately $51.1 million, before deducting underwriting discounts and commissions and offering expenses payable by AVEO. The financing was led by investors Deerfield Management, New Enterprise Associates and Cormorant Capital.

- **Announced Restructuring of Existing Term Loan with Closing of New Tranched, $35 Million Debt Facility, Potentially Providing for Working Capital into 2022.** The Company announced today the closing of a tranched, $35 million debt facility with Hercules Capital, Inc. and its affiliates. The new facility has a maturity of 36 months, extendable up to 48-months, and an interest-only period of 12 months, extendable up to 30 months upon the achievement of performance milestones related to the approval and commercialization of tivozanib. 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 NDA by the FDA as a treatment for RCC, and certain other terms and conditions. An additional two $5 million tranches will become available after that time – one if net product revenues of tivozanib reach $20.0 million within a specified time frame, and the other at the lender's consent. As previously announced, the FDA has assigned AVEO's NDA a Prescription Drug User Fee Act target action date of March 31, 2021.

Second Quarter 2020 Financial Results

- AVEO ended Q2 2020 with $71.4 million in cash, cash equivalents and marketable securities as compared with $47.7 million at December 31, 2019.
- Total revenue was approximately $0.7 million in each of Q2 2020 and Q2 2019.
- Research and development expense for Q2 2020 was $4.4 million compared with $2.6 million for Q2 2019.
- General and administrative expense for Q2 2020 was $3.7 million compared with $3.0 million for Q2 2019.
- Net loss for Q2 2020 was $7.3 million, or net loss of $0.42 per basic and diluted share, compared with net loss of $3.1 million for Q2 2019, or net loss of $0.20 per basic and diluted share, respectively. The net loss in Q2 2019 reflects a $2.2 million non-cash gain that was attributable to the decrease in fair value of the 2016 private placement warrant liability that principally resulted from a decrease in the stock price that occurred within the period.

Financial Guidance

AVEO believes that its as-adjusted $79.5 million in cash, cash equivalents and marketable securities as of June 30, 2020, consisting of $71.4 million in cash, cash equivalents and marketable securities at June 30, 2020 together with the $2.8 million KKC milestone and the $5.3 million in new loan funding from Hercules, along with 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 our going concern assessment. Accordingly, the Company continues to have a going concern opinion.

About Tivozanib (FOTIVDA®)

Tivozanib (FOTIVDA®) is an oral, once-daily, next-generation 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 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.[8,9] 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[2] and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC.[10] 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 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 and other countries by AVEO's partner EUSA 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 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 potential for tivozanib as a treatment option for patients with advanced HCC or relapsed/refractory or advanced RCC, following earlier TKI and immunotherapy treatment; 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; the period in which AVEO expects to have cash to fund its operations and the contingencies upon which such guidance is dependent ;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 tivozanib's clinical trials, including its data with respect to PFS, the rate of adverse events, OS and other information that the FDA may determine for approval; 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; AVEO's ability to access up to $20.0 million of 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. Hutson et al. Clinical Genitourinary Cancer; Vol. 15, No. 1, 72-6.
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7. ZS Assoc. 2017 Sales Revenue
8. Fotivda (Tivozanib) SmPC August 2017
9. Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9
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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,	
	2020	2019	2020	2019
Revenues:				
Collaboration and licensing revenue	$ 494	$ 493	$ 987	$ 1,947
Partnership royalties	255	210	546	367
	749	703	1,533	2,314
Operating expenses:				
Research and development	4,419	2,611	12,245	9,463
General and administrative	3,737	2,986	7,409	5,441
	8,156	5,597	19,654	14,904
Loss from operations	(7,407)	(4,894)	(18,121)	(12,590)
Other income (expense), net:				
Interest expense, net	(349)	(451)	(664)	(1,015)
Change in fair value of PIPE Warrant liability	450	2,210	3,098	11,025
Other income (expense), net	101	1,759	2,434	10,010
Net loss	$ (7,306)	$ (3,135)	$ (15,687)	$ (2,580)
Net loss per share - basic and diluted	$ (0.42)	$ (0.20)	$ (0.94)	$ (0.18)
Weighted average number of common shares outstanding	17,364	15,902	16,722	14,574

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	$ 71,449	$ 47,745
Accounts receivable	1,208	1,631
Prepaid expenses and other current assets	1,571	1,224
Property and equipment, net	96	—
Operating lease right-of-use asset	1,120	—
Other assets	158	—
Total assets	$ 75,602	$ 50,600
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 8,906	$ 9,482
Loans payable, net of discount	11,133	15,766
Deferred revenue and research and development reimbursements	3,798	4,619
PIPE Warrant liability	1,999	5,097
Operating lease liability	924	—
Other liabilities	790	790
Stockholder's equity	48,052	14,846
Total liabilities and stockholders' equity	$ 75,602	$ 50,600