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 5, 2021

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 5, 2021, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2021. 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 2021 earnings press release issued by the Company on August 5, 2021
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 5, 2021

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

Exhibit 99.1

AVEO Oncology Reports Second Quarter 2021 Financial Results and Provides Business Update

– Total 2Q 2021 Revenue of $7.6 Million Includes
FOTIVDA® (tivozanib) U.S. Net Product Revenue of $6.7 Million –

– Pivotal Phase 3 TiNivo-2 Trial of FOTIVDA in Combination with OPDIVO® (nivolumab) on Track to Initiate Enrollment in 3Q 2021 –

– COVID-19 Related Manufacturing Supply Shortages to Push Potential Registrational Study Start for Ficlatuzumab to 2023 -

– Company to Host Conference Call Today at 4:30 p.m. ET –

BOSTON, Mass. – August 5, 2021 – AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company, today reported financial results for the second quarter ended June 30, 2021, and provided a business update.

“We are pleased to report our first full quarter of FOTIVDA sales, which reflect its commercial uptake since being launched on March 22, 2021. The strength of our early commercial launch reflects the execution of our commercial organization and highlights the high unmet need that exists in the indicated treatment population,” said Michael Bailey, president and chief executive officer of AVEO. “As the first therapy approved specifically for adults with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies, we believe FOTIVDA could become a standard of care in this setting and look forward to building on our positive momentum in the coming quarters. Supporting the potential future growth of FOTIVDA, our clinical strategy for an immunotherapy combination is moving forward, with the start of enrollment for the pivotal Phase 3 TiNivo-2 trial of FOTIVDA and OPDIVO expected in the third quarter of this year, an important step forward in our strategy to assess its potential in earlier lines of therapy.”

Mr. Bailey continued: “With respect to ficlatuzumab, while we and our clinical collaborators are very encouraged with the data in head and neck squamous cell carcinoma (HNSCC) presented at this year’s American Society of Clinical Oncology (ASCO) Annual Meeting, due to the shortage of required key raw materials and manufacturing supplies also used in COVID-19 vaccine manufacturing, we currently anticipate the potential start date for a registrational study in this indication to be pushed back from the first half of 2022 into 2023. In the interim, we will continue our dialogue with our contract manufacturer regarding timing of drug supply and regulators to identify the optimal registrational study design for the program and look forward to providing updates on this, and any potential partnering discussions, in the coming quarters.”

Second Quarter 2021 Highlights

- **Strong Start for U.S. Commercial Launch of FOTIVDA for the Treatment of Adult Patients with Relapsed or Refractory Advanced RCC Following Two or More Prior Systemic Therapies**.
    - U.S. net product revenue for the second quarter of 2021 was $6.7 million, which reflects inventory shipped to distributors and a gross-to-net estimate of 16% during the quarter, but does not include initial stocking of $1.1 million in March. As of June 30, 2021, total U.S. net product revenue since FOTIVDA's commercial launch on March 22, 2021 was $7.8 million.
        - 283 commercial prescriptions were filled in the second quarter of 2021, with increasing demand each month, and total prescriptions from launch through July 31, 2021 were 453.
        - Quarter-end inventory of approximately two weeks suggests that the Company's quarterly sales are primarily driven by end user demand.
    - 207 samples were requested and delivered from launch through July 31, 2021.
    - Over 175 accounts have ordered through July 31, 2021.

- **Planned Pivotal Phase 3 TiNivo-2 Trial in IO Relapsed or Refractory RCC on Track to Open for Enrollment in the Third Quarter of 2021.** The Company expects to commence the pivotal Phase 3 TiNivo-2 trial evaluating FOTIVDA in combination with OPDIVO, Bristol Myers Squibb's (NYSE: BMS) antibody directed against programmed death ligand-1 therapy, in patients with advanced relapsed or refractory RCC following prior immunotherapy exposure this quarter. Per the previously announced March 2021 clinical trial collaboration and supply agreement, BMS will provide OPDIVO clinical drug supply for the trial and AVEO will serve as the study sponsor and will be responsible for costs associated with the trial execution.

- **Long-Term Efficacy Follow Up and Additional Tolerability Data from the Phase 3 TIVO-3 Study Presented at the 2021 ASCO Annual Meeting in June.** Data showed that patients treated with tivozanib in the TIVO-3 study demonstrated over 20 months durability of response, with overall survival relative to sorafenib continuing to improve with longer follow up. In addition, an analysis of treatment-emergent adverse events (TEAEs) showed longer time to onset and fewer dose reductions for TEAEs related to tivozanib as compared to sorafenib. A copy of each presentation is available at www.aveooncology.com.

- **Positive Results from Randomized Phase 2 Study of Ficlatuzumab in Combination with Cetuximab (ERBITUX®) in Pan-Refractory, Metastatic HNSCC Presented at the 2021 ASCO Annual Meeting in June; COVID-19 Related Manufacturing Supply Shortages to Push Potential Start Date for Registrational Study in Human Papillomavirus (HPV) Negative HNSCC to 2023.** In June 2021, the Company announced positive results from a randomized confirmatory Phase 2 study of ficlatuzumab, AVEO's hepatocyte growth factor (HGF) targeted antibody, alone or in combination with cetuximab, an EGFR-targeted antibody, in patients with metastatic HNSCC who relapsed

or were refractory to prior immunotherapy, chemotherapy, and cetuximab (pan-refractory). Of note, patients with HPV negative disease, a subgroup normally associated with poorer outcomes, who received the ficlatuzumab and cetuximab combination demonstrated both a superior overall response rate and median progression free survival. A copy of the presentation is available at www.aveooncology.com.

Primarily due to the shortage of required key raw materials and manufacturing supplies also used in COVID-19 vaccine manufacturing, the delivery of the clinical supply of ficlatuzumab, originally expected in the first half of 2022, has been delayed. As a result of the delay, the Company now anticipates the potential start date for a registrational study in HPV negative HNSCC will be in 2023. The Company expects to continue to discuss potential ficlatuzumab pivotal study designs with the U.S. Food and Drug Administration and to continue ongoing partnership dialogues.

- **Kevin Cullen, M.D. Appointed to AVEO Board of Directors in April 2021.** Dr. Cullen, a widely recognized clinical oncologist with a specialty in head and neck cancer, is the Marlene and Stewart Greenebaum Distinguished Professor in Oncology and director of the Program in Oncology at the University of Maryland School of Medicine. He also serves as director of the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center.

Second Quarter 2021 Financial Highlights

- AVEO ended Q2 2021 with $102.9 million in cash, cash equivalents and marketable securities as compared with $61.8 million at December 31, 2020.
- Total revenue for Q2 2021 was approximately $7.6 million compared with $0.7 million for Q2 2020.
- FOTIVDA U.S. net product revenue was $6.7 million.
- Research and development expense for Q2 2021 was $6.9 million compared with $4.4 million for Q2 2020.
- Selling, general and administrative expense for Q2 2021 was $14.9 million compared with $3.7 million for Q2 2020.
    - The increase in selling, general and administrative expense for Q2 2021 is primarily due to costs associated with the commercial launch of FOTIVDA.
- Net loss for Q2 2021 was $13.6 million, or net loss of $0.40 per basic and diluted share, compared with a net loss of $7.3 million for Q2 2020, or net loss of $0.42 per basic and diluted share.
    - Net loss for Q2 2021 reflects an approximate $2.6 million non-cash gain attributable to the reversal of the fair market value of the PIPE Warrant liability upon the expiration of the PIPE Warrants on May 16, 2021.

Financial Guidance

AVEO believes that its $102.9 million in cash, cash equivalents and marketable securities as of June 30, 2021, along with expected net product revenues from the commercial launch of FOTIVDA in the United States, would enable AVEO to maintain its current operations for a period

of at least 12 months following the filing of its Quarterly Report on Form 10-Q for the quarter ended June 30, 2021.

AVEO expects commercial spend will be approximately $40 million for the year. Gross margins are expected to be in the mid-to-high 80th percentile and research and development expense is expected to now be approximately $30 million during 2021. The estimated approximate $10 million decrease in expected R&D expense is primarily attributable to the aforementioned delay in clinical supply manufacturing for ficlatuzumab. In addition, AVEO expects general and administrative expense will be approximately $20 million for the year.

Conference Call and Webcast

In connection with this announcement, AVEO will host a conference call and audio webcast today, August 5, 2021, at 4:30 PM Eastern Time. The call can be accessed by dialing (844) 882-7841 (U.S. and Canada) or (574) 990-9828 (international). The passcode for the conference call is 3857963. To access the live webcast, or the subsequent archived recording, please visit the Calendar of Events sub-section within the Investors section of the AVEO website at www.aveooncology.com.

About FOTIVDA® (tivozanib)

FOTIVDA® (tivozanib) is an oral, next-generation vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI). It is a potent, selective inhibitor of VEGFRs 1, 2, and 3 with a long half-life designed to improve efficacy and tolerability. AVEO received U.S. Food and Drug Administration (FDA) approval for FOTIVDA on March 10, 2021 for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. FOTIVDA was approved in August 2017 in the European Union and other countries in the territory of its partner EUSA Pharma (UK) Limited for the treatment of adult patients with advanced RCC. FOTIVDA has been shown to significantly reduce regulatory T-cell production in preclinical models.[1] FOTIVDA was discovered by Kyowa Kirin.

INDICATIONS

FOTIVDA is indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypertension and Hypertensive Crisis: Control blood pressure prior to initiating FOTIVDA. Monitor for hypertension and treat as needed. For persistent hypertension despite use of anti-hypertensive medications, reduce the FOTIVDA dose.

Cardiac Failure: Monitor for signs or symptoms of cardiac failure throughout treatment with FOTIVDA.

Cardiac Ischemia and Arterial Thromboembolic Events: Closely monitor patients who are at increased risk for these events. Permanently discontinue FOTIVDA for severe arterial thromboembolic events, such as myocardial infarction and stroke.

Venous Thromboembolic Events: Closely monitor patients who are at increased risk for these events. Permanently discontinue FOTIVDA for severe venous thromboembolic events.

Hemorrhagic Events: Closely monitor patients who are at risk for or who have a history of bleeding.

Proteinuria: Monitor throughout treatment with FOTIVDA. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment with FOTIVDA.

Thyroid Dysfunction: Monitor before initiation and throughout treatment with FOTIVDA.

Risk of Impaired Wound Healing: Withhold FOTIVDA for at least 24 days before elective surgery. Do not administer for at least 2 weeks following major surgery and adequate wound healing. The safety of resumption of FOTIVDA after resolution of wound healing complications has not been established.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Discontinue FOTIVDA if signs or symptoms of RPLS occur.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Allergic Reactions to Tartrazine: The 0.89 mg capsule of FOTIVDA contains FD&C Yellow No.5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible patients.

ADVERSE REACTIONS

The most common (≥20%) adverse reactions were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis, and the most common Grade 3 or 4 laboratory abnormalities (≥5%) were sodium decreased, lipase increased, and phosphate decreased.

DRUG INTERACTIONS

Strong CYP3A4 Inducers: Avoid coadministration of FOTIVDA with strong CYP3A4 inducers.

USE IN SPECIFIC POPULATIONS

Lactation: Advise not to breastfeed.
Females and Males of Reproductive Potential: Can impair fertility.

Hepatic Impairment: Adjust dosage in patients with moderate hepatic impairment. Avoid use in patients with severe hepatic impairment.

To report SUSPECTED ADVERSE REACTIONS, contact AVEO Pharmaceuticals, Inc. at 1-833-FOTIVDA (1-833-368-4832) or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

Please see FOTIVDA Full Prescribing Information which is available at www.FOTIVDA.com.

About Advanced Renal Cell Carcinoma

According to the American Cancer Society's 2021 statistics, renal cell carcinoma (RCC) is the most common type of kidney cancer, which is among the ten most common cancers in both men and women. Approximately 73,750 new cases of kidney cancer will be diagnosed annually and about 14,830 people will die from this disease. In patients with late-stage disease, the five-year survival rate is 13%. Agents that target the vascular endothelial growth factor (VEGF) pathway have shown significant antitumor activity in RCC.[2] According to a 2019 publication, 50% of the approximately 10,000 patients who progress following two or more lines of therapy choose not to receive further treatment,[3] which may be attributable to tolerability concerns and a lack of data to support evidence-based treatment decisions in this highly relapsed or refractory patient population.

About AVEO Pharmaceuticals, Inc.

AVEO is a commercial-stage, oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for patients with cancer. AVEO currently markets FOTIVDA® (tivozanib) in the U.S. for the treatment of adult patients with relapsed or refractory renal cell carcinoma (RCC) following two or more prior systemic therapies. AVEO continues to develop FOTIVDA in immuno-oncology combinations in RCC and other indications, and has several other investigational programs in clinical development. AVEO is committed to creating an environment of diversity, equity and inclusion to diversify representation within the Company.

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," "design," "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: AVEO's ability to successfully sell and distribute FOTIVDA to patients in the United States; the potential for FOTIVDA as a treatment option for patients with relapsed or refractory 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; the anticipated patient enrollment date for AVEO's pivotal Phase 3 TiNivo-2 study; AVEO's plans, strategies and execution for current and future clinical trials of tivozanib, ficlatuzumab and AV-380 and for commercialization of FOTIVDA in the United States; the advancement of AVEO's pipeline, including the advancement of ficlatuzumab and AV-380 in multiple clinical studies; the availability of clinical supplies of ficlatuzumab; the potential efficacy, safety and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies in refractory HPV negative, advanced HNSCC and other indications; the potential outcomes from studies of its product candidates to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab and AV-380 in areas of unmet need; the period in which AVEO expects to have cash to fund its operations; AVEO's strategy, prospects, plans and objectives for FOTIVDA and its product candidates and for AVEO generally; the potential commercial opportunity of FOTIVDA and AVEO's other product candidates; and AVEO's estimates for its cash runway and the contingencies on which such runway is dependent. 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 to successfully implement its strategic plans, including its ability to successfully commercialize FOTIVDA and to obtain and maintain market and third party payor acceptance of FOTIVDA; 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 risks relating to the timing and costs of seeking and obtaining regulatory approvals; AVEO's dependence on third-party vendors for the development, manufacture, supply, storage and distribution of FOTIVDA, ficlatuzumab and its other product candidates; 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's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with regulatory requirements applicable to FOTIVDA and its product candidates; AVEO's ability to obtain sufficient clinical supplies of its product candidates; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to FOTIVDA and its other product candidates; unplanned capital requirements; uncertainties related to AVEO's ability to access future borrowings under the Hercules loan agreement, which turns on the achievement of milestones related to sales of FOTIVDA in the U.S., which milestones may not be achieved; adverse general economic, political 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 commercialize FOTIVDA, manufacture clinical and commercial product and timely initiate new trials or complete its ongoing clinical trials; competitive factors; and those risks discussed in the sections titled "Risk Factor Summary," "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. Pawlowski N et al. AACR 2013. Poster 3971
2. J Angulo and O Shapiro, Cancers (Basel) 2019 Sep; 11(9): 1227. [10.3390/cancers11091227]
3. Decision Resources. RCC landscape and forecast. December 12, 2019.

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,	
	2021	2020	2021	2020
Revenues:				
FOTIVDA U.S. product revenue, net	$ 6,735	$ -	$ 7,801	$ -
Partnership licensing and royalty revenue	821	749	1,675	1,533
	7,556	749	9,476	1,533
Operating expenses:				
Cost of products sold	822	-	960	-
Research and development	6,878	4,419	12,675	12,245
Selling, general and administrative	14,920	3,737	30,020	7,409
	22,620	8,156	43,655	19,654
Loss from operations	(15,064)	(7,407)	(34,179)	(18,121)
Other income (expense), net:				
Interest expense, net	(1,128)	(349)	(1,739)	(664)
Change in fair value of PIPE Warrant liability	2,595	450	199	3,098
Other income (expense), net	1,467	101	(1,540)	2,434
Net loss	$ (13,597)	$ (7,306)	$ (35,719)	$ (15,687)
Net loss per share - basic and diluted	$ (0.40)	$ (0.42)	$ (1.16)	$ (0.94)
Weighted average number of common shares outstanding	34,362	17,364	30,915	16,722

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 102,920	$ 61,761
Trade receivables, net and partnership receivables	5,585	1,197
Prepaid expenses and other current assets	3,235	2,550
Property and equipment, net	310	343
Operating lease right-of-use asset	676	903
Other assets	258	158
Total assets	$ 112,984	$ 66,912
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 14,760	$ 12,393
Loans payable, net of discount	32,725	13,772
Deferred revenue and research and development reimbursements	1,601	2,716
PIPE Warrant liability	-	199
Operating lease liability	473	705
Other liabilities	3,222	1,833
Stockholder's equity	60,203	35,294
Total liabilities and stockholders' equity	$ 112,984	$ 66,912

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

AVEO Investor Relations Contact:
Hans Vitzthum, LifeSci Advisors
(617) 430-7578
hans@lifesciadvisors.com