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): May 5, 2022

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 May 5, 2022, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Form 8-K and Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Q1 2022 earnings press release issued by the Company on May 5, 2022
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: May 5, 2022

By: /s/ Michael Bailey

Michael Bailey

President and Chief Executive Officer

AVEO Oncology Reports First Quarter 2022 Financial Results

– Total Q1 2022 Net Revenue of $20.9 Million including $20.1 Million of FOTIVDA® (tivozanib) U.S. Net Product Revenue –

– Q1 2022 FOTIVDA Prescriptions Increased by 25% Compared With Q4 2021 –

– Company Reaffirms Full Year 2022 FOTIVDA U.S. Net Product Revenue Guidance of $100 to $110 Million –

– Company to Host Conference Call Today at 8:30 a.m. ET –

BOSTON – May 5, 2022 – AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2022.

"We recently celebrated the one-year anniversary of our U.S. commercial launch of FOTIVDA® (tivozanib). During the first quarter of 2022, we reported that, based on third party data, FOTIVDA had taken the leadership position in new patient starts for our targeted third-line relapsed or refractory advanced (R/R) renal cell carcinoma (RCC) population. This is a tremendous accomplishment, which we view as a leading indicator of progress towards our goal of becoming the overall market share leader and standard of care in the third-line R/R RCC setting, which we believe would in turn drive our continued growth. Based on what we have seen and heard to date, we continue to feel confident about our $100 million to $110 million full year 2022 FOTIVDA U.S. net product revenue guidance," stated Michael Bailey, President and Chief Executive Officer of AVEO. "In addition, with our Phase 3 TiNivo-2 trial evaluating tivozanib in combination with nivolumab underway, we are seeking to generate data to support regulatory approval of tivozanib (combined with nivolumab) in the larger second line R/R RCC market following prior immune checkpoint inhibitor therapy."

"Our team also continues to advance our pipeline of monoclonal antibodies. Collectively, we believe our commercial and clinical development activities offer exciting opportunities to improve patient care while also building long-term value for our shareholders," said Mr. Bailey.

First Quarter 2022 and Recent Highlights

- **Continued quarter over quarter growth of FOTIVDA U.S. net product revenue and prescriptions in Q1 2022.**
  - First quarter 2022 U.S. net product revenue increased 20% to $20.1 million compared with U.S. net product revenue of $16.8 million in the fourth quarter of 2021, which reflects inventory shipped to distributors during the quarter and a gross-to-net estimate of 18.5% during the first quarter of 2022.
    - 977 commercial prescriptions filled in the first quarter of 2022, representing a 25% increase from 780 commercial prescriptions filled in the fourth quarter of 2021.
    - FOTIVDA, based on third party data, has continued to hold its leadership position in the share of new patients starts in third-line R/R RCC for the first quarter. AVEO views new patient share starts as an important leading indicator of progress toward its objective to become the overall market share leader and the standard of care in the third-line R/R RCC setting.

- **Encouraging long-term follow up data for progression free survival (PFS) and overall survival (OS) from the Phase 3 TIVO-3 Clinical Trial of tivozanib in R/R advanced RCC patients were presented at the 2022 ASCO GU Cancers Symposium.**
    - These new long-term PFS data from patients with five years of follow up further support the durable response and improved PFS previously observed in patients treated with FOTIVDA, including:
        - Landmark long-term PFS rates were consistently higher among patients treated with FOTIVDA as compared with patients treated with sorafenib (12% vs. 2% and 8% vs. 0% at three and four years, respectively), representing a clinically meaningful outcome for patients in the third- and fourth-line treatment setting.
        - Long-term OS was also analyzed and a non-significant trend favoring FOTIVDA continued to emerge with accumulation of events (HR 0.89).

- **Topline data for first-line cohort of the DEDUCTIVE trial were presented at the 2022 American Society of Clinical Oncology Gastrointestinal (ASCO GI) Cancers Symposium.**
    - New efficacy and safety data from the first line (cohort A) of the Phase 1b/2 clinical trial of tivozanib in combination with AstraZeneca's IMFINZI® (durvalumab) demonstrated a 28% partial response (PR) rate and disease control rate of 72% (PR plus stable disease) with a median PFS of 7.3 months and a 1-year OS of 76%. The data continues to support the efficacy and safety of tivozanib as an attractive vascular endothelial growth factor receptor inhibitor to use in combination with immune checkpoint inhibitors in first line metastatic hepatocellular carcinoma (HCC) patients.
    - The DEDUCTIVE trial is currently enrolling cohort B of second line patients after treatment with bevacizumab and atezolizumab. This cohort, which will enroll up to 20 subjects, has the potential to be the first clinical study to demonstrate benefit in the emerging population of HCC patients who have previously received immunotherapy.

- **Enrollment ongoing for Phase 3 TiNivo-2 Trial in R/R RCC following prior immunotherapy; Expect to complete enrollment in the first half of 2023.**
    - AVEO continues to enroll patients in the Phase 3 TiNivo-2 clinical trial evaluating tivozanib in combination with nivolumab (OPDIVO®), Bristol Myers Squibb's antibody directed against PD-1, as compared with tivozanib monotherapy in patients with R/R RCC who have progressed following one or two lines of therapy, one of which was an immune checkpoint inhibitor. If successful, we believe data from this trial has the potential to support U.S. Food and Drug Administration (FDA) approval of tivozanib in combination with nivolumab in R/R RCC and expand the market opportunity for FOTIVDA into the larger second line R/R RCC setting. Bristol Myers Squibb is providing nivolumab clinical drug supply pursuant to a clinical trial collaboration and supply agreement. AVEO currently expects enrollment in the TiNivo-2 trial to be completed in the first half of 2023.

- **Secured clinical trial collaboration and supply agreement with NiKang Therapeutics, Inc. (NiKang) to evaluate tivozanib in combination with NKT2152.**
    - On track to initiate a Phase 2 clinical trial to evaluate the safety and efficacy of tivozanib in combination with NKT2152, NiKang's hypoxia inducible factor 2α (HIF2α), to treat clear cell RCC in mid-2022.

- **Started scale up activities for the manufacturing of ficlatuzumab clinical supply in the second quarter of 2022.**
    - AVEO started scale up activities for the manufacturing of ficlatuzumab clinical supply in the second quarter of 2022 to enable the initiation of a potential registrational clinical trial in human papillomavirus (HPV) negative recurrent or metastatic head and neck squamous

cell carcinoma (R/M HNSCC) in the first half of 2023. AVEO expects to continue to discuss the registrational pivotal clinical trial designs with the FDA and to continue to seek a strategic partner. In September 2021, AVEO announced that the FDA granted Fast Track designation for the investigation of the combination of ficlatuzumab and cetuximab for the treatment of patients with R/R HNSCC.

First Quarter 2022 Financial Highlights

- At March 31, 2022, AVEO reported $79.0 million in cash, cash equivalents and marketable securities, as compared with $87.3 million at December 31, 2021.
- Total revenue for the first quarter of 2022 was approximately $20.9 million compared with $1.9 million for the first quarter of 2021.
- FOTIVDA U.S. net product revenue was $20.1 million for the first quarter of 2022 compared with $1.1 million for the first quarter of 2021.
- Research and development expense for the first quarter of 2022 was $10.2 million compared with $5.8 million for the first quarter of 2021.
- Selling, general and administrative expense for the first quarter of 2022 was $17.3 million compared with $15.1 million for the first quarter of 2021. The increase in selling, general and administrative expense for the first quarter 2022 is primarily due to a full quarter of costs associated with the commercial launch of FOTIVDA.
- Net loss for the first quarter of 2022 was $10.2 million, or net loss of $0.30 per basic and diluted share, compared with a net loss of $22.1 million for the first quarter of 2021, or net loss of $0.81 per basic and diluted share.

Financial Guidance

AVEO believes that its $79.0 million in cash, cash equivalents and marketable securities as of March 31, 2022, along with expected net product revenues from the sales of FOTIVDA in the United States, will enable AVEO to maintain its current operations for a period of more than 12 months from the date of filing of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022.

AVEO currently expects to achieve full year 2022 FOTIVDA U.S. net product revenues between $100.0 million and $110.0 million. AVEO expects that commercial expenses will be approximately $50.0 million in 2022. AVEO expects general and administrative expenses will remain at approximately $20.0 million for the year. Research and development expenses are expected to be in the range of $60.0 million to $70.0 million in 2022 in support of AVEO's existing pipeline plans. In addition, AVEO expects that gross margins will continue to be in the mid-to-high 80th percentile in 2022.

Conference Call and Webcast

In connection with this announcement, AVEO will host a conference call and audio webcast today, May 5, 2022, at 8:30 A.M. Eastern Time. The call can be accessed by dialing (800) 954-1051 (U.S. and Canada) or (303) 223-0117 (international). The passcode for the conference call is 22018215. 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 advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. AVEO continues to develop FOTIVDA in immuno-oncology and other novel targeted combinations in RCC and other indications, and has 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 "advance," "aim," "anticipate," "believe," "continue," "could," "design," "estimate," "expect," "goal," "intend," "look forward," "may," "plan," "potential," "project," "promising," "seek," "should," "strategy," "will," "would," 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 expectations of achieving quarter over quarter sales growth and an increase in its sales ramp of FOTIVDA in future periods; AVEO's, plans, strategies and 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 HCC, clear cell RCC and other indications; the date enrollment will be completed for AVEO's pivotal Phase 3 TiNivo-2 trial; AVEO's plans, strategies and execution for current and future clinical trials and preclinical studies of tivozanib and ficlatuzumab; the availability of clinical supplies of ficlatuzumab; the anticipated commencement date for a Phase 2 clinical trial to evaluate the safety and efficacy of tivozanib in combination with NKT2152; the potential efficacy, safety and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies in R/M HNSCC and other indications; AVEO's ability to pursue regulatory strategies based on the results of clinical trials and preclinical studies of its product candidates, including AVEO's ability to obtain FDA approval of tivozanib in combination with nivolumab for the treatment of R/R RCC; 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; AVEO's estimates for its cash runway and the contingencies on which such runway is dependent; and statements regarding AVEO's performance, including but not limited to statements in the section titled "Financial Guidance." 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 achieve quarter over quarter sales growth of FOTIVDA; the percentage of FOTIVDA prescriptions being made to patients who are in the third- and fourth-line treatment setting maintaining or increasing over time; 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 and collaborators, 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, AV-380 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 and maintain adequate protection for intellectual property rights relating to FOTIVDA and its product candidates; unplanned capital requirements; 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.

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

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
FOTIVDA U.S. product revenue, net	$ 20,086	$ 1,066
Partnership licensing and royalty revenue	834	854
	20,920	1,920
Operating expenses:		
Cost of products sold	2,434	138
Research and development	10,160	5,797
Selling, general and administrative	17,337	15,100
	29,931	21,035
Loss from operations	(9,011)	(19,115)
Other income (expense), net:		
Interest expense, net	(1,188)	(611)
Change in fair value of PIPE Warrant liability	—	(2,396)
	(1,188)	(3,007)
Net loss	$ (10,199)	$ (22,122)
Net loss per share	$ (0.30)	$ (0.81)
Weighted average number of common shares outstanding	34,475	27,429

Consolidated Balance Sheet Data
(In thousands)

	March 31, 2022	December 31, 2021
Assets		
Cash, cash equivalents and marketable securities	$ 79,038	$ 87,326
Trade receivables, net and partnership receivables	13,774	11,601
Inventory	1,694	1,656
Prepaid expenses and other current assets	3,220	4,153
Property and equipment, net	259	276
Operating lease right-of-use asset	130	178
Other assets	100	151
Total assets	$ 98,215	$ 105,341
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 20,296	$ 18,142
Loans payable, net of discount	38,189	37,960
Deferred revenue and research and development reimbursements	—	578
Operating lease liability	8	11
Other liabilities	2,780	2,780
Stockholder's equity	36,942	45,870
Total liabilities and stockholders' equity	$ 98,215	$ 105,341