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): March 14, 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 March 14, 2022, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three and twelve months ended December 31, 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	Fiscal year 2021 earnings press release issued by the Company on March 14, 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: March 14, 2022

By: /s/ Michael Bailey

Michael Bailey

President and Chief Executive Officer

AVEO Oncology Reports Full Year and Fourth Quarter 2021 Financial Results

– Total 2021 Net Revenue of $42.3 Million –

– FOTIVDA® (tivozanib) U.S. Net Product Revenue of $38.9 Million since March 22, 2021 –

– FOTIVDA U.S. Net Product Revenue of $16.8 Million for 4Q 2021, Driven by a 26% Increase in Prescriptions Filled Compared to 3Q 2021 –

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

– Long-term data from pivotal TIVO-3 study presented at ASCO GU 2022 continue to demonstrate durable disease control and positive trend for overall survival for FOTIVDA –

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

BOSTON – March 14, 2022 – AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company, today reported financial results for the fourth quarter and full year ended December 31, 2021, and provided financial guidance for 2022.

"We have seen quarter over quarter growth in FOTIVDA® (tivozanib) sales since its commercial launch on March 22, 2021, including closing the year with U.S. net product revenue of $38.9 million for 2021 and $16.8 million of U.S. net product revenue in the fourth quarter of 2021. As we look to 2022, we expect to build on our commercial momentum by continuing to expand our prescriber base and increase the utilization of FOTIVDA in the third-line setting. We believe we made significant progress on both fronts in 2021 and look to build on this momentum in 2022," said Michael Bailey, President and Chief Executive Officer of AVEO. "In addition to our commercial team's educational and awareness initiatives, we believe the long-term progression free survival (PFS) data presented last month at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) further support the durability of disease control demonstrated by FOTIVDA in the third- and fourth-line treatment setting. This marks the first presentation of five year follow-up data for patients being treated in this setting and helps guide clinical treatment. As we look ahead to 2022 and beyond, we remain confident that FOTIVDA has the potential to become a standard of care for adult patients with relapsed or refractory (R/R) advanced renal cell carcinoma (RCC) that have received two or more prior systemic treatments."

"Our clinical team continues to make steady progress with expanding the opportunities for FOTIVDA in an effort to move to earlier settings in combinations with novel therapies as well as advancing our pipeline of monoclonal antibodies that collectively we believe will build long-term value for our shareholders."

Fourth Quarter 2021 and Recent Highlights

- **Ended 2021 with quarter over quarter growth of FOTIVDA net sales and prescriptions heading into 2022**
  - Fourth quarter 2021 U.S. net product revenue increased 17% from $14.3 million U.S. net product revenue in the third quarter of 2021 to $16.8 million, which reflects inventory shipped to distributors and a gross-to-net estimate of 14% during the fourth quarter. As of

December 31, 2021, U.S. net product revenue since FOTIVDA's commercial launch on March 22, 2021 was $38.9 million, which reflects a gross-to-net-estimate of 15% for the year.
    - 780 commercial prescriptions filled in the fourth quarter of 2021, representing a 26% increase from 619 commercial prescriptions filled in the third quarter of 2021.
  - FOTIVDA took the leadership position in the share of third-line RCC new patient starts in December 2021, which continued through the latest January 2022 data, as reported in IQVIA's BrandImpact report. This report suggests FOTIVDA is being more broadly adopted in the earlier third-line setting, which may result in an increase in the average treatment duration over time.
    - AVEO Specialty Pharmacy Sales Data demonstrated that the rate of early discontinuations decreased in the fourth quarter as utilization moves to earlier lines of therapy.

- **Positive new five year follow-up data for PFS 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 to patients treated with sorafenib (12% vs. 2% and 7.6% 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 overall survival (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.

- **Initiated Pivotal Phase 3 TiNivo-2 Trial in Advanced Refractory RCC following Prior Immunotherapy.**
  - AVEO initiated the Phase 3 TiNivo-2 clinical trial evaluating tivozanib in combination with nivolumab (OPDIVO®), Bristol Myers Squibb's antibody directed against programmed death-1, in patients with advanced refractory RCC following one or two lines of therapy, one of which must be an immunotherapy. If successful, this trial has the potential to significantly expand the market opportunity for FOTIVDA in the larger second line RCC setting. Bristol Myers Squibb is providing nivolumab clinical drug supply pursuant to a clinical trial collaboration and supply agreement. We expect TiNivo-2 enrollment to be completed in the first half of 2023.

- **Entered clinical development collaboration with NiKang Therapeutics, Inc. (NiKang) to evaluate the combination of NKT2152 (HIF2α) and tivozanib to treat advanced RCC.**
  - AVEO entered into a clinical trial collaboration and supply agreement with NiKang to evaluate NKT2152, NiKang's hypoxia inducible factor 2α (HIF2α), in combination with tivozanib in RCC patients who have not responded to or relapsed from prior therapies. AVEO anticipates the Phase 2 clinical trial to evaluate the combination is expected to commence in 2022.

- **Entered into a clinical trial collaboration and supply agreement with Merck KGaA, Darmstadt, Germany to evaluate ficlatuzumab in combination with ERBITUX® (cetuximab) in patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC).**
  - This combination therapy has demonstrated the potential to play a meaningful part in the treatment of patients with human papillomavirus (HPV) negative R/M HNSCC, which is the majority of the patient population and is typically associated with particularly poorer patient outcomes. AVEO will serve as the trial sponsor and will be responsible for costs associated with the execution of the trial.
  - AVEO has 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 HPV negative R/M HNSCC in the first half of 2023. AVEO expects to continue to discuss potential ficlatuzumab pivotal clinical trial designs with the U.S. Food and Drug Administration (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.

- **Update on Phase 1 clinical trial of AV-380.**
  - The last patient was dosed in the Phase 1 healthy subject clinical trial of AV-380.
  - Initial data observed a reduction of GDF15 in subjects and no drug related adverse events were identified. However, operational errors at the trial site have caused data integrity concerns and AVEO has notified the FDA to confirm the suitability of the data for regulatory purposes and whether AVEO may publish the data from this trial. AVEO does not expect that the data quality issues in the Phase 1 clinical trial will impact its plans to initiate a Phase 1b clinical trial in cancer patients in the second half of 2022.

- **Jeb Ledell Appointed as Chief Operating Officer.**
  - AVEO appointed Mr. Ledell as Chief Operating Officer in December 2021, where he is responsible for overseeing operational functions key to maximizing AVEO's organizational efficiency and advancing its pipeline of products. Mr. Ledell joins AVEO from Enzyvant Therapeutics, where he served as chief operating officer and led key business operations during the recent FDA approval of RETHYMIC®. Prior to joining Enzyvant Therapeutics, Mr. Ledell served as the chief operating officer at Compass Therapeutics and Horizon Discovery Group, during which time he led operations at both organizations through several changes in scale.

- **Additional $5.0 million made available to AVEO under its Loan Facility with Hercules Capital, Inc. (Hercules) and its affiliates.**
  - In late December 2021, AVEO achieved sales Performance Milestone II of $35.0 million in net product revenues from sales of FOTIVDA ahead of the April 1, 2022 deadline. Following satisfaction of Performance Milestone II, AVEO drew down the additional $5.0 million tranche in 2021.

- **Entered Preclinical Research Collaboration with Actinium Pharmaceuticals, Inc. (Actinium) to Develop First-in-Class Actinium-225 ErbB3 Targeting Radiotherapy for Solid Tumors.**
    - In February 2022, AVEO entered into a research collaboration to develop and study a first-in-class antibody radio-conjugate (ARC) targeting ErbB3, also known as HER3. Actinium will utilize its Antibody Warhead Enabling technology platform and extensive radiotherapy know-how to conjugate one of AVEO's ErbB3 targeted antibodies with Actinium-225, a potent alpha-emitting radioisotope, to form a novel Ac-225 ErbB3 targeted radiotherapy.

Fourth Quarter and Year End 2021 Financial Highlights

- At December 31, 2021, AVEO reported $87.3 million in cash, cash equivalents and marketable securities, as compared with $61.8 million at December 31, 2020.
- Total revenue for the fourth quarter of 2021 was approximately $17.6 million compared with $0.9 million for the fourth quarter of 2020. Total revenue for full year 2021 was approximately $42.3 million compared to $6.0 million for full year 2020.
- FOTIVDA U.S. net product revenue was $16.8 million and $38.9 million for the fourth quarter and full year 2021, respectively.
- Research and development expense for the fourth quarter of 2021 was $6.1 million compared with $4.6 million for the fourth quarter of 2020. Research and development expense for the full year 2021 was $26.3 million compared with $22.7 million for the full year 2020.
- Selling, general and administrative expense for the fourth quarter of 2021 was $15.7 million compared with $9.0 million for the fourth quarter of 2020. Selling, general and administrative expense for the full year 2021 was $60.8 million compared with $22.2 million for the full year 2020. The increase in selling, general and administrative expense for the fourth quarter and full year 2021 is primarily due to costs associated with the commercial launch of FOTIVDA.
- Net loss for the fourth quarter of 2021 was $7.3 million, or net loss of $0.21 per basic and diluted share, compared with a net loss of $11.5 million for the fourth quarter of 2020, or net loss of $0.44 per basic and diluted share.
- Net loss for the full year 2021 was $53.3 million, or net loss of $1.63 per basic and diluted share, compared with a net loss of $35.6 million for the full year 2020, or net loss of $1.66 per basic and diluted share.

Financial Guidance

AVEO believes that its $87.3 million in cash, cash equivalents and marketable securities as of December 31, 2021, 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 Annual Report on Form 10-K for the year ended December 31, 2021.

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 spend will be approximately $50.0 million in 2022. AVEO expects general and administrative expense will remain at approximately $20.0 million for the year. Research and development expenses will be in the range of $60.0 million to $70.0 million in 2022 in support of our 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, March 14, 2021, at 8:30 AM Eastern Time. The call can be accessed by dialing (877) 423-9813 (U.S. and Canada) or (201) 689-8573 (international). The passcode for the conference call is 13727273. 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 “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 expectations of achieving quarter over quarter sales growth and an increase in its sales ramp of FOTIVDA in future periods; AVEO’s, plans, strategies 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 other indications; the date enrollment will be completed for AVEO’s pivotal Phase 3 TiNivo-2 study; AVEO’s plans, strategies and execution for current and future clinical trials and preclinical studies of tivozanib, ficlatuzumab, AV-380 and AVEO's ErbB3 targeted antibodies; the advancement of AVEO’s pipeline, including the advancement of tivozanib, ficlatuzumab and AV-380 in multiple clinical trials and preclinical studies; the availability of clinical supplies of ficlatuzumab and AV-380; the potential efficacy, safety and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies in HNSCCand other indications; AVEO's ability to pursue regulatory strategies based on the results of clinical trials and preclinical studies of its product candidates; 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; 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 ongoing access challenges arising from the COVID-19 pandemic and related variants; 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, 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 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 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.
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Years Ended December 31,		Three Months Ended December 31,	
	2021	2020	2021	2020
Revenues:				
FOTIVDA U.S. product revenue, net	$ 38,874	$ —	$ 16,755	$ —
Partnership licensing and royalty revenue	3,421	6,019	891	886
	42,295	6,019	17,646	886
Operating expenses:				
Cost of products sold	4,737	—	2,033	—
Research and development	26,298	22,679	6,121	4,574
Selling, general and administrative	60,814	22,217	15,652	9,008
	91,849	44,896	23,806	13,582
Loss from operations	(49,554)	(38,877)	(6,160)	(12,696)
Other income (expense), net:				
Interest expense, net	(4,045)	(1,605)	(1,153)	(522)
Other income	58	—	58	—
Change in fair value of PIPE Warrant liability	199	4,898	—	1,714
	(3,788)	3,293	(1,095)	1,192
Net income (loss)	$ (53,342)	$ (35,584)	$ (7,255)	$ (11,504)
Net income (loss) per share	$ (1.63)	$ (1.66)	$ (0.21)	$ (0.44)
Weighted average number of common shares outstanding	32,661	21,402	34,384	26,252

Consolidated Balance Sheet Data
(In thousands)

	December 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 87,326	$ 61,761
Trade receivables, net and partnership receivables	11,601	1,197
Inventory	1,656	—
Prepaid expenses and other current assets	4,153	2,550
Property and equipment, net	276	343
Operating lease right-of-use asset	178	903
Other assets	151	158
Total assets	$ 105,341	$ 66,912
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 18,142	$ 12,393
Loans payable, net of discount	37,960	13,772
Deferred revenue and research and development reimbursements	578	2,716
PIPE Warrant liability	—	199
Operating lease liability	11	705
Other liabilities	2,780	1,833
Stockholder's equity	45,870	35,294
Total liabilities and stockholders' equity	$ 105,341	$ 66,912

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