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 10, 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 May 10, 2021, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 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	Q1 2021 earnings press release issued by the Company on May 10, 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: May 10, 2021

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

Exhibit 99.1

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

– U.S. Commercial Launch Underway with Fully Deployed Sales Force Following FDA Approval of FOTIVDA® (tivozanib) on March 10, 2021 –

– FOTIVDA Net Product Revenue of $1.1 Million from Initial Distributor Orders in the Last Week of Q1; All Distributors Have Placed Reorders for Q2 –

– Entered Clinical Trial Collaboration and Supply Agreement with Bristol Myers Squibb for Planned Pivotal Phase 3 TiNivo-2 Study of FOTIVDA in Combination with OPDIVO® (nivolumab); Study Anticipated to Commence Mid-2021 –

– Phase 2 Open Label Randomized Study Results of Ficlatuzumab in HNSCC to be Presented at ASCO; Phase 3 Decision Anticipated Mid-2021 –

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

BOSTON, Mass. – May 10, 2021 – AVEO Oncology (Nasdaq: AVEO), a commercial and clinical development stage biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2021 and provided a business update.

“The first quarter of 2021 was a transformational time for AVEO marked by the U.S. Food and Drug Administration (FDA) approval and launch of FOTIVDA, our first commercial product, and the advancement of our pipeline, all of which is supported by a strong balance sheet,” said Michael Bailey, president and chief executive officer of AVEO. “Our sales team is now fully deployed, and we are encouraged by the early commercial activity supporting the FOTIVDA launch. We look forward to continuing to execute on our goal of establishing FOTIVDA as a standard of care within its renal cell carcinoma (RCC) indication.”

“In parallel, we remain focused on the continued advancement of the remainder of our clinical programs. This includes the evaluation of FOTIVDA in the immunotherapy combination setting, with patient enrollment in the pivotal Phase 3 TiNivo-2 study of FOTIVDA in combination with OPDIVO anticipated to commence mid-year and the Phase 2 hepatocellular carcinoma (HCC) DEDUCTIVE trial reporting encouraging Phase 1b results at ASCO GI earlier this year. Beyond FOTIVDA, we continue to expect several key inflection points with the balance of our clinical pipeline later this year, including a go/no go decision on progressing to a pivotal study for ficlatuzumab in head and neck squamous cell carcinoma (HNSCC), the advancement of our Phase 1 study of AV-380 and an update on potential clinical development plans for AV-203.”

FOTIVDA U.S. Regulatory and Commercial Updates

- **U.S. Commercial Launch Underway Following FDA Approval of FOTIVDA for the Treatment of Adult Patients with Relapsed or Refractory Advanced RCC Following Two or More Prior Systemic Therapies**.
    - Announced FDA approval of FOTIVDA for the treatment of adults with relapsed or refractory advanced RCC following two or more prior systemic therapies on March 10, 2021.
    - Net product revenue for the first quarter of 2021 was $1.1 million, which reflects inventory shipped to distributors and a 15.0% gross to net estimate in the last week of March as FOTIVDA became commercially available on March 22, 2021.
    - All distributors that made orders in the first quarter have placed reorders for the second quarter.
    - As of April 30, 2021, 49 prescriptions have been filled and 75 samples have been requested and delivered.
    - In March 2021, AVEO announced that the National Comprehensive Cancer Network updated its Clinical Practice Guidelines to include FOTIVDA as a recommended regimen for subsequent therapy.

Tivozanib Clinical Updates

- **Additional Data from the TIVO-3 Study to be Presented at 2021 ASCO Annual Meeting in June 2021.** Additional data from the TIVO-3 study will be featured during two poster presentations at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2021. The presentations, titled “TIVO-3: Durability of response and updated overall survival of tivozanib versus sorafenib in metastatic renal cell carcinoma (mRCC)” and “Temporal characteristics of treatment-emergent adverse events and dose modifications with tivozanib and sorafenib in the phase 3 TIVO-3 study of relapsed or refractory mRCC”, will be featured on Friday, June 4.
- **Announced a Collaboration with Bristol Myers Squibb to Evaluate FOTIVDA in Combination with OPDIVO in a Planned Pivotal Phase 3 TiNivo-2 Trial in IO Relapsed or Refractory RCC.** In March 2021, AVEO announced that it entered into a clinical trial collaboration and supply agreement with Bristol Myers Squibb (NYSE: BMS) to evaluate FOTIVDA in combination with OPDIVO, Bristol Myers Squibb’s anti-PD-1 therapy, in the planned pivotal Phase 3 TiNivo-2 trial in patients with advanced relapsed or refractory RCC following prior immunotherapy exposure. Bristol Myers Squibb will provide OPDIVO clinical drug supply for the study. AVEO will serve as the study sponsor and will be responsible for costs associated with the trial execution. AVEO recently

received feedback from the FDA on the trial design and expects to commence enrollment in the trial in mid-2021.

- **Presented New Analyses from the Phase 3 TIVO-3 Study at ASCO 2021 GU Cancers Symposium.** In February 2021, AVEO presented key subgroup and quality of life analyses from the Phase 3 TIVO-3 study at the ASCO 2021 Genitourinary (GU) Cancers Symposium. The results further demonstrate the potential tolerability benefits of tivozanib. A copy of each presentation is available in the Scientific Publications & Presentations section of AVEO's website.

- **Results from Phase 1b Portion of DEDUCTIVE Study in HCC Presented at 2021 ASCO GI Cancer Symposium.** In January 2021, results from the Phase 1b portion of the Phase 1b/2 DEDUCTIVE clinical trial of tivozanib in combination with IMFINZI® (durvalumab), AstraZeneca's (LSE/STO/Nasdaq: AZN) human monoclonal antibody directed against programmed death-ligand 1, in patients with HCC were presented at the 2021 ASCO Gastrointestinal (GI) Cancers Symposium. There were no dose-limiting toxicities with the combination recorded in the DEDUCTIVE trial. In addition, the combination demonstrated a 29% partial response (PR) rate and a 71% disease control rate (PR + stable disease), which is comparable to findings with bevacizumab and TECENTRIQ® (atezolizumab), an emerging standard of care in the same setting. Completion of enrollment in the ongoing Phase 2 portion of the study, which is expected to enroll up to an additional 30 subjects, is anticipated later this year.

Ficlatuzumab Clinical Update

- **Enrollment Complete in Phase 2 Open Label Randomized Study of Ficlatuzumab in HNSCC; Results Expected to Be Presented at ASCO in June 2021; Phase 3 Go/No Go Decision Anticipated for Mid-2021.** In January 2021, AVEO announced completion of enrollment in its randomized confirmatory Phase 2 study of ficlatuzumab as a single agent or in combination with cetuximab (ERBITUX®), an EGFR-targeted antibody, in metastatic HNSCC patients who have failed prior immunotherapy, chemotherapy and cetuximab. Ficlatuzumab is AVEO's potent humanized immunoglobulin G1 (IgG1) monoclonal antibody that targets hepatocyte growth factor (HGF). The study was designed to confirm findings from a Phase 1/2 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 survival and overall survival compared to historical controls.

  Results from the Phase 2 study are expected to be presented in a poster discussion at ASCO in June 2021. Following the ASCO data presentation, AVEO plans to announce a go/no go Phase 3 decision for ficlatuzumab in HNSCC.

  In September 2020, AVEO regained full global rights to ficlatuzumab and has initiated clinical manufacture of ficlatuzumab to supply a potential Phase 3 clinical trial in HNSCC, as well as additional potential Phase 2 studies in pancreatic cancer and acute myeloid leukemia.

AV-380 Clinical Update

- **Phase 1 Clinical Study Initiated Following FDA Acceptance of IND Filing.** Recently, AVEO initiated enrollment for a Phase 1 study of AV-380, a potent humanized IgG1 monoclonal antibody that targets growth differentiation factor 15 (GDF15), for the potential treatment of cancer cachexia.

AV-203 Clinical Update

- **To Regain Ex-North American Rights to AV-203.** In March 2021, AVEO announced it will regain rights to AV-203 outside of North America, its clinical-stage potent humanized IgG1 monoclonal antibody that targets ErbB3 (also known as HER3), following the voluntary termination of its collaboration and license agreement by CANbridge Life Sciences. AVEO will regain rights to AV-203 in all territories globally, and CANbridge has initiated the process to transfer all preclinical data and materials to AVEO. The Company expects to provide an update on the AV-203 clinical development plan in the second half of 2021.

Corporate Updates

- **Strong Balance Sheet to Support U.S. Launch of FOTIVDA.** In the first quarter of 2021, AVEO added approximately $78.1 million to its balance sheet, consisting of a $20.0 million drawdown under its previously announced $45.0 million loan and security agreement with Hercules Capital. Inc. (NYSE: HTGC, Hercules), $3.1 million from warrant exercises as of March 31, 2021, $3.4 million in stock sales under its at-the-market sales agreement with SVB Leerink LLC and $51.6 million in net proceeds from a public offering of its common stock.

- **Strengthened Board of Directors with Two New Appointments.** AVEO has recently announced the appointments of Kevin Cullen, M.D., and Corinne D. Epperly, M.D., MPH, to its Board of Directors.

  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.

  Dr. Epperly brings over 15 years of experience in oncology as a physician and scientist, blending medicine and business with a proven track record in oncology drug development and launches, commercial and medical strategy, marketing, M&A and operations gained at Iovance Biotherapeutics, VBL Therapeutics, Bristol Myers Squibb, Goldman Sachs and the National Cancer Institute of the NIH.

- **Appointment of Mike Ferraresso to Chief Commercial Officer.** In March 2021, AVEO announced the appointment of Mike Ferraresso to chief commercial officer. He is

responsible for managing AVEO's commercial strategy and operations, including the commercialization of FOTIVDA. Mr. Ferraresso, who joined AVEO in December 2017, most recently served as AVEO's senior vice president, business analytics and commercial operations. He has over 20 years of commercial pharmaceutical and biotechnology experience, including 15 years developing and commercializing oncology products.

First Quarter 2021 Financial Highlights

- AVEO ended Q1 2021 with $121.4 million in cash, cash equivalents and marketable securities as compared with $61.8 million at December 31, 2020.
- Total revenue for Q1 2021 was approximately $1.9 million compared with $0.8 million for Q1 2020.
- Research and development expense for Q1 2021 was $5.8 million compared with $7.8 million for Q1 2020.
- Selling, general and administrative expense for Q1 2021 was $15.1 million compared with $3.7 million for Q1 2020.
- Net loss for Q1 2021 was $22.1 million, or net loss of $0.81 per basic and diluted share, compared with a net loss of $8.4 million for Q1 2020, or net loss of $0.52 per basic and diluted share.
    - Net loss for Q1 2021 reflects an approximate $2.4 million non-cash loss attributable to the increase in the fair value of the 2016 private placement warrant liability that principally resulted from increases in the stock volatility rate that occurred within the first quarter, as well as a shorter remaining term as the warrants approach expiration. Net loss in Q1 2020 reflects an approximate $2.6 million non-cash gain attributable to the decrease in the fair value of the 2016 private placement warrant liability that principally resulted from the decrease in the stock price that occurred within the fiscal year.

Financial Guidance

AVEO believes that its $121.4 million in cash and cash equivalents as of March 31, 2021, along with 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.

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 be approximately $40 million for existing pipeline plans during 2021. In addition, quarterly general and administrative expense should approximate the level seen during the first quarter of this year.

Conference Call and Webcast

In connection with this announcement, AVEO will host a conference call and audio webcast today, May 10, 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 3996993. To access the live webcast, or the subsequent archived recording, please visit 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 an oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for cancer patients. AVEO's strategy is to focus its resources toward the 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, FOTIVDA® (tivozanib), received U.S. Food and Drug Administration (FDA) approval on March 10, 2021 for the treatment of adult patients with relapsed or refractory 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 EUSA territory for the treatment of adult patients with advanced RCC. AVEO has previously reported promising early clinical data on ficlatuzumab (anti-HGF IgG1 mAb) in head and neck cancer, pancreatic cancer and acute myeloid leukemia and is conducting a randomized Phase 2 confirmatory clinical trial of ficlatuzumab for the potential treatment of head and neck cancer. AVEO's pipeline of product candidates also includes AV-380 (anti-GDF15 IgG1 mAb). AVEO has previously reported the acceptance of its investigational new drug application in the U.S. for AV-380 and its initiation of a Phase 1 clinical trial for the potential treatment of cancer cachexia. AVEO's earlier-stage pipeline includes monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 mAb) and AV-353 (anti-Notch 3 mAb). AVEO is committed to creating an environment of diversity and inclusion.

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: 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; 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 FOTIVDA in the United States; the advancement of AVEO's pipeline, including the advancement of ficlatuzumab and AV-380 in multiple clinical studies; the potential outcomes from studies of ficlatuzumab 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; and AVEO's strategy, prospects, plans and objectives for FOTIVDA and its product candidates and for AVEO 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: 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 to raise the substantial additional funds required to achieve its goals, including those goals pertaining to the commercialization 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 and its 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; uncertainties related to AVEO's ability to access future borrowings under the Hercules loan agreement, which turns on the achievement of milestones related to the commercialization 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 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. 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 March 31,	
	2021	2020
Revenues:		
FOTIVDA product revenue, net	$ 1,066	$ -
Collaboration and licensing revenue	493	493
Partnership royalties	361	291
	1,920	784
Operating expenses:		
Cost of products sold	138	-
Research and development	5,797	7,826
Selling, general and administrative	15,100	3,672
	21,035	11,498
Loss from operations	(19,115)	(10,714)
Other income (expense), net:		
Interest expense, net	(611)	(315)
Change in fair value of PIPE Warrant liability	(2,396)	2,648
Other income (expense), net	(3,007)	2,333
Net loss	$ (22,122)	$ (8,381)
Net loss per share - basic and diluted	$ (0.81)	$ (0.52)
Weighted average number of common shares outstanding	27,429	16,081

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 121,414	$ 61,761
Trade receivables, net and partnership receivables	2,566	1,197
Prepaid expenses and other current assets	2,082	2,550
Property and equipment, net	326	343
Operating lease right-of-use asset	790	903
Other assets	258	158
Total assets	$ 127,436	$ 66,912
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 13,971	$ 12,393
Loans payable, net of discount	32,437	13,772
Deferred revenue and research and development reimbursements	2,171	2,716
PIPE Warrant liability	2,595	199
Operating lease liability	592	705
Other liabilities	3,222	1,833
Stockholder's equity	72,448	35,294
Total liabilities and stockholders' equity	$ 127,436	$ 66,912

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