

**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 16, 2021

AVEO Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-34655
(Commission
File Number)

04-3581650
(IRS Employer
Identification No.)

30 Winter Street
Boston, Massachusetts
(Address of Principal Executive Offices)

02108
(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 16, 2021, AVEO Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2020. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 [Fiscal year 2020 earnings press release issued by the Company on March 16, 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: March 16, 2021

By: /s/ Michael Bailey

Michael Bailey

President and Chief Executive Officer



AVEO Oncology Reports Full Year 2020 Financial Results and Provides Business Update

- *FOTIVDA® (tivozanib) Approved for Adult Patients with Relapsed or Refractory Advanced Renal Cell Carcinoma Following Two or More Prior Systemic Therapies; AVEO Plans to Make FOTIVDA Available to Patients in the U.S. by March 31, 2021 –*
- *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); Trial Expected to Commence Mid-2021 -*
- *Enrollment Complete in Phase 2 Open Label Randomized Study of Ficlaturuzumab in HNSCC; Results and Phase 3 Decision on Track for Mid-2021 –*
- *Regained Ex-North American Rights to AV-203; AVEO Now Holds Global Rights to Three Clinical Assets in Addition to FOTIVDA North American Rights -*
- *\$20M Tranche Drawdown Complete in Connection with FOTIVDA Approval Under Amended Hercules Loan Agreement -*
- *Announced IP Strategy to Potentially Extend FOTIVDA Exclusivity to November 2028 –*

BOSTON, Mass. – March 16, 2021 – AVEO Oncology (Nasdaq: AVEO) today reported financial results for the full year ended December 31, 2020 and provided a business update.

“The U.S. Food and Drug Administration’s (FDA) recent approval of FOTIVDA marks a transformative event for AVEO, and we are eager to demonstrate FOTIVDA’s potential to serve as a meaningful new treatment option within the growing relapsed or refractory advanced renal cell carcinoma (RCC) patient population. We look forward to bringing this meaningful new therapy to patients in the U.S. by the end of this month,” said Michael Bailey, president and chief executive officer of AVEO. “In parallel, we remain focused on the evaluation of FOTIVDA in the immunotherapy combination setting, with the pivotal Phase 3 TiNivo-2 study of FOTIVDA in combination with OPDIVO expected to commence patient enrollment mid-year.”

“We also anticipate notable progress within our clinical programs, with several key inflection points expected to occur in the coming year. This includes a decision on the initiation of a pivotal study of ficlatuzumab in head and neck squamous cell carcinoma (HNSCC), and advancement of our Phase 1 study of AV-380. We look forward to providing updates on our progress in the coming months.”

FOTIVDA U.S. Regulatory, Commercial, and IP Updates

- **FOTIVDA Approved by the FDA for the Treatment of Adult Patients with Relapsed or Refractory Advanced RCC Following Two or More Prior Systemic Therapies.** On March 10, 2021, AVEO announced FDA approval of FOTIVDA in the United States for
-

the treatment of adults with relapsed or refractory advanced RCC following two or more prior systemic therapies. FOTIVDA is an oral, next-generation vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI). AVEO plans to make FOTIVDA available to patients in the U.S. by March 31, 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, its pivotal Phase 3 trial comparing tivozanib to sorafenib in RCC patients who are relapsed or refractory to two or more prior therapies, at the American Society of Clinical Oncology (ASCO) 2021 Genitourinary (GU) Cancers Symposium. The results further demonstrate the benefits of tivozanib over sorafenib. A copy of each presentation is available in the Scientific Publications & Presentations section of AVEO's website.
- **Updated IP Strategy Offers Potential for Tivozanib Patent Term Extension to November 2028.** AVEO holds an exclusive license to two issued U.S. patents for tivozanib, one pertaining to the tivozanib composition of matter, which expires in April 2022, and the other pertaining to a crystalline form of tivozanib, which expires in November 2023. A patent term extension of up to five years may be available under the Hatch-Waxman Act, although only one patent can be extended under the Act. AVEO currently intends to file applications for patent term extension on both patents in parallel to provide optionality in its exclusivity strategy. Depending upon which patent AVEO ultimately chooses to extend, if a full five-year extension is granted for such patent, tivozanib's exclusivity period could reach either April 2027 or November 2028.

Tivozanib Immuno-Oncology Updates

- **Announced Collaboration with Bristol Myers Squibb to Evaluate FOTIVDA in Combination with OPDIVO in Pivotal Phase 3 TiNivo-2 Trial in IO Relapsed or Refractory RCC.** In March 2021, AVEO announced that it has entered into a clinical trial collaboration and supply agreement with Bristol Myers Squibb to evaluate FOTIVDA in combination with OPDIVO, Bristol Myers Squibb's anti-PD-1 therapy, in the 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 expects to begin enrollment in the trial in mid-2021 subject to FDA feedback on the trial design anticipated in the second quarter of 2021.
 - **Results from Phase 1b Portion of DEDUCTIVE Study in Hepatocellular Carcinoma (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 (PD-L1), in patients with HCC were presented at the 2021 ASCO Gastrointestinal (GI) Cancers
-

Symposium. There were no dose-limiting toxicities with the combination. In addition, the combination demonstrated a 29% partial response (PR) rate and 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.

- **Results from Phase 1b/2 TiNivo Study of Tivozanib in Combination with OPDIVO® (nivolumab) in RCC Published in Annals of Oncology.** In November 2020, AVEO announced that previously reported results from the Phase 1b/2 TiNivo study of oral tivozanib in combination with intravenous OPDIVO (nivolumab), an immune checkpoint, or PD-1, inhibitor, for the treatment of advanced RCC, were published in Annals of Oncology. The article, titled “TiNivo: Safety and Efficacy of Tivozanib-Nivolumab Combination Therapy in Patients with Metastatic Renal Cell Carcinoma”, is available online via [this link](#).

Ficlatuzumab Update

- **Enrollment Complete in Phase 2 Open Label Randomized Study of Ficlatuzumab in HNSCC; Results Expected to Be Presented at a Medical Meeting in Mid-2021; Phase 3 Decision on Track 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, an EGFR-targeted antibody, in metastatic HNSCC patients who have failed prior immunotherapy, chemotherapy and cetuximab (ERBITUX®). 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 at a medical meeting in mid-2021. In that timeframe, AVEO plans to announce a Phase 3 decision for ficlatuzumab. 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 Update

- **Phase 1 Clinical Study Initiated Following FDA Acceptance of IND Filing.** In January 2021, AVEO announced that its Investigational New Drug (IND) application for AV-380, a potent humanized IgG1 monoclonal antibody that targets growth differentiation factor 15 (GDF15), for the potential treatment of cancer cachexia, was accepted by the FDA. A Phase 1 study in healthy subjects has been initiated.

AV-203 Update

- **Regained 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.

Corporate Updates

- **Announced Drawdown of \$20 Million Tranche Under \$45 Million Debt Facility with Hercules Capital.** In March 2021, AVEO announced that it completed a drawdown of \$20 million under its previously announced \$45 million loan and security agreement with Hercules Capital, Inc. (NYSE: HTGC, Hercules) and its affiliates. With the closing of the second tranche, which was made available in connection with the recent FDA approval of FOTIVDA, AVEO has drawn down a total of \$35 million under its loan and security agreement with Hercules. Under the terms of the loan agreement, an additional \$10 million will become available if certain sales criteria and other conditions are met.
- **Announced Appointment of Mike Ferraresso to Chief Commercial Officer.** In March 2021, AVEO announced the appointment of Mike Ferraresso to chief commercial officer. He will be 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.
- **Announced Appointment of Corinne D. Epperly, MD, MPH to Board of Directors.** In January 2021, AVEO announced the appointment of Corinne D. Epperly, MD, MPH, to its Board of Directors. 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.
- **Announced Appointment of David Crist as Vice President of Sales.** In October 2020, AVEO announced the appointment of David W. Crist as vice president of sales. Mr. Crist, who brings to AVEO over 20 years of oncology sales experience in both launch-stage and late-stage companies, is responsible for building out AVEO's sales force in preparation for the commercial launch of FOTIVDA in the U.S.

A current summary of AVEO's activities and corporate updates is available in AVEO's Corporate Presentation on the Investors portion of AVEO's website at investor.aveooncology.com.

Full Year 2020 Financial Highlights

- AVEO ended 2020 with \$61.8 million in cash, cash equivalents, and marketable securities as compared with \$47.7 million at December 31, 2019.
- Total revenue for 2020 was approximately \$6.0 million compared with \$28.8 million for 2019, which included the \$25.0 million upfront payment in connection with Kyowa Kirin's buy back of tivozanib non-oncology rights.
- Research and development expense for 2020 was \$22.7 million compared with \$18.0 million for 2019.
- General and administrative expense for 2020 was \$22.2 million compared with \$11.2 million for 2019.
- Net loss for 2020 was \$35.6 million, or net loss of \$1.66 per basic and diluted share, compared with a net income of \$9.4 million, or net income of \$0.61 per basic and diluted share, in 2019.
 - Net loss in 2020 reflects an approximate \$4.9 million non-cash gain attributable to the decrease in the fair value of the 2016 private placement warrant liability that principally resulted from decreases in the stock price and stock volatility rate that occurred within the fiscal year, as well as a shorter remaining term as the warrants approach expiration. Net income in 2019 reflects an approximate \$11.6 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 \$61.8 million in cash and cash equivalents as of December 31, 2020, along with proceeds from the \$20 million drawdown under the Hercules loan facility in March 2021 and from warrant exercises to date, together with anticipated partnership cost sharing reimbursements, royalties from EUSA Pharma (UK) Limited's (EUSA) FOTIVDA sales, product revenues upon the commercial launch of FOTIVDA in the United States and the potential additional \$10 million in credit under the Hercules loan agreement, would allow AVEO to fund planned operations into 2022.

The above guidance estimates the expenses associated with the commercial launch of FOTIVDA in the United States will be approximately \$40 million during the year ended December 31, 2021.

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 models¹. 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 ($\geq 20\%$) adverse reactions were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis, and the most common Grade 3 or 4 laboratory abnormalities ($\geq 5\%$) 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.AVEOoncology.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: AVEO's planned timing for making FOTIVDA available to patients in the U.S.; 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 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 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 and supply of FOTIVDA and its product candidates; and AVEO's ability to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its strategic partners, to achieve development and commercialization objectives under these arrangements; AVEO'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](https://doi.org/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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Collaboration and licensing revenue	\$ 494	\$ 493	\$ 4,774	\$ 27,934
Partnership royalties	392	271	1,245	861
	<u>886</u>	<u>764</u>	<u>6,019</u>	<u>28,795</u>
Operating expenses:				
Research and development	4,574	4,512	22,679	17,958
Selling, general and administrative	9,008	2,886	22,217	11,211
	<u>13,582</u>	<u>7,398</u>	<u>44,896</u>	<u>29,169</u>
Loss from operations	(12,696)	(6,634)	(38,877)	(374)
Other income (expense), net:				
Interest expense, net	(522)	(333)	(1,605)	(1,815)
Change in fair value of PIPE Warrant liability	1,714	2,506	4,898	11,577
Other income (expense), net	1,192	2,173	3,293	9,762
Net income (loss)	<u>\$ (11,504)</u>	<u>\$ (4,461)</u>	<u>\$ (35,584)</u>	<u>\$ 9,388</u>
Basic net income (loss) per share				
Net income (loss) per share	\$ (0.44)	\$ (0.28)	\$ (1.66)	\$ 0.61
Weighted average number of common shares outstanding	26,252	16,077	21,402	15,331
Diluted net income (loss) per share				
Net income (loss) per share	\$ (0.44)	\$ (0.28)	\$ (1.66)	\$ 0.61
Weighted average number of common shares and dilutive common share equivalents outstanding	26,252	16,077	21,402	15,376

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	December 31, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	\$ 61,761	\$ 47,745
Accounts receivable	1,197	1,631
Prepaid expenses and other current assets	2,550	1,224
Property and equipment, net	343	—
Operating lease right-of-use asset	903	—
Other assets	158	—
Total assets	\$ 66,912	\$ 50,600
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	\$ 12,393	\$ 9,482
Loans payable, net of discount	13,772	15,766
Deferred revenue and research and development reimbursements	2,716	4,619
PIPE Warrant liability	199	5,097
Operating lease liability	705	—
Other liabilities	1,833	790
Stockholder's equity	35,294	14,846
Total liabilities and stockholders' equity	\$ 66,912	\$ 50,600

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