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): November 7, 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 November 7, 2022, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Q3 2022 earnings press release issued by the Company on November 7, 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: November 7, 2022

By: /s/ Michael Bailey

Michael Bailey

President and Chief Executive Officer

AVEO Oncology Reports Third Quarter 2022 Financial Results

– Total Q3 2022 Net Revenue of $30.4 million, including $30.2 million of FOTIVDA® (tivozanib) U.S. Net Product Revenue –

– Announced entering a definitive agreement under which LG Chem will acquire AVEO for $15.00 per share in an all-cash transaction with an implied equity value of $566 million on a fully diluted basis –

BOSTON – November 7, 2022 – AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for patients with cancer, today reported financial results for the third quarter ended September 30, 2022.

Third Quarter 2022 Financial Highlights

- At September 30, 2022, AVEO reported $77.4 million in cash, cash equivalents and marketable securities, as compared with $77.2 million at the end of June 30, 2022 and $87.3 million at December 31, 2021.
- Total revenue for the third quarter of 2022 was approximately $30.4 million compared with $15.2 million for the third quarter of 2021.
- FOTIVDA U.S. net product revenue was $30.2 million for the third quarter of 2022 compared with $25.0 million in the second quarter of 2022 and $14.3 million for the third quarter of 2021.
- In the third quarter of 2022, 1,284 commercial prescriptions were filled, representing an 11% increase compared with 1,157 filled in the second quarter of 2022 and a 107% increase compared with 619 filled in the third quarter of 2021.
- Research and development expense for the third quarter of 2022 was $11.1 million compared with $7.5 million for the third quarter of 2021.
- Selling, general and administrative expense for the third quarter of 2022 was $17.6 million compared with $15.1 million for the third quarter of 2021.
- Net loss for the third quarter of 2022 was $3.3 million, or net loss of $0.09 per basic and diluted share, compared with a net loss of $10.4 million for the third quarter of 2021, or net loss of $0.30 per basic and diluted share.

Recent Highlights

The United States Patent and Trademark Office is expected to grant AVEO's patent application directed to methods of treating subjects with refractory advanced renal cell carcinoma using tivozanib on November 22, 2022. AVEO plans to list this patent in the United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations as it relates to FOTIVDA with an expiration date of November 5, 2039.

Proposed LG Chem Transaction

On October 18, 2022, AVEO and LG Chem, Ltd. (LG Chem) announced that they have entered into a definitive agreement under which LG Chem will acquire AVEO for $15.00 per share in an all-cash transaction with an implied equity value of $566 million on a fully diluted basis. The combination of LG Chem's Life Sciences division and AVEO is expected to create a global oncology organization with a robust portfolio of innovative products supported by full capabilities from discovery to clinical, biologics manufacturing and U.S. commercialization, at a scale capable of broadly delivering on its mission to improve the lives of patients with cancer.

The transaction, which was unanimously approved by both companies' Boards of Directors, is expected to close in early 2023, subject to customary closing conditions, including approval by AVEO shareholders and receipt of regulatory approvals. The transaction is not subject to any financing condition. LG Chem expects to finance the transaction with existing and available cash resources. Upon completion of the transaction, AVEO's shares will no longer trade on the Nasdaq.

Due to the pending transaction, AVEO will not host a conference call to discuss its quarterly financial results and withdraws its previously issued financial guidance for fiscal year 2022, last updated on August 4, 2022.

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.[2] 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.[3] 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,[4] 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.

Additional Information

This communication may be deemed solicitation material in respect of the proposed acquisition of AVEO by LG Chem. AVEO expects to file with the U.S Securities and Exchange Commission (SEC) a proxy statement and other relevant documents with respect to a special meeting of the stockholders of AVEO to approve the proposed merger. Investors of AVEO are urged to read the definitive proxy statement and other relevant materials carefully and in their entirety when they become available because they will contain important information about AVEO, LG Chem and the proposed merger. Investors may obtain a free copy of these materials (when they are available) and other documents filed by AVEO with the SEC at the SEC's website at *www.sec.gov*, at AVEO's website at www.aveooncology.com or by sending a written request to AVEO at 30 Winter Street, Boston, Massachusetts 02108. The information contained on, or accessible through, AVEO's website is not incorporated by reference into this communication, and you should not consider any information contained in, or that can be accessed through, AVEO's website as part of this communication or in deciding whether to support the approval of the proposed merger. AVEO has included its website in this communication solely as an inactive textual reference.

Participants in the Solicitation

AVEO and its directors, executive officers and certain other members of management and employees may be deemed to be participants in soliciting proxies from AVEO's stockholders in connection with the proposed merger. Information regarding the persons who may, under the rules of the SEC, be considered to be participants in the solicitation of AVEO's stockholders in connection with the proposed merger will be set forth in AVEO's definitive proxy statement for its special stockholders meeting. Additional information regarding these individuals and any direct or indirect interests they may have in the proposed merger will be set forth in the definitive proxy statement when and if it is filed with the SEC in connection with the proposed merger.

Cautionary Note Regarding Forward-Looking Statements

This communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. These forward-looking statements generally include statements that are predictive in nature and depend on or refer to future events or conditions, and include words such as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume" and "continue" as well as variations of such words and similar expressions. By their nature, forward-looking statements involve risks and uncertainty because they relate to events and depend on circumstances that will occur in the future, and there are many factors that could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements include, among other things, statements about the potential benefits of the proposed acquisition of AVEO by LG Chem (the "*proposed transaction*"); the prospective performance and outlook of AVEO's business, performance and opportunities; any potential strategic benefits, synergies or opportunities expected as a result of the proposed transaction; the ability of the parties to complete the

proposed transaction and the expected timing of completion of the proposed transaction; as well as any assumptions underlying any of the foregoing.

These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. There can be no guarantee that the proposed transaction will be completed, or that it will be completed as currently proposed, or at any particular time. Neither can there be any guarantee that AVEO will achieve any particular future financial results. In particular, our expectations could be affected by, among other things: the risk that the proposed transaction may not be completed in a timely manner or at all; the possibility that competing offers or acquisition proposals for AVEO will be made; the possibility that required regulatory, stockholder or other approvals or other conditions to the consummation of proposed transaction may not be satisfied on a timely basis or at all (and the risk that such approvals may result in the imposition of conditions that could adversely affect LG Chem or AVEO or the expected benefits of the proposed transaction); regulatory actions or delays or government regulation generally, including potential regulatory actions or delays relating to the completion of the potential transaction; the occurrence of any event, change or other circumstance that could give rise to the right of LG Chem or AVEO to terminate the definitive merger agreement governing the terms and conditions of the proposed transaction; effects of the announcement, pendency or consummation of the proposed transaction on AVEO's ability to retain and hire key personnel, its ability to maintain relationships with its customers, suppliers and others with whom it does business, its business generally or its stock price; risks related to the diversion of management's attention from ongoing business operations and opportunities; the risk that stockholder litigation in connection with the proposed transaction may result in significant costs of defense, indemnification and liability; the possibility that the proposed transaction may be more expensive to complete than anticipated, including as a result of unexpected factors or events; and other risks and factors referred to from time to time in AVEO's filings with the Securities and Exchange Commission, including AVEO's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent Quarterly Reports on Form 10-Q, including those related to the uncertainties inherent in the research and development of new and existing healthcare products, including clinical and regulatory developments and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection; safety, quality or manufacturing issues or delays; changes in expected or existing competition; and domestic and global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures. The effects of the COVID-19 pandemic may give rise to risks that are currently unknown or amplify the risks associated with many of these factors. AVEO is providing the information in this communication as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

References

1. ZS Associates. US emerging pharma and biotech first launches: A story of over-and underperformance. June 21, 2022.
2. Pawlowski N et al. AACR 2013. Poster 3971.
3. J Angulo and O Shapiro, Cancers (Basel) 2019 Sep; 11(9): 1227. [10.3390/cancers11091227]
4. Decision Resources. RCC landscape and forecast. December 12, 2019.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
FOTIVDA U.S. product revenue, net	$ 30,190	$ 14,318	$ 75,282	$ 22,119
Partnership licensing and royalty revenue	259	855	1,391	2,530
	30,449	15,173	76,673	24,649
Operating expenses:				
Cost of products sold	3,964	1,744	9,463	2,704
Research and development	11,074	7,502	33,552	20,177
Selling, general and administrative	17,579	15,142	51,991	45,162
	32,617	24,388	95,006	68,043
Loss from operations	(2,168)	(9,215)	(18,333)	(43,394)
Other income (expense), net:				
Interest expense, net	(1,098)	(1,153)	(3,451)	(2,892)
Change in fair value of PIPE Warrant liability	—	—	—	199
	(1,098)	(1,153)	(3,451)	(2,693)
Net loss	$ (3,266)	$ (10,368)	(21,784)	(46,087)
Net loss per share	$ (0.09)	$ (0.30)	$ (0.63)	$ (1.44)
Weighted average number of common shares outstanding	34,618	34,374	34,533	32,081

Consolidated Balance Sheet Data
(In thousands)

	September 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents and marketable securities	$ 77,398	$ 87,326
Trade receivables, net and partnership receivables	19,764	11,601
Inventory	1,106	1,656
Prepaid expenses and other current assets	2,463	4,153
Property and equipment, net	225	276
Operating lease right-of-use asset	32	178
Other assets	245	151
Total assets	$ 101,233	$ 105,341
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 30,928	$ 18,142
Loans payable, net of discount	38,678	37,960
Deferred revenue and research and development reimbursements	—	578
Operating lease liability	2	11
Other liabilities	2,780	2,780
Stockholder's equity	28,845	45,870
Total liabilities and stockholders' equity	$ 101,233	$ 105,341