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): September 8, 2020

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 (*see* General Instruction A.2. below):

☐ 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 8.01. Other Events.

On September 8, 2020, AVEO Pharmaceuticals, Inc. (the "Company") issued a press release announcing the decision by Biodesix, Inc. ("Biodesix") to exercise its Opt-Out rights (as defined below) under the Co-Development and Collaboration Agreement (the "Co-Development Agreement"), dated April 9, 2014, as amended, by and between the Company and Biodesix. Pursuant to the Co-Development Agreement, the Company entered into a worldwide co-development and collaboration agreement with Biodesix to develop and commercialize ficlatuzumab. The Biodesix Agreement generally provides for each party to contribute 50% of all clinical, regulatory, manufacturing and other costs to develop ficlatuzumab and to share equally in any future revenue from development or commercialization, subject to opt-out rights and certain other exceptions. Under the Co-Development Agreement, the Company granted Biodesix perpetual, non-exclusive rights to certain intellectual property, including all clinical and biomarker data related to ficlatuzumab, to develop and commercialize VeriStrat®, Biodesix's proprietary companion diagnostic test. Biodesix granted the Company perpetual, non-exclusive rights to certain intellectual property, including diagnostic data related to VeriStrat, with respect to the development and commercialization of ficlatuzumab. Each license includes the right to sublicense, subject to certain exceptions. Prior to the first commercial sale of ficlatuzumab, each party had the right to elect to discontinue its funding obligation for further development or commercialization efforts with respect to ficlatuzumab in exchange for reduced economics in the program, which is referred to as an "Opt-Out." Pursuant to the terms of the Co-Development Agreement, as a result of Biodesix's election to Opt-Out, Biodesix shall (i) continue to be responsible for reimbursement of development costs with respect to the ongoing Phase 2 investigator-sponsored clinical trial of ficlatuzumab in combination with ERBITUX® (cetuximab) in head and neck squamous cell cancer, (ii) cease to be entitled to 50% sharing of profits resulting from commercialization of ficlatuzumab, (iii) be entitled to a low double digit royalty on future product sales and 25% of future licensing revenue, less approximately $2.5 million Biodesix would be required to pay to the Company pursuant to the October 2016 amendment to the Co-Development Agreement and (iv) remain responsible for development obligations under the Co-Development Agreement with respect to VeriStrat (and Biodesix and the Company will be obligated to negotiate a commercialization agreement with respect to VeriStrat). As a result of Biodesix's decision to Opt-Out, the Company will have sole decision-making authority with respect to further development and commercialization of ficlatuzumab. The Co-Development Agreement will remain in effect until the expiration of all payment obligations between the parties related to development and commercialization of ficlatuzumab, unless earlier terminated.

The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on September 8, 2020.

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: September 8, 2020

By: /s/ Erick Lucera
Erick Lucera
Chief Financial Officer

AVEO Oncology Regains Full Global Rights to Ficlatuzumab

Announces Decision to Fund Clinical Manufacture of Ficlatuzumab
for Potential Phase 3 Study and Update to Biodesix Partnership

No Change to AVEO Cash Runway Guidance

BOSTON, Mass. – September 8, 2020 – AVEO Oncology (Nasdaq: AVEO) today announced that it has regained full global rights to ficlatuzumab, AVEO's potent hepatocyte growth factor (HGF) inhibitory antibody which binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities. AVEO also announced today that it plans to fund the clinical manufacture of ficlatuzumab to enable a potential registrational Phase 3 clinical trial in head and neck squamous cell cancer (HNSCC), as well as additional potential development in Phase 2 studies in pancreatic cancer and acute myeloid leukemia (AML). Following the decision, Biodesix, a leading diagnostic company, has exercised its contractual right to reduce its future financial obligations in exchange for reduced partnership economics. Under the terms of the agreement between AVEO and Biodesix, Biodesix will continue to fund 50% of the ongoing HNSCC Phase 2 trial, and will be entitled to a low double digit royalty on any future product sales as well as 25% of future licensing revenue, subject to certain limitations.

"We are very pleased to regain full rights to another late-stage asset. This comes at a strategic point in our Company's history, as we continue to build a commercial biopharmaceutical company with a broad oncology portfolio that has the potential to enable a long-term, sustainable growth model," said Michael Bailey, president and chief executive officer of AVEO. "The early data we have seen in the randomized, open-label HNSCC study with ficlatuzumab combined with cetuximab (ERBITUX®) has led us to the decision to secure additional clinical manufacturing capacity, which we expect to fund within our previously announced cash runway guidance, in order to prepare for a potential HNSCC pivotal study. We look forward to presenting final results from the Phase 2 study in the middle of 2021, and to providing an update on our potential pivotal program within that timeframe."

Ficlatuzumab is being studied in an ongoing randomized, open-label confirmatory Phase 2 study in combination with cetuximab, an EGFR-targeted antibody, in cetuximab-resistant, recurrent metastatic HNSCC. The study was designed to confirm findings from a Phase 1 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 and overall survival compared to historical controls. The Phase 2 multi-center study is being conducted under the direction of Julie E. Bauman, MD, MPH, Professor of Medicine, Chief, Division of Hematology/Oncology, Associate Director of Translational Research, University of Arizona Cancer Center. Enrollment is expected to conclude in the fourth quarter of 2020, and results from the study are expected to be presented at a scientific meeting in 2021.

For more information, please refer to the Current Report on Form 8-K which will be filed by AVEO with the U.S. Securities & Exchange Commission on September 8, 2020.

About AVEO Pharmaceuticals, Inc.

AVEO is developing an oncology pipeline designed to provide a better life for patients with cancer. AVEO's strategy is to focus its resources toward 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, tivozanib (FOTIVDA®) is approved in the European Union and other countries in the EUSA territory for the treatment of adult patients with advanced renal cell carcinoma. AVEO is working to develop and potentially commercialize tivozanib in North America as a treatment for renal cell carcinoma and hepatocellular carcinoma. AVEO has previously reported promising early clinical data on ficlatuzumab (anti-HGF mAb) in head and neck cancer, acute myeloid leukemia and pancreatic cancer and is conducting a randomized Phase 2 confirmatory clinical trial of ficlatuzumab in head and neck cancer. AVEO's earlier-stage pipeline includes several monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 mAb), AV-380 (anti-GDF15 mAb) and AV-353 (anti-Notch 3 mAb). AVEO is committed to creating an environment of diversity and inclusion as a foundation for innovation.

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," "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 advancement of AVEO's pipeline, including the advancement of ficlatuzumab in multiple clinical studies; the potential efficacy, safety, and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies; the potential for outcomes from studies of ficlatuzumab to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab in areas of unmet need; the potential for tivozanib as a treatment option for patients with advanced HCC or relapsed/refractory or 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 tivozanib in the United States; AVEO's expectations about its cash runway and its cash runway guidance; and AVEO's strategy, prospects, plans and objectives for its product candidates and for the Company 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: whether the results of TIVO-3 are sufficient to

obtain marketing approval for tivozanib in the U.S., which turns on the ability of AVEO to demonstrate to the satisfaction of the FDA the safety and efficacy of tivozanib based upon the findings of TIVO-3, including its data with respect to PFS, the rate of adverse events, OS and other information that the FDA may determine for approval; 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, including, in particular, tivozanib and ficlatuzumab; 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 faces other risks relating to its business as well, including risks relating to the timing and costs of seeking and obtaining regulatory approval; AVEO's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with regulatory requirements applicable to its product candidates; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates; AVEO's ability to successfully implement its strategic plans, including its ability to successfully launch and commercialize tivozanib if it may be approved for commercialization by the FDA; AVEO's ability to raise the substantial additional funds required to achieve its goals, including those goals pertaining to the development and commercialization of tivozanib; unplanned capital requirements; AVEO's ability to access up to $20.0 million of the Hercules loan facility, which turns on the achievement of milestones related to the approval and commercialization of tivozanib in the U.S., which milestones may not be achieved; adverse general economic 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.

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