AVEO PHARMACEUTICALS INC
Form 8-K
September 12, 2016

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 9, 2016

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.)**
One Broadway, 14th Floor		**02142**

Cambridge, Massachusetts
(Address of Principal Executive Offices) (Zip Code)
Registrant s telephone number, including area code: (617) 588-1960

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))

Item 8.01 Other Events.

AVEO Pharmaceuticals, Inc. (AVEO) today announced discontinuation of the FOCAL study, a Phase 2, global, randomized, double-blind, placebo controlled clinical study, evaluating ficlatuzumab, AVEO s HGF inhibitory antibody, in combination with erlotinib (Tarceva®), an epidermal growth factor receptor tyrosine kinase inhibitor (EGFR TKI) in first line, VeriStrat (BDX 004) Poor (VSP), EGFR-mutated NSCLC patients. VeriStrat is a proprietary biomarker test developed by Biodesix to select patients for entry into the trial.

The FOCAL study was prospectively designed to confirm results from a retrospective exploratory analysis of a randomized Phase 2 clinical trial (Study P06162) comparing the combination of ficlatuzumab and gefitinib (IRESSA®), an EGFR TKI therapy, to gefitinib monotherapy in previously untreated Asian patients with advanced NSCLC who had tested positive for both EGFR mutation and VSP. Study P06162 demonstrated a statistically significant improvement in overall survival (OS) and progression free survival (PFS) for patients in the gefitinib plus ficlatuzumab arm that were classified as VSP.

After experiencing slower than expected enrollment, a blinded interim analysis of the FOCAL study was conducted and found that patients who were positive for both VSP and EGFR mutations, who were known to be selected for poor prognosis, experienced materially higher discontinuation rates than observed in both the general ITT population and retrospective exploratory subgroup population of Study P06162, which was the basis for the FOCAL study design. This observation significantly compromised the feasibility of the trial. The parties have mutually agreed to discontinue the study. The parties intend to further discuss the details for the discontinuation of the study and future development of ficlatuzumab.

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 9, 2016

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