FIVE PRIME THERAPEUTICS INC
Form 8-K
June 06, 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): June 4, 2016

Five Prime Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36070**	**26-0038620**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Two Corporate Drive

South San Francisco, California **94080**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code: (415) 365-5600

(Former name or former address, if changed since last report)

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

Partial Clinical Hold of Phase 1b

Five Prime Therapeutics, Inc. (FivePrime) and Human Genome Sciences, Inc. (HGS) entered into a License and Collaboration Agreement, effective March 16, 2011 (the License Agreement), pursuant to which FivePrime exclusively licensed to HGS rights to develop and commercialize FP-1039, FivePrime s FGFR1 fusion protein, in the United States, the European Union and Canada. On August 2, 2012, GlaxoSmithKline (GSK) acquired HGS and HGS is now a wholly owned subsidiary of GSK.

GSK is conducting and funding a Phase 1b clinical trial of FP-1039, which GSK refers to as GSK3052230, in malignant pleural mesothelioma (MPM) patients (clinicaltrials.gov identifier: NCT01868022).

On June 3, 2016, GSK informed FivePrime that GSK had met with the Food and Drug Administration (FDA) and that the FDA had imposed a partial clinical hold on GSK s Phase 1b trial of FP-1039/GSK3052230. The partial clinical hold was imposed because some lots of the FP-1039/GSK3052230 clinical trial material are trending out of specification due to the vials GSK used for filled drug product, which may limit the supply available for new patients. The issue was identified by GSK through its standard quality control practices. While this partial clinical hold is in effect, GSK may continue to dose already-enrolled MPM patients with FP-1039/GSK3052230 in the Phase 1b trial but GSK may not enroll new MPM patients into the trial.

GSK is undertaking additional testing and root cause analyses to better ascertain the impact of this issue on drug supply (including whether in-line filtration during FP-1039/GSK3052230 administration will resolve the observed issues), the extent to which the current drug supply of FP-1039/GSK3052230 may be used in the Phase 1b trial, and whether and when GSK may restart trial enrollment to new patients.

GSK plans to enroll and dose up to 30 MPM patients at the 15 mg/kg dose of FP-1039/GSK3052230. As of April 18, 2016, GSK had enrolled 23 MPM patients at the 15 mg/kg dose level, of which 18 were on study as of that date.

ASCO Presentation

On June 4, 2016, FivePrime issued a press release announcing that updated data from the ongoing GlaxoSmithKline-sponsored Phase 1 clinical trial of FP-1039/GSK3052230 in mesothelioma patients was featured in a poster presentation on June 4, 2016 at the 2016 American Society of Clinical Oncology s (ASCO) Annual Meeting in Chicago by Dr. Jose Trigo from the Hospital Universitario Virgen de la Victoria in Málaga, Spain.

A copy of the press release is filed herewith as Exhibits 99.1 and the information contained therein is incorporated by reference into this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated June 4, 2016.

2

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.

Five Prime Therapeutics, Inc.

By: /s/ Francis Sarena
Francis Sarena
Executive Vice President, General Counsel & Secretary

Dated: June 6, 2016

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated June 4, 2016.