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): May 4, 2019

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.)**

111 Oyster Point Boulevard **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))

Indicated 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. ☐

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, par value $0.001 per share	**FPRX**	**The Nasdaq Stock Market LLC**

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2019, Five Prime Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "Current Report") and is incorporated herein by reference.

The information provided in this Item 2.02 of this Current Report, including Exhibit 99.1 hereto, 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 filing.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On May 4, 2019, Bryan Irving provided the Company notice that he will resign from his position as the Company's Executive Vice President and Chief Scientific Officer, effective May 30, 2019, in order to pursue another opportunity.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by the Company on May 8, 2019

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
Chief Strategy Officer and Secretary

Dated: May 8, 2019

Five Prime Therapeutics Reports First Quarter 2019 Results

SOUTH SAN FRANCISCO, Calif.—(BUSINESS WIRE)--May 8, 2019— Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, today announced its results for the first quarter and provided an update on the company's recent activities.

The company also provided an update on the Phase 3 FIGHT trial testing bemarituzumab in combination with mFOLFOX6 in patients with gastric (GC) or gastroesophageal junction (GEJ) cancer that overexpresses FGFR2b.

"We and our partners have made steady progress advancing all five clinical programs in our pipeline, and we are swiftly responding to new information from the Phase 3 FIGHT trial," said Aron Knickerbocker, Chief Executive Officer of Five Prime Therapeutics. "In light of biomarker screening results from the FIGHT trial, we have made the decision to conduct an early futility analysis, which we expect to occur in the first half of 2020. We believe this is both clinically and fiscally responsible."

First Quarter 2019 Business Highlights and Milestones

Clinical Pipeline:

Bemarituzumab (FPA144) is a first-in-class isoform-selective antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) in development as a targeted immunotherapy for tumors that overexpress FGFR2b.

- Based on the FIGHT trial design, patients are being selected for enrollment by: (a) tissue IHC testing (FGFR2b protein overexpression), (b) blood ctDNA testing (*FGFR2* gene amplification), or (c) both IHC and ctDNA testing, as data support that patients with tumors meeting criteria in any of the three biomarker categories may benefit from the addition of bemarituzumab to front-line chemotherapy.
- The FIGHT trial marks the first time that FGFR2b protein overexpression has been measured on a large scale in front-line patients with advanced gastric and GEJ cancers. Greater than 30% of patients screened have tested positive for FGFR2b overexpression by IHC alone, which is significantly higher than expected. The company expected 10% of patients to test positive by either IHC and/or ctDNA tests in the FIGHT trial. Also, the company expected that patients who tested positive for FGFR2b overexpression by IHC alone would represent a minority of the patients enrolled in the FIGHT trial, but these patients represent the vast majority of biomarker positive patients in the FIGHT trial.
- Because the composition of the enrolled patient population differs from the company's expectations, Five Prime plans to conduct an early futility analysis.

FPA150 (anti-B7-H4) is a first-in-class anti-B7-H4 antibody designed to target tumor cells by blocking B7-H4 from sending an inhibitory signal to CD8 T cells and by enhancing killing of B7-H4 overexpressing tumors through ADCC. B7-H4 is frequently overexpressed in breast, ovarian and endometrial cancers.

- The company initiated dosing in the Phase 1b monotherapy expansion portion of the Phase 1a/1b trial in February 2019. The company expects to initiate dosing in May 2019 in a safety lead-in evaluating FPA150 in combination with Keytruda® (pembrolizumab) in patients with advanced ovarian cancer that overexpresses B7-H4.
- The abstract titled "Phase 1a/1b study of first-in-class B7-H4 antibody, FPA150, as monotherapy in patients with advanced solid tumors" was accepted for a poster presentation at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. Preliminary safety data from the Phase 1a/1b trial will be presented.
- Additional safety data along with preliminary efficacy data from the Phase 1b monotherapy expansion cohorts are expected to be presented at the European Society for Medical Oncology (ESMO) 2019 Annual Congress.

FPT155 (CD80-Fc) is a first-in-class CD80-Fc fusion protein that uses the binding interactions of soluble CD80 to directly engage CD28 to enhance its co-stimulatory T cell activity without inducing super agonism and to block CTLA-4 from competing for endogenous CD80, allowing CD28 signaling to prevail in T cell activation in the tumor microenvironment.

- The company presented preclinical data regarding FPT155 during the New Drugs on the Horizon Oral Session at the 2019 American Association for Cancer Research (AACR) Annual Meeting.
- The company expects to present data from the Phase 1a dose escalation portion of the ongoing Phase 1a/1b trial at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November 2019.

Cabiralizumab (FPA008) is an antibody that inhibits CSF1R and has been shown to block the activation and survival of tumor-associated macrophages.

- A Phase 2 trial testing the combination of cabiralizumab with Opdivo® (nivolumab) with and without chemotherapy in approximately 160 patients with locally advanced or metastatic pancreatic cancer that has progressed during or after one line of chemotherapy is ongoing at sites in the U.S., Canada, Europe, Japan, Korea and Taiwan.

BMS-986258 (anti-TIM-3) is a fully-human monoclonal antibody targeting TIM-3 (T cell immunoglobulin and mucin domain-3), an immune checkpoint receptor that may limit the duration and magnitude of T cell responses. This is the first clinical candidate from the discovery collaboration between Five Prime and BMS that includes targets in three immune checkpoint pathways.

- The Phase 1/2 clinical trial continues to progress.

Corporate Highlights

- In January 2019, the company announced a corporate restructuring to focus resources on clinical development and late-stage research programs, primarily eliminating positions in research, pathology and manufacturing.

Summary of Financial Results and Guidance:

Cash Position: Cash, cash equivalents and marketable securities totaled $237.0 million as of March 31, 2019, compared to $270.1 million as of December 31, 2018. The decrease in cash, cash equivalents and marketable securities was primarily attributed to quarterly operating expenses that exceeded quarterly revenues.

Revenue: Collaboration and license revenue for the first quarter of 2019 decreased by $27.1 million, or 84%, to $5.3 million from $32.5 million for the first quarter of 2018. This decrease was primarily related to the $25.0 million milestone earned in the first quarter of 2018 relating to the dosing of the first patient in the BMS Phase 2 clinical trial of cabiralizumab in combination with Opdivo with and without chemotherapy.

R&D Expenses: Research and development expenses for the first quarter of 2019 decreased by $11.8 million, or 27%, to $31.8 million from $43.6 million for first quarter of 2018. This decrease was primarily related to companion diagnostic expense incurred in the first quarter of 2018, with no corresponding expense in the first quarter of 2019 and lower compensation costs, and lower clinical trial expenses that were partially offset by higher manufacturing costs related to the FPA150 program.

G&A Expenses: General and administrative expenses for both the first quarters of 2019 and 2018 were $10.5 million.

Net Loss: Net loss for the first quarter of 2019 was $35.4 million, or ($1.02) per basic and diluted share, compared to a net loss of $20.4 million, or ($0.63) per basic and diluted share, for the first quarter of 2018.

Shares Outstanding: Total shares outstanding were 34,838,684 as of March 31, 2019.

Cash Guidance: Five Prime expects full-year 2019 net cash used in operating activities to be between $117 and $122 million and estimates ending 2019 with cash, cash equivalents and marketable securities between $148 and $153 million.

Conference Call Information

Five Prime will host a conference call and live audio webcast today at 4:30 p.m. (ET) / 1:30 p.m. (PT) to discuss its financial results and provide a corporate update. To participate in the conference call, please dial (877) 878-2269 (domestic) or (253) 237-1188 (international) and refer to conference ID 9689855. To access the live webcast please visit the “Events & Presentations” page under the “Investors” tab on Five Prime’s website at www.fiveprime.com. An archived copy of the webcast will be available on Five Prime’s website beginning approximately two hours after the conference call. Five Prime will maintain an archived replay of the webcast on its website for at least 30 days after the conference call.

About the FIGHT Trial

The Phase 3 FIGHT (**F**GFR2b **I**nhibition in **G**astric and Gastroesop**h**ageal Junction Cancer **T**reatment) trial is a double-blind randomized and controlled study evaluating 15 mg/kg of bemarituzumab or placebo given every two weeks combined with modified FOLFOX6 (mFOLFOX6) chemotherapy in patients with GC or GEJ cancer whose tumors overexpress FGFR2b. The primary endpoint is overall survival (OS), with key secondary endpoints being progression-free survival (PFS), objective response rate (ORR), safety and pharmacokinetic (PK) parameters.

The Phase 3 FIGHT trial is the first prospective FGFR2b-specific front-line gastric study that is evaluating bemarituzumab and mFOLFOX6 in advanced GC and GEJ cancer across clinical trial sites

in Asia, the US, and Europe. Zai Lab and Five Prime have a strategic development collaboration under which Zai Lab will manage the Phase 3 portion of the FIGHT trial in China.

Unmet Need in Gastric Cancer (GC) and Gastroesophageal Junction (GEJ) cancer

Gastric cancer, including GEJ cancer, is the fifth most common cancer worldwide and third leading cause of cancer death. Gastric cancer is the second most common cancer in China.

Current first-line chemotherapy treatment delays progression by approximately six months compared to best supportive care, but median OS remains poor with literature-reported ranges of approximately 10 to 11 months and PFS of approximately six months. The presence of FGFR2b overexpression is present in patients with GC/GEJ and is associated with a worse prognosis. Few treatment options following progression are available after first-line chemotherapy, and a significant unmet need remains in the treatment of GC/GEJ worldwide.

Five Prime has partnered with two companion diagnostics companies to identify FGFR2b overexpression using an immunohistochemistry (IHC) test and *FGFR2* gene amplification using circulating tumor DNA (ctDNA) analysis. Five Prime is using both assays to select patients for the FIGHT trial.

About Bemarituzumab

Bemarituzumab is a first-in-class, isoform-selective, humanized monoclonal antibody in clinical development as a targeted immunotherapy for tumors that overexpress FGFR2b, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family. Bemarituzumab blocks FGFs 7, 10 and 22 from binding to FGFR2b, and has been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells. Clinical results to date suggest that the specificity of bemarituzumab avoids the dose-limiting toxicities that have been seen with less selective pan-FGFR tyrosine kinase inhibitors that act on multiple FGFRs, including FGFR2.

About Five Prime Therapeutics

Five Prime Therapeutics, Inc. discovers and develops innovative protein therapeutics to improve the lives of patients with serious diseases. Five Prime's product candidates have innovative mechanisms of action and address patient populations in need of better therapies. The company focuses on researching and developing immuno-oncology and targeted cancer therapies paired with companion diagnostics to identify patients who are most likely to benefit from treatment with Five Prime's product candidates. Five Prime has entered into strategic collaborations with leading global pharmaceutical companies and has promising product candidates in clinical and preclinical development. For more information, please visit www.fiveprime.com or follow us on LinkedIn, Twitter and Facebook.

Cautionary Note on Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Five Prime's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding (i) the timing of initiation, progress and scope of clinical trials for Five Prime's product candidates; (ii) the potential use of Five Prime's product candidates, including in combination with other products, to treat certain patients; (iii) the extent of protein overexpression and gene amplification in certain patient populations; (iv) the timing

of the presentation of data for Five Prime's product candidates; (v) Five Prime's full-year 2019 net cash used in operating activities; and (vi) the amount of Five Prime's cash, cash equivalents and marketable securities at the end of 2019. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during research, preclinical or clinical studies, changes in expected or existing competition, changes in the regulatory, pricing or reimbursement environment, and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Five Prime's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" contained therein. Except as required by law, Five Prime assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Source: Five Prime Therapeutics, Inc.

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