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): February 27, 2020

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))

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**

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 February 27, 2020, Five Prime Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 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 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by the Company on February 27, 2020
104	Cover Page Interactive Data File (the cover page XBRL tags are 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.

Five Prime Therapeutics, Inc.

By: /s/ Francis Sarena
Francis Sarena
Chief Strategy Officer and Secretary

Dated: February 27, 2020

Five Prime Therapeutics Reports Fourth Quarter and Full Year 2019 Results

2020 data milestones remain on track for proprietary programs

SOUTH SAN FRANCISCO, Calif.—(BUSINESS WIRE)—February 27, 2020— Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a clinical-stage biotechnology company focused on developing immune modulators and precision therapies for solid tumor cancers, today announced results for the fourth quarter and year ended December 31, 2019, in addition to providing an update on the company's recent activities.

"Our 2020 focus is on generating clinical data from three proprietary programs that will allow us to prioritize future pipeline investments," said William Ringo, interim Chief Executive Officer and Chairman of the Board. "Additionally, we are advancing our novel late-stage research programs and plan to bring one new program into preclinical development later this year. We are also looking to acquire early-stage clinical assets that we can develop to generate actionable data in the near- to medium-term by utilizing our clinical development and translational expertise."

2020 Milestones and Review of 2019 Business Highlights

Clinical Pipeline:

Bemarituzumab (anti-FGFR2b) 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. Bemarituzumab is being evaluated in combination with mFOLFOX6 in the Phase 3 FIGHT (**F**GFR2b **I**nhibition in **G**astric and Gastroesop**h**ageal Junction Cancer **T**reatment) trial.

- The company has paused enrollment in the FIGHT trial pending the occurrence of a sufficient number of events to trigger a futility analysis that is expected to occur in mid-2020.
- Approximately 150 patients with newly diagnosed advanced stage gastric cancer were enrolled into the FIGHT trial before the company paused enrollment in the fourth quarter of 2019.
- The company expects that it will only resume enrollment in the FIGHT trial if the trial passes the futility analysis and the company will look to enter into a collaboration or license agreement that will pay for all or substantially all of any future development and commercialization costs for bemarituzumab.
- In the event that the company is unable to secure a partner, it will consider alternatives that would allow for the advancement of the bemarituzumab program, including converting the FIGHT trial to a Phase 2 or Phase 2/3 clinical trial.

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 remains on track to generate data by mid-2020 from the Phase 1 combination of FPA150 plus pembrolizumab in a cohort of ovarian cancer patients with B7-H4 overexpression.

- The company presented safety and preliminary FPA150 efficacy results from the Phase 1a/1b clinical trial at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting and the 2019 European Society for Medical Oncology (ESMO) Congress.
- Data from the Phase 1a/1b trial of FPA150 showed that the drug was well tolerated in monotherapy and in combination at a recommended dose of 20mg/kg every three weeks. While an efficacy signal for FPA150 as monotherapy was observed, the response was not sufficient for the company to move forward in developing the compound as a single agent.
- The company continues to evaluate FPA150 in combination with Keytruda in a Phase 1b cohort of patients with ovarian cancer that overexpresses B7-H4, but does not plan to advance the clinical development of the combination independently in the near term given the cost of advancing this combination in clinical development when compared to current resources and priorities.
- The company believes B7-H4 may be a potential target to treat tumors that overexpress B7-H4 using antibody drug candidates (ADCs), bi-specific antibodies, or CAR-T therapies that incorporate FPA150 or one of the company's other B7-H4 antibodies.

FPT155 (CD80-Fc) is a first-in-class CD80-Fc fusion protein that directly engages CD28 without superagonism and binds to CTLA-4, promoting T cell activation in the tumor microenvironment.

- The company remains on track to generate early monotherapy efficacy data in 2020.
- The company has completed nine monotherapy dose escalation cohorts and is currently dosing patients in the 280mg dose level in the Phase 1a portion of the study. The company has not observed evidence of superagonism in the trial. Dose escalation continues and the company has initiated screening of patients for enrollment in an exploratory cohort evaluating FPT155 in patients with tumors more likely to have T cell infiltration.
- The company has observed pharmacodynamic (PD) biomarker data in the Phase 1a dose escalation portion of the trial that show expansion of central memory T cells in blood. This expansion of central memory T cells is consistent with the mechanism of action of FPT155 observed in preclinical studies.
- Based on this early clinical PD data and the safety data to date, the company plans to add a cohort to the ongoing Phase 1a/1b trial to test the combination of escalating doses of FPT155 and an anti-PD(L)-1 therapy in patients with non-small cell lung cancer followed by an expansion in this same patient population at a selected dose of FPT155 in combination with an anti-PD(L)-1 therapy.
- The company presented initial safety results from dose escalation in the FPT155 Phase 1 study at the 2019 Society for Immunotherapy of Cancer (SITC) Annual Meeting. This study is designed to characterize the safety and pharmacokinetic (PK)/pharmacodynamic (PD) profile of FPT155 and identify a recommended dose for ongoing clinical development.

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

- In February 2020, the company announced that the Phase 2 trial of cabiralizumab plus *Opdivo*® (nivolumab) with and without chemotherapy in advanced pancreatic cancer being conducted by Bristol-Myers Squibb Company (BMS) did not meet its primary endpoint.
- BMS informed the company that while BMS has no near-term plans for additional sponsored development of cabiralizumab, it will continue to support the evaluation of cabiralizumab in select,

ongoing investigator-sponsored trials and may continue to assess future development opportunities for the investigational asset. In addition, BMS informed the company that no new safety signals were observed in the Phase 2 clinical trial.

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.

- BMS continues to conduct the Phase 1/2 clinical trial testing the combination of BMS-986258 with *Opdivo* or hyaluronidase, with the objective of evaluating the safety and tolerability of the combination.
- The next anticipated event from this trial is BMS's potential transition of the trial from the Phase 1 portion of the trial to the Phase 2 portion of the trial.

2020 and 2019 Corporate Highlights

- In February 2020, the company announced a global license agreement with Seattle Genetics, Inc. to develop and commercialize novel ADC therapies using monoclonal antibodies developed by Five Prime that are directed to a single target. Under the terms of the agreement, the company received a $5 million upfront payment and is eligible to receive progress-dependent development and regulatory milestone payments as well as cumulative commercial milestone payments. Cumulative milestone payments may reach up to $525 million for the first two ADC product candidates.
- In October 2019, the company announced a corporate restructuring to extend its cash runway without impacting or delaying the data timelines of its clinical programs while still advancing its three wholly-owned, late-stage research programs. This followed a restructuring in January 2019 to focus on clinical development and later-stage research priorities.
- In September 2019, the company announced a management transition and the appointment of William Ringo as interim Chief Executive Officer in addition to his position as Chairman of the Board of Directors.
- During 2019, the company announced the appointment of Lori Lyons-Williams and Carol Schafer to its board of directors and the resignation of Dr. Lewis T. "Rusty" Williams and Dr. Sheila Gujrathi from the Board.

Summary of Fourth Quarter and Full Year 2019 Financial Results and 2020 Guidance:

Cash Position: Cash, cash equivalents and marketable securities totaled $157.9 million as of December 31, 2019, compared to $271.7 million as of December 31, 2018. The decrease was attributable to cash used in operating activities throughout the year.

Revenue: Collaboration and license revenue for the fourth quarter of 2019 decreased by $0.8 million, or 20%, to $3.2 million from $4.0 million for the fourth quarter of 2018. The decrease was primarily due to the completion of the research term of the company's immuno-oncology research collaboration with BMS in March 2019.

Collaboration and license revenue for the year ended December 31, 2019 decreased by $35 million, or 70.1%, to $14.9 million from $49.9 million for the year ended December 31, 2018. Lower revenue was the result of a decrease in revenue recognized under several partner collaboration agreements, including the company's October 2015 cabiralizumab collaboration agreement, November 2014 collaboration agreement, and immuno-oncology research collaboration agreement with BMS as well as lower collaboration revenues from the company's partnerships with Zai Lab and UCB.

R&D Expenses: Research and development expenses for the fourth quarter of 2019 decreased by $8.8 million, or 25.4%, to $25.9 million from $34.7 million primarily due to lower compensation costs resulting from the January 2019 corporate restructuring, decreased clinical trial expenses related to the cabiralizumab trial, lower preclinical costs, reduced use of temporary resources, clinical services, specialty laboratory services, lower manufacturing costs for bemarituzumab and FPA150, and lower miscellaneous research and development costs. These decreases were partially offset by increased impairment charges for lab equipment and higher companion diagnostic expenses relating to bemarituzumab.

Research and development expenses for the year ended December 31, 2019 decreased by $42.3 million, or 27.0%, to $114.1 million from $156.4 million for the year ended December 31, 2018. The decrease was attributable principally to lower compensation costs resulting from the January 2019 corporate restructuring, lower preclinical program and clinical service expenses, decreased companion diagnostic clinical trial expense, the use of fewer temporary resources, lower allocated costs resulting from the restructurings, and milestone payments resulting from the dosing of the first patient in two clinical trials. These savings were partially offset by higher bioanalytic and specialty laboratory, and clinical trial expenses that were required to advance the bemarituzumab and FPA150 programs as well as an impairment charge for lab equipment.

G&A Expenses: General and administrative expenses for the fourth quarter of 2019 decreased by $0.2 million, or 2.1%, to $9.4 million from $9.6 million.

General and administrative expenses for the year ended December 31, 2019 increased by $3.0 million, or 7.8%, to $42.7 million from $39.7 million. The increase was primarily the result of higher allocated costs related to the corporate restructurings, higher compensation costs, and higher professional services fees that were partially offset by a reduction in the use of temporary resources.

Net Loss: Net loss for the fourth quarter of 2019 was $31.4 million, or $0.89 per basic and diluted share, compared to a net loss of $38.8 million, or $1.12 per basic and diluted share for the fourth quarter of 2018.

Net loss for the full year 2019 was $137.2 million, or $3.92 per basic and diluted share, compared to a net loss of $140.4 million, or $4.13 per basic and diluted share, for the full year 2019.

Shares Outstanding: Weighted average shares outstanding for the fourth quarter of 2019 was 35,175,624 as of December 31, 2019.

Cash Guidance: Five Prime expects full-year 2020 net cash used in operating activities to be between $77 and $82 million and estimates ending 2020 with cash, cash equivalents and marketable securities between $77 and $82 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 3872638. 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 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. Forward-looking statements contained in this press release include statements regarding (i) the timing of progress and scope of clinical trials for Five Prime’s product candidates, including the timing of the planned futility analysis for the FIGHT trial; (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 in certain patient populations; (iv) the timing of the presentation of data for Five Prime’s product candidates; (v) Five Prime’s potential receipt of upfront and milestone payments and royalties under the license agreement with Seattle Genetics; (vi) the impact of the October 2019 restructuring on Five Prime’s cash runway and the data timelines of Five Prime’s clinical trials; (vii) Five Prime’s estimated full-year 2020 net cash used in operating activities; and (viii) Five Prime’s estimated cash, cash equivalents and marketable securities at the end of 2020. Actual results may differ materially from these forward-looking statements. 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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