

FIVE PRIME THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 02/23/17 for the Period Ending 02/23/17

Address	TWO CORPORATE DRIVE SOUTH SAN FRANCISCO, CA 94080
Telephone	415-365-5600
CIK	0001175505
Symbol	FPRX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 23, 2017

Five Prime Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-36070
(Commission
File Number)

26-0038620
(I.R.S. Employer
Identification No.)

Two Corporate Drive
South San Francisco, California
(Address of principal executive offices)

94080
(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 2.02 Results of Operations and Financial Condition.

On February 23, 2017, Five Prime Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided in this Form 8-K, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the Company on February 23, 2017

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 23, 2017

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the Company on February 23, 2017

Five Prime Announces Fourth Quarter and Full Year 2016 Financial Results

SOUTH SAN FRANCISCO, Calif., Feb.23, 2017 (GLOBE NEWSWIRE) — Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, today provided a corporate update and reported financial results for the fourth quarter and full year ending December 31, 2016.

“2016 was a year of tremendous progress in Five Prime’s clinical and preclinical pipeline,” said Lewis T. “Rusty” Williams, M.D., Ph.D., president and chief executive officer of Five Prime. “We advanced our three clinical-stage programs and look forward to announcing data from each of these programs this year. With a concerted focus on building out our pipeline, we also unveiled three preclinical programs that we advanced into IND-enabling activities. We are on track to meet our goal of filing at least one IND application for a new molecule each year for the foreseeable future, beginning this year.”

2016 Business Highlights and Recent Developments

Clinical Pipeline:

- **Cabiralizumab (FPA008):** an investigational antibody that inhibits CSF1R and has been shown to block the activation and survival of monocytes and macrophages. In the setting of advanced cancer, tumor-associated macrophages can inhibit the immune system’s ability to eradicate the disease. In pigmented villonodular synovitis (PVNS), a CSF-1-driven tumor, the bulk of the tumor mass in joints is formed by the macrophages themselves. Five Prime and Bristol-Myers Squibb (BMS) have an exclusive worldwide collaboration agreement for the development and commercialization of cabiralizumab for these and potentially additional indications.
 - **Initiated Phase 1b portion of cabiralizumab/OPDIVO trial.**

In October 2016, Five Prime initiated the Phase 1b portion of the clinical trial evaluating the immunotherapy combination of cabiralizumab with the PD-1 immune checkpoint inhibitor OPDIVO® (nivolumab) in multiple tumor types. Five Prime and BMS are evaluating the safety, tolerability and preliminary efficacy of the combination in advanced solid tumors, including non-small cell lung cancer, squamous cell carcinoma of the head and neck, pancreatic cancer, glioblastoma, renal cell carcinoma and ovarian cancer. Five Prime expects to complete enrollment in the current Phase 1b trial cohorts in the second half of 2017.
 - **Advanced the Phase 2 trial of cabiralizumab in patients with tenosynovial giant cell tumor (TGCT), also known as pigmented villonodular synovitis (PVNS).**

Five Prime expects to complete enrollment of the Phase 2 trial of cabiralizumab in PVNS in the first half of 2017. Five Prime is evaluating clinical measures, including response rate, pain and range of motion in approximately 30 PVNS patients.

-
- **Five Prime plans to seek regulatory guidance on a pivotal trial in diffuse PVNS.**
 - **Five Prime plans to disclose clinical data from the cabiralizumab PVNS trial at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting and from the cabiralizumab immuno-oncology trial in the second half of 2017.**
 - **FPA144:** an isoform-selective antibody in development as a targeted immuno-therapy for tumors that overexpress FGFR2b, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family. FPA144 has been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells. Five Prime retains global development and commercialization rights to FPA144.
 - **Opened new gastric cancer cohorts and added a bladder cancer cohort in Phase 1 monotherapy trial of FPA144.** Enrollment continues in the expansion portion of the trial, evaluating the safety, PK and efficacy of biweekly 15 mg/kg infusions of FPA144 in patients with gastric cancer whose tumors highly overexpress FGFR2b. During the third quarter of 2016, Five Prime added cohorts to evaluate FPA144 in patients with bladder cancer whose tumors overexpress FGFR2b and in patients with gastric cancer whose tumors express moderate or low levels of FGFR2b. Five Prime reported initial single-agent efficacy and safety data at the ASCO 2016 Annual Meeting and at the ASCO 2016 Gastrointestinal Cancers Symposium.
 - **Five Prime plans to seek regulatory guidance on a registrational path for FPA144 in combination with chemotherapy as an early-line gastric cancer therapy.**
 - **Five Prime plans to disclose updated clinical data from the FPA144 program at the ASCO 2017 Annual Meeting.**
 - **FP-1039** : a protein drug designed to block FGF signaling. As a ligand trap, FP-1039 binds to and neutralizes a subset of FGF ligands (such as FGF2), preventing these growth-promoting and angiogenic proteins from reaching FGFR1 on the surface of tumor cells.
 - **Five Prime plans to make decisions on potential future development of FP-1039 in mesothelioma after data on objective response rate, disease control rate and progression-free survival are mature.** Five Prime regained full rights to FP-1039 from GlaxoSmithKline (GSK) in September 2016. GSK is completing the ongoing Phase 1b trial combining FP-1039 with 1st-line pemetrexed and cisplatin in untreated, unresectable mesothelioma. GSK concluded trial recruitment with 25 patients enrolled at the 15 mg/kg dose in June 2016, and continues to dose and follow patients.
 - **Five Prime plans to disclose clinical data from this program at the European Society for Medical Oncology (ESMO) 2017 Congress.**

Preclinical Research and Development:

- **Five Prime unveiled three preclinical development candidates in IND-enabling studies at its R&D Day in New York City in December 2016.**
 - **FPA150 (anti-B7-H4)**
 - An antibody designed for two mechanisms of action: to block an inhibitory T cell checkpoint pathway and to enhance killing of B7-H4-expressing tumors by ADCC.
 - Investigational New Drug (IND) application planned for the fourth quarter of 2017.
 - **FPA154 (GITR agonist antibody)**
 - A tetravalent agonist antibody designed for greater GITR activation versus conventional antibodies. Conventional GITR agonist antibodies have two GITR binding sites while FPA154 has four.
 - IND application planned for the fourth quarter of 2017.
 - **FPT155 (CD80)**
 - A natural, multi-targeting immune modulator that stimulates T cell responses through three critical pathways: CTLA4 blockade, CD28 agonism (without superagonism) and PD-L1 blockade that removes a potent inhibitory checkpoint.
 - IND planned in 2018.
- Progress in pre-clinical and research programs is on track for the company to achieve the goal of filing at least one IND application for a new molecule each year for the foreseeable future, beginning this year.
- **Completed multiple immuno-oncology research screens to identify new targets and drug candidates.** Five Prime's research team completed functional screens on CD8 T cells and regulatory T cells, as well as a comprehensive screen of all extracellular binding interactions in the "immunome," a defined subset of 700 extracellular proteins enriched for potential immune cell modulators. Five Prime conducted the screens to identify new immuno-oncology targets, which the company is prioritizing for further development as targets for new drug candidates or drug candidates themselves, either as monotherapies or as part of rational combination regimens.
- **Five Prime will feature three preclinical research poster presentations during the 2017 American Association for Cancer Research (AACR) Annual Meeting, April 1 - 5, 2017, in Washington, D.C.**

Summary of Financial Results and Guidance:

- **Cash Position.** Cash, cash equivalents and marketable securities totaled \$421.7 million on December 31, 2016 compared to \$517.5 million on December 31, 2015. The decrease in year-end cash in 2016 was primarily attributable to net cash used in operations to advance the company's clinical and preclinical pipeline.
- **Revenue.** Collaboration and license revenue for the fourth quarter of 2016 was \$8.3 million compared to \$363.3 million for the fourth quarter of 2015. During the fourth quarter of 2015, the company recognized the entire upfront payment of \$350 million as revenue under the cabiralizumab license and collaboration agreement with BMS. Collaboration and license revenue for the full year 2016 was \$30.7 million compared to \$379.8 million for the full year 2015.
- **R&D Expenses.** Research and development expenses for the fourth quarter of 2016 increased by \$8.2 million, or 39%, to \$29.1 million from \$21.0 million in the fourth quarter of 2015. Full year 2016 research and development expenses increased by \$23.9 million, or 34%, to \$94.1 million in 2016 from \$70.2 million in 2015. These increases were primarily related to advancing the FPA144 program in a phase 1 clinical trial, advancing the cabiralizumab program in immuno-oncology and PVNS, and advancing our internal immuno-oncology preclinical and research activities.
- **G&A Expenses.** General and administrative expenses for the fourth quarter of 2016 increased by \$1.9 million, or 22%, to \$10.5 million from \$8.6 million in the fourth quarter of 2015. Full year 2016 general and administrative expenses were \$35.8 million, an increase of \$13.2 million, or 58%, from \$22.6 million in 2015. This increase was primarily due to increases in personnel related expenses, including stock-based compensation.
- **Net Income (Loss).** Net loss for the fourth quarter of 2016 was \$20.1 million, or \$0.73 per basic share and diluted share, compared to net income of \$296.1 million, or \$11.37 per basic share and \$10.63 per diluted share, for the fourth quarter of 2015. Full year 2016 net loss was \$65.7 million, or \$2.44 per basic share and diluted share, compared to net income of \$249.6 million, or \$9.73 per basic share and \$9.23 per diluted share. These decreases in net income were primarily related to recognizing the 2015 upfront payment of \$350 million as revenue under the cabiralizumab license and collaboration agreement with BMS.

Cash Guidance. Five Prime expects full-year 2017 net cash used in operating activities to be less than \$120 million. The company estimates ending 2017 with approximately \$300 million in cash, cash equivalents and marketable securities.

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 60580589. 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

Five Prime Therapeutics, Inc. discovers and develops innovative therapeutics to improve the lives of patients with serious diseases. Five Prime's comprehensive discovery platform, which encompasses virtually every medically relevant extracellular protein, positions it to explore pathways in cancer, inflammation and their intersection in immuno-oncology, an area with significant therapeutic potential and a growing focus of the company's R&D activities. Five Prime has entered into strategic collaborations with leading global pharmaceutical companies and has promising product candidates in clinical and late preclinical development. For more information, please visit www.fiveprime.com.

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 about (i) the timing of IND filings; (ii) the timing of initiation, progress and scope of clinical trials for Five Prime's product candidates, including regarding the completion of enrollment in such trials; (iii) Five Prime's full-year 2017 net cash used in operating activities; and (iv) the estimated amount of Five Prime's cash, cash equivalents and marketable securities at the end of 2017. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of Five Prime's collaborators to support or advance collaborations or product candidates, and unexpected litigation or other disputes. Other factors that may cause Five Prime's 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" sections 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.

Five Prime Therapeutics, Inc.
Selected Balance Sheets Data
(in thousands)

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 421,748	\$ 517,466
Total assets	448,281	548,285
Total current liabilities (excluding deferred revenue)	24,591	61,859
Deferred revenue (in total, including short term portion)	32,006	48,777
Total stockholders' equity	391,575	433,206

Five Prime Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except per share amounts)

	<u>For The Three Months</u> <u>Ended</u> <u>December 31,</u>		<u>For The Year Ended</u> <u>December 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Collaboration and license revenue	\$ 8,262	\$363,341	\$ 30,691	\$379,801
Operating expenses:				
Research and development	29,149	20,956	94,072	70,197
General and administrative	10,522	8,602	35,831	22,631
Total operating expenses	39,671	29,558	129,903	92,828
Operating income (loss)	(31,409)	333,783	(99,212)	286,973
Interest income	646	155	2,467	484
Income (loss) before income tax	(30,763)	333,938	(96,745)	287,457
Income tax benefit (provision)	10,657	(37,810)	31,048	(37,810)
Net income (loss)	\$ (20,106)	\$296,128	\$ (65,697)	\$249,647
Basic net income (loss) per common share	\$ (0.73)	\$ 11.37	\$ (2.44)	\$ 9.73
Diluted net income (loss) per common share	\$ (0.73)	\$ 10.63	\$ (2.44)	\$ 9.23
Shares used to compute basic net income (loss) per common share	27,436	26,043	26,955	25,661
Shares used to compute diluted net income (loss) per common share	27,436	27,850	26,955	27,035

Heather Rowe
Investor Relations
415-365-5737
heather.rowe@fiveprime.com

Amy Kendall
Corporate Communications
415-365-5776
amy.kendall@fiveprime.com