



## Five Prime Announces Fourth Quarter and Full Year 2017 Financial Results

February 27, 2018

- *Clinical pipeline expected to more than double in 2018*
- *Global Phase 3 clinical trial of bemarituzumab in gastric cancer anticipated to begin in 2018*
- *Positive initial data in pancreatic cancer driving cabiralizumab advancement*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 27, 2018-- 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, 2017.

"2017 was a year of continued progress across our pipeline," said Aron Knickerbocker, chief executive officer of Five Prime Therapeutics. "Notably, positive and important data in microsatellite stable pancreatic cancer are driving further development of the cabiralizumab/Opdivo<sup>®</sup> combination in this cancer type, which is associated with tremendous unmet need, and in which no response to immunotherapy has been demonstrated. We also presented data in 2017 showing clinical benefit with cabiralizumab in patients with PVNS, and with bemarituzumab in patients with gastric cancer. In 2018, our clinical pipeline is on track to more than double to five products, and we will initiate our first global registrational clinical trial. Our unique discovery platform is proving to be an IND engine, and more programs are forthcoming. Additionally, our strategic alliances and strong balance sheet position us well to further advance our multiple assets."

### 2017 Business Highlights and Recent Developments

#### Clinical Pipeline:

**Cabiralizumab (FPA008):** an antibody that inhibits CSF1R and has been shown to block the activation and survival of monocytes and macrophages.

- **Completed enrollment of the ongoing Phase 1a/1b trial of cabiralizumab/Opdivo<sup>®</sup> (nivolumab) and Five Prime continues to treat patients who remain in the study.**
  - Five Prime completed enrollment in the trial, including patients with pancreatic cancer who were added to the trial after encouraging data were observed in the initial Phase 1b cohort of 31 patients with late-line pancreatic cancer.
  - Five Prime and Bristol-Myers Squibb Company (BMS) are evaluating the safety, tolerability and preliminary efficacy of the immunotherapy combination of cabiralizumab with the PD-1 immune checkpoint inhibitor Opdivo<sup>®</sup> (nivolumab) 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.
- **BMS initiated randomized Phase 2 clinical trial in patients with locally advanced or metastatic pancreatic cancer.**
  - In January 2018, BMS initiated a randomized Phase 2 clinical trial (NCT03336216), evaluating cabiralizumab and Opdivo<sup>®</sup> (nivolumab) with and without chemotherapy compared to chemotherapy alone in patients with advanced pancreatic cancer. The Phase 2 trial is expected to enroll approximately 160 patients with locally advanced or metastatic pancreatic cancer that has progressed during or after one line of chemotherapy.
  - The advancement of the cabira/ Opdivo<sup>®</sup> (nivolumab) combination into Phase 2 development triggered a \$25 million payment to Five Prime.
  - Five Prime and others have previously demonstrated evidence of synergy by combining CSF-1R and PD-1 antibodies with chemotherapy in preclinical models of pancreatic cancer.
- **Presented initial Phase 1a/1b data demonstrating early efficacy signal in heavily pre-treated patients with advanced pancreatic cancer with microsatellite stable (MSS) disease.**
  - In November 2017, Five Prime and BMS presented initial clinical safety data from all cohorts in the Phase 1a/1b clinical trial of cabiralizumab and Opdivo<sup>®</sup> (nivolumab), and efficacy data from the Phase 1b pancreatic cancer cohort. In this Phase 1b cohort of heavily pre-treated patients with advanced pancreatic cancer (n=31 evaluable patients), durable clinical benefit was observed in five patients (16%), including confirmed objective responses in four patients with microsatellite stable (MSS) disease (objective response rate of 13%, confirmed by blinded independent review committee), a patient population in which no prior responses to immunotherapy have been demonstrated.
  - Preliminary results show that the safety profile of cabiralizumab plus Opdivo<sup>®</sup> (nivolumab) was generally consistent with that of monotherapy of the two drugs.
- **Advanced the ongoing Phase 1/2 trial of cabiralizumab in patients with pigmented villonodular synovitis (PVNS).**
  - Five Prime reported initial trial data at the ASCO Annual Meeting in June 2017, showing that cabiralizumab demonstrated clinical benefit in patients with PVNS.
  - The company is enrolling up to 30 additional patients in the Phase 2 portion of the trial to refine the dosing schedule to optimize the therapeutic index of cabiralizumab in this chronic disease setting. Data from these additional patients are intended to enable a go/no go decision by the end of 2018 on whether to advance cabiralizumab in PVNS into a pivotal trial.
  - Five Prime estimates the combined prevalence of diffuse PVNS is approximately 67,500 patients in the U.S., EU5 and Japan.

**Bemarituzumab (FPA144):** an isoform-selective antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) in development as a targeted immuno-therapy for tumors that overexpress FGFR2b.

- **Initiated Phase 1 portion (NCT03343301) of the FGFR2b Inhibition in Gastric Cancer Treatment (FIGHT) Phase 1/3 clinical trial, a global registrational study.**
  - The FIGHT trial will evaluate bemarituzumab in combination with the modified FOLFOX6 regimen (mFOLFOX6) versus placebo plus mFOLFOX6 in approximately 550 patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b or have *FGFR2* gene amplification.
  - In January 2018, Five Prime initiated patient dosing in the Phase 1 portion of the FIGHT trial. This safety lead-in portion of the study is designed to identify a recommended dose of bemarituzumab and to support the Phase 3 portion of the trial.
  - The Phase 3 portion of the FIGHT trial is expected to begin in 2018 and will include sites in the U.S., Europe and Asia, including China, South Korea and Japan, where the incidence of gastric cancer is high.
  - Five Prime will use immunohistochemistry (IHC) and circulating tumor DNA (ctDNA) tests to identify the estimated 10% of patients with gastric cancer who would be eligible for the trial.
- **Entered into strategic development collaboration and exclusive license agreement in Greater China for bemarituzumab with Zai Lab in December 2017.** Five Prime's collaboration with Zai Lab will increase the speed of the FIGHT trial and lower Five Prime's global development costs for the FIGHT trial. Five Prime earned a \$5 million upfront payment and is eligible to receive up to \$39 million in development and regulatory milestone payments. Five Prime is also eligible to receive from Zai Lab a royalty percentage on net sales of bemarituzumab in Greater China ranging from the high teens to the low twenties.
- **In December 2017, Five Prime filed a clinical trial application (CTA) for bemarituzumab in China.** With its collaborators at Zai Lab, Five Prime is aiming to initiate clinical trial sites in China for the FIGHT trial by the end of 2018.
- **Enrolling patients in Phase 1 safety trial of bemarituzumab monotherapy in unselected patients with gastric cancer in Japan, where the incidence of gastric cancer is high.** Completion of this Phase 1 trial is intended to enable the inclusion of Japanese patients in the Phase 3 portion of the FIGHT trial.
- **Advanced the Phase 1 monotherapy cohort testing bemarituzumab in patients with metastatic bladder cancer.** The company continues to enroll patients in the Phase 1 clinical trial cohort testing bemarituzumab as a treatment for patients with metastatic bladder cancer whose tumors overexpress FGFR2b.

**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. B7-H4 is frequently overexpressed in breast, ovarian, endometrial and bladder cancers.

- **Investigational New Drug (IND) application submitted December 2017.**
  - Five Prime anticipates initiating the Phase 1 trial in the first half of 2018.
- **Data featured in an oral poster discussion during the ESMO 2017 Congress.**
  - Data presented suggest that FPA150, which possesses T cell checkpoint and ADCC activity, has the potential to be an effective therapeutic by improving anti-tumor immune responses in patients with cancer.

**BMS TIM-3 Antibody:** Achieved a \$5 million milestone payment for the first IND filing by BMS for a therapeutic candidate under the immuno-oncology research collaboration with Five Prime.

- In January 2018, BMS filed an IND for the first clinical candidate from the immuno-oncology research collaboration with Five Prime. The candidate is a fully-human monoclonal antibody targeting TIM-3 (T-cell immunoglobulin and mucin domain-3), an immune checkpoint receptor that is known to limit the duration and magnitude of T-cell responses.
- In December 2017, BMS extended the research term an additional year to March 2019. This is the second extension to the original research term under the agreement that was established in March 2014.

#### **Preclinical Research and Development:**

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

- Preclinical data on FPT155 were featured in a poster presentation at the 2017 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October. Work done in preclinical models with FPT155 suggests that it has the potential to be a potent T-cell co-stimulator with strong monotherapy antitumor activity, and it may have a synergistic effect when combined with anti-PD1 therapy.
- Five Prime anticipates filing an IND application or a foreign equivalent in mid-2018.

#### **Target discovered by Five Prime in its respiratory disease collaboration exclusively licensed by partner GSK.**

- In August 2017, GSK exercised its right to license exclusively a drug target discovered by Five Prime in the respiratory disease collaboration between the companies. This resulted in a \$500,000 payment to Five Prime.
- This is the second respiratory target that GSK exclusively licensed from Five Prime under the respiratory disease collaboration.

#### **Summary of Financial Results and Guidance:**

- **Cash Position.** Cash, cash equivalents and marketable securities totaled \$292.7 million on December 31, 2017 compared to \$421.7 million on December 31, 2016. The decrease in year-end cash in 2017 was primarily attributable to net cash used in

operations to advance the company's clinical and preclinical pipeline. On January 29, 2018, Five Prime completed a public offering resulting in estimated net proceeds of approximately \$108 million.

- **Revenue.** Collaboration and license revenue for the fourth quarter of 2017 increased by \$4.9 million, or 59%, to \$13.2 million from \$8.3 million for the fourth quarter of 2016. Five Prime earned a \$5 million milestone payment from BMS in the fourth quarter of 2017 for the first IND application by BMS for a therapeutic candidate under the immune checkpoint pathway discovery collaboration. Collaboration and license revenue for the full year 2017 increased by \$8.8 million, or 29%, to \$39.5 million from \$30.7 million for the full year 2016. This difference was primarily from increases in revenue from the cabiralizumab collaboration agreement with BMS and the immune checkpoint pathway discovery collaboration with BMS.
- **R&D Expenses.** Research and development expenses for the fourth quarter of 2017 increased by \$3.6 million, or 12%, to \$32.7 million from \$29.1 million in the fourth quarter of 2016. Full year 2017 research and development expenses increased by \$56.8 million, or 60%, to \$150.9 million from \$94.1 million in 2016. These increases were primarily related to advancing the bemarizumab program in a Phase 1 clinical trial, advancing the cabiralizumab program in immuno-oncology and PVNS, advancing the FPA150 program to an IND application, and advancing our internal immuno-oncology preclinical and research activities.
- **G&A Expenses.** General and administrative expenses for both the fourth quarters of 2017 and 2016 was \$10.5 million. Full year 2017 general and administrative expenses were \$40.0 million, an increase of \$4.2 million, or 12%, from \$35.8 million in 2016. This increase was primarily due to greater facilities expenses related to our new corporate office and personnel related expenses, including stock-based compensation.
- **Net Income (Loss).** Net loss for the fourth quarter of 2017 was \$29.2 million, or \$1.04 per basic share and diluted share, compared to a net loss of \$20.1 million, or \$0.73 per basic and diluted share, for the fourth quarter of 2016. Full year 2017 net loss was \$150.2 million, or \$5.38 per basic share and diluted share, compared to a net loss of \$65.7 million, or \$2.44 per basic share and diluted share for the full year 2016. These increases in net loss were primarily related to advancing the clinical pipeline and preclinical research and development.

**Cash Guidance.** Five Prime expects full-year 2018 net cash used in operating activities to be less than \$135 million, which includes the previously mentioned milestone payments earned by Five Prime. The company estimates ending 2018 with approximately \$250 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 7184787. To access the live webcast please visit the "Events & Presentations" page under the "Investors" tab on Five Prime's website at [www.fiveprime.com](http://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 the 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](http://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 IND filings; (ii) the timing of initiation, progress and scope of clinical trials for Five Prime's product candidates; (iii) the extent of gene amplification and protein overexpression in certain patient populations; (iv) the prevalence and incidence of certain diseases; ; (v) Five Prime's potential receipt of milestone payments and royalties; (vi) Five Prime's full-year 2018 net cash used in operating activities; and (vii) the amount of Five Prime's cash, cash equivalents and marketable securities at the end of 2018. 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.

#### Five Prime Therapeutics, Inc.

##### Selected Balance Sheets Data

(in thousands)

	December 31, 2017	December 31, 2016
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and marketable securities	\$ 292,690	\$ 421,748
Total assets	344,047	448,281
Total current liabilities (excluding deferred revenue)	38,268	24,591

Deferred revenue (in total, including short term portion)	22,936	32,006
Total stockholders' equity	265,202	391,575

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

	For The Three Months Ended		For The Year Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
Collaboration and license revenue	\$ 13,218	\$ 8,262	\$ 39,508	\$ 30,691
Operating expenses:				
Research and development	32,671	29,149	150,908	94,072
General and administrative	10,479	10,522	40,002	35,831
Total operating expenses	43,150	39,671	190,910	129,903
Operating income (loss)	(29,932)	(31,409)	(151,402)	(99,212 )
Interest income and other expense	721	646	2,884	2,467
Income (loss) before income tax	(29,211)	(30,763)	(148,518)	(96,745 )
Income tax benefit (provision)	—	10,657	(1,704 )	31,048
Net income (loss)	\$ (29,211)	\$ (20,106)	\$ (150,222)	\$ (65,697 )
Basic net income (loss) per common share	\$ (1.04 )	\$ (0.73 )	\$ (5.38 )	\$ (2.44 )
Diluted net income (loss) per common share	\$ (1.04 )	\$ (0.73 )	\$ (5.38 )	\$ (2.44 )
Shares used to compute basic net income (loss) per common share	28,129	27,436	27,945	26,955
Shares used to compute diluted net income (loss) per common share	28,129	27,436	27,945	26,955

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Five Prime Therapeutics, Inc.  
Heather Rowe, 415-365-5737  
Senior Director, Investor Relations and Corporate Communications  
[heather.rowe@fiveprime.com](mailto:heather.rowe@fiveprime.com)