



Five Prime Therapeutics Announces Third Quarter 2018 Financial Results

November 6, 2018

- Initiated Phase 3 FIGHT global registrational trial of bemarituzumab in gastric and gastroesophageal junction (GEJ) cancer
- Initiated FPA150 dosing in B7-H4 positive patients in Phase 1 exploratory cohort
- Opened enrollment for the FPT155 Phase 1 clinical trial in Australia
- Announced industry veteran David V. Smith will join as Executive Vice President and Chief Financial Officer

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 6, 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 fiscal quarter ended September 30, 2018.

"With five programs in the clinic, we and our partners are advancing drug candidates to target multiple immune cell types in the tumor microenvironment, focusing on drugs that demonstrate single-agent activity or activity in tumor types that have been insensitive to checkpoint inhibitors," said Aron Knickerbocker, Chief Executive Officer of Five Prime Therapeutics. "Since our last earnings call, we dosed the first patient in our Phase 3 FIGHT pivotal trial of bemarituzumab in gastric and GEJ cancer. BMS also continues to advance the randomized Phase 2 clinical trial evaluating cabiralizumab and OPDIVO® in patients with advanced pancreatic cancer."

Mr. Knickerbocker continued, "In addition, FPA150, our first-in-class B7-H4 antibody, is generating strong interest from investigators, and we are ahead of schedule in initiating our dose exploration basket cohort in patients whose tumors overexpress B7-H4. Additionally, we are screening patients in Australia for our Phase 1 clinical trial of FPT155, our first-in-class CD80 fusion protein. FPT155 induces strong single-agent activity in multiple preclinical models, and we look forward to evaluating this drug in various tumor settings."

Third Quarter 2018 Business Highlights and Recent Developments

Clinical Pipeline:

[Bemarituzumab \(FPA144\)](#): A first-in-class isoform-selective antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) in development as a targeted immuno-therapy for tumors that overexpress FGFR2b.

- Five Prime initiated patient dosing in the randomized, controlled Phase 3 FIGHT (FGFR2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment) global registrational trial ([NCT03694522](#)).
 - The FIGHT trial is designed to evaluate 15 mg/kg of bemarituzumab in combination with mFOLFOX6 against placebo in combination with mFOLFOX6 in approximately 550 patients with advanced gastric or GEJ cancer.
 - Five Prime plans to conduct the FIGHT trial at over 200 clinical trial sites in North America, Europe and Asia. In China, Five Prime is conducting the trial in collaboration with Zai Lab.
 - Five Prime is using immunohistochemistry (IHC) and circulating tumor DNA (ctDNA) tests to identify the estimated 10% of patients with FGFR2b-overexpressing gastric and GEJ cancer who would be eligible for the trial.
- An abstract featuring data on bemarituzumab in combination with mFOLFOX6 from the Phase 1 safety lead-in ([NCT03343301](#)) has been accepted as a poster presentation at the ASCO GI conference in January.

[Cabiralizumab \(FPA008\)](#): An antibody that inhibits CSF1R and has been shown to block the activation and survival of tumor-associated macrophages.

- Bristol-Myers Squibb Company (BMS) is currently enrolling patients in a randomized, open-label, multi-arm Phase 2 clinical trial to determine the efficacy of cabiralizumab in combination with OPDIVO (nivolumab), with and without chemotherapy, as a second-line treatment for patients with pancreatic cancer ([NCT03336216](#)). BMS plans to enroll approximately 160 pancreatic cancer patients from the United States, Canada, Europe, Japan, Korea and Taiwan, each of whom will be randomized to one of four study arms based on the patient's prior therapy.
- Stand Up To Cancer and BMS are supporting the study titled Nivolumab + Cabiralizumab + Gemcitabine Versus Gemcitabine in Patients With Stage IV Pancreatic Cancer Achieving Disease Control in Response to First-line Chemotherapy (GemCaN Trial) ([NCT03697564](#)). This is a randomized Phase 2 front-line maintenance trial to determine whether the combination of gemcitabine with cabiralizumab and OPDIVO can provide prolonged disease control in patients with advanced pancreatic cancer compared to gemcitabine alone.
- Apexigen, Inc. and BMS continue to support a Phase 1/1b clinical trial to evaluate APX005M (anti-CD40) in combination with cabiralizumab and OPDIVO ([NCT03502330](#)). The expansion portion of the trial will study the triple drug combination in patients with melanoma, non-small cell lung cancer or renal cell carcinoma whose disease has progressed on a prior regimen containing a PD-1 or PD-L1 inhibitor without intervening therapy.

[FPA150 \(anti-B7-H4\)](#): A first-in-class anti-B7-H4 antibody designed to target tumor cells through two mechanisms of action: (i) by blocking B7-H4 from sending an inhibitory signal to CD8 T cells and (ii) by enhancing killing of B7-H4 overexpressing tumors by ADCC. B7-H4 is frequently overexpressed

in breast, ovarian and endometrial cancers.

- In October 2018, Five Prime initiated an exploratory cohort to investigate FPA150 monotherapy in patients with tumors that overexpress B7-H4 at a dose predicted to be active based on preclinical data. Five Prime plans to enroll up to 10 patients whose tumors overexpress B7-H4 in this exploratory cohort to evaluate potential preliminary clinical activity of FPA150.
- The exploratory cohort is part of an ongoing Phase 1a/1b clinical trial of FPA150 ([NCT03514121](#)) in multiple cancers. The Phase 1a dose escalation portion of the trial is evaluating FPA150 monotherapy in advanced solid tumors. Five Prime is advancing through dose escalation and is currently evaluating the seventh of eight expected dose levels.
- After completing the Phase 1a dose escalation portion of the trial, Five Prime plans to select a dose and initiate the Phase 1b expansion portion of the trial to evaluate FPA150 monotherapy in disease-specific cohorts of patients whose tumors overexpress B7-H4, initially in HR+/HER2- and triple-negative breast cancers, ovarian cancer and endometrial cancer.
- Five Prime anticipates presenting Phase 1 data at a medical conference in 2019.

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

- Studies in preclinical models suggest FPT155 has the potential to be a potent T cell co-stimulator with strong monotherapy antitumor activity and may have a synergistic effect when combined with anti-PD1 therapy.
- Five Prime is conducting a Phase 1a/1b clinical trial of FPT155 in Australia in patients with solid tumors. The objectives of this trial are to gain data on safety, pharmacokinetics and potential preliminary single-agent activity of FPT155. In October 2018, the company opened enrollment in the Phase 1a dose escalation portion of the trial.

BMS-986258 (anti-TIM-3): 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.

- BMS is conducting a Phase 1/2 clinical trial to evaluate BMS-986258 as a single agent and in combination with each of OPDIVO and Halozyme's rHuPH20 (recombinant human hyaluronidase, PH20) enzyme in patients with advanced malignant tumors ([NCT03446040](#)).
- BMS-986258 is the first clinical candidate from BMS's immuno-oncology research collaboration with Five Prime.
- BMS's poster #P684 titled "Preclinical Studies of TIM-3 Blockade Supporting Clinical Development of BMS-986258, an Anti-TIM-3 Monoclonal Antibody" will be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November.

Corporate

- Five Prime announced David V. Smith will join as Executive Vice President and Chief Financial Officer on November 26.

Summary of Financial Results and Guidance:

- **Cash Position.** Cash, cash equivalents and marketable securities totaled \$321.6 million as of September 30, 2018, compared to \$292.7 million as of December 31, 2017. The increase in cash, cash equivalents and marketable securities was primarily attributable to \$107.6 million in net proceeds from the January 2018 public offering of common stock and \$34.5 million in milestone and upfront payments Five Prime received from collaboration partners, net of cash used by Five Prime in operations to advance its clinical stage programs as well as preclinical research and development.
- **Revenue.** Collaboration and license revenue for the third quarter of 2018 decreased by \$2.5 million, or 30%, to \$5.8 million from \$8.3 million for the third quarter of 2017. This decrease was primarily due to decreased revenue recognized under the cabiralizumab collaboration with BMS and the fibrosis and CNS collaboration with UCB, offset by the collaboration and license revenue from Five Prime's China collaboration with Zai Lab executed in December 2017.
- **R&D Expenses.** Research and development expenses for the third quarter of 2018 increased by \$2.0 million, or 5%, to \$44.7 million from \$42.7 million in the third quarter of 2017. This increase was primarily related to milestone payments triggered by the dosing of the first patient in the Phase 3 FIGHT trial and increased clinical expenses to advance Five Prime's development programs and employee compensation, offset by decreased spending on preclinical programs.
- **G&A Expenses.** General and administrative expenses for the third quarter of 2018 increased by \$0.1 million, or 1%, to \$9.8 million from \$9.7 million in the third quarter of 2017. This was primarily due to increased patent, legal and consulting expenses, offset by reduced personnel and other miscellaneous costs.
- **Net Loss.** Net loss for the third quarter of 2018 was \$47.2 million, or \$1.37 per basic and diluted share, compared to a net loss of \$43.3 million, or \$1.54 per basic and diluted share, for the third quarter of 2017.
- **Shares Outstanding.** Total shares outstanding were 34.5 million as of September 30, 2018.

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. Five Prime has revised its guidance and now estimates ending 2018 with approximately \$265 million in cash, cash equivalents and marketable securities, an increase from its previous guidance of approximately \$250 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 6489275. 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 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 preclinical development. For more information, please visit www.fiveprime.com or follow us on [LinkedIn](#), [Twitter](#) and [Facebook](#).

Cautionary Note on 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 our 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 and the number of potential patients eligible for treatment with our products; (iv) the prevalence and incidence of certain diseases; (v) the timing of the presentation of data for Five Prime's product candidates; (vi) the date David V. Smith will join Five Prime as Executive Vice President and Chief Financial Officer; (vii) Five Prime's full-year 2018 net cash used in operating activities; and (viii) 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 Sheet Data

(in thousands)

	September 30, 2018	December 31, 2017
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 321,596	\$ 292,690
Total assets	366,364	344,047
Total current liabilities (excluding deferred revenue)	37,832	38,268
Deferred revenue (in total, including short term portion)	13,087	22,936
Total stockholders' equity	296,778	265,202

Five Prime Therapeutics, Inc.

Condensed Statements of Operations

(in thousands, except per share amounts)

	For The Three Months Ended September 30, 2018	For The Three Months Ended September 30, 2017	For The Nine Months Ended September 30, 2018	For The Nine Months Ended September 30, 2017
Collaboration revenue	\$ 5,771	\$ 8,333	\$ 45,837	\$ 26,290
Operating expenses:				
Research and development	44,687	42,733	121,619	118,237
General and administrative	9,832	9,674	30,092	29,523
Total operating expenses	54,519	52,407	151,711	147,760
Loss from operations	(48,748)	(44,074)	(105,874)	(121,470)
Interest and other income, net	1,504	792	4,180	2,162

Loss before income tax	(47,244)	(43,282)	(101,694)	(119,308)
Income tax provision	-	-	-	(1,703)
Net loss	\$ (47,244)	\$ (43,282)	\$ (101,694)	\$ (121,011)
Basic and diluted net loss per common share	\$ (1.37)	\$ (1.54)	\$ (3.01)	\$ (4.34)
Weighted-average shares used to compute basic and diluted net loss per common share	34,482	28,020	33,740	27,883

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Source: Five Prime Therapeutics, Inc.

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