Five Prime Therapeutics Announces First Quarter 2018 Financial Results

May 8, 2018

- *Cabiralizumab advanced into a randomized Phase 2 trial in pancreatic cancer*
- *Five Prime initiated the Phase 1 portion of the FIGHT Phase 1/3 global registrational trial of bemarituzumab in gastric cancer*
- *FPA150, a first-in-class B7-H4 antibody, entered a Phase 1 monotherapy trial*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 8, 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 March 31, 2018.

“We were pleased that, during the quarter, BMS initiated a Phase 2 clinical trial to evaluate cabiralizumab and OPDIVO® as a second-line treatment in patients with advanced pancreatic cancer,” said Aron Knickerbocker, chief executive officer of Five Prime Therapeutics. “This randomized, open-label trial has an active comparator arm and is being conducted at multiple sites. This quarter was also a period of pipeline expansion and clinical advancements for Five Prime. FPA150, our first-in-class B7-H4 antibody, recently entered clinical development. We also initiated the safety lead-in for the global Phase 1/3 FIGHT trial of bemarituzumab in gastric cancer, our first registrational trial. Beyond expanding our own pipeline, our platform continues to fuel our collaborators’ pipelines. During the quarter, UCB licensed a drug target identified using our discovery platform and BMS began clinical development of a unique TIM-3 antibody identified through our immuno-oncology research collaboration.”

First Quarter 2018 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 macrophages.

- BMS is conducting a randomized Phase 2 clinical trial in patients with locally advanced or metastatic pancreatic cancer.
  - In January 2018, Bristol-Myers Squibb Company (BMS) initiated a randomized Phase 2 clinical trial (NCT03336216) to evaluate cabiralizumab and OPDIVO® with and without chemotherapy compared to chemotherapy alone as a second-line treatment 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 cabiralizumab and OPDIVO® combination into Phase 2 development triggered a $25 million milestone payment to Five Prime.
  - Five Prime and others have previously demonstrated evidence of synergy by combining CSF1R and PD-1 antibodies with chemotherapy in preclinical models of pancreatic cancer.
- Treatment is ongoing in Five Prime’s Phase 1a/1b clinical trial of cabiralizumab and OPDIVO® (nivolumab).
  - Five Prime and BMS are evaluating the safety, tolerability and preliminary efficacy of the immunotherapy combination of cabiralizumab with the PD-1 immune checkpoint inhibitor OPDIVO® in advanced solid tumors. The trial has completed enrollment, patients continue to be treated and biopsies are being assessed for a panel of tissue biomarkers for approximately one third of the patients.
  - Five Prime and BMS enrolled an additional 35 patients with pancreatic cancer in the Phase 1a portion of the trial to assess efficacy, safety and multiple tissue biomarkers measured in pre- and on-treatment biopsy samples.
- The abstract titled “Pharmacodynamics (PD) and Genomic Profiling of Pts Treated with cabiralizumab (cabira) + nivolumab (NIVO) Provide Evidence of On-Target Tumor Immune Modulations and Support Future Clinical Applications” was accepted for a poster presentation at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting on Monday, June 4.
- Ongoing Phase 1/2 clinical trial (NCT02471716) of cabiralizumab in patients with pigmented villonodular synovitis (PVNS).
  - Five Prime is enrolling a second cohort of up to 30 additional patients in the Phase 2 portion of the trial to evaluate a less frequent 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 Five Prime will advance cabiralizumab in PVNS into a pivotal trial in 2019.
  - 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.

- In December 2017, Five Prime initiated the Phase 1 portion (NCT03343301) of the Phase 1/3 FIGHT (FGFR2b Inhibition in G astric and Gastroesophageal Junction Cancer Treatment) global registrational trial.
  - The Phase 3 portion of the FIGHT trial will evaluate bemarituzumab in combination with the modified FOLFOX6 standard of care chemotherapy regimen (mFOLFOX6) versus placebo plus mFOLFOX6 in approximately 550 patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b.
  - The Phase 1 safety lead-in portion of the trial is designed to identify a recommended dose of bemarituzumab in combination with mFOLFOX6 to support the initiation of the Phase 3 portion of the trial.

    - The Phase 3 portion of the trial is expected to begin in the second half of 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 is using immunohistochemistry (IHC) and circulating tumor DNA (ctDNA) tests to identify the estimated 10% of patients with FGFR2b-overexpressing gastric cancer who would be eligible for the trial. In April, Five Prime and Personal Genome Diagnostics (PGDx) announced a collaboration to develop a plasma-based ctDNA *in vitro* companion diagnostic to identify patients for the trial.
    - Five Prime has filed a clinical trial application for bemarituzumab in China and, via its collaboration with Zai Lab, anticipates initiating clinical trial sites in China by the end of 2018.
- In April, Five Prime closed the bladder cancer cohort of its Phase 1 clinical trial after evaluating thefeasibility and timing of activating additional clinical sites, the rate of patient enrollment in the bladder cancer cohort and the current landscape of potential treatment options for bladder cancer patients.
- The abstract titled “FIGHT: A Phase 3 Randomized, Double-Blind, Placebo Controlled Study Evaluating (Bemarituzumab) FPA144 and Modified FOLFOX6 (mFOLFOX6) in Patients with Previously Untreated Advanced Gastric and Gastroesophageal Cancer with a Dose Finding Phase 1 Lead-In” was accepted for a poster presentation at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting on June 3.

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 overexpressing tumors by ADCC. B7-H4 is frequently overexpressed in breast, ovarian, endometrial and bladder cancers.

- In March, Five Prime initiated patient dosing in a Phase 1a/1b clinical trial of FPA150 monotherapy with a dose-escalation phase in solid tumors, which will be followed by dose expansion in pre-specified cohorts of patients whose tumors have high B7-H4 expression levels, as measured by an IHC molecular diagnostic test. The initial targeted tumors are advanced or metastatic breast, ovarian, endometrial and bladder cancers. Phase 1a dose escalation endpoints include identification of a maximum tolerated dose (MTD), safety, and pharmacokinetics (PK) of FPA150. Phase 1b dose expansion endpoints include objective response rate, as well as safety and PK.
- In an oral presentation at the AACR 2018 Annual Meeting in April, Five Prime presented data showing dose-dependent anti-tumor activity of FPA150 *in vivo* as a monotherapy and complete tumor regressions in preclinical tumor models when given in combination with PD-1 blockade.

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

- In December 2017, 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.
- During the quarter, BMS initiated dosing of patients in a Phase 1 study.

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.

- 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 anticipates submitting an IND application or a foreign equivalent in the second half of 2018.

Corporate:

- In January, the Company completed a public offering of common stock, raising net proceeds of approximately $108 million.
- In February, Five Prime received $4.2 million from Zai Lab in connection with the license and collaboration agreement for bemarituzumab in Greater China.
- In March, Five Prime received a $25 million milestone payment from BMS for the initiation of the Phase 2 clinical trial evaluating cabiralizumab and OPDIVO® (nivolumab)with and without chemotherapy in patients with advanced pancreatic cancer.
- In March, UCB elected to exclusively license an undisclosed drug target for inflammatory diseases. Five Prime identified the target using its discovery platform.
- In March, the Company announced that Marc Belsky, Senior Vice President and Chief Financial Officer, had resigned to pursue another opportunity. Linda Rubinstein has been appointed interim CFO. A search is currently underway to identify a new permanent CFO.

Summary of Financial Results and Guidance:

- **Cash Position**. Cash, cash equivalents and marketable securities totaled $389.4 million as of March 31, 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 $25.0 million in milestone payments Five Prime received from collaboration partners net of cash used by Five Prime in operations to advance its three clinical stage programs as well as preclinical research and development.

- **Revenue**. Collaboration and license revenue for the first quarter of 2018 increased by $22.4 million, or 222%, to $32.5 million from $10.1 million for the first quarter of 2017. This increase was primarily related to the $25.0 million earned in the first quarter of 2018 for the milestone achieved under the cabiralizumab collaboration agreement with BMS for the initiation of the Phase 2 clinical trial of cabiralizumab in pancreatic cancer.
- **R&D Expenses**. Research and development expenses for the first quarter of 2018 increased by $9.8 million, or 29%, to $43.6 million from $33.8 million in the first quarter of 2017. This increase was primarily related to increased spending on the bemarituzumab program, including in connection with the initiation of the Phase 1 portion of the FIGHT trial, and the initiation of the FPA150 Phase 1 trial.
- **G&A Expenses**. General and administrative expenses for both the first quarter of 2018 and 2017 were $10.5 million.
- **Net Loss**. Net loss for the first quarter of 2018 was $20.4 million, or $0.63 per basic and diluted share, compared to a net loss of $33.4 million, or $1.21 per basic and diluted share, for the first quarter of 2017.
- **Shares Outstanding**. Total shares outstanding were 34.3 million as of March 31, 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 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 6585139. 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 late 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 IND filings; (ii) the timing of initiation, progress and scope of clinical trials for Five Prime’s product candidates; (iii) the extent of protein overexpression in certain patient populations; (iv) the prevalence and incidence of certain diseases; (v) Five Prime’s full-year 2018 net cash used in operating activities; and (vi) 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)

	March 31, 2018	December 31, 2017
Balance Sheet Data		
Cash, cash equivalents and marketable securities	$ 389,426	$ 292,690
Total assets	436,714	344,047
Total current liabilities (excluding deferred revenue)	36,723	38,268
Deferred revenue (in total, including short term portion)	19,259	22,936
Total stockholders' equity	362,216	265,202

Five Prime Therapeutics, Inc.
Condensed Statements of Operations

(in thousands, except per share amounts)

	For The Three Months Ended March 31, 2018	For The Three Months Ended March 31, 2017
Collaboration and license revenue	$ 32,486	$ 10,135
Operating expenses:		
Research and development	43,552	33,760
General and administrative	10,478	10,486
Total operating expenses	54,030	44,246
Operating loss	(21,544)	(34,111)
Interest and other income, net	1,159	668
Other loss, net	(5)	-
Loss before income tax	(20,390)	(33,443)
Income tax benefit	-	-
Net loss	$ (20,390)	$ (33,443)
Basic and diluted net loss per common share	$ (0.63)	$ (1.21)
Weighted-average shares used to compute basic and diluted net loss per common share	32,314	27,657

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