Five Prime Therapeutics Reports Third Quarter 2019 Results

November 6, 2019

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 6, 2019-- 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 its results for the third quarter and provided an update on the company's recent activities.

"We have advanced all of our wholly-owned programs according to our plan for 2019," said William Ringo, Chairman and interim Chief Executive Officer of Five Prime Therapeutics. "As we approach 2020, we have repositioned Five Prime with a focus on prioritizing our pipeline based on upcoming data readouts, while also extending our cash runway, in order to maximize the long-term potential of the company."

Third Quarter 2019 Business Highlights and Milestones

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 enrolled approximately 140 patients with newly diagnosed advanced stage gastric cancer into the FIGHT trial, representing approximately 25% of projected total trial enrollment, and has paused pre-screening of patients for enrollment in the trial.
- The prevalence of FGFR2b overexpression in this patient population is approximately 30% based on global pre-screening data.
- The company expects to conduct a planned futility analysis for the FIGHT trial in mid-2020. The purpose of the futility analysis is to ensure the trial is adequately powered to detect an overall survival benefit at full enrollment.

FPA150 (anti-B7-H4) is a first-in-class B7-H4 antibody designed to target tumor cells by enhancing killing of B7-H4 overexpressing tumors through ADCC and by blocking B7-H4 from sending an inhibitory signal to CD8 T cells. B7-H4 is frequently overexpressed in breast, ovarian and endometrial cancers.

- The company presented a poster at the European Society for Medical Oncology (ESMO) Congress with preliminary FPA150 efficacy results from the monotherapy Phase 1b expansion cohorts at the 20mg/kg dose in patients with breast, ovarian or endometrial cancers that overexpress B7-H4.
- As of the August 9, 2019 data cut-off date, one patient in the ovarian cohort had a confirmed response; 11 patients had stable disease and remained on therapy. As of the data cut-off date, 31 patients across the ovarian, endometrial and breast cohorts were evaluable for response.
- The company also presented safety data for four patients in the combination arm of FPA150 with Keytruda® (pembrolizumab) suggesting that FPA150 could be combined at a full dose of 20 mg/kg every three weeks with the standard dose of pembrolizumab.

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

- On November 9, the company will present initial safety data from the Phase 1 clinical trial of FPT155 in patients with advanced solid tumors in a poster presentation at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting in National Harbor, Maryland.
- FPT155 data presented at SITC will include initial safety results from the Phase 1a dose escalation portion of the trial, which is designed to characterize the safety and pharmacokinetic (PK)/pharmacodynamic (PD) profile of FPT155 and identify a recommended dose for the Phase 1b portion of the trial.

Cabiralizumab (anti-CSF1R) is an antibody that inhibits CSF1R and has been shown to block the activation and survival of tumor-associated macrophages. Pursuant to a worldwide collaboration agreement, Bristol-Myers Squibb (BMS) has an exclusive worldwide license for the development and commercialization of cabiralizumab, and Five Prime retains the rights to a U.S. co-promotion option.

- Bristol-Myers Squibb has completed enrollment in the randomized Phase 2 trial testing the combination of cabiralizumab with Opdivo® (nivolumab) with and without chemotherapy in approximately 160 patients with locally advanced or metastatic pancreatic cancer that has progressed during or after one line of chemotherapy.
- The next anticipated event from the Phase 2 trial is the announcement of actionable data from BMS in 2020.

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.

- The Phase 1/2 clinical trial continues to progress, with the expected size of the trial increased to 383 patients in July 2019.

Corporate Highlights

- In October, the company announced a corporate restructuring to extend its cash runway without impacting or delaying the data timelines of its clinical programs. The company will retain a small research group focused on advancing three wholly-owned, late-stage research programs.
- In September, the company's board of directors appointed William Ringo as interim Chief Executive Officer in addition to his position as Chairman of the Board of Directors.

Summary of Financial Results and Guidance:

Cash Position: Cash, cash equivalents and marketable securities totaled $186.0 million as of September 30, 2019, compared to $214.1 million as of June 30, 2019. The decrease in cash, cash equivalents and marketable securities was primarily attributable to quarterly operating expenses that exceeded quarterly revenues.

Revenue: Collaboration and license revenue for the third quarter of 2019 decreased by $2.8 million, or 48.3%, to $3.0 million from $5.8 million for the third quarter of 2018. This decrease was primarily related to the completion of the research term under the immuno-oncology research collaboration with BMS in March 2019 and from progress made towards the company's performance obligation under the original collaboration agreement.

R&D Expenses: Research and development expenses for the third quarter of 2019 decreased by $17.8 million, or 39.8%, to $26.9 million from $44.7 million for the third quarter of 2018. This decrease was primarily due a one-time milestone payment triggered by the dosing of the first patient in the Phase 3 FIGHT trial in the third quarter of 2018. Lower compensation costs, pre-clinical and research activities, manufacturing and diagnostic expenses and the reduction in the use of temporary resources contributed to the decrease and were partially offset by increased clinical trial expense to advance the company's bemarituzumab, FPA150, and FPT155 clinical programs.

G&A Expenses: General and administrative expenses for the third quarter of 2019 increased by $3.4 million, or 34.7%, to $13.2 million from $9.8 million for the third quarter of 2018. The increase was primarily due to increased compensation costs offset by a reduction in the use of temporary resources.

Net Loss: Net loss for the third quarter of 2019 was $36.1 million, or $1.03 per basic and diluted share, compared to a net loss of $47.2 million, or $1.37 per basic and diluted share, for the third quarter of 2018.

Shares Outstanding: Weighted average shares outstanding for the third quarter of 2019 was 34,996,298 as of September 30, 2019.

Cash Guidance: Five Prime expects full-year 2019 net cash used in operating activities to be between $117 and $122 million and estimates ending 2019 with cash, cash equivalents and marketable securities between $148 and $153 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 5769473. 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. develops innovative protein therapeutics to improve the lives of patients with cancer. The company focuses on developing immune modulators and precision therapies for solid tumor cancers paired with companion diagnostics to identify patients who are most likely to benefit from treatment with Five Prime's product candidates. The company's product candidates have innovative mechanisms of action and address patient populations in need of better therapies. 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.

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; (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) the impact of the restructuring on the data timelines of Five Prime's clinical trials; (vi) Five Prime's full-year 2019 net cash used in operating activities; and (vii) the amount of Five Prime's cash, cash equivalents and marketable securities at the end of 2019. 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.

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

	September 30 2019	December 31, 2018
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 185,987	$ 270,138
Total assets	258,540	321,534
Total current liabilities (excluding deferred revenue)	26,356	26,059
Deferred revenue (in total, including short term portion)	7,176	11,893
Total stockholders' equity	178,434	265,139

Five Prime Therapeutics, Inc
Condensed Statement of Operations
(in thousands, except per share data)

	For The Three Months Ended September 30		For The Six Months Ended September 30	
	2019	**2018**	**2019**	**2018**
Collaboration and license revenue	$ 2,984	$ 5,771	$ 11,664	$ 45,837
Operating expenses:				
Research and development	26,948	44,687	88,126	121,619
General and administrative	13,206	9,832	33,377	30,092
Total operating expenses	40,154	54,519	121,503	151,711
Loss from operations	(37,170)	(48,748)	(109,839)	(105,874)
Interest income and other loss, net	1,100	1,531	3,996	4,212
Other (lss)/gain), net	1	(27)	(2)	(32)
Loss before income tax	(36,069)	(47,244)	(105,845)	(101,694)
Income tax provision	-	-	-	-
Net loss	$ (36,069)	$ (47,244)	$ (105,845)	$ (101,694)
Basic and diluted net loss per common share	$ (1.03)	$ (1.37)	$ (3.03)	$ (3.01)
Weighted-average shares used to compute basic and diluted net loss per common share	34,996	34,482	34,901	33,740

Five Prime Therapeutics, Inc.
Shares outstanding
9/30/2019

Total shares outstanding as of:

September 30, 2019	35,099,100

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