Five Prime Therapeutics Reports Second Quarter 2019 Results

August 7, 2019

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 7, 2019-- Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, today announced its results for the second quarter and provided an update on the company's recent activities.

"We are pleased that enrollment in our Phase 3 FIGHT trial continues to exceed expectations due to FGFR2b biomarker prevalence above 30% and continued strong investigator support. We are enthusiastic about the potential of bemarituzumab to be an important new medicine for patients with previously untreated, advanced gastric cancer," said Aron Knickerbocker, Chief Executive Officer of Five Prime Therapeutics. "We estimate that the FIGHT trial will reach sufficient enrollment in the coming months to support the planned, event-driven futility analysis in the first half of 2020, allowing us to pause enrollment in the fourth quarter of this year. This is consistent with our portfolio prioritization, which is currently focused on conducting the FIGHT trial, advancing the most promising FPA150 opportunities, as well as assessing safety and dose finding for FPT155."

Second 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 and mFOLFOX6 are being evaluated in combination with mFOLFOX6 in the Phase 3 FIGHT (FGFR2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment) trial.

- Enrollment in the FIGHT trial continues ahead of projections due to FGFR2b biomarker prevalence that has remained steady at more than 30%, strong clinical trial execution, and continued support and enthusiasm from clinical investigators.
- The company plans to conduct an early futility analysis for the FIGHT trial during the first half of 2020. The purpose of the futility analysis is to ensure the trial is adequately powered to detect an overall survival benefit at full enrollment.
- Consistent with its portfolio prioritization and given the higher than expected enrollment rate, the company will pause enrollment in the FIGHT trial when sufficient patients have been enrolled in the trial to support the planned futility analysis. The company expects the pause in enrollment to occur during the fourth quarter of 2019.

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.

- Five Prime will present a poster at the European Society for Medical Oncology (ESMO) Congress that will include preliminary FPA150 data from the monotherapy Phase 1b expansion cohorts at the 20 mg/kg dose in patients with breast, ovarian or endometrial cancers that overexpress B7-H4 and early safety data from the Phase 1a lead-in testing FPA150 in combination with Keytruda®.
- The company presented preliminary monotherapy safety data from the dose escalation and exploration portions of the Phase 1a/1b trial of FPA150 in patients with advanced solid tumors at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.

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.

- Enrollment is proceeding according to plan in the dose escalation portion of the Phase 1a/1b trial, with six dose level cohorts enrolled and dose escalation continuing.
- An abstract was submitted for the Society for Immunotherapy of Cancer (SITC) Annual Meeting, where the company expects to present safety and pharmacokinetic data from the Phase 1a dose escalation portion of the ongoing Phase 1a/1b 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.

- The next anticipated event is completion of enrollment in the 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.

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, and, in July, the expected size of the trial was increased from 308 to 383 patients.

Corporate Highlights

- During the second quarter, the company announced the appointment of Carol Schafer and Lori Lyons-Williams to its board of directors. The company also announced the departure of Dr. Sheila Gujrathi from the board.

Summary of Financial Results and Guidance:

Cash Position: Cash, cash equivalents and marketable securities totaled $214.1 million as of June 30, 2019, compared to $237.0 million as of March 31, 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 second quarter of 2019 decreased by $4.3 million, or 56.6%, to $3.3 million from $7.6 million for the second quarter of 2018. This decrease was primarily related to lower collaboration revenues from BMS due to a reduction in activities in the Phase 1a/1b trial of the combination of cabiralizumab and nivolumab and the completion of the research term under the immuno-oncology research collaboration in March 2019.

R&D Expenses: Research and development expenses for the second quarter of 2019 decreased by $4.0 million, or 12.0%, to $29.4 million from $33.4 million for the second quarter of 2018. This decrease was primarily due to lower compensation costs, as well lower manufacturing costs related to FPT155 drug production and lower diagnostic costs related to the FIGHT trial. These cost reductions were partially offset by higher CRO costs that were related to strong patient enrollment and the opening of new clinical trial sites.

G&A Expenses: General and administrative expenses for the second quarter of 2019 decreased by $0.1 million, or 1%, to $9.7 million from $9.8 million for the second quarter of 2018. The decrease was primarily due to decreased use of consultants in a number of functions across the company.

Net Loss: Net loss for the second quarter of 2019 was $34.4 million, or $0.99 per basic and diluted share, compared to a net loss of $34.1 million, or $0.99 per basic and diluted share, for the second quarter of 2018.

Shares Outstanding: Weighted average shares outstanding for the second quarter of 2019 was 34,909,479 as of June 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 3575436. 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 protein therapeutics to improve the lives of patients with serious diseases. Five Prime’s product candidates have innovative mechanisms of action and address patient populations in need of better therapies. The company focuses on researching and developing immuno-oncology and targeted cancer therapies paired with companion diagnostics to identify patients who are most likely to benefit from treatment with Five Prime’s product candidates. 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

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 initiation, 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) Five Prime’s full-year 2019 net cash used in operating activities; and (vi) the amount of Five Prime’s cash, cash equivalents and marketable securities at the end of 2019. 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.

Source: Five Prime Therapeutics, Inc.

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Selected Balance Sheets Data
(in thousands)

	June 30, 2019	December 31, 2018
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 214,131	$ 270,138
Total assets	292,911	321,534
Total current liabilities (excluding deferred revenue)	30,588	26,059
Deferred revenue (in total, including short term portion)	8,114	11,893
Total stockholders' equity	206,612	265,139

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

	For The Three Months Ended June 30		For The Six Months Ended June 30	
	2019	**2018**	**2019**	**2018**
Collaboration and license revenue	$ 3,333	$ 7,580	$ 8,680	$ 40,066
Operating expenses:				
Research and development	29,425	33,380	61,178	76,932
General and administrative	9,661	9,782	20,171	20,260
Total operating expenses	39,086	43,162	81,349	97,192
Loss from operations	(35,753)	(35,582)	(72,669)	(57,126)
Interest income and other loss, net	1,362	1,522	2,893	2,676
Loss before income tax	(34,391)	(34,060)	(69,776)	(54,450)
Income tax provision	-	-	-	-
Net loss	$ (34,391)	$ (34,060)	$ (69,776)	$ (54,450)
Basic and diluted net loss per common share	$ (0.99)	$ (0.99)	$ (2.00)	$ (1.63)
Weighted-average shares used to compute basic and diluted net loss per common share	34,909	34,401	34,852	33,363

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