November 6, 2017

Five Prime Announces Third Quarter 2017 Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2017 (GLOBE NEWSWIRE) -- 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 quarter ending September 30, 2017.

"This is an exciting time at Five Prime, as many of our programs are reaching important inflection points," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "Importantly, later this week at the SITC annual meeting, we and BMS plan to report our first clinical data from the Phase 1a/1b immuno-oncology trial studying cabiralizumab with OPDIVO®. The oral late-breaking presentation will highlight preliminary safety, PK and PD data, and initial efficacy from one of the expansion cohorts. We expect all of the cohorts in the trial to be fully enrolled before the end of 2017. Furthermore, we anticipate starting a Phase 1/3 chemotherapy combination trial with FPA144 before year end. The Phase 1 component will serve as a lead-in to our planned global registrational trial of FPA144 as a front-line therapy in patients with metastatic gastric cancer whose tumors overexpress FGFR2b. Additionally, we are on track to file an IND for FPA150, our anti-B7-H4 antibody during the fourth quarter, which would position us to initiate a Phase 1 trial early in 2018.

With the start of 2018, we also look forward to welcoming Aron Knickerbocker as the new president and CEO of Five Prime."

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.

  - Advanced the ongoing Phase 1a/1b trial of cabiralizumab/OPDIVO® in immuno-oncology.

  - Five Prime and Bristol-Myers Squibb (BMS), are evaluating the safety, tolerability and preliminary efficacy of the immunotherapy combination of cabiralizumab with the PD-1 immune checkpoint inhibitor OPDIVO® (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.

  - Five Prime has completed enrollment in some of the Phase 1b cohorts and expects the remaining cohorts to enroll fully during the fourth quarter of 2017.

  - Data on preliminary safety, pharmacokinetic and pharmacodynamic data as well as initial efficacy from one of the expansion cohorts that enrolled quickly are scheduled to be presented in a late-breaking oral presentation at the Society for Immunotherapy of Cancer (SITC) meeting on Saturday, November 11, 2017.

  - Advanced the ongoing Phase 1/2 trial of cabiralizumab in patients with PVNS.

  - Five Prime reported initial trial data at ASCO in June 2017, showing that cabiralizumab demonstrated clinical benefit in patients with PVNS. The company is preparing to enroll 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. These additional data are intended to support a pivotal trial for cabiralizumab in PVNS.

- **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, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family.

  - Preparing to start the FIGHT Phase 1/3 clinical trial to test the combination of FPA144 with front-line chemotherapy in patients with metastatic gastric and gastro-esophageal junction cancer. By the end of 2017, Five Prime plans to begin dosing patients in the Phase 1 portion of the FIGHT Phase 1/3 clinical trial in order to test the safety of ascending doses of FPA144 in combination with the FOLFOX6 chemotherapy regimen in unselected patients. This safety lead-in portion of the trial will support the start of the Phase 3 portion of the trial, which Five Prime expects to initiate in 2018. The randomized, controlled Phase 3 trial would serve as a global registrational study and will evaluate FPA144 plus FOLFOX6 versus placebo plus FOLFOX6 in patients whose tumors overexpress

FGFR2b or have FGFR2 gene amplification.

- Applying companion diagnostics to identify the estimated 10% of patients with gastric and gastro-esophageal junction cancer eligible for enrollment in the Phase 1/3 trial. Five Prime plans to use immunohistochemistry (IHC) and circulating tumor DNA (ctDNA) tests to identify eligible patients for its global Phase 3 clinical trial. Five Prime believes the addition the ctDNA test will double the eligible patient population to 10% from the previous 5% identified by IHC testing alone.

- Enrolling patients in Phase 1 safety trial of FPA144 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 planned global Phase 3 clinical trial.

- Closed enrollment of gastric cancer cohorts in the Phase 1 monotherapy trial of FPA144. As Five Prime prepares for the initiation of its front-line Phase 1/3 clinical trial, it has closed enrollment of the gastric cancer expansion cohorts in its ongoing Phase 1 clinical trial evaluating the safety, PK and efficacy of biweekly 15 mg/kg infusions of FPA144.

- Advanced the Phase 1 monotherapy cohort testing FPA144 in patients with metastatic bladder cancer. The company continues to enroll patients in the Phase 1 clinical trial cohort testing FPA144 as a treatment for patients with metastatic bladder cancer whose tumors overexpress FGFR2b, as assessed by the company's IHC test.

- Presenting new data on FGFR2b expression in bladder cancer at SITC 2017. Poster P51, entitled "FGFR2b Expression and Baseline Immune Signature to Guide FPA144 Development in Urothelial Cancer," will be featured in poster sessions on Friday, November 10, 2017, from 12:30-2:00 pm ET and 6:30-8:00 pm ET.

- **FP-1039**: a protein drug designed to block FGF signaling. As a ligand trap, FP-1039 binds to and neutralizes a subset of FGF ligands (such as FGF2), preventing these growth-promoting and angiogenic proteins from reaching FGFR1 on the surface of tumor cells.

- Data from the phase 1b trial in mesothelioma were presented in an oral session at the European Society for Medical Oncology (ESMO) 2017 Congress in September. The Phase 1b trial evaluated FP-1039 with front-line pemetrexed and cisplatin in untreated, unresectable mesothelioma. Five Prime is transferring the process from its former partner, GSK, and developing and a more commercially viable cell line and process; no clinical supply is available at this time. Five Prime is exploring partnering this program.

Preclinical Research and Development:

- Continue to advance first-in-class preclinical development candidates in IND-enabling studies.

- 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 and endometrial cancers.
- Data featured in an oral poster discussion during the ESMO 2017 Congress 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.
- Investigational New Drug (IND) application planned for December 2017.

- FPT155 (CD80-Fc)
- A multi-targeting immune modulator that can stimulate T cell responses through three critical pathways: CTLA4 blockade, CD28 agonism (without superagonism) and PD-L1 blockade.
- 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 antitumor activity, and it may have a synergistic effect when combined with anti-PD1 therapy.
- On track for an IND application in mid-2018.

- **Target discovered by Five Prime in its respiratory disease collaboration exclusively licensed by partner GSK.**
  - In August, GSK exercised its right to exclusively license 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.

Leadership:

- **Aron Knickerbocker selected by Board of Directors to succeed Dr. Rusty Williams as President and CEO of Five Prime effective January 1, 2018. Dr. Rusty Williams will be named Executive Chairman.**

- **Bryan Irving, Ph.D. appointed Senior Vice President, Research.**

Summary of Financial Results and Guidance:

- **Cash Position.** Cash, cash equivalents and marketable securities totaled $320.8 million on September 30, 2017, compared to $421.7 million on December 31, 2016. The decrease in cash was primarily attributable to cash used in operations to advance FPA144 and cabiralizumab clinical development and preclinical development programs toward IND applications.

- **Revenue.** Collaboration revenue for the third quarter of 2017 increased by $1.6 million to $8.3 million from $6.7 million in the third quarter of 2016. This increase was primarily due to revenue recognized under the 2015 cabiralizumab collaboration agreement with BMS, under which Five Prime is reimbursed for the expenses from the cabiralizumab immuno-oncology trial.

- **R&D Expenses.** Research and development expenses for the third quarter of 2017 increased by $18.8 million to $42.7 million from $23.9 million in the third quarter of 2016. This increase was primarily related to advancing our FPA144 development program and the FPA150 and FPT155 programs toward IND applications.

- **G&A Expenses.** General and administrative expenses for the third quarter of 2017 increased by $0.6 million to $9.7 million from $9.1 million in the third quarter of 2016. This increase was primarily due to accruing rent for the lease on our new corporate office to be occupied in December 2017.

- **Net Loss.** Net loss for the third quarter of 2017 was $43.3 million, or $1.54 per basic and diluted share, compared to a net loss of $19.4 million, or $0.72 per basic and diluted share, for the third quarter of 2016.

- **Shares Outstanding.** Total shares outstanding were 28.9 million as of September 30, 2017.

Cash Guidance. Five Prime expects full-year 2017 net cash used in operating activities to be less than $120 million. The company estimates ending 2017 with slightly less than $300 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 general business update. To participate in the conference call, please dial (877) 878-2269 (domestic) or (253) 237-1188 (international) and refer to conference ID 95493696. 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 and will be archived and available for replay 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 a growing 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.

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 about (i) the timing of initiation, progress and scope of clinical trials for our product candidates; (ii) the potential use of our product candidates to treat patients; (iii) the extent of gene amplification and protein overexpression in and the size of certain patient populations; (iv) the timing of the filing of INDs; (v) the timing of data disclosures; and (vi) our estimated 2017 net cash used in operating activities and estimated year-end balance of cash, cash equivalents and marketable securities. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment,

failure of Five Prime's collaborators to support or advance collaborations or product candidates, and unexpected litigation or other disputes. Other factors that may cause Five Prime's 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" sections 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, 2017	December 31, 2016
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 320,758	$ 421,748
Total assets	357,417	448,281
Total current liabilities (excluding deferred revenue)	33,151	24,591
Deferred revenue (in total, including short term portion)	22,009	32,006
Total stockholders' equity	286,089	391,575

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

	For the Three Months Ended Sept. 30, 2017	For the Three Months Ended Sept. 30, 2016	For the Nine Months Ended Sept. 30, 2017	For the Nine Months Ended Sept. 30, 2016
Collaboration and license revenue	$ 8,333	$ 6,680	$ 26,290	$ 22,429
Operating expenses:				
Research and development	42,733	23,890	118,237	64,923
General and administrative	9,674	9,146	29,523	25,309
Total operating expenses	52,407	33,036	147,760	90,232
Operating loss	(44,074)	(26,356)	(121,470)	(67,803)
Interest income	792	639	2,162	1,821
Loss before income tax	(43,282)	(25,717)	(119,308)	(65,982)
Income tax (provision) benefit	-	6,303	(1,703)	20,391
Net loss	$ (43,282)	$ (19,414)	$ (121,011)	$ (45,591)
Basic and diluted net loss per common share	$ (1.54)	$ (0.72)	$ (4.34)	$ (1.70)
Weighted-average shares used to compute basic and diluted net loss per common share	28,020	27,139	27,883	26,794

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Source: Five Prime Therapeutics, Inc.