May 4, 2017

Five Prime Announces First Quarter 2017 Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., May 04, 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 March 31, 2017.

"We had a productive quarter at Five Prime, in which we made notable progress in our clinical and preclinical programs," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "We achieved an important milestone by completing enrollment in the Phase 2 part of the ongoing trial of cabiralizumab in patients with pigmented villonodular synovitis, or PVNS. Additionally, we have completed enrollment in some of the Phase 1b cohorts in the cabiralizumab immuno-oncology trial. Each of our three clinical-stage programs advanced and we look forward to announcing clinical trial data from these programs this year. Additionally, we continue to make progress in our pre-clinical programs and, beginning this year, are on track to file at least one IND application for a new molecule each year for the foreseeable future."

Business Highlights and Recent Developments

Clinical Pipeline:

- **Cabiralizumab (FPA008):** an investigational antibody that inhibits CSF1R and has been shown to block the activation and survival of monocytes and macrophages. In the setting of advanced cancer, tumor-associated macrophages (TAMs) can inhibit the immune system's ability to eradicate the disease. In the CSF-1-driven tumor diffuse tenosynovial giant cell tumor (dsTGCT), also known as pigmented villonodular synovitis (PVNS), the bulk of the tumor mass in joints is formed by the macrophages themselves. Five Prime and Bristol-Myers Squibb (BMS) have an exclusive worldwide collaboration agreement for the development and commercialization of cabiralizumab for these and potentially additional indications.

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

  - 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® (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. The companies are also evaluating cabiralizumab as monotherapy and in combination with OPDIVO® in additional tumor settings.

  - Five Prime and BMS are also assessing multiple tissue biomarkers on tumors, TAMs and T cells. These assessments are guiding optimal dose selection to maximize the probability of success in future development.

  - Five Prime completed enrollment in some of the Phase 1b cohorts in the cabiralizumab immuno-oncology trial and expects to complete enrollment in all of the current Phase 1b trial cohorts in the second half of 2017.

  - The company expects to announce initial clinical trial data from the cabiralizumab immuno-oncology trial in the second half of 2017.

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

  - In April, Five Prime completed enrollment in the initially planned 30-patient cohort of the Phase 2 part of the ongoing clinical trial evaluating cabiralizumab in patients with PVNS, an aggressive tumor confined to the synovium. Five Prime is evaluating clinical measures, including response rate, pain and range of motion.

  - Five Prime plans to seek regulatory guidance to initiate a pivotal trial studying cabiralizumab in PVNS to begin in 2018.

  - The company also plans to disclose initial clinical data from the cabiralizumab PVNS trial at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting.

- **FPA144:** an isoform-selective antibody 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. FPA144 has

been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells.

- Advanced the Phase 1 monotherapy trial of FPA144 in patients with gastric cancer. Enrollment continues in the expansion portion of the trial, evaluating the safety, PK and efficacy of biweekly 15 mg/kg infusions of FPA144 in patients with gastric cancer whose tumors overexpress FGFR2b.

- Plan to disclose updated gastric cancer clinical trial data from the FPA144 program at the ASCO 2017 Annual Meeting.

- Plan to seek regulatory guidance on a registrational path for FPA144 in combination with chemotherapy as a front-line gastric cancer therapy. Preclinical data suggest that the combination of FPA144 with standard-of-care chemotherapy is additive. Five Prime plans to initiate a combination trial of FPA144 with chemotherapy to advance into front-line therapy.

- Plan to launch a Phase 1 safety trial for FPA144 in patients with gastric cancer in Japan. The observed incidence of gastric cancer is higher in Asian populations than in other populations. Five Prime recently received clinical trial notification (CTN) approval from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan and plans to initiate a Phase 1 monotherapy clinical trial in Japan in the third quarter of 2017.

- Advanced the Phase 1 monotherapy trial of FPA144 in patients with bladder cancer. Five Prime observed a complete response in a Stage 4 metastatic bladder cancer patient who received FPA144 in the dose escalation portion of the trial. That patient remains in remission and on treatment since April 15, 2015. The company opened an additional cohort in the Phase 1 clinical trial to test FPA144 as a treatment for bladder cancer patients whose tumors overexpress FGFR2b, as assessed by the company's immunohistochemistry (IHC) test. Five Prime is adding sites that specialize in bladder cancer.

- **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.

- Patients continue to be dosed with FP-1039 in the ongoing Phase 1b clinical trial in mesothelioma. Five Prime regained full rights to FP-1039 from GlaxoSmithKline (GSK) in September 2016. GSK is completing the ongoing Phase 1b trial combining FP-1039 with front-line pemetrexed and cisplatin in untreated, unresectable mesothelioma. GSK concluded trial recruitment with 25 patients enrolled at the 15 mg/kg dose in June 2016. Further clinical development of FP-1039 in mesothelioma will be determined after data are mature.

- Five Prime plans to disclose clinical data from the FP-1039 program at the European Society for Medical Oncology (ESMO) 2017 Congress.

Preclinical Research and Development:

- **Featured three preclinical research poster presentations during the 2017 American Association for Cancer Research (AACR) Annual Meeting that took place from April 1 - 5 in Washington, D.C.**
  - Preclinical results demonstrated that both anti-CSF-1R and anti-GITR synergize with anti-PD1 therapy.
  - Highlighted Five Prime's robust *in vitro* and *in vivo* platforms to discover new immuno-oncology targets.

- **Continues to advance three 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.
  - Investigational New Drug (IND) application planned for the fourth quarter of 2017.

  - FPA154 (GITR agonist antibody)
  - A tetravalent agonist antibody designed for greater GITR activation versus conventional antibodies. Conventional GITR agonist antibodies have two GITR binding sites while FPA154 has four.
  - IND application planned for the fourth quarter of 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.
  - IND application planned in 2018.

- **Progress in pre-clinical and research programs.**

- Five Prime is on track to achieve the goal of filing at least one IND application for a new molecule each year for the foreseeable future, beginning this year.

- **Continues to conduct multiple immuno-oncology research screens to identify new targets and drug candidates.**
  - Five Prime initiated antibody campaigns for new targets.
  - Five Prime's research team previously conducted *in vivo* screens of approximately 700 immune-related cell surface proteins to find immune proteins that could be new targets for validation as potential novel immuno-oncology therapeutics.

Summary of Financial Results and Guidance:

- **Cash Position.** Cash, cash equivalents and marketable securities totaled $380.3 million on March 31, 2017, compared to $421.7 million on December 31, 2016. The decrease in cash was primarily attributable to cash used in operations to advance the FPA144 clinical trial, the cabiralizumab Phase 2 clinical trial in PVNS and preclinical development programs.

- **Revenue.** Collaboration revenue for the first quarter of 2017 increased by $3.6 million to $10.1 million from $6.5 million in the first 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 first quarter of 2017 increased by $14.9 million to $33.8 million from $18.9 million in the first quarter of 2016. This increase was primarily related to advancing cabiralizumab in the Phase 2 clinical trial in PVNS and the Phase 1a/1b clinical trial in immuno-oncology, advancing the FPA144 Phase 1 clinical trial and further advancing preclinical development programs.

- **G&A Expenses.** General and administrative expenses for the first quarter of 2017 increased by $2.4 million to $10.5 million from $8.1 million in the first quarter of 2016. This increase was primarily due to increases in payroll and stock-based compensation expenses.

- **Net Loss.** Net loss for the first quarter of 2017 was $33.4 million, or $1.21 per basic and diluted share, compared to a net loss of $13.0 million, or $0.49 per basic and diluted share, for the first quarter of 2016.

- **Shares Outstanding.** Total shares outstanding were 28.6 million as of March 31, 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 approximately $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 corporate update. To participate in the conference call, please dial (877) 878-2269 (domestic) or (253) 237-1188 (international) and refer to conference ID 4178195. 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
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 prevalence of certain diseases; (v) the timing of the filing of INDs; (vi) the timing of data disclosures; and (vii) 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 Sheets Data
(in thousands)

	March 31, 2017	December 31, 2016
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 380,317	$ 421,748
Total assets	409,081	448,281
Total current liabilities (excluding deferred revenue)	22,152	24,591
Deferred revenue (in total, including short term portion)	28,823	32,006
Total stockholders' equity	357,049	391,575

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

	For The Three Months Ended March 31, 2017	For The Three Months Ended March 31, 2016
Collaboration and license revenue	$ 10,135	$ 6,520
Operating expenses:		
Research and development	33,760	18,856
General and administrative	10,486	8,057
Total operating expenses	44,246	26,913
Operating loss	(34,111)	(20,393)
Interest income	668	536
Loss before income tax	(33,443)	(19,857)
Income tax benefit	-	6,817
Net loss	$ (33,443)	$ (13,040)
Basic and diluted net loss per common share	$ (1.21)	$ (0.49)
Weighted-average shares used to compute basic and diluted net loss per common share	27,657	26,351

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