August 8, 2017

Five Prime Announces Second Quarter 2017 Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif. , Aug. 08, 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 June 30, 2017.

"We continued to make significant progress on our clinical and pre-clinical programs during the quarter," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "We are advancing our large Phase 1a/1b immuno-oncology trial studying cabiralizumab with OPDIVO® in multiple tumor settings. We completed enrollment in some of the cohorts and are on track to complete enrollment in all the cohorts by the end of the year. We and BMS also plan to disclose initial clinical trial data at the SITC annual meeting in November. At the ASCO annual meeting, we announced initial clinical trial data from our Phase 1/2 trial of cabiralizumab in pigmented villonodular synovitis, or PVNS, in which cabiralizumab clearly demonstrated clinical benefit in patients. We also reported encouraging monotherapy activity for FPA144 in heavily pretreated gastric cancer patients, and plan to initiate a front-line chemotherapy combination trial. Additionally, we're on track to file at least one IND application for a new molecule each year, including this year."

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.

  - 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 completed enrollment in some of the Phase 1b cohorts and expects to complete enrollment in all the cohorts in the second half of 2017.

  - Five Prime and BMS expect to present initial clinical trial data at the Society for Immunotherapy of Cancer (SITC) meeting in November.

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

  - Announced initial clinical trial data at the 2017 American Society of Clinical Oncology (ASCO) Annual meeting in June.
    - There were no dose-limiting toxicities (DLTs) observed at doses up to 4 mg/kg.
    - Cabiralizumab demonstrated clinical benefit in patients with PVNS.
      - Most patients enrolled at the 4 mg/kg dose experienced tumor reduction.
      - 5 out of 11 patients had a radiographic response (4 confirmed).
      - Improvement in median Ogilvie-Harris composite score of pain and function was reported in both responders and non-responders.

  - Five Prime plans 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 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. Five Prime plans to initiate a global pivotal trial of FPA144 combined with chemotherapy as a front-line treatment for metastatic gastric cancer. In addition, Five Prime is adding a blood-based diagnostic tool to increase the addressable population to 10% of patients with gastric cancer.

- 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.

- Announced updated clinical trial data from the Phase 1 trial of single-agent FPA144 at the 2017 ASCO Annual Meeting.

- FPA144 was well tolerated at doses tested up to 15 mg/kg in patients with advanced solid tumors, including patients with gastric cancer.
- FPA144 monotherapy demonstrated early evidence of anti-tumor efficacy in heavily pre-treated patients (median of 3 prior lines of therapy).
  - Radiographic responses:
    - 5 Partial Responses (4 confirmed, 1 unconfirmed) in 21 patients (across three dose levels)
    - Objective Response Rate (ORR): 19%
    - Median duration of response of 15.4 weeks

- Activities underway to initiate a global registrational clinical trial in 2018 for FPA144 in combination with chemotherapy as a front-line gastric cancer therapy.

- Launched a Phase 1 safety trial for FPA144 monotherapy in 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.

- Developing companion diagnostics to identify the 10% of gastric cancer patients eligible for FPA144 therapy. Five Prime plans to use either immunohistochemistry (IHC) or circulating tumor DNA (ctDNA) tests to identify eligible patients for its global Phase 3 clinical trial. By adding the ctDNA test, Five Prime believes it will double the eligible patient population to 10% from the previous 5% identified by IHC testing alone.

- Preparing for a Phase 1 safety trial to test the combination of FPA144 with chemotherapy. Five Prime plans to begin dosing patients in a Phase 1 clinical trial to test the safety of ascending doses of FPA144 in combination with chemotherapy by the end of 2017. This safety trial will support the start of the global Phase 3 clinical trial.

- Discussing design of Phase 3 clinical trial with regulatory authorities. Five Prime has begun discussions with regulatory authorities and is actively working on the design of the Phase 3 clinical trial of FPA144 in combination with chemotherapy as a front-line gastric cancer therapy.

- Advanced the Phase 1 monotherapy trial of FPA144 in patients with bladder cancer. 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 IHC test. Five Prime is adding sites that specialize in bladder cancer to support enrollment in this cohort.

- **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.

- Clinical data from the phase 1b trial in mesothelioma have been accepted as an oral presentation at the European Society for Medical Oncology (ESMO) 2017 Congress in September. Our former partner, GlaxoSmithKline (GSK), is completing the 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.

Preclinical Research and Development:

- **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.

- **Continue 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. B7-H4 is frequently overexpressed in breast, ovarian and endometrial cancers.
  - Investigational New Drug (IND) application planned for the fourth quarter of 2017.

- FPA150 was selected for an oral poster discussion during the ESMO 2017 Congress.

- 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.
- Potential 2018 IND application.

- 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.
- Potential 2018 IND application.

Summary of Financial Results and Guidance:

- **Cash Position.** Cash, cash equivalents and marketable securities totaled $350.7 million on June 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 the FPA144 clinical development program, the cabiralizumab Phase 2 clinical trial in PVNS and preclinical development programs.

- **Revenue.** Collaboration revenue for the second quarter of 2017 decreased by $1.4 million to $7.8 million from $9.2 million in the second quarter of 2016. This decrease was primarily due to completing the research term of our research collaboration with GSK in respiratory diseases in July 2016 offset by 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 second quarter of 2017 increased by $19.5 million to $41.7 million from $22.2 million in the second 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 and advancing pre-clinical development programs towards IND filings.

- **G&A Expenses.** General and administrative expenses for the second quarter of 2017 increased by $1.3 million to $9.4 million from $8.1 million in the second quarter of 2016. This increase was primarily due to increases in payroll and stock-based compensation expenses.

- **Net Loss.** Net loss for the second quarter of 2017 was $44.3 million, or $1.58 per basic and diluted share, compared to a net loss of $13.1 million, or $0.49 per basic and diluted share, for the second quarter of 2016.

- **Shares Outstanding.** Total shares outstanding were 28.8 million as of June 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 corporate update. To participate in the conference call, please dial (877) 878-2269 (domestic) or (253) 237-1188 (international) and refer to conference ID 61862496. 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 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 Sheets Data
(in thousands)

	June 30, 2017	December 31, 2016
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 350,718	$ 421,748
Total assets	380,111	448,281
Total current liabilities (excluding deferred revenue)	22,244	24,591
Deferred revenue (in total, including short term portion)	25,358	32,006
Total stockholders' equity	323,274	391,575

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

	For The Three Months Ended June 30, 2017	For The Three Months Ended June 30, 2016	For The Six Months Ended June 30, 2017	For The Six Months Ended June 30, 2016
Collaboration and license revenue	$ 7,822	$ 9,229	$ 17,957	$ 15,749
Operating expenses:				
Research and development	41,744	22,177	75,504	41,033
General and administrative	9,363	8,106	19,849	16,163
Total operating expenses	51,107	30,283	95,353	57,196
Operating loss	(43,285)	(21,054)	(77,396)	(41,447)
Interest income	702	646	1,370	1,182
Loss before income tax	(42,583)	(20,408)	(76,026)	(40,265)
Income tax (provision) benefit	(1,703)	7,271	(1,703)	14,088
Net loss	$ (44,286)	$ (13,137)	$ (77,729)	$ (26,177)
Basic and diluted net loss per common share	$ (1.58)	$ (0.49)	$ (2.79)	$ (0.98)
Weighted-average shares used to compute basic and diluted net loss per common share	27,946	26,924	27,813	26,619

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