August 4, 2016

Five Prime Announces Second Quarter 2016 Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., Aug. 04, 2016 (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 second quarter ended June 30, 2016.

"We're pleased with the progress we've made through the first half of the year and remain on track with our clinical programs," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "At ASCO in June, we announced early but encouraging Phase 1 data for our FGFR2b antibody, FPA144, including confirmed partial responses in three of nine patients with FGFR2b+ gastric tumors and one confirmed complete response in a patient with bladder cancer. Notably, FPA144 recently received FDA Orphan Drug Designation in patients with FGFR2b+ gastric cancer. Development of our anti-CSF1R antibody, FPA008, now named cabiralizumab, is also progressing according to plan. We still expect the Phase 1b dose expansion portion of the trial combining cabiralizumab with OPDIVO® (nivolumab) in multiple tumor types to begin during the second half of 2016. Also on track is our Phase 2 clinical trial of cabiralizumab in patients with pigmented villonodular synovitis (PVNS), a rare indication for which we received FDA Orphan Drug Designation."

Business Highlights and Recent Developments

Clinical Pipeline:

- **FPA008 (cabiralizumab):** an investigational antibody that inhibits CSF1R and has been shown to block the activation and survival of monocytes and macrophages. In some cancers, macrophages suppress the immune system's ability to kill cancer cells. In pigmented villonodular synovitis (PVNS), macrophages form the bulk of the tumor mass in joints. Cabiralizumab blocks the activation and survival of these cell types. Five Prime and Bristol-Myers Squibb (BMS) have an exclusive worldwide collaboration agreement for the development and commercialization of cabiralizumab.
  - **Advanced Phase 1a/1b cabiralizumab/OPDIVO combination trial.**
    Five Prime continued dose exploration in the Phase 1a/1b clinical trial evaluating the safety, tolerability and preliminary efficacy of the immunotherapy combination of cabiralizumab with OPDIVO, BMS's PD-1 immune checkpoint inhibitor. The trial is currently expected to enroll up to 280 patients and remains on target to move into Phase 1b during the second half of 2016.
  - **Advanced clinical trial of cabiralizumab in patients with PVNS into Phase 2 in May.**
    Five Prime advanced cabiralizumab into the Phase 2 dose expansion portion of the ongoing Phase 1/2 trial in PVNS, a CSF-1 receptor-driven tumor. The Phase 2 portion is evaluating clinical measures including response rate, pain and range of motion in approximately 30 PVNS patients. The U.S. Food and Drug Administration (FDA) granted cabiralizumab Orphan Drug Designation for the treatment of PVNS. Five Prime estimates the U.S. prevalence for diffuse PVNS patients may be as high as 25,000 patients.
- **FPA144:** an isoform-selective antibody in development as a targeted immuno-therapy for tumors that over-express 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.
  - **In July, received FDA Orphan Drug Designation for FPA144 for the treatment of gastric cancer and cancer of the gastroesophageal junction in patients whose tumors overexpress FGFR2b.**
  - **Presented data from the ongoing Phase 1 trial of FPA144 in an oral session at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in June.**

    FPA144 monotherapy demonstrated early evidence of anti-tumor efficacy in gastric cancer patients with FGFR2b protein overexpression from Part 1b and Part 2 of the trial. These heavily pre-treated patients had received between 1 and 6 prior therapies with a median of 2 prior therapies. The highlights of the data presented at ASCO include:

    Efficacy as of the April 1, 2016 data cutoff:
    - 3 confirmed partial responses (PRs) out of 9 gastric cancer patients treated (33%); 1 of these 3 PRs was confirmed after the data cutoff

- 7 of 9 gastric cancer patients with disease control (3 PRs + 4 stable disease), disease control rate (DCR) = 77%
- 12-week progression-free survival (PFS) in 6 of 9 gastric cancer patients (67%)
- Median duration of treatment of 112 days (range 42-182 days), with 2 of 9 gastric cancer patients still on study
- A patient with metastatic bladder cancer in the dose escalation portion of the trial in solid tumors achieved a confirmed complete response (CR)

  In addition to the 3 PRs in gastric cancer noted above, there was an additional unconfirmed PR in the 10th gastric cancer patient with FGFR2b protein overexpression, whose scan became available after the data cutoff.

Safety as of the April 1, 2016 data cutoff:

- No dose-limiting toxicities (DLTs); maximum-tolerated dose (MTD) was not reached
- No treatment-related serious adverse events (SAEs)
- The most common treatment-related AEs (> 5%) were all grades 1 or 2: fatigue (22.5%), nausea (20%) and vomiting (12.5%)

- **Presented preclinical data for FPA144 at the American Association for Cancer Research (AACR) Annual Meeting.** FPA144 was featured in two presentations at the AACR Annual Meeting in April 2016. Five Prime demonstrated that FPA144's enhanced ADCC mechanism drives innate and adaptive immune responses in the tumor microenvironment, recruiting NK and T cells into the tumor. Additionally, FPA144 produced an additive effect on tumor growth inhibition when combined with PD-1 blockade. These pre-clinical findings suggest the therapeutic potential for a combination of FPA144 with a checkpoint inhibitor.

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

  - GSK presented data in mesothelioma patients from the ongoing Phase 1b trial of FP-1039 at the 2016 ASCO Annual Meeting.

  - Although GSK has terminated its FP-1039 license from Five Prime, GSK is continuing to conduct the ongoing study of FP-1039 in combination with 1st-line pemetrexed and cisplatin in patients with untreated, unresectable mesothelioma. GSK has now capped the trial at the 25 patients enrolled at the 15 mg/kg dose.

  - The trial data are not sufficiently mature for Five Prime to make decisions yet on potential future development of FP-1039 in mesothelioma. Those decisions will be based on our future assessment of the response rate and durability in this trial, as well as other considerations, such as drug supply and manufacturing.

Preclinical Research and Development:

- **Progressed internal immuno-oncology research programs**. Five Prime continues to advance multiple immuno-oncology candidates through preclinical development and expects to have two programs entering pre-IND studies before the end of 2016. The company anticipates filing one IND by the end of 2017 and to have preclinical assets sufficient to keep the pace of one IND per year for the foreseeable future.

- **GSK licensed intellectual property for respiratory disease target identified using Five Prime's proprietary protein discovery platform.** In June, GSK exercised its option to take an exclusive license to the intellectual property related to a target under the 2012 respiratory diseases research collaboration between the companies. This triggered a $1.5 million license payment to Five Prime, which was recognized as revenue in the second quarter. Five Prime is eligible to receive up to $92.75 million in contingent milestone payments for each product that targets the licensed protein.

Summary of Financial Results and Guidance:

- **Cash Position.** Cash, cash equivalents and marketable securities totaled $469.2 million on June 30, 2016, compared to $517.5 million on December 31, 2015. The decrease in cash was primarily attributable to cash used in operations to advance the FPA144 clinical trial, preclinical programs and tax payments.
- **Revenue.** Collaboration revenue for the second quarter of 2016 increased by $2.9 million to $9.2 million from $6.3 million in the second quarter of 2015. This increase was primarily due to revenue recognized under the 2015 cabiralizumab collaboration agreement with BMS, under which Five Prime is reimbursed for the immuno-oncology trial expenses.

- **R&D Expenses.** Research and development expenses for the second quarter of 2016 increased by $8.9 million, or 66.9%, to $22.2 million from $13.3 million in the second quarter of 2015. This increase was primarily related to advancing the FPA144 clinical trial, preclinical development and immuno-oncology research programs.
- **G&A Expenses.** General and administrative expenses for the second quarter of 2016 increased by $3.5 million, or 76.1%, to $8.1 million from $4.6 million in the second quarter of 2015. This increase was primarily due to increases in cash and stock-based compensation expenses.
- **Net Loss.** Net loss for the second quarter of 2016 was $13.1 million, or $0.49 per basic and diluted share, compared to a net loss of $11.5 million, or $0.45 per basic and diluted share, for the second quarter of 2015.
- **Shares Outstanding.** Total shares outstanding were 28.3 million as of June 30, 2016.

Cash Guidance. Five Prime continues to expect full-year 2016 net cash used in operating activities to be less than $120 million, comprising less than $90 million used in operations and less than $30 million used for tax payments. The company estimates ending 2016 with approximately $400 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 47543495. 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 IND filings; (ii) the timing of initiation, progress and scope of clinical trials for Five Prime's product candidates; (iii) Five Prime's full-year 2016 net cash used in operating activities and the portion of net cash used in operating activities attributable to tax payments; and (iv) the amount of Five Prime's cash, cash equivalents and marketable securities at the end of 2016. 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, 2016	December 31, 2015
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 469,226	$ 517,466
Total assets	497,768	548,285
Total current liabilities (excluding deferred revenue)	28,534	61,859
Deferred revenue (in total, including short term portion)	40,159	48,777
Total stockholders' equity	426,696	433,206

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Collaboration revenue	$ 9,229	$ 6,315	$ 15,749	$ 10,602
Operating expenses:				
Research and development	22,177	13,310	41,033	24,521
General and administrative	8,106	4,596	16,163	8,816
Total operating expenses	30,283	17,906	57,196	33,337
Loss from operations	(21,054)	(11,591)	(41,447)	(22,735)
Interest income	646	117	1,182	225
Loss before income tax	(20,408)	(11,474)	(40,265)	(22,510)
Income tax benefit	7,271	—	14,088	—
Net loss	$ (13,137)	$ (11,474)	$ (26,177)	$ (22,510)
Basic and diluted net loss per common share	$ (0.49)	$ (0.45)	$ (0.98)	$ (0.89)
Weighted-average shares used to compute basic and diluted net loss per common share	26,924	25,690	26,619	25,383

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Source: Five Prime Therapeutics, Inc.

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