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Five Prime Therapeutics Reports Second Quarter 2015 Results and Provides Business Update

- *Immuno-Oncology Trial of FPA008 and Nivolumab Initiating in August*
- *Added GITR Antibody Program to Immuno-Oncology Pipeline*
- *FP-1039 Preliminary Data to be Presented at World Conference on Lung Cancer*

SOUTH SAN FRANCISCO, Calif., Aug. 6, 2015 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a clinical-stage biotechnology company focused on discovering and developing novel protein therapeutics for cancer and inflammatory diseases, today provided a corporate update and reported financial results for the second quarter ending June 30, 2015.

"Five Prime is actively building a comprehensive and complementary portfolio of immuno-oncology candidates and programs that target macrophages, immune check points, T cell agonist pathways and regulatory T cells in the tumor microenvironment," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "Regarding our clinical programs, we recently received IND clearance for our Phase 1a/1b clinical trial to evaluate the combination of our CSF1 receptor antibody, FPA008, and Bristol-Myers Squibb's nivolumab, and plan to initiate dosing this month. In July, we began dosing patients in our Phase 1/2 clinical trial of FPA008 in PVNS, a tumor driven by the CSF1 pathway. On the research side, we added a T cell agonist to our early pipeline with the in-licensing of Inhibrx's antibodies to GITR, a pathway we identified in our protein library and proprietary *in vivo* screens as one of the most potent inhibitors of tumor growth. We also licensed to bluebird bio our novel human antibodies to an undisclosed target to develop CAR T cell therapies for hematologic malignancies and solid tumors."

"Looking ahead, we expect data from two of our clinical programs before year end. GSK intends to present initial data from the Phase 1b clinical trial of FP-1039 in squamous non-small cell lung cancer and mesothelioma patients at the World Conference on Lung Cancer in September, and we plan to report preliminary data from the open label portion of our Phase 1 study of FPA008 in rheumatoid arthritis patients by year end."

Business Highlights and Recent Developments

Pipeline:

- **FPA008:** FPA008 targets macrophages and monocytes, which are activated or elevated in multiple disease settings. In cancer, tumor-associated macrophages suppress the immune system's ability to kill cancer cells. In joint diseases, such as PVNS and RA, synovial macrophages play a central role in the disease process.
 - **Initiated Phase 1/2 Clinical Trial of FPA008 in PVNS.** In July, Five Prime initiated patient dosing in its Phase 1/2 clinical trial of FPA008 in pigmented villonodular synovitis (PVNS), an orphan indication. During the Phase 1 dose escalation portion of the trial, Five Prime will assess safety and pharmacodynamics of multiple ascending doses of FPA008 to determine the dose for expansion. During the Phase 2 expansion, the company will evaluate tumor response rate and duration, as well as measures of pain and joint function, in approximately 30 patients. Five Prime plans to complete dose escalation and move into dose expansion by the end of 2015 or early 2016.
 - **Prepared for Initiation of Phase 1a/1b FPA008/Nivolumab Combination Trial in Collaboration with Bristol-Myers Squibb (BMS).** In July, Five Prime received IND clearance for the Phase 1a/1b clinical trial to explore the combination of FPA008 and nivolumab, BMS's PD-1 immune checkpoint antibody, in multiple tumor types. The trial will evaluate the safety, tolerability and preliminary efficacy of the combination in patients with non-small cell lung cancer, melanoma, head and neck cancer, pancreatic cancer, colorectal cancer and malignant glioma. Five Prime plans to initiate patient dosing during August and to present the trial design at the International Cancer Immunotherapy Conference in September. The company expects to complete Phase 1a dose escalation and expand into Phase 1b with the selected dose of FPA008 in late 2015 or early 2016.
 - **Continued Dosing Rheumatoid Arthritis (RA) Patients in Open-Label Portion of Phase 1 Clinical Trial of FPA008.** Five Prime continued to dose FPA008 in RA patients with active disease who are on methotrexate in its Phase 1 clinical trial. The company plans to report preliminary open-label data from RA patients by the end of 2015.
- **Continued Enrollment in the Phase 1 Clinical Trial of FPA144.** Five Prime continued to enroll its Phase 1a/1b clinical trial of FPA144, an FGF receptor 2b-selective antibody. By the end of 2015, Five Prime expects to complete Phase 1a dose escalation in patients with solid tumors, including gastric cancer, and to begin the Phase 1b expansion at a selected dose in gastric cancer patients whose tumors have evidence of FGFR2b protein overexpression or *FGFR2* gene amplification. The company anticipates preliminary Phase 1a data will be available by the end of 2015 or early

2016.

- **Continued Enrollment in the Phase 1b Clinical Trial of FP-1039/GSK3052230 in Squamous Non-Small Cell Lung Cancer (NSCLC) and Mesothelioma.** GlaxoSmithKline (GSK) continued to enroll patients in the Phase 1b clinical trial of FP-1039, an FGF ligand trap, combined with standard doses of chemotherapy. Patients with newly-diagnosed or recurrent squamous non-small cell lung cancer whose tumors have amplification of the *FGF receptor 1* gene are being studied in Arms A and B, respectively. In Arm C, GSK is studying patients with malignant pleural mesothelioma, a tumor in which the FGF2 ligand is overexpressed. GSK intends to present preliminary safety and efficacy data from the trial at the World Conference on Lung Cancer in September.

Research Programs:

- **Established Strategic Research and License Agreement With Inhibrx for Novel GITR Antibodies.** In July, Five Prime established a research collaboration and license agreement for Inhibrx's novel glucocorticoid-induced tumor necrosis factor receptor (GITR) antibodies. The program is currently at lead selection stage and could potentially reach IND in 2017. Using its comprehensive protein library and proprietary in vivo screening technologies, Five Prime identified the GITR pathway as one of the most potent inhibitors of tumor growth. Additionally, agonist antibodies have demonstrated the ability to induce tumor regressions in preclinical models, particularly when administered with other immuno-oncology therapies. The Inhibrx technology represents a potentially best-in-class approach for engineering a multivalent GITR agonistic antibody. Five Prime paid an upfront license fee of \$10 million to Inhibrx in July 2015.
- **Entered into License Agreement with bluebird bio for Novel Antibodies to Develop CAR T Cell Therapy.** In May, Five Prime granted an exclusive license to bluebird bio to research, develop and commercialize chimeric antigen receptor (CAR) T cell therapies using Five Prime's proprietary human antibodies to an undisclosed target for hematologic malignancies and solid tumors. Five Prime received a \$1.5 million upfront payment, and is eligible for development, regulatory, and commercial milestones payments of up to \$131 million per licensed product as well as tiered royalties on future product sales.
- **Continued to Advance Immuno-Oncology Research Programs.** Five Prime continues to progress its immuno-oncology product candidates toward preclinical development, with fully human antibody campaigns underway to multiple targets. The company provided background on its immuno-oncology discovery methods and preclinical data on novel immune checkpoint candidates during its Research and Development Day in May. Five Prime plans to present further updates at scientific conferences and remains on track for one new IND per year from its research programs beginning in 2017.

Summary of Financial Results and Guidance:

- **Cash Position.** Cash, cash equivalents and marketable securities totaled \$207.4 million on June 30, 2015 compared with \$149.1 million on December 31, 2014. The increase was primarily attributable to Five Prime's January 2015 public offering of common stock, offset by cash used in operations.
- **Revenue.** Collaboration and license revenue for the second quarter of 2015 increased by \$1.3 million, or 26%, to \$6.3 million from \$5.0 million in the second quarter of 2014, primarily due to the \$1.5 million upfront license payment from bluebird bio.
- **R&D Expenses.** Research and development expenses for the second quarter of 2015 increased by \$1.4 million, or 12%, to \$13.3 million from \$11.9 million in the second quarter of 2014. This increase was primarily related to advancing the FPA008 development program into additional indications and expanding the company's internal immuno-oncology research and preclinical activities.
- **G&A Expenses.** General and administrative expenses for the second quarter of 2015 increased by \$1.6 million, or 53%, to \$4.6 million from \$3.0 million in the second quarter of 2014. This increase was primarily due to increases in personnel related expenses, including stock-based compensation and facility costs.
- **Net Loss.** Net loss for the second quarter of 2015 was \$11.5 million, or \$0.45 per basic and diluted share, compared with a net loss of \$9.9 million, or \$0.46 per basic and diluted share, for the second quarter of 2014. This increase in net loss was primarily related to advancing the FPA008 development program into additional indications and expanding internal immuno-oncology research and preclinical activities.

Updated 2015 Cash Guidance. Five Prime expects full-year 2015 net cash used in operating activities to be between \$65 and \$70 million and estimates ending 2015 with between \$158 and \$163 million in cash, cash equivalents and marketable securities. With the addition of the GITR program to the pipeline in July 2015, Five Prime expects to have cash to fund operations through 2017, without entering into any additional collaboration or license agreements or receiving any future milestone payments. This provides sufficient runway to move Five Prime's three clinical programs beyond efficacy data readouts and to move one or more new immuno-oncology candidates into clinical trials.

Conference Call Information

Five Prime will host a conference call and live audio webcast today at 5 p.m. (ET) / 2 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 97608881. 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) the reporting of clinical data regarding Five Prime's product candidates; (iv) Five Prime's full-year 2015 net cash used in operating activities; (v) the amount of Five Prime's cash, cash equivalents and marketable securities at the end of 2015; and (vi) the period during which FivePrime expects to be able to fund operations. 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 millions)

	June 30, December 31,	
	2015	2014
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$207.4	\$149.1
Total assets	215.5	155.6
Total current liabilities (excluding deferred revenue)	8.5	7.9
Deferred revenue (in total, including short term portion)	59.4	60.6
Total stockholders' equity	145.9	85.2

Five Prime Therapeutics, Inc.
Condensed Statements of Operations Data
(in millions)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014

Collaboration and license revenue	\$6.3	\$5.0	\$10.6	\$8.5
Operating expenses:				
Research and development	13.3	11.9	24.5	20.8
General and administrative	<u>4.6</u>	<u>3.0</u>	<u>8.8</u>	<u>6.3</u>
Total operating expenses	17.9	14.9	33.3	27.1
Interest income	<u>0.1</u>	<u>--</u>	<u>0.2</u>	<u>0.1</u>
Net loss	<u>\$ (11.5)</u>	<u>\$ (9.9)</u>	<u>\$ (22.5)</u>	<u>\$ (18.5)</u>
Basic and diluted net loss per common share	<u>\$ (0.45)</u>	<u>\$ (0.46)</u>	<u>\$ (0.89)</u>	<u>\$ (0.92)</u>

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