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Five Prime Announces Fourth Quarter and Full Year 2015 Financial Results

SOUTH SAN FRANCISCO, Calif., March 10, 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 fourth quarter and full year ending December 31, 2015.

"2015 was a transformational year for Five Prime," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "Of note, our license and collaboration agreement with Bristol-Myers Squibb (BMS) maximizes the clinical and commercial potential of FPA008 and the exceptional terms have strengthened our financial position. In addition, we are encouraged by the early safety and efficacy data from FPA144 in patients with gastric cancer, and we look forward to assessing its potential in other indications. Beyond our clinical programs, we also made progress in our internal immuno-oncology research programs, and continue to be on track to file an IND application in 2017."

2015 Business Highlights and Recent Developments

Clinical Development:

- | **FPA008:** an investigational antibody that inhibits CSF1R and has been shown in preclinical models to block the activation and survival of monocytes and macrophages.
 - | **Established Exclusive Worldwide License and Collaboration Agreement with BMS for FPA008.** In October 2015, Five Prime and BMS entered into an exclusive worldwide license and collaboration agreement for the development and commercialization of FPA008. Five Prime received a \$350 million upfront payment during the fourth quarter and is eligible to receive up to \$1.4 billion in development and regulatory milestone payments as well as royalty percentages ranging from the high teens to the low twenties on future worldwide net sales of FPA008. Five Prime also has an option to co-promote FPA008 in the United States.
 - | **Initiated Phase 1a/1b FPA008/OPDIVO Combination Trial.** In September 2015, Five Prime initiated patient dosing in the Phase 1a/1b clinical trial evaluating the safety, tolerability and preliminary efficacy of the immunotherapy combination of FPA008 with OPDIVO (nivolumab), BMS's PD-1 immune checkpoint inhibitor. Five Prime expects to expand into Phase 1b in multiple tumor settings in the second half of 2016.
 - | **Initiated Phase 1/2 Clinical Trial of FPA008 in Pigmented Villonodular Synovitis (PVNS).** In the third quarter of 2015, Five Prime initiated patient dosing in its Phase 1/2 clinical trial in PVNS, a CSF1R-driven tumor and an orphan indication. The company expects to begin Phase 2 expansion, which will evaluate tumor response rate and duration as well as measures of pain and joint function, in mid-2016. The company submitted an epidemiology study focusing on the incidence and prevalence of this rare disease for presentation at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.
- | **FPA144: an anti-FGF receptor 2b (FGFR2b) Monoclonal Antibody Engineered to Recruit NK Cells into the Tumor Microenvironment. During the fourth quarter of 2015, Five Prime completed dose escalation in the ongoing Phase 1 trial of single-agent FPA144 and began dose expansion at a selected dose in new cohorts of gastric cancer patients whose tumors overexpress FGFR2b. In January 2016, Five Prime presented preliminary data from the dose escalation portion of the trial at the ASCO Gastrointestinal Cancers Symposium, which showed:**
 - | Two partial responses in six gastric cancer patients with IHC 3+ FGFR2b-positive gastric cancer;
 - | A partial response in a patient whose bladder cancer overexpressed FGFR2b; and
 - | FPA144 was well tolerated and differentiated from small molecule kinase inhibitors targeting the pathway, which often cause hyperphosphatemia and other dose-limiting toxicities.

Based on results to date, Five Prime continues to evaluate FPA144 as a monotherapy in refractory gastric cancer, as a combination therapy for gastric cancer, and as a potential treatment for other types of cancer. The company submitted an abstract for presentation at the ASCO 2016 Annual Meeting in June and will present preclinical data regarding FPA144's ability to reprogram immune cells in the tumor microenvironment at the American Association for Cancer Research (AACR) Annual Meeting in April 2016.

- | **FP-1039/GSK3052230, an FGF Ligand Trap.** GlaxoSmithKline (GSK) presented data from the ongoing open-label Phase 1b trial in patients with squamous non-small cell lung cancer (sqNSCLC) and mesothelioma at the World Conference on Lung Cancer in September 2015. In January 2016, GSK and Five Prime agreed to stop enrollment in the sqNSCLC patient cohorts given the change in treatment paradigms following approvals of immuno-oncology agents and the increasingly competitive landscape in sqNSCLC. In addition, the companies agreed that GSK would

continue to enroll mesothelioma patients based on encouraging preliminary data from the mesothelioma arm of the trial.

On March 9, 2016, GSK notified Five Prime that it was providing 180-day notice of termination of the FP-1039 license and collaboration agreement for convenience. Five Prime plans to work with GSK to ensure completion of enrollment in the ongoing mesothelioma arm of the Phase 1b study and to transfer the asset and program back to Five Prime. Five Prime continues to be encouraged by the progress of this Phase 1b trial. Mesothelioma could represent a potentially attractive market opportunity for a company like Five Prime. Five Prime will base decisions on future development of FP-1039 on whether the quality and durability of responses in this population is maintained in this trial. GSK has submitted mesothelioma data for presentation at the ASCO 2016 Annual Meeting.

Preclinical Research and Development:

- | **Progressed Internal Immuno-Oncology Research Programs.** During 2015, Five Prime continued to expand its immuno-oncology research efforts and advanced multiple candidates into preclinical development. The company continues to be on track to file an IND application in 2017.
- | **Established New GTR Agonist Program.** Five Prime in-licensed novel, potentially best-in-class, multivalent glucocorticoid-induced tumor necrosis factor receptor (GTR) antibodies from Inhibrx during the third quarter of 2015. Their unique multivalent format facilitates clustering of GTR on T cells, which should result in superior T cell activation compared to conventional antibodies.
- | **Enhanced the Company's Ability to Generate Therapeutic Antibodies and Move Them More Rapidly Toward IND Applications.** In October 2015, Five Prime secured a license from Open Monoclonal Technology (OMT) to access mono- and bi-specific antibody platforms and antibody repertoire sequencing technology for the generation of novel therapeutic candidates. In December 2015, Five Prime obtained a license from Xoma Ltd. to one of Xoma's proprietary phage display libraries for antibody discovery.

Other Licenses and Collaborations:

- | **Entered into License Agreement with bluebird bio for Antibodies to Develop CAR T Cell Therapy.** In May 2015, 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. The agreement included a \$1.5 million upfront payment and subsequent milestone payments to Five Prime, which together could total over \$130 million per licensed product if certain development, regulatory, and commercial milestones are achieved. Five Prime is also eligible to receive tiered royalties on product sales.
- | **GSK Exercised Options to Reserve Multiple Protein Targets Discovered by Five Prime for Respiratory Disease.** GSK paid Five Prime \$600,000 in target reservation fees.

Finance:

- | **Completed Public Offering of Common Stock.** In January 2015, Five Prime completed an underwritten public offering of common stock, raising net proceeds of \$78.7 million.

Summary of Financial Results and Guidance:

- | **Cash Position.** Cash, cash equivalents and marketable securities totaled \$517.5 million on December 31, 2015 compared to \$149.1 million on December 31, 2014. The increase in year-end 2015 cash was primarily attributable to the \$350 million upfront payment received in December 2015 from BMS for the FPA008 license and collaboration agreement.
- | **Revenue.** Collaboration revenue for the fourth quarter of 2015 increased by \$358.7 million to \$363.3 million from \$4.6 million in the fourth quarter of 2014, primarily due to revenue recognized under the FPA008 license and collaboration agreement with BMS. Collaboration revenue for the full year 2015 increased by \$360.6 million to \$379.8 million in 2015 from \$19.2 million in 2014 primarily due to revenue recognized under the collaborations with BMS, UCB and GSK.
- | **R&D Expenses.** Research and development expenses for the fourth quarter of 2015 increased by \$8.4 million, or 67%, to \$21.0 million from \$12.6 million in the fourth quarter of 2014. Full year 2015 research and development expenses increased by \$27.0 million, or 63%, to \$70.2 million in 2015 from \$43.2 million in 2014. This increase was primarily related to advancing the FPA008 program in immuno-oncology and PVNS, and advancing internal immuno-oncology research and preclinical activities, including expenses related to in-licensing GTR antibodies.
- | **G&A Expenses.** General and administrative expenses for the fourth quarter of 2015 increased by \$4.6 million, or 115%, to \$8.6 million from \$4.0 million in the fourth quarter of 2014. Full year 2015 general and administrative expenses were \$22.6 million, an increase of \$9.0 million, or 66%, from \$13.6 million in 2014. This increase was primarily due to increases in personnel related expenses, including stock-based compensation, facility costs and

recruiting related to expansion of operations.

- 1 **Net Income (Loss).** Net income for the fourth quarter of 2015 was \$296.1 million, or \$11.37 per basic share and \$10.63 per diluted share, compared to a net loss of \$11.8 million, or \$0.55 per basic and diluted share, for the fourth quarter of 2014. Full year 2015 net income was \$249.6 million, or \$9.73 per basic share and \$9.23 per diluted share, compared to a net loss of \$37.4 million, or \$1.79 per basic and diluted share in 2014. These increases in net income were primarily related to the revenue recognized under the FPA008 license and collaboration agreement with BMS.

Cash Guidance. Five Prime expects 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 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 50136086. 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 data regarding Five Prime's product candidates; (iv) Five Prime's potential receipt of milestone payments and royalties; (v) Five Prime's full-year 2016 net cash used in operating activities; and (vi) 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)

	As of December 31,	
	2015	2014
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$517,466	\$149,054
Total assets	548,285	155,631
Total current liabilities (excluding deferred revenue)	61,859	7,877
Deferred revenue (in total, including short term portion)	48,777	60,566
Total stockholders' equity	433,206	85,205

Five Prime Therapeutics, Inc.
Condensed Statements of Operations
(In Thousands Except Per Share Amounts)

	For The Three Months Ended December 31,		For The Year Ended December 31,	
	2015	2014	2015	2014
Collaboration revenue	\$ 363,341	\$ 4,645	\$379,801	\$ 19,231
Operating expenses:				
Research and development	20,956	12,571	70,197	43,173
General and administrative	8,602	3,968	22,631	13,632
Total operating expenses	<u>29,558</u>	<u>16,539</u>	<u>92,828</u>	<u>56,805</u>
Operating income (Loss)	333,783	(11,894)	286,973	(37,574)
Interest and other income, net	155	68	484	150
Income (loss) before income tax	<u>333,938</u>	<u>(11,826)</u>	<u>287,457</u>	<u>(37,424)</u>
Provision for income tax	(37,810)	—	(37,810)	—
Net income (loss)	<u>\$ 296,128</u>	<u>\$(11,826)</u>	<u>\$249,647</u>	<u>\$(37,424)</u>
Basic net income (loss) per common share	\$ 11.37	\$ (0.55)	\$ 9.73	\$ (1.79)
Diluted net income (loss) per common share	<u>\$ 10.63</u>	<u>\$ (0.55)</u>	<u>\$ 9.23</u>	<u>\$ (1.79)</u>
Shares used to compute basic net income (loss) per common share	<u>26,043</u>	<u>16,835</u>	<u>25,661</u>	<u>20,865</u>
Shares used to compute diluted net income (loss) per common share	<u>27,850</u>	<u>16,835</u>	<u>27,035</u>	<u>20,865</u>

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