



November 3, 2016

Five Prime Announces Third Quarter 2016 Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., Nov. 03, 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 third quarter ended September 30, 2016.

"We have continued to make progress on all of our clinical and preclinical programs during the quarter," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "We achieved an important milestone by advancing into the Phase 1b portion of our clinical trial evaluating the immunotherapy combination of cabiralizumab (FPA008) with nivolumab in multiple tumor types. We believe targeting both the CSF1R and PD-1 pathways has the potential to produce a synergistic therapeutic effect. Our Phase 1 trial evaluating FPA144 in patients with gastric cancer is also progressing well. We have added cohorts to enroll gastric cancer patients with tumors at varying levels of FGFR2b expression as well as a cohort to evaluate bladder tumors that overexpress FGFR2b. Additionally, we continue to advance our pre-clinical programs and have begun IND-enabling activities for three of our immuno-oncology therapeutic candidates."

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 can inhibit the immune system's ability to eradicate the disease. In pigmented villonodular synovitis (PVNS), a CSF-1-driven tumor, 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.
 - | **Initiated Phase 1b portion of cabiralizumab/OPDIVO trial.**
In October 2016, Five Prime initiated the Phase 1b portion of the clinical trial evaluating the immunotherapy combination of cabiralizumab with the PD-1 immune checkpoint inhibitor OPDIVO® (nivolumab) in multiple tumor types. Five Prime and BMS are evaluating the safety, tolerability and preliminary efficacy of the combination 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 Phase 1a/1b trial is expected to enroll approximately 280 patients.
 - | **Advanced the Phase 2 trial of cabiralizumab in patients with PVNS.**
Five Prime continued enrollment and dosing in the Phase 2 trial of cabiralizumab in PVNS. During Phase 2, Five Prime is evaluating clinical measures, including response rate, pain and range of motion, in approximately 30 PVNS patients.
- | **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. Five Prime retains global development and commercialization rights to FPA144.
 - | **Opened new gastric cancer cohorts and added a bladder cancer cohort in Phase 1 monotherapy trial of FPA144.** 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 highly overexpress FGFR2b. During the quarter, Five Prime added cohorts to evaluate FPA144 in patients with bladder cancer whose tumors overexpress FGFR2b and in patients with gastric cancer whose tumors express moderate or low levels of FGFR2b. Five Prime reported encouraging initial single-agent efficacy and safety data at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.
 - | **Announced FDA Orphan Drug Designation for FPA144 in July for the treatment of gastric cancer and cancer of the gastroesophageal junction in patients whose tumors overexpress FGFR2b.**
- | **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.

Although Five Prime regained full rights to FP-1039 from GlaxoSmithKline (GSK) in September, GSK will complete the ongoing Phase 1b trial combining FP-1039 with first-line pemetrexed and cisplatin in untreated, unresectable mesothelioma. GSK concluded trial recruitment with 25 patients enrolled at the 15 mg/kg dose, and continues to dose and follow patients. Five Prime plans to make decisions on potential future development of FP-1039 in mesothelioma once objective response rate, disease control rate and progression-free survival data are sufficiently mature.

Preclinical Research and Development:

- 1 **IND-enabling studies initiated for preclinical development candidates.** Five Prime advanced multiple preclinical immuno-oncology programs and initiated IND-enabling activities for three therapeutic candidates. In vivo data from preclinical studies of Five Prime's tetravalent GTR agonist antibody (FPA154) have been accepted for presentation in a poster at the Society for Immunotherapy of Cancer (SITC) Annual Meeting on November 11, 2016. Five Prime intends to share further details on all three programs during its R&D Day in New York City on December 8. The company's goal is to file at least one IND application for a new molecule each year for the foreseeable future, beginning in 2017.
- 1 **Completed multiple immuno-oncology research screens to identify new targets and drug candidates.** Five Prime's research team completed functional screens on CD8 T cells and regulatory T cells, as well as a comprehensive screen of all extracellular binding interactions in the "immunome," a defined subset of extracellular proteins selectively expressed on immune cells. The screens were conducted in order to identify new immuno-oncology targets, which the company is prioritizing for further development as new drug candidates, either as monotherapies or as part of combination regimens.

Summary of Financial Results and Guidance:

- 1 **Cash Position.** Cash, cash equivalents and marketable securities totaled \$440.7 million on September 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.
- 1 **Revenue.** Collaboration revenue for the third quarter of 2016 increased by \$0.8 million to \$6.7 million from \$5.9 million in the third 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 expenses from the cabiralizumab immuno-oncology trial.
- 1 **R&D Expenses.** Research and development expenses for the third quarter of 2016 decreased by \$0.8 million to \$23.9 million from \$24.7 million in the third quarter of 2015. In the third quarter of 2015, the company recorded an \$8.0 million expense related to in-licensing. Adjusted for this expense, research and development expenses increased \$7.2 million over the prior year's quarter, primarily related to advancing the FPA144 clinical trial, preclinical development and immuno-oncology research programs.
- 1 **G&A Expenses.** General and administrative expenses for the third quarter of 2016 increased by \$3.9 million to \$9.1 million from \$5.2 million in the third quarter of 2015. This increase was primarily due to increases in payroll and stock-based compensation expenses.
- 1 **Net Loss.** Net loss for the third quarter of 2016 was \$19.4 million, or \$0.72 per basic and diluted share, compared to a net loss of \$24.0 million, or \$0.93 per basic and diluted share, for the third quarter of 2015.
- 1 **Shares Outstanding.** Total shares outstanding were 28.4 million as of September 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 more than \$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 3243563. 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)

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 440,698	\$ 517,466
Total assets	465,126	548,285
Total current liabilities (excluding deferred revenue)	24,123	61,859
Deferred revenue (in total, including short term portion)	36,223	48,777
Total stockholders' equity	403,975	433,206

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

	<u>Three Months Ended</u> <u>September 30,</u> <u>2016</u>		<u>Nine Months Ended</u> <u>September 30,</u> <u>2015</u>	
Collaboration revenue	\$ 6,680	\$ 5,858	\$ 22,429	\$ 16,460
Operating expenses:				
Research and development	23,890	24,720	64,923	49,241
General and administrative	9,146	5,213	25,309	14,029
Total operating expenses	<u>33,036</u>	<u>29,933</u>	<u>90,232</u>	<u>63,270</u>
Loss from operations	(26,356)	(24,075)	(67,803)	(46,810)
Interest income	639	104	1,821	329
Loss before income tax	(25,717)	(23,971)	(65,982)	(46,481)
Income tax benefit	6,303	—	20,391	—
Net loss	<u>\$ (19,414)</u>	<u>\$ (23,971)</u>	<u>\$ (45,591)</u>	<u>\$ (46,481)</u>
Basic and diluted net loss per common share	<u>\$ (0.72)</u>	<u>\$ (0.93)</u>	<u>\$ (1.70)</u>	<u>\$ (1.82)</u>
Weighted-average shares used to compute basic and diluted net loss per common share	<u>27,139</u>	<u>25,825</u>	<u>26,794</u>	<u>25,532</u>

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