



May 5, 2016

Five Prime Announces First Quarter 2016 Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., May 05, 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 first quarter ending March 31, 2016.

"We are pleased with the progress in our clinical programs during the first quarter of this year," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "We reported encouraging data for FPA144, including preliminary Phase 1 data demonstrating several partial responses in patients with FGFR2b+ tumors, as well as pre-clinical findings that suggest that FPA144 drives innate and adaptive responses to help drive an immune cascade in a patient's tumor. We continue Phase 1a dose exploration in our trial combining FPA008 with OPDIVO (nivolumab) in multiple tumor types, and are on track to begin the Phase 1b dose expansion portion during the second half of 2016. In addition, we recently began screening patients and expect to begin patient dosing soon in the Phase 2 portion of our clinical trial of FPA008 in patients with pigmented villonodular synovitis (PVNS), a rare indication for which we received orphan drug designation in January."

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. Five Prime and Bristol-Myers Squibb (BMS) have an exclusive worldwide collaboration agreement for the development and commercialization of FPA008.
 - | **Phase 1a/1b FPA008/OPDIVO Combination Trial Advances and Evolves.** Five Prime continued dose exploration in the Phase 1a/1b clinical trial evaluating the safety, tolerability and preliminary efficacy of the immunotherapy combination of FPA008 with OPDIVO, BMS's PD-1 immune checkpoint inhibitor. The trial is currently expected to enroll approximately 280 patients and remains on track to move into Phase 1b during the second half of 2016.
 - n Phase 1b has been modified to now explore combination therapy in the following tumor types: non-small cell lung, head and neck, pancreatic, renal, ovarian and glioblastoma.
 - n Five Prime increased the size of the Phase 1a portion of the study to enroll more patients at the highest selected FPA008 dose as monotherapy, and at the highest selected FPA008 dose in combination therapy with OPDIVO. The new 1a expansion, which is planned to be done in parallel with Phase 1b, will allow Five Prime to more rapidly and efficiently examine the safety and activity of both monotherapy and combination in patients with tumor types not currently addressed in the Phase 1b cohorts.
 - | **Advanced Clinical Trial of FPA008 in Patients with PVNS.**
Five Prime recently began patient screening for the Phase 2 portion of the ongoing Phase 1/2 clinical trial of FPA008 in PVNS, a CSF-1 receptor-driven tumor. Patient dosing is expected to begin soon in the Phase 2 portion of the trial, which will evaluate clinical measures, including response rate, pain and range of motion in approximately 30 PVNS patients. The U.S. Food and Drug Administration (FDA) granted FPA008 orphan drug designation for the treatment of PVNS in January 2016. Five Prime also recently collaborated with an academic group to complete an epidemiology study, which suggests the U.S. prevalence for diffuse PVNS patients may be as high as 25,000 patients, and expects to submit the full manuscript for future publication.
- | **FPA144:** an isoform-selective antibody in development as a targeted therapy for tumors that over-express FGFR2b. FPA144 has been engineered for enhanced antibody-dependent cell-mediated cytotoxicity, or ADCC, to increase direct tumor cell killing by recruiting natural killer (NK) cells.
 - | **Presented preliminary data from the dose escalation portion of the Phase 1 trial of FPA144 monotherapy at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium in January:**
 - n Two partial responses in six gastric cancer patients with IHC 3+ FGFR2b-positive gastric cancer;
 - n A partial response in a patient whose bladder cancer overexpressed FGFR2b; and
 - n FPA144 was well tolerated with the most common treatment-emergent adverse events being Grades 1 or 2 and self-limiting.
 - | Clinical data from the Phase 1 clinical trial will be updated in an oral presentation during the ASCO Annual Meeting in June 2016.
 - | **Amended the Phase 1 trial to add new cohorts.** The trial will include additional cohorts to assess the

activity and safety of FPA144 in gastric cancer with low or moderate levels of FGFR2b expression, as well as in other tumor types that express FGFR2b.

Presented preclinical data for FPA144 at the American Association for Cancer Research (AACR)

Annual Meeting. FPA144 was featured in two presentations at the AACR 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 in gastric cancer.

- 1 **Continued enrollment of mesothelioma patients in Phase 1b trial of FP-1039, an FGF Ligand Trap.** In January 2016, GSK and Five Prime agreed to stop enrollment in the squamous non-small cell lung cancer (sqNSCLC) patient arms given the change in sqNSCLC treatment paradigms, but the companies agreed that GSK would continue enrolling mesothelioma patients based on encouraging preliminary data from that arm of the trial. In March 2016, GSK provided a 180-day notice of termination of the FP-1039 license and collaboration agreement. Five Prime is working with GSK to complete the mesothelioma study and to transfer the asset and program back to Five Prime. Mesothelioma could represent a potentially attractive market opportunity for Five Prime, and decisions on the development of FP-1039 in mesothelioma will be based on the quality and durability of responses in this trial, as well as other considerations, such as drug supply and manufacturing. GSK has submitted mesothelioma data for presentation at the ASCO 2016 Annual Meeting.

Preclinical Research and Development:

Progressed Internal Immuno-Oncology Research Programs. Five Prime continues to advance multiple candidates into 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.

Summary of Financial Results and Guidance:

- 1 **Cash Position.** Cash, cash equivalents and marketable securities totaled \$482.0 million on March 31, 2016, compared to \$517.5 million on December 31, 2015. The decrease in first quarter 2016 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 first quarter of 2016 increased by \$2.2 million to \$6.5 million from \$4.3 million in the first quarter of 2015. This was primarily due to revenue recognized under the 2015 FPA008 license and collaboration agreement with BMS, under which Five Prime is reimbursed for the immuno-oncology trial expenses.
- 1 **R&D Expenses.** Research and development expenses for the first quarter of 2016 increased by \$7.1 million, or 63%, to \$18.3 million from \$11.2 million in the first quarter of 2015. This increase was primarily related to advancing the FPA144, preclinical and immuno-oncology research programs.
- 1 **G&A Expenses.** General and administrative expenses for the first quarter of 2016 increased by \$4.4 million, or 105%, to \$8.6 million from \$4.2 million in the first quarter of 2015. This increase was primarily due to increases in stock-based compensation expenses.
- 1 **Net Loss.** Net loss for the first quarter of 2016 was \$13.0 million, or \$0.49 per basic and diluted share, compared to a net loss of \$11.0 million, or \$0.44 per basic and diluted share, for the first quarter of 2015.
- 1 **Shares Outstanding.** Total shares outstanding were 28.2 million as of April 29, 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 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 96354727. 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 full-year 2016 net cash used in operating activities and the portion of net cash used in operating activities attributable to tax payments; and (v) 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>March 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$481,986	\$ 517,466
Total assets	509,256	548,285
Total current liabilities (excluding deferred revenue)	33,573	61,859
Deferred revenue (in total, including short term portion)	44,129	48,777
Total stockholders' equity (deficit)	428,137	433,206

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

	Three Months Ended	
	March 31,	
	<u>2016</u>	<u>2015</u>
Collaboration revenue	\$ 6,520	\$ 4,287
Operating expenses:		
Research and development	18,278	11,211
General and administrative	8,635	4,220
Total operating expenses	<u>26,913</u>	<u>15,431</u>
Loss from operations	(20,393)	(11,144)
Interest income	<u>536</u>	<u>108</u>
Loss before income tax	(19,857)	(11,036)
Income tax benefit	<u>6,817</u>	<u>—</u>
Net loss	<u><u>\$(13,040)</u></u>	<u><u>\$(11,036)</u></u>
Basic and diluted net loss per common share	<u><u>\$ (0.49)</u></u>	<u><u>\$ (0.44)</u></u>
Weighted-average shares used to compute basic and diluted net loss per common share	<u><u>26,351</u></u>	<u><u>25,072</u></u>

Investor Relations

415-365-5737

heather.rowe@fiveprime.com

Amy Kendall

Corporate Communications

415-365-5776

amy.kendall@fiveprime.com

 Primary Logo

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