# Five Prime Therapeutics Announces Second Quarter 2018 Financial Results

August 8, 2018

- *Cabiralizumab continues to advance in randomized Phase 2 trial in pancreatic cancer*
- *Bemarituzumab has advanced through Phase 1 safety lead-in of Phase 1/3 FIGHT global trial in gastric cancer; preparation for Phase 3 portion underway*
- *Four product candidates in the clinic, fifth planned by end of 2018*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 8, 2018-- 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 fiscal quarter ended June 30, 2018.

"We are pleased with the progress across our pipeline, including BMS's ongoing randomized Phase 2 clinical trial to evaluate cabiralizumab and OPDIVO® with and without chemotherapy as a second-line treatment in patients with advanced pancreatic cancer," said Aron Knickerbocker, chief executive officer of Five Prime Therapeutics. "We've also advanced bemarituzumab through the Phase 1 safety lead-in portion of the global FIGHT trial in gastric cancer and are on track to begin the Phase 3 portion of the trial before the end of the year. Additionally, we are pleased that the first clinical candidate from our immuno-oncology research collaboration with BMS, the TIM-3 antibody BMS-986258, is now in a Phase 1/2 trial investigating it as a single agent and in combination with OPDIVO. FPA150, our first-in-class B7-H4 antibody, is receiving strong interest from investigators and is progressing well in the Phase 1 trial."

Mr. Knickerbocker continued, "We are committed to making prudent clinical development decisions. Although we continue to observe efficacy in the PVNS Phase 2 trial, we have decided not to advance cabiralizumab into a pivotal trial in PVNS in 2019 because patients with this chronic, non-malignant disease demonstrate a lower tolerance for side effects, such as periorbital edema, relative to patients with cancer."

**Second Quarter 2018 Business Highlights and Recent Developments**

**Clinical Pipeline:**

**Cabiralizumab (FPA008):** An antibody that inhibits CSF1R and has been shown to block the activation and survival of macrophages.

- Bristol-Myers Squibb Company (BMS) continues to advance a randomized Phase 2 clinical trial in patients with locally advanced or metastatic pancreatic cancer.
  - The Phase 2 clinical trial (NCT03336216) evaluates cabiralizumab and OPDIVO (nivolumab) with and without mFOLFOX6 or gemcitabine/Abraxane chemotherapy compared to chemotherapy alone as a second-line treatment in patients with advanced pancreatic cancer. The Phase 2 trial is expected to enroll approximately 160 patients from the United States, Europe, Japan and Taiwan.
- Enrollment has closed and treatment continues in Five Prime's Phase 1a/1b clinical trial of cabiralizumab and OPDIVO (nivolumab).
  - Five Prime and BMS are evaluating the safety, tolerability and preliminary efficacy of the immunotherapy combination of cabiralizumab with the PD-1 immune checkpoint inhibitor OPDIVO in advanced solid tumors, including in more than 70 patients with pancreatic cancer.
  - A poster titled "Pharmacodynamics (PD) and Genomic Profiling of Pts Treated with cabiralizumab (cabira) + nivolumab (NIVO) Provide Evidence of On-Target Tumor Immune Modulations and Support Future Clinical Applications" was presented and chosen for oral discussion at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting on June 4.
    - Data suggest cabiralizumab in combination with nivolumab decreases immunosuppressive macrophages and increases CD8+ effector T-cells in the tumor microenvironment.
    - These data, together with preliminary clinical response data observed in patients with low tumor mutational burden, support further clinical development of cabiralizumab plus nivolumab in multiple indications, including pancreatic cancer.
- Five Prime has decided not to advance cabiralizumab in pigmented villonodular synovitis (PVNS), a rare, locally aggressive, non-malignant tumor of the synovium, into a pivotal trial under the current dosing schedule.
  - Five Prime has been enrolling a second cohort in the Phase 2 portion of a Phase 1/2 clinical trial (NCT02471716) to evaluate dosing every 4-6 weeks instead of every 2 weeks to optimize the therapeutic index of cabiralizumab in PVNS.
  - Although Five Prime continues to observe efficacy in this second cohort, the frequency of dose interruptions and discontinuations suggests that the current dosing schedule is unlikely to be optimal for a pivotal trial in this chronic, non-fatal disease.
  - The company is considering alternative dosing schedules as there continues to be a high unmet need for patients with PVNS.

- Apexigen, Inc. and Yale Cancer Center announced a clinical trial collaboration to evaluate APX005M (anti-CD40) in combination with cabiralizumab and OPDIVO. The phase 1/1b study (NCT03502330) is designed to identify a safe dose of APX005M to be added to cabiralizumab and OPDIVO. The expansion portion of the trial will study the triple drug combination in patients with melanoma, non-small cell lung cancer (NSCLC) or renal cell carcinoma (RCC) whose disease has progressed on a prior regimen containing a PD-1 or PD-L1 inhibitor without intervening therapy.

**Bemarituzumab (FPA144):** A first-in-class isoform-selective antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) in development as a targeted immuno-therapy for tumors that overexpress FGFR2b.

- Five Prime advanced through the Phase 1 safety lead-in portion (NCT03343301) of the Phase 1/3 FIGHT (FGFR2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment) global registrational trial.
    - The company expects to initiate patient dosing in the randomized, controlled Phase 3 portion of the trial before the end of the year in the U.S., Europe and Asia, including China and South Korea, where the incidence of gastric cancer is high.
    - The trial will evaluate bemarituzumab in combination with the modified FOLFOX6 standard-of-care chemotherapy regimen (mFOLFOX6) versus placebo plus mFOLFOX6 in approximately 550 patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b.
    - Five Prime is using immunohistochemistry (IHC) and circulating tumor DNA (ctDNA) tests to identify the estimated 10% of patients with FGFR2b-overexpressing gastric cancer who would be eligible for the trial.
- A poster titled “FIGHT: A Phase 3 Randomized, Double-Blind, Placebo Controlled Study Evaluating (Bemarituzumab) FPA144 and Modified FOLFOX6 (mFOLFOX6) in Patients with Previously Untreated Advanced Gastric and Gastroesophageal Cancer with a Dose Finding Phase 1 Lead-In” was presented at the 2018 ASCO Annual Meeting on June 3.

**FPA150 (anti-B7-H4):** A first-in-class antibody targeting B7-H4 designed to have two mechanisms of action: to block an inhibitory T-cell checkpoint pathway and to enhance killing of B7-H4 overexpressing tumors by ADCC. B7-H4 is frequently overexpressed in breast, ovarian, endometrial and bladder cancers.

- Five Prime continues to dose patients with FPA150 monotherapy in solid tumors in the dose escalation phase of the Phase 1a/1b clinical trial.
- Dose escalation will be followed by expansion in pre-specified cohorts of patients whose tumors have high B7-H4 expression levels, as measured by an IHC molecular diagnostic test. The initial targeted tumors for the expansion cohorts are breast, ovarian, endometrial and bladder cancers.
- During the dose escalation, Five Prime will also open an exploratory cohort to investigate FPA150 monotherapy in patients with tumors that overexpress B7-H4.

**BMS-986258 (anti-TIM-3):** A fully-human monoclonal antibody targeting TIM-3 (T-cell immunoglobulin and mucin domain-3), an immune checkpoint receptor that is known to limit the duration and magnitude of T-cell responses.

- In January 2018, BMS began a Phase 1/2 trial (NCT03446040), of BMS-986258, which is testing the antibody both as a single-agent and in combination with OPDIVO.
- BMS-986258 is the first clinical candidate from BMS’s immuno-oncology research collaboration with Five Prime.

**Preclinical Research and Development:**

**FPT155 (CD80-Fc):** A first-in-class CD80 fusion protein that uses the binding interactions of soluble CD80 to (i) directly engage CD28 to further enhance its co-stimulatory T-cell activation activity without inducing super agonism, and (ii) block CTLA-4 from competing for endogenous CD80, allowing CD28 signaling to prevail in T-cell activation in the tumor microenvironment.

- Studies in preclinical models suggest FPT155 has the potential to be a potent T-cell co-stimulator with strong monotherapy antitumor activity and may have a synergistic effect when combined with anti-PD1 therapy.
- Five Prime anticipates initiating a Phase 1 clinical trial of FPT155 in Australia in the fourth quarter of 2018.

**Summary of Financial Results and Guidance:**

- **Cash Position**. Cash, cash equivalents and marketable securities totaled $352.8 million as of June 30, 2018, compared to $292.7 million as of December 31, 2017. The increase in cash, cash equivalents and marketable securities was primarily attributable to $107.6 million in net proceeds from the January 2018 public offering of common stock and $34.5 million in milestone and upfront payments Five Prime received from collaboration partners net of cash used by Five Prime in operations to advance its three clinical stage programs as well as preclinical research and development.
- **Revenue**. Collaboration and license revenue for the second quarter of 2018 decreased by $0.2 million, or 3%, to $7.6 million from $7.8 million for the second quarter of 2017. This decrease was primarily due to decreased revenue recognized under the cabiralizumab collaboration agreement with BMS and the Fibrosis and CNS collaboration with UCB, offset by the collaboration and license revenue from our China collaboration with Zai Lab executed in December 2017.

- **R&D Expenses**. Research and development expenses for the second quarter of 2018 decreased by $8.3 million, or 20%, to $33.4 million from $41.7 million in the second quarter of 2017. This decrease was primarily related to decreased spending on preclinical programs offset by an increase in clinical expenses to advance our development programs.
- **G&A Expenses**. General and administrative expenses for the second quarter of 2018 increased by $0.4 million, or 4%, to $9.8 million from $9.4 million in the second quarter of 2017. This is primarily due to increased consulting and facility costs offset by reduced personnel costs, including stock-based compensation.
- **Net Loss**. Net loss for the second quarter of 2018 was $34.1 million, or $0.99 per basic and diluted share, compared to a net loss of $44.3 million, or $1.58 per basic and diluted share, for the second quarter of 2017.
- **Shares Outstanding**. Total shares outstanding were 34.5 million as of June 30, 2018.

**Cash Guidance.** Five Prime expects full-year 2018 net cash used in operating activities to be less than $135 million, which includes the previously mentioned milestone payments earned by Five Prime. Five Prime estimates ending 2018 with approximately $250 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 4194786. 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 Therapeutics**

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 the 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 or follow us on LinkedIn, Twitter and Facebook.

**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 regarding (i) the timing of the filing of INDs or their foreign equivalents; (ii) the timing of initiation, progress and scope of clinical trials for Five Prime's product candidates; (iii) the potential use of our product candidates, including in combination with other products, to treat patients; (iv) the extent of protein overexpression in certain patient populations; (v) the prevalence and incidence of certain diseases; (vi) Five Prime's full-year 2018 net cash used in operating activities; and (vii) the amount of Five Prime's cash, cash equivalents and marketable securities at the end of 2018. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during research, preclinical or clinical studies, changes in expected or existing competition, changes in the regulatory, pricing or reimbursement environment, and unexpected litigation or other disputes. Other factors that may cause 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" 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, 2018 | December 31, 2017 |
|---|---|---|
| **Balance Sheet Data:** | | |
| Cash, cash equivalents and marketable securities | $ 352,766 | $ 292,690 |
| Total assets | 396,778 | 344,047 |
| Total current liabilities (excluding deferred revenue) | 26,873 | 38,268 |
| Deferred revenue (in total, including short term portion) | 14,156 | 22,936 |
| Total stockholders' equity | 336,858 | 265,202 |

**Five Prime Therapeutics, Inc.**
**Condensed Statements of Operations**

***(in thousands, except per share amounts)***

| | For The Three Months Ended June 30, 2018 | For The Three Months Ended June 30, 2017 | For The Six Months Ended June 30, 2018 | For The Six Months Ended June 30, 2017 |
|---|---|---|---|---|
| Collaboration revenue | $ 7,580 | $ 7,822 | $ 40,066 | $ 17,957 |
| Operating expenses: | | | | |
| Research and development | 33,380 | 41,744 | 76,932 | 75,504 |
| General and administrative | 9,782 | 9,363 | 20,260 | 19,849 |
| Total operating expenses | 43,162 | 51,107 | 97,192 | 95,353 |
| Loss from operations | (35,582) | (43,285) | (57,126) | (77,396) |
| Interest and other income, net | 1,522 | 702 | 2,676 | 1,370 |
| Loss before income tax | (34,060) | (42,583) | (54,450) | (76,026) |
| Income tax provision | | (1,703) | | (1,703) |
| Net loss | $ (34,060) | $ (44,286) | $ (54,450) | $ (77,729) |
| Basic and diluted net loss per common share | $ (0.99) | $ (1.58) | $ (1.63) | $ (2.79) |
| Weighted-average shares used to compute basic and diluted net loss per common share | 34,401 | 27,946 | 33,363 | 27,813 |

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