

FIVE PRIME THERAPEUTICS INC

FORM 8-K (Current report filing)

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 19, 2017

Five Prime Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36070
(Commission
File Number)

26-0038620
(I.R.S. Employer
Identification No.)

Two Corporate Drive
South San Francisco, California
(Address of principal executive offices)

94080
(Zip Code)

Registrant's telephone number, including area code: (415) 365-5600

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicated by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement**License and Collaboration Agreement**

On December 19, 2017 (the “Effective Date”), Five Prime Therapeutics, Inc. (“FivePrime”) entered into a License and Collaboration Agreement (the “Agreement”) with Zai Lab (Shanghai) Co., Ltd. (“Zai”), pursuant to which FivePrime granted Zai exclusive rights to develop and commercialize FivePrime’s proprietary afucosylated FGFR2b antibody known as FPA144, and all fragments, conjugates, derivatives and modifications thereof (the “Licensed Antibody”) in China, Hong Kong, Macau and Taiwan (each, a “region,” and collectively, the “Territory”).

Under the terms of the Agreement, Zai will be responsible, at its expense, for (i) developing and commercializing products containing the Licensed Antibody (each, a “Licensed Product”) under a territory development plan and (ii) performing certain development activities to support FivePrime’s global development and registration of Licensed Products, including FivePrime’s global Phase 3 registrational trial of FPA144 in combination with FOLFOX in front-line gastric and gastroesophageal cancer (the “FPA144-004 Study”) in the Territory, under a global development plan.

Pursuant to the Agreement, Zai will make an upfront payment of \$5 million to FivePrime. Additionally, with respect to each Licensed Product, FivePrime will be eligible to receive up to \$39 million in specified developmental and regulatory milestone payments.

Zai will also be obligated to pay FivePrime a royalty, on a Licensed Product-by-Licensed Product and region-by-region basis, in the high teens or low twenties, depending on the number of patients Zai enrolls in the FPA144-004 Study, subject to reduction in certain circumstances, on net sales of each Licensed Product in the Territory until the latest of (i) the 11th anniversary of the first commercial sale of such Licensed Product in such region, (ii) the expiration of certain patents covering such Licensed Product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such Licensed Product expires in such region. FivePrime cannot determine the date on which Zai’s potential royalty payment obligations to FivePrime would expire because Zai has not yet developed any Licensed Products under the Agreement and therefore FivePrime cannot at this time identify the date of the first commercial sale or any related patents covering or regulatory exclusivity periods with respect to such Licensed Product.

Under the Agreement, provided that Zai enrolls and treats a specified number of patients in the FPA144-004 Study in China, Zai is eligible to receive a low single-digit percentage royalty, on a Licensed Product-by-Licensed Product basis on net sales of a Licensed Product outside the Territory until the 10th anniversary of the first commercial sale of each such Licensed Product outside the Territory.

Unless earlier terminated by either party, the Agreement will expire on a Licensed Product-by-Licensed Product and region-by-region basis upon the expiration of Zai’s payment obligations with respect to each Licensed Product under the Agreement. Zai may terminate the Agreement in its entirety at any time with advance written notice. Either party may terminate the Agreement in its entirety with written notice for the other party’s material breach if such party fails to cure the breach. FivePrime may terminate the Agreement in its entirety with written notice for Zai’s material breach of its diligence obligations with respect to development and obtaining marketing approval, and may terminate the agreement on a region-by-region basis for Zai’s breach of its diligence obligations with respect to timely commercialization of a Licensed Product in a region following marketing approval. FivePrime may terminate the agreement in its entirety if Zai or its affiliates or sublicensees commences a legal action challenging the validity, enforceability or scope of any of FivePrime’s patents in the Territory. Either party also may terminate the Agreement in its entirety upon certain insolvency events involving the other party.

The foregoing description of the Agreement is only a summary and is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to FivePrime’s Annual Report on Form 10-K for the fiscal year ending December 31, 2017.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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 FivePrime’s expectations and assumptions as of the date of this Current Report on Form 8-K. 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 Current Report on Form 8-K include statements regarding the (i) the development of FPA144; (ii) the number of patients that Zai will be able to enroll and treat in the Territory; and (iii) Five Prime’s potential receipt of upfront and milestone payments and royalties. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during 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 Current Report on Form 8-K are discussed in FivePrime’s most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission, including the “Risk Factors” contained therein. Except as required by law, FivePrime assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued December 19, 2017

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 19, 2017

Five Prime Therapeutics, Inc.

By: /s/ Francis Sarena

Francis Sarena

Chief Strategy Officer and Secretary

Five Prime Therapeutics and Zai Lab Announce Exclusive License Agreement for FPA144 Anti-FGFR2b Antibody in Greater China and Global Strategic Development Collaboration

Planned global Phase 3 FIGHT trial in front-line gastric and gastro-esophageal junction cancers to include sites in China where disease incidence is the highest in the world

SOUTH SAN FRANCISCO, Calif. and SHANGHAI, China, Dec. 19, 2017 — Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a biotechnology company discovering and developing innovative immuno-oncology protein therapeutics, and Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced an exclusive license agreement for FPA144 in Greater China and global strategic development collaboration. Five Prime's FPA144 is a first-in-class isoform-selective, humanized monoclonal antibody in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, including gastric and gastro-esophageal junction cancer. China has one of the highest incidence rates of gastric cancer in the world, with approximately 680,000 new cases annually. ^{1,2} The randomized, controlled Phase 3 portion of the FIGHT trial evaluating FPA144 plus chemotherapy is expected to start in the second half of 2018 and would serve as a global registrational study for the treatment of front-line gastric and gastro-esophageal junction cancers. Zai Lab will manage the Phase 3 portion of the trial in China.

"We believe Zai Lab is the right partner for FPA144 in Greater China for this innovative product," said Aron Knickerbocker, Chief Operating Officer of Five Prime and incoming Chief Executive Officer (effective January 1, 2018). "China accounts for more than 40% of new gastric cancer cases globally ², so it is critical to align strategically with a strong collaborator with the infrastructure, relationships and resources to help us advance FPA144 global development expeditiously. Zai Lab is ideally positioned given their experienced leadership team, focus on innovative drugs, and established expertise and network within oncology. We look forward to working with Zai Lab to carry out our worldwide development program for FPA144 and accelerate enrollment in the global Phase 3 portion of the FIGHT trial."

"Five Prime has pioneered the development of some very exciting and highly-targeted antibodies, including FPA144, which we believe holds tremendous promise for cancer patients in Greater China. We are committed to working with Five Prime to accelerate the global development timelines for this important investigational therapy," stated Samantha Du, Chairman and CEO of Zai Lab. "This strategic collaboration highlights the strength of our team and business model as the partner of choice in China and in delivering innovative therapies to patients in China and beyond."

Under the terms of the agreement, Five Prime has granted Zai Lab an exclusive license to develop and commercialize FPA144 in the Greater China territory: China, Hong Kong, Macau, and Taiwan. Zai Lab will be responsible for conducting the Phase 3 FIGHT trial in Greater China, including screening, enrollment and treatment of patients, and for commercialization of FPA144 in the Greater China territory. Five Prime will manufacture and supply FPA144 for the study. A Joint Steering Committee will be formed between the companies to oversee

development, regulatory and commercialization activities in greater China. Five Prime will receive a \$5 million upfront payment and is eligible to receive up to \$39 million in development and regulatory milestone payments. Five Prime is also eligible to receive from Zai Lab a royalty percentage on net sales of FPA144 in Greater China ranging from the high teens to the low twenties. Given the strategic importance of China to the development and commercialization of FPA144 and to align the interests of the two companies globally, Zai Lab is also eligible to receive a low single-digit royalty from Five Prime on net sales of FPA144 outside of Greater China.

“Gastric cancer is the fifth most common cancer in the world and the second most common in China. Patients whose tumors overexpress FGFR2b or have *FGFR2* gene amplification have an especially poor prognosis,” said Dr. Shukui Qin, the Executive Member of the Asian Clinical Oncology Society, Senior Vice President of Chinese Society of Clinical Oncology and the Director of Cancer Center of People’s Liberation Army. “I am encouraged that we may be able to identify those patients with companion diagnostics and potentially treat them more effectively with a highly targeted therapy like FPA144. There is a critical need for more effective and safe therapies for gastric cancer patients here, so I am pleased that I and my fellow oncologists throughout China can play an important role in the FIGHT trial.”

About FPA144

FPA144 is an isoform-selective, humanized monoclonal antibody in clinical 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 also been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells.

FPA144 is being evaluated as a potential treatment for gastric cancer and bladder cancer. In a Phase 1 trial, FPA144 demonstrated monotherapy activity in heavily pre-treated patients with FGFR2b-positive gastric cancer and did not exhibit certain toxicities that have been seen with less selective FGFR2 small molecule therapeutics. An estimated 10% of patients with gastric cancer have tumors that overexpress FGFR2b or have FGFR2 gene amplification, which is associated with poor prognosis.

About Five Prime

Five Prime Therapeutics, Inc. (NASDAQ:FPRX) 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.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. The company's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and global unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

Five Prime 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 the initiation, progress and scope of the FIGHT clinical trial; (ii) the potential use of FPA144 to treat patients with gastric and gastro-esophageal junction cancer; (iii) the extent of *FGFR2* gene amplification and FGFR2b protein overexpression in patients with gastric and gastro-esophageal junction cancer; and (iv) Five Prime's potential receipt of milestone payments and royalties. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during non-clinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected and changes in expected or existing competition. 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.

Zai Lab Forward-Looking Statements

This press release includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding the timing of the initiation, progress and scope of the FIGHT clinical trial, the potential use of FPA144 to treat patients with gastric and gastro-esophageal junction cancer, Five Prime's potential receipt of milestone payments and royalties from Zai Lab and Zai Lab's potential receipt of royalties from Five Prime. You can identify forward-looking statements because they contain words such as "believes" and "expects." Forward-looking statements are based on Zai Lab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause

actual results to differ materially from those in the forward-looking statements are set forth in Zai Lab's filings with the Securities and Exchange Commission. Zai Lab undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

REFERENCES:

¹ Translational Gastrointestinal Cancer, Vol 2, Supplement 1 (June 2013); *A current view of gastric cancer in China*, Zhaode Bu, Jiafu Ji

² CA: A Cancer Journal for Clinicians, 25 January 2016; *Cancer statistics in China, 2015*, Wanqing Chen et al

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