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): October 18, 2017

FibroGen, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36740**	**77-0357827**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
(Address of principal executive offices, including zip code)

(415) 978-1200
(Registrant's telephone number, including area code)

Not Applicable
(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:

☐ 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))

Indicate 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 8.01 Other Events

On October 18, 2017, FibroGen, Inc. (Company) and its subsidiary, FibroGen China Medical Technology Development Co., Ltd., announced that the China Food and Drug Administration has accepted the Company's submission of its New Drug Application (NDA) for registration of roxadustat (FG-4592 or 罗沙司他), a novel oral investigational treatment for anemia in dialysis-dependent chronic kidney disease (CKD) and non-dialysis-dependent CKD patients. Under the terms of FibroGen's agreement with AstraZeneca AB, a collaboration partner of the Company, the NDA submission triggers a $15 million milestone payment, payable to the Company by AstraZeneca.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Announces Acceptance by China FDA of Roxadustat New Drug Application (NDA) for Treatment of Anemia Associated with Dialysis and Non-Dialysis Chronic Kidney Disease (CKD)" dated October 18, 2017

SIGNATURES

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

Dated: October 18, 2017

FIBROGEN, INC.

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Counsel

FibroGen

NEWS RELEASE

FIBROGEN ANNOUNCES ACCEPTANCE BY CHINA FDA OF ROXADUSTAT NEW DRUG APPLICATION (NDA) FOR TREATMENT OF ANEMIA ASSOCIATED WITH DIALYSIS AND NON-DIALYSIS CHRONIC KIDNEY DISEASE (CKD)

Triggers Milestone Payment of $15 Million by AstraZeneca

SAN FRANCISCO, Oct. 18, 2017 — FibroGen, Inc. (NASDAQ:FGEN), a science-based biopharmaceutical company, and its subsidiary FibroGen China Medical Technology Development Co., Ltd. (FibroGen China), today announced that the China Food and Drug Administration (CFDA) has accepted the company's recently submitted New Drug Application for registration of roxadustat (FG-4592 or 罗沙司他), a novel oral investigational treatment for anemia in dialysis-dependent CKD (DD-CKD) and non-dialysis-dependent CKD (NDD-CKD) patients. Under the terms of FibroGen's agreement with AstraZeneca, the NDA submission triggers a $15 million milestone payment, payable to FibroGen by AstraZeneca.

"This is an important milestone for FibroGen and for roxadustat. We look forward to working with the CFDA on this important new drug registration application process," said Thomas B. Neff, FibroGen's Chief Executive Officer. "In China, there is a significant need for a new therapeutic for patients with anemia associated with CKD, a serious and potentially life-threatening condition."

"We are grateful for the opportunity to address a substantial unmet medical need for the treatment of anemia associated with CKD in China, where the CKD dialysis population is growing rapidly and large segments of the CKD non-dialysis population are not reached by current therapies," said Chris Chung, FibroGen's Vice President of China Operations. "If approved, roxadustat will be the first HIF-PHI available worldwide, with China as the first approval country for this first-in-class drug."

The New Drug Application for roxadustat is based on the results of FibroGen's two Phase 3 multi-center, randomized, controlled studies conducted in China, one study in CKD dialysis comparing roxadustat against a branded epoetin alfa, and one study in CKD non-dialysis comparing roxadustat against placebo. Both of the Phase 3 studies met their primary efficacy endpoints with no new or unexpected safety signals identified.

About Anemia Associated with CKD in China

Anemia commonly develops in association with chronic kidney disease and is linked to significant morbidity and mortality in both the dialysis and non-dialysis populations. CKD affects an estimated 119.5 million patients in China. Although CKD may occur at any age, it is more common in aging populations, and its prevalence is increasing. CKD can be both a cause and a consequence of cardiovascular disease and is a critical healthcare issue. With the exception of kidney transplantation, there is no treatment available that is curative, or has the ability to stop kidney deterioration.

The dialysis population in China, which exceeds 400,000 patients, has been growing at a double-digit rate. The number of patients that require anemia therapy in China and other emerging markets is expected to increase steadily, as the CKD population continues to grow and the number of hemodialysis and peritoneal dialysis patients increases. There is a significant opportunity for roxadustat to treat patients on dialysis (hemodialysis and peritoneal dialysis) and not on dialysis, as well as to address need in the large number of patients whose anemia remains undertreated or untreated in China.

About Roxadustat

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule in global Phase 3 clinical development worldwide as a therapy for anemia associated with chronic kidney disease (CKD) with the potential to offer a safer, more effective, more convenient, and more accessible treatment than the current therapies available for anemia in CKD, such as injectable erythropoiesis stimulating agents (ESAs). Roxadustat promotes erythropoiesis through increasing endogenous erythropoietin, improving iron regulation, and reducing hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis – increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of CKD patients – including in the presence of inflammation and without a need for supplemental intravenous iron.

FibroGen, along with collaboration partners Astellas Pharma Inc. and AstraZeneca AB, has designed a Phase 3 program to support regulatory approval of roxadustat for both NDD-CKD and DD-CKD patients worldwide. To date, this is the largest Phase 3 clinical program in anemia, enrolling more than 10,000 subjects worldwide. FibroGen anticipates filing a U.S. New Drug Application (NDA) for roxadustat for the treatment of anemia associated with CKD in 2018.

FibroGen and its partner AstraZeneca are collaborating on the development and commercialization of roxadustat in the U.S., China, and other markets. In China, FibroGen China is conducting all clinical trials and will hold all roxadustat regulatory licenses and permits to be issued by China regulatory authorities. After market approval, FibroGen China will manage manufacturing and medical affairs and AstraZeneca will manage launch and commercialization activities in China. FibroGen and Astellas are collaborating for the development and commercialization of roxadustat in Europe, Japan, the Commonwealth of Independent States, the Middle East, and South Africa.

In the next stage of its development program, roxadustat is entering a Phase 2/3 clinical trial in China and a Phase 3 clinical trial in the U.S. for the treatment of anemia in patients with myelodysplastic syndromes (MDS).

For information about roxadustat studies currently recruiting patients, please visit clinicaltrials.gov at: https://clinicaltrials.gov/ct2/results?term=FG-4592&Search=Search

About FibroGen, Inc.

FibroGen, Inc., headquartered in San Francisco, CA with subsidiary offices in Beijing and Shanghai, PRC, is a leading science-based biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology and clinical development to advance innovative medicines for the treatment of anemia, and fibrotic disease and cancer. Roxadustat, the company’s most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase activity in worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD) with the exception of China, where a new drug application is currently under review by the CFDA for

regulatory approval. Roxadustat is also entering Phase 3 development for anemia in myelodysplastic syndromes (MDS). Pamrevlumab, a fully-human monoclonal antibody, that inhibits the activity of CTGF, is in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), pancreatic cancer, and Duchenne muscular dystrophy (DMD). FibroGen is also developing a biosynthetic cornea in China. For more information, please visit www.fibrogen.com.

Forward-Looking Statements

This release contains forward-looking statements regarding our strategy, future plans and prospects, including statements regarding the development of the company's product candidate roxadustat in China, the potential safety and efficacy profile of roxadustat and its potential to treat patients, including in anemia associated with myelodysplastic syndromes, and our clinical plans, including timing for planned initiation of clinical trials in China and the U.S. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of our various programs, including the enrollment and results from ongoing and potential future clinical trials for pamrevlumab, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and June 30, 2017, respectively, filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release, except as required by law.

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Contact

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