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): March 31, 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))

Item 8.01 Other Events

On March 31, 2017, FibroGen, Inc. issued a press release in which it reported approval by the China Food and Drug Administration of its clinical trial application in China for a Phase 2/3 pivotal trial of roxadustat in anemia associated with lower risk myelodysplastic syndromes. The Company received notification of the approval on March 21, 2017.

A copy of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “FibroGen Announces China FDA Approval of CTA to Conduct Pivotal Phase 2/3 Clinical Trial of Roxadustat in Anemia Associated with Lower Risk MDS” dated March 31, 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.

FIBROGEN, INC.

Dated: March 31, 2017

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

INDEX TO EXHIBITS

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FIBROGEN

NEWS RELEASE

FIBROGEN ANNOUNCES CHINA FDA APPROVAL OF CTA TO CONDUCT PIVOTAL PHASE 2/3 CLINICAL TRIAL OF ROXADUSTAT IN ANEMIA ASSOCIATED WITH LOWER RISK MDS

Expands Roxadustat Development Program Into Oncology-Related Anemia in China

SAN FRANCISCO, March 31, 2017 — FibroGen, Inc. (NASDAQ: FGEN), a science-based biopharmaceutical company, today announced the approval by the China Food and Drug Administration (CFDA) of the Company's clinical trial application (CTA) in China for a Phase 2/3 pivotal trial of roxadustat in anemia associated with lower risk myelodysplastic syndromes (MDS). FibroGen and AstraZeneca (NYSE:AZN) are collaborating on the development and commercialization of roxadustat in China, the U.S., and other major markets. FibroGen is conducting all clinical trials and regulatory submissions in both the U.S. and China, and will retain all regulatory licenses and manufacturing permits in China.

This Phase 2/3 clinical trial will evaluate the safety and efficacy of roxadustat in non-transfusion dependent, lower risk MDS patients with anemia. The initial open-label portion of the study is expected to enroll up to 40 patients, with 135 patients planned for the randomized, double-blind, placebo-controlled Phase 3 portion of the study, in which subjects will be randomized 2:1 to receive roxadustat or placebo three-times-weekly (TIW) for 26 weeks. The Company expects to initiate this Phase 2/3 study in the second half of 2017.

In addition, the Company anticipates initiating a U.S. Phase 3 MDS clinical trial in the third quarter of 2017. The pivotal U.S. study is a randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of roxadustat for the treatment of anemia in transfusion-dependent lower risk MDS patients.

About MDS Anemia in China

Myelodysplastic syndromes ("MDS") are a group of disorders characterized by poorly formed or dysfunctional blood cells, leading to anemia in most patients. Anemia is associated with increased risk of hospitalization, cardiovascular complication, need for blood transfusion, exacerbation of other serious medical conditions, and death. In addition, anemia frequently leads to significant fatigue, cognitive dysfunction, and decreased quality of life. Currently, there is no medicine approved for treating anemia in MDS in China. MDS patients typically rely on repeated blood transfusions; however, in China, due to limited blood supply and challenges in accessing transfusions, anemia in most MDS patients is undertreated.

About Roxadustat

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule in global Phase 3 clinical development as a potential therapy for anemia associated with chronic kidney disease (CKD). Roxadustat

is a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) that promotes erythropoiesis through increasing endogenous erythropoietin, improving iron regulation, and reducing hepcidin. Administration of roxadustat has been shown in clinical trials 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.

Roxadustat is currently advancing through Phase 3 clinical trials worldwide, supported by extensive Phase 2 clinical data demonstrating correction and maintenance of hemoglobin levels in multiple subpopulations of CKD anemia patients. To date, roxadustat has been evaluated in Phase 1 and Phase 2 studies, involving more than 1,400 subjects. Globally, a total of 15 Phase 3 studies, with target enrollment of about 10,000 patients worldwide, are currently being conducted to support independent regulatory approvals of roxadustat in both non-dialysis-dependent and dialysis-dependent CKD patients in the U.S., Europe, Japan, and China. Roxadustat is also entering a Phase 3 clinical trial in the U.S., and a Phase 2/3 in China for treatment of anemia in patients with myelodysplastic syndromes (MDS). For information about roxadustat studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen, Inc.

FibroGen, Inc., headquartered in San Francisco with subsidiary offices in Beijing and Shanghai, is a leading science-based biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in fibrosis and hypoxia-inducible factor (HIF) biology and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat (FG-4592), the company's most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase activity in Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), and is entering Phase 3 development for anemia in lower risk myelodysplastic syndromes (MDS). Pamrevlumab (FG-3019), a fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor (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, including in anemia associated with myelodysplastic syndromes, the potential for regulatory submissions, and our clinical plans, including timing for planned initiation of clinical trials in China and the U.S. 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 non-clinical and clinical programs, including enrollment and conduct of our clinical trials, and our collaboration partners' clinical trials for roxadustat in anemia associated with CKD, the continued progress of our plans and programs in China, including clinical development of and regulatory filing outcomes for anemia associated with myelodysplastic syndromes, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, 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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