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): June 7, 2018

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 June 7, 2018, FibroGen, Inc. issued a press release in which it announced completion of patient enrollment in its Phase 3 studies supporting U.S. NDA submission for roxadustat in anemia associated with chronic kidney disease.

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 Completion of Enrollment in U.S. Phase 3 Clinical Program for Roxadustat in Anemia Associated with Chronic Kidney Disease" dated June 7, 2018

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: June 7, 2018

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

FibroGen

NEWS RELEASE

FibroGen Announces Completion of Enrollment in U.S. Phase 3 Clinical Program for Roxadustat in Anemia Associated with Chronic Kidney Disease

SAN FRANCISCO, Calif., June 7, 2018 – FibroGen, Inc. (NASDAQ: FGEN), a biopharmaceutical company, today announced the completion of patient enrollment in the Phase 3 studies supporting the U.S. new drug application (NDA) submission for roxadustat in anemia associated with chronic kidney disease (CKD). The Phase 3 clinical program is evaluating the use of roxadustat for the treatment of anemia in both dialysis-dependent and non-dialysis-dependent CKD patients.

“We are pleased to have achieved this critical step in our roxadustat Phase 3 clinical program, and we look forward to reporting topline results from these studies by the end of this year, with pooled safety analyses available in 2019,” said K. Peony Yu, Chief Medical Officer, FibroGen. “The results of these studies will support the submission of an NDA in the first half of 2019.”

A total of approximately 9,000 CKD patients were enrolled across the seven studies sponsored by FibroGen and its partners Astellas Pharma Inc. and AstraZeneca in both dialysis-dependent patients and non-dialysis-dependent patients. Subpopulations of interest include patients initiating dialysis (incident dialysis) and patients with inflammation.

Previously reported results from extensive Phase 2 studies and Phase 3 studies from China and from Japan have shown roxadustat to be effective in correcting and/or maintaining hemoglobin levels in various populations of CKD patients with anemia. Roxadustat has shown positive effects on iron metabolism, and the ability to correct and maintain hemoglobin levels without requiring concomitant administration of intravenous iron. Roxadustat has been well-tolerated in all studies to date.

“This is an exciting time for us as we advance the first oral therapy for anemia in CKD one step closer to patients,” said Thomas B. Neff, Chief Executive Officer, FibroGen. “Our goal is to provide these patients and those who care for them with a new therapeutic option with the potential to be safer, more effective, more convenient, and more accessible than currently available therapies.”

About CKD and Anemia Anemia is a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin (“Hb”), a protein in red blood cells that carries oxygen to cells throughout the body. Anemia is associated with increased risk of hospitalization, cardiovascular complications, need for blood transfusion, exacerbation of other serious medical conditions, and death. In addition, anemia frequently causes significant fatigue, cognitive dysfunction, and decreased quality of life. The more severe the anemia, as measured by lower Hb levels, the greater the health impact on patients. Severe anemia is common in patients with CKD, cancer, MDS, inflammatory diseases, and other serious illnesses. Even when it accompanies prevalent and serious diseases, anemia is often not effectively treated.

Anemia is particularly prevalent in patients with CKD, which is a critical healthcare problem in the U.S. and Europe, and most commonly caused by diabetes and hypertension. CKD affects more than 200 million people worldwide and significantly increases healthcare costs for those patients. CKD is generally a progressive disease characterized by gradual loss of kidney function that may eventually lead to kidney failure, which is also known as end-stage renal disease ("ESRD"). Patients with ESRD require renal replacement therapy — either dialysis treatment or kidney transplantation. CKD accompanied by anemia is associated with worse health outcomes than CKD alone, including more rapid disease progression and an increased death rate. There are five stages of CKD that are primarily defined by a measure of the filtration function of the kidney (GFR).

In the U.S., according to the USRDS, a majority of dialysis eligible CKD patients are currently on dialysis. Of the approximately 475,000 patients receiving dialysis in the U.S., approximately 83% were being treated with ESAs for anemia. Despite the presence of anemia in stages 3 and 4 CKD patients, in clinical practice, patients typically do not receive ESA treatment for their anemia until they initiate dialysis. As of 2014, approximately 14% of U.S. NDD-CKD patients were being treated with ESAs prior to initiation of dialysis (2016 USRDS ADR). In many CKD patients, the disease progresses gradually over decades and patients can spend years suffering from the symptoms and negative health effects of anemia before they receive treatment. Many of these patients die from cardiovascular events before they initiate dialysis.

About Roxadustat

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule currently 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 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.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia in patients with CKD in territories including Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa. AstraZeneca and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia in patients with CKD in the U.S., China, and other markets.

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. Globally, the Phase 3 program encompasses a total of 15 Phase 3 studies 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.

About FibroGen

FibroGen, Inc., headquartered in San Francisco, with subsidiary offices in Beijing and Shanghai, is a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor (HIF), connective tissue growth factor (CTGF) biology, and clinical development to advance innovative medicines for the treatment of anemia, 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 a New Drug Application currently under review in China by the State Drug Administration or SDA (formerly the China Food and Drug Administration). Roxadustat is in Phase 3 clinical development in the U.S. and Europe for anemia associated with myelodysplastic syndromes (MDS). Pamrevlumab, an anti-CTGF human monoclonal antibody, is advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for 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 candidates pamrevlumab and roxadustat, the potential safety and efficacy profile of our product candidates, and our clinical, regulatory, and commercial plans, and those of our partners. 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," "will", "should," "on track," "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, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, and our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2018 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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