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): July 25, 2016

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 July 25, 2016, FibroGen, Inc. issued a press release with its collaboration partner Astellas Pharma Inc. confirming the initiation of their Phase 3 studies of roxadustat in patients with chronic kidney disease ("CKD") in Japan and announcing results from their two completed Phase 2 studies of roxadustat in patients with CKD in Japan. 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 "Astellas and FibroGen Announce First Patient Treated in Phase 3 Studies and Positive Phase 2 Results of Roxadustat in Patients with Chronic Kidney Disease in Japan" dated July 25, 2016

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: July 26, 2016

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

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release titled “Astellas and FibroGen Announce First Patient Treated in Phase 3 Studies and Positive Phase 2 Results of Roxadustat in Patients with Chronic Kidney Disease in Japan” dated July 25, 2016

Astellas and FibroGen Announce First Patient Treated in Phase 3 Studies and Positive Phase 2 Results of Roxadustat in Patients with Chronic Kidney Disease in Japan

Tokyo and San Francisco, July 25, 2016 — Astellas Pharma Inc. (TSE:4503, "Astellas") and FibroGen, Inc. (Nasdaq: FGEN) ("FibroGen"), today announced the dosing of the first patient in Phase 3 trials in Japan of roxadustat (development code: ASP1517/FG-4592) for treatment of anemia in chronic kidney disease (CKD), which triggered a $10 million milestone payment from Astellas to FibroGen. The initiation of Phase 3 studies in Japan follows the positive results from two Phase 2 studies in Japan of roxadustat in CKD patients on dialysis and in CKD patients not on dialysis.

In the Phase 2 studies in Japan of CKD patients receiving dialysis and not receiving dialysis, roxadustat was well tolerated and met the primary objective of demonstrating dose-related rates of hemoglobin (Hb) increase measured over the first six weeks of treatment, as well as anemia correction and Hb maintenance over the 24-week treatment period.

"Anemia is a common consequence of CKD and contributes to the poor quality of life associated with this disease," said Dr. Bernie Zeiher, President, Development of Astellas. "We are pleased to advance roxadustat to Phase 3 studies in Japan, as a potential new oral treatment of anemia in CKD patients."

"We are encouraged by accumulated results showing roxadustat's potential to be effective in treating anemia and well tolerated in Phase 2 clinical studies around the globe in multiple types of CKD patients with anemia. We appreciate the strong support from patients and physicians with respect to the roxadustat clinical development program, and believe roxadustat has the potential to improve the care of CKD patients with anemia," said Thomas B. Neff, Chief Executive Officer of FibroGen.

About the Studies

The Phase 2 study in Japan of CKD patients not on dialysis was a multi-center, randomized, parallel-group, placebo-controlled, double-blind study over 24 weeks. The subjects, 107 CKD patients not yet receiving dialysis, were randomized to one of three roxadustat treatment arms (50 mg, 70 mg, 100 mg) or to a placebo arm, with roxadustat orally administered three times weekly (TIW) for the first six weeks of the study to evaluate dose response of efficacy and safety. This was followed by dose titration every four weeks until hemoglobin response was achieved, at which point hemoglobin was maintained with patients randomized to one of two dosing regimens (continuation of TIW dosing or a change to weekly (QW) dosing).

Results showed achievement in the full analysis set of dose response in the three roxadustat treatment arms, with a mean rate of Hb increase of 0.200, 0.453, and 0.570 g/dL per week (50 mg, 70 mg, 100 mg, respectively), as measured over the first six weeks of the study, compared to a mean Hb decrease of 0.052 g/dL per week in subjects receiving placebo. Of note, 93.8% of roxadustat-treated subjects achieved hemoglobin correction as measured by hemoglobin response defined as Hb more than or equal to 10 g/dL and Hb increase of at least 1 g/dL from baseline. In the placebo arm, hemoglobin response was achieved in 14.8% of the subjects. Roxadustat was well tolerated, with no deaths and no major adverse cardiovascular events reported for roxadustat-treated patients.

The Phase 2 study in Japan in 130 CKD patients receiving dialysis was a multi-center, randomized, darbepoetin-controlled, double blind (roxadustat arms), open-label (darbepoetin) study over 24 weeks in CKD patients on chronic stable dialysis. The subjects who had discontinued previous standard-of-care therapy (erythropoiesis-stimulating agents) to reach Hb levels of < 9.5 g/dL were randomized to one of three roxadustat arms (administered orally TIW at a fixed dose) or to the darbepoetin arm (darbepoetin administered intravenously QW) over the first six weeks of the study to evaluate dose response of efficacy and safety, followed by dose titration to the desired Hb level every four weeks.

During weeks 18 to 24, average Hb levels achieved (a secondary endpoint) in the full analysis set were 10.31 g/dL (1.33 g/dL Hb increase), 10.20 g/dL (1.37 g/dL Hb increase), and 10.53 g/dL (1.57 g/dL Hb increase), respectively, in the roxadustat treatment arms, compared to 10.25 g/dL (1.42 g/dL Hb increase) in the darbepoetin arm. Roxadustat was well tolerated in this study, with one death reported in a subject who suffered from bacterial pneumonia and thromboembolism, whose death was deemed unrelated to roxadustat; no deaths were reported in the other treatment arms.

FibroGen and development partner Astellas have, in total, completed six roxadustat Phase 2 studies in CKD patients on dialysis and CKD patients not on dialysis in the U.S., Europe and China. The results reported in these Phase 2 studies in Japan are consistent with the results from the Phase 2 studies in other regions. Completion of these studies enabled Astellas to initiate the Phase 3 clinical development program in Japan in 2016. This is consistent with the ongoing Phase 3 clinical development program for roxadustat and treatment of anemia in CKD patients that includes 10 current Phase 3 studies: eight global studies in support of U.S. and Europe requirements and two studies in support of China marketing approval.

About roxadustat

Roxadustat is currently in Phase 3 development as a potential therapy for anemia associated with CKD in both patients on dialysis and not on dialysis. Roxadustat is an orally administered small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase activity. HIF is a protein transcription factor that induces the natural physiological response to conditions of low oxygen, “turning on” erythropoiesis (the process by which red blood cells are produced) and other protective pathways.

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. For information about roxadustat studies that are currently recruiting patients, please visit clinicaltrials.gov at this link:

https://clinicaltrials.gov/ct2/results?term=roxadustat&Search=Search.

About Chronic Kidney Disease

Chronic kidney disease (CKD) affects more than 200 million people worldwide and more than 30 million adults in the U.S. Although it can occur at any age, it becomes more common in aging populations, and the prevalence is increasing. Anemia is a common complication of CKD and is associated with significant morbidity and mortality in dialysis and non-dialysis populations. In addition, CKD can be both a cause and a consequence of cardiovascular disease and is now a critical worldwide healthcare issue that represents a large and growing unmet medical need. Currently, no curative treatment or ability to stop kidney deterioration in patients with CKD exists with the exception of kidney transplantation.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

About FibroGen

FibroGen is a research-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. The company utilizes its extensive experience in fibrosis and hypoxia-inducible factor (HIF) biology to generate development programs in multiple therapeutic areas. Its most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases, or HIF-PHs, in Phase 3 clinical development for the treatment of anemia in CKD. A second product candidate, FG-3019, is a monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), pancreatic cancer, and Duchenne muscular dystrophy. For more information please visit: www.fibrogen.com.

Forward-Looking Statements: Astellas

This press release includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future. Statements made in the future tense, and words such as “anticipate,” “expect,” “project,” “continue,” “believe,” “plan,” “estimate,” “pro forma,” “intend,” “potential,” “target,” “forecast,” “guidance,” “outlook,” “seek,” “assume,” “will,” “may,” “should,” and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Actual results may differ materially depending on a number of factors. This press release contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these pharmaceuticals nor provide medical advice of any kind.

Forward-Looking Statements: FibroGen

This release contains forward-looking statements, including statements regarding the tolerability of roxadustat, the potential ability of roxadustat to correct and maintain hemoglobin levels in CKD patients not on dialysis, and the potential for continued safety or efficacy in our Phase 3 studies. Our actual results may differ materially from these early data and any forward-looking statements due to risks and uncertainties that are described in our Annual Report on Form 10-K and our quarterly reports on Form 10-Q filed with the Securities and Exchange Commission, 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.

Astellas Contact:

Corporate Communications
TEL: 03-3244-3201 FAX: 03-5201-7473
http://www.astellas.com/en

FibroGen Contact:

Leanne C. Price
FibroGen, Inc.
lprice@fibrogen.com
1.415.978.1200