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 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))

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 31, 2017, FibroGen, Inc. and its collaboration partner, Astellas Pharma Inc., issued a press release in which they announced topline results from the first Phase 3 trial completed in Japan by Astellas Pharma Inc. for roxadustat for anemia in chronic kidney disease patients on peritoneal dialysis with or without previous treatment with erythropoiesis-stimulating agents.

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 Positive Topline Results from First Japan Phase 3 Trial for Roxadustat in Chronic Kidney Disease Patients with Anemia" dated October 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.

Dated: October 31 2017

FIBROGEN, INC.

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

Press Release

Astellas and FibroGen Announce Positive Topline Results from First Japan Phase 3 Trial for Roxadustat in Chronic Kidney Disease Patients with Anemia

Tokyo and San Francisco, October 31, 2017 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") and FibroGen, Inc. (Nasdaq: FGEN, CEO: Thomas B. Neff, "FibroGen") today announced that the first Phase 3 trial in Japan evaluating roxadustat (development code: ASP1517/FG-4592) for anemia in chronic kidney disease (CKD) patients on peritoneal dialysis (PD) with or without previous treatment with erythropoiesis-stimulating agents (ESAs) demonstrated positive efficacy results from Week 18 to Week 24 of the treatment period. The study enrolled a total of 56 PD patients, 43 patients previously receiving ESAs (ESA-conversion patients), and 13 patients not previously receiving ESAs (ESA-naïve patients). Roxadustat was well tolerated and shown to maintain hemoglobin (Hb) levels within the target Hb range in both ESA-conversion patients and ESA-naïve patients. The Hb maintenance rate, measured as the proportion of subjects with average Hb levels within the target Hb range of 10.0 to 12.0 g/dL for Weeks 18 to 24, was 92.3% in ESA-naïve and 74.4% in ESA-conversion patients. The preliminary safety analysis for this trial is consistent with the safety profile of roxadustat in previous clinical trials.

"We are encouraged by these Phase 3 data and will continue to advance roxadustat in late-stage clinical studies with the goal of bringing this important therapeutic option to patients in need," said Mike Allen, M.D, senior vice president, urology/nephrology therapeutic area head, Astellas. "Anemia is common among patients with advanced kidney disease and is one of the factors that contribute to the suffering of patients with this disease."

"We are pleased to see these positive results from the first completed Japan Phase 3 study for roxadustat," said Thomas B. Neff, CEO, FibroGen, Inc. "We appreciate the dedicated efforts of our partner Astellas, as we work together to bring this new therapy to patients with anemia associated with CKD in Japan."

Further detailed data from this study are expected to be reported in the future.

Astellas is a sponsor of a total of six Phase 3 studies of roxadustat in Japan for anemia associated with CKD in both dialysis and non-dialysis patients.

###

About the Study

The multicenter, randomized, open-label, non-comparative Phase 3 trial evaluated the safety and efficacy of roxadustat for anemia in 56 CKD patients receiving PD therapy. 43 patients were previously receiving ESAs (ESA-conversion patients), and 13 patients were not previously receiving ESAs (ESA-naïve patients). The ESA-naïve subjects were randomized to one of two roxadustat treatment arms with a starting dose of either 50 mg or 70 mg, orally administered three times weekly (TIW), evaluating hemoglobin (Hb) correction. The ESA-conversion subjects received a roxadustat starting dose of either 70 mg or 100 mg based on the dose of ESAs they were previously receiving, evaluating Hb levels in conversion. The efficacy endpoint was maintenance rate of the target Hb level measured at week 18 to week 24 (time frame: up to week 24). Maintenance rate of the target Hb level was defined as the proportion of subjects achieving the average Hb level of 10.0 to 12.0 g/dL for Weeks 18 to 24).

About Chronic Kidney Disease

CKD affects more than 200 million people worldwide[1] and specifically in Japan, the prevalence of CKD has increased significantly over time.[2] 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 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

1 Ojo, A. Addressing the Global Burden of Chronic Kidney Disease Through Clinical and Translational Research. Transactions of the American Clinical and Climatological Association. 2014; 125: 229-246.

2 Nagata M, Ninomiya T, Doi Y, Yonemoto K, Kubo M, Hata J, Tsuruya K, Iida M, Kiyohara Y. *Nephrol Dial Transplan*t. 2010 Aug; 25(8):2557-64.

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. Roxadustat is also in clinical development for anemia in MDS. 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 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 https://www.astellas.com/en.

About FibroGen, Inc.

FibroGen, Inc., headquartered in San Francisco, California, 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), except in 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 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.

Astellas Cautionary Notes

The safety and efficacy of the agent discussed herein are under investigation and have not been established. There is no guarantee that the agent will receive regulatory approval and become commercially available for the uses being investigated. Information about pharmaceutical products (including products currently in development) which is included in this press release are not intended to constitute an advertisement or medical advice.

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management’s current assumptions and beliefs in light of the information currently

available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

FibroGen 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 Japan, including whether any additional Phase III or other ongoing studies in Japan will support the results described above, whether the results will be sufficient to support filing for regulatory approval, if undertaken by Astellas in Japan, the potential safety and efficacy profile of roxadustat and its potential to treat patients. 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 FibroGen's and its collaboration partners' Phase 3 trials for roxadustat, 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.

Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473

Karen L. Bergman
FibroGen, Inc.
VP, Investor Relations and Corporate Communications
TEL: +1-415-978-1433
kbergman@fibrogen.com