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): May 31, 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 May 31, 2018, FibroGen, Inc. and its collaboration partner, Astellas Pharma Inc., issued a press release in which they announced topline results from the double-blind Phase 3 study completed in Japan by Astellas Pharma Inc. for roxadustat in hemodialysis-dependent chronic kidney disease patients with anemia.

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 Topline Results from Double-Blind Japan Phase 3 Study for Roxadustat in Hemodialysis Chronic Kidney Disease Patients with Anemia" dated May 31, 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: May 31, 2018

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

Press Release

Astellas and FibroGen Announce Topline Results from Double-Blind Japan Phase 3 Study for Roxadustat in Hemodialysis Chronic Kidney Disease Patients with Anemia

TOKYO and San Francisco, May 31, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and FibroGen, Inc. (Nasdaq: FGEN, CEO: Thomas B. Neff, "FibroGen") today announced that the fourth Japan Phase 3 study for roxadustat met its primary endpoint. This study evaluated the efficacy and safety of roxadustat compared to darbepoetin alfa (genetical recombination) ("darbepoetin alfa") in hemodialysis-dependent chronic kidney disease (CKD) patients with anemia and previously treated with recombinant human erythropoietin (rHuEPO) or darbepoetin alfa.

"We are encouraged by these positive data from our Phase 3 key study in Japan, and are pleased with our overall development progress to date in the region," said Salim Mujais, M.D., senior vice president and global therapeutic area head, Medical Specialties Development, Astellas. "We look forward to continuing to advance the development of roxadustat to hopefully provide the value of a new therapeutic option to patients suffering from CKD with anemia."

"The positive topline results from this latest Japan Phase 3 study are consistent with previously reported results from roxadustat Phase 3 studies in Japan and in China, and from our extensive Phase 2 program," said K. Peony Yu, M.D., Chief Medical Officer, FibroGen. "We are pleased with the growing body of clinical evidence showing roxadustat to be well tolerated and efficacious in treating anemia in CKD patients, including patients on hemodialysis and those on peritoneal dialysis in various regions worldwide."

In the study, average hemoglobin (Hb) levels were effectively maintained at 10.99 g/dL at Weeks 18 to 24 in roxadustat-treated hemodialysis patients previously treated with erythropoiesis-stimulating agents (ESAs). The primary efficacy endpoint of change in average Hb levels from baseline to Weeks 18 to 24 was -0.04 g/dL and -0.03 g/dL in the roxadustat-treated group and in the darbepoetin-treated group, respectively. The non-inferiority of roxadustat to darbepoetin alfa in change of average Hb from baseline was confirmed as the lower bound of the 95% confidence interval (-0.18, 0.15) of the treatment difference was greater than the pre-specified non-inferiority margin (-0.75 g/dL).

Roxadustat was well tolerated in this study, and the safety profile of roxadustat was consistent with that observed in previous studies both in dialysis and non-dialysis patients.

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. This study is the final Phase 3 study in Japan evaluating roxadustat for the treatment of anemia in CKD patients on dialysis. Astellas is planning the submission of the new drug application in Japan for this indication later this year. The two Japan Phase 3 studies in non-dialysis patients are ongoing.

About the Study

The multi-center, randomized, darbepoetin alfa-controlled, double-blind Phase 3 study enrolled a total of 303 hemodialysis chronic kidney disease patients with anemia converted from rHuEPO or darbepoetin alfa. Subjects randomized to the roxadustat treatment arm received roxadustat three times a week orally and darbepoetin alfa placebo. Subjects randomized to the darbepoetin alfa treatment arm received darbepoetin-alfa once a week intraveneously and roxadustat placebo. The primary efficacy endpoint is change of average Hb levels from baseline during the evaluation period of 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 physiological response to conditions of low oxygen, “turning on” erythropoiesis (the process by which red blood cells are produced).

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.

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.

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. For more information, please visit our website at https://www.astellas.com/en

About FibroGen

FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, 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), 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), except in China, where a New Drug Application is currently under review by the State Drug Administration, or SDA (formerly the China Food and Drug Administration, or CFDA). Roxadustat is also 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.

Astellas Cautionary Notes

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 FibroGen 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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Contacts for inquiries or additional information:

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

FibroGen, Inc.
Karen L. Bergman
Vice President, Investor Relations and Corporate Communications
1 (415) 978-1433
kbergman@fibrogen.com