
**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): September 20, 2018

FibroGen, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36740
(Commission
File Number)

77-0357827
(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 September 20, 2018, our collaboration partner Astellas Pharma Inc. (“Astellas”) issued a press release in which it announced results from ALPS, its Phase 3 placebo-controlled clinical trial of roxadustat for the treatment of anemia in chronic kidney disease patients not on dialysis. As FibroGen has other ongoing Phase 3 studies that are expected to complete shortly, in order to avoid any bias in the conduct of those studies, particularly as to adjudication of certain event classes, FibroGen has not at this time reviewed the underlying data with respect to the Astellas study. A copy of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this Item 8.01 is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Item 8.01 of this report will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by the Company that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release titled “Astellas Announces Positive Topline Results for Global Phase 3 Trial of Roxadustat in Chronic Kidney Disease (CKD) Patients with Anemia Not on Dialysis” dated September 20, 2018</u>

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: September 20, 2018

By: /s/ Michael Lowenstein

Michael Lowenstein
Chief Legal Officer



Press Release

Astellas Announces Positive Topline Results for Global Phase 3 Trial of Roxadustat in Chronic Kidney Disease (CKD) Patients with Anemia not on Dialysis

TOKYO, September 20, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that roxadustat, an inhibitor of hypoxia inducible factor (HIF) prolyl hydroxylase activity, met its primary endpoints in the Phase 3 ALPS study by demonstrating superiority in efficacy versus placebo in terms of both hemoglobin (Hb) response rate in the first 24 weeks and Hb change from baseline at Weeks 28 to 52.¹ The preliminary safety analysis for this trial shows an overall event profile consistent with the results seen in previous roxadustat studies in CKD patients with anemia.

"The ALPS study adds to the growing body of evidence to support roxadustat as a potential treatment of anemia associated with CKD," said Salim Mujais, M.D, senior vice president and global therapeutic area head, Medical Specialties Development, Astellas. "This condition can have a debilitating impact on the patients affected, and we look forward to continuing our work to potentially make a new therapeutic option available to the physicians who care for them."

The ALPS study is the first of three Astellas Phase 3 studies conducted mainly in EMEA to report. The study forms part of a wider large-scale global Phase 3 development program for roxadustat conducted in collaboration with its partner FibroGen, Inc. (NASDAQ: FGEN), and will ultimately support filing and reimbursement in Europe. The ALPS study is a randomized, double-blind, placebo-controlled study of the efficacy and safety of roxadustat for the treatment of anemia in CKD in patients not on dialysis.²

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

About the ALPS Study

The ALPS study is a Phase 3, multi-center, double-blind, placebo-controlled study with a treatment duration of 52-104 weeks. The study population consists of patients with anemia of CKD (average screening Hb \leq 10 g/dL) and not receiving dialysis. Patients were randomized to either roxadustat or placebo in a 2:1 ratio. The study was designed to evaluate the efficacy and safety of roxadustat compared to placebo and has two primary endpoints. The first primary endpoint is the proportion of patients who achieved Hb response in the first 24 weeks (for US submission). The second primary endpoint is the change in Hb from baseline to the average level of week 28-52, regardless of rescue therapy (for EMA submission).

About Chronic Kidney Disease and Anemia

CKD is estimated to affect more than 200 million people worldwide.³ Although CKD can occur at any age, it becomes more common in aging populations, and the prevalence is increasing.⁴ Anemia is a common

complication of CKD and is associated with significant morbidity and mortality in dialysis and non-dialysis populations. In the EU5 (Germany, Italy, Spain, France, UK), approximately 371,000 patients have Stage 5 CKD and of which approximately 291,000 have anemia; and approximately 724,000 patients have Stage 4 CKD and of which approximately 432,000 patients have anemia.⁵ In addition, CKD can be both a cause and a consequence of cardiovascular disease⁶ and is now a critical worldwide healthcare issue⁷ that represents a large and growing unmet medical need.

Around 10% of the European population is affected by some degree of chronic kidney disease, and approximately 70 million Europeans have lost kidney function to some extent⁸ – this leaves them at risk of becoming dependent on renal replacement therapies including dialysis or organ transplantation.

About roxadustat

Roxadustat, discovered and developed by FibroGen, is a compound 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 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 is collaborating with FibroGen on the development of roxadustat for the potential treatment of anemia in patients with CKD and myelodysplastic syndromes in territories including Europe, the Commonwealth of Independent States, the Middle East and South Africa. FibroGen and AstraZeneca are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in patients with CKD in the U.S., China and other markets. For information about roxadustat studies, please visit clinicaltrials.gov at this link: https://clinicaltrials.gov/ct2/results?t_erm=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. For more information, please visit our website at <https://www.astellas.com/en>

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.

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ROX/18/0007/APEL

Date of preparation: September 2018

- 1 Data on File. A Phase 3, Randomized, Double-Blind, Placebo Controlled Study of the Efficacy and Safety of Roxadustat for the Treatment of Anemia in Chronic Kidney Disease Patients not on Dialysis September 2018
- 2 [Clinicaltrials.gov](https://clinicaltrials.gov). Safety and Efficacy Study of Roxadustat to Treat Anemia in Patients With Chronic Kidney Disease (CKD), Not on Dialysis. Found online at: <https://clinicaltrials.gov/ct2/show/NCT02174627?term=roxadustat&draw=2&rank=14> (Last accessed: June 2018)
- 3 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.
- 4 Bruce E. Robinson. Epidemiology of Chronic Kidney Disease and Anemia. *J Am Med Dir Assoc* 2006; 7: S3–S6)
- 5 Chronic Kidney Disease | Epidemiology | Europe Data. © 2016 DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.
- 6 M. Liu et al 2014, Cardiovascular disease and its relationship with chronic kidney, Available at: <https://www.europeanreview.org/wp/wp-content/uploads/2918-2926.pdf> Last accessed September 2018
- 7 Mark J. Sarnak et al, 2003 Kidney Disease as a Risk Factor for Development of Cardiovascular Disease Available at: <https://www.ahajournals.org/doi/pdf/10.1161/01.CIR.0000095676.90936.80> Last accessed September 2018
- 8 52nd European Renal Association – European Dialysis and Transplant Association Congress, *Chronic Kidney Disease – a Challenge for European Healthcare Systems*, 28th-31st May 2015, London. Available at: http://www.era-edta2015.org/press/1_150526_18.00_Press%20Release_CHRONIC_KIDNEY_DISEASE_Challenge.pdf Last accessed May 2016.