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 1, 2018, Japan Standard Time

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 1, 2018, Japan Standard Time, FibroGen, Inc. and its collaboration partner, Astellas Pharma Inc., issued a press release in which they announced that Astellas submitted an application for marketing approval in Japan of roxadustat for the treatment of anemia associated with chronic kidney disease in patients on dialysis.

This submission triggers a $15 million milestone payment from Astellas to FibroGen.

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 Submits New Drug Application in Japan of Roxadustat for the Treatment of Anemia Associated with Chronic Kidney Disease in Patients on Dialysis" dated October 1, 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: October 1, 2018

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

Press Release

Astellas Submits New Drug Application in Japan of
Roxadustat for The Treatment of Anemia
Associated with Chronic Kidney Disease in Patients on Dialysis

TOKYO and San Francisco, October 1, 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 Astellas submitted a New Drug Application (NDA) for marketing approval in Japan of roxadustat (generic name, development code: ASP1517/FG-4592) for the treatment of anemia associated with Chronic Kidney Disease (CKD) in patients on dialysis. The results obtained from four Phase 3 studies conducted in CKD patients on dialysis in Japan support this NDA submission.

"We are pleased to report the submission of the Japan NDA for roxadustat as a treatment of anemia associated with CKD in patients on dialysis," said Bernhardt G. Zeiher, M.D., Chief Medical Officer, Astellas. "We believe roxadustat offers a potential new oral therapeutic option for a condition which can have a debilitating impact on patients with renal disease."

"We are excited about this critical advancement as we work together to bring this new therapy to patients with anemia associated with CKD in Japan," said K. Peony Yu, M.D., Chief Medical Officer, FibroGen. "We appreciate the joint team's dedicated effort and commitment to addressing important unmet medical needs of these patients and their physicians."

Anemia is a common complication of CKD and is associated with significant morbidity and mortality in dialysis and non-dialysis populations. 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. Treatment for anemia in CKD patients is a critical worldwide healthcare issue that represents a large and growing unmet medical need.

About Chronic Kidney Disease (CKD) and Anemia

CKD is estimated affect more than 200 million people worldwide*1 and specifically in Japan, the prevalence of CKD has increased significantly over time.*2 Although CKD 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.

About Roxadustat

Roxadustat, discovered and developed by FibroGen, is a compound currently in Phase 3 development on a global basis 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 of roxadustat for the potential treatment of anemia in patients with CKD and myelodysplastic syndromes in territories including Japan, 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?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. For more information, please visit our website at https://www.astellas.com/en

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, completing worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application (NDA) currently under review in China by the State Drug Administration (SDA). Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China 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.

(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, No. 125, p. 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, vol. 25, no.8, 2557-2564.

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 June 30, 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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