# 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): June 6, 2016

# 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)

 $\begin{tabular}{ll} (415) \ 978-1200 \\ (Registrant's telephone number, including area code) \end{tabular}$ 

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 June 6, 2016, our collaboration partner in Japan and Europe, Astellas Pharma Inc. ("Astellas"), notified us that they had initiated their Japan Phase 3 study of roxadustat for the treatment of anemia associated with chronic kidney disease in patients on dialysis. Pursuant to our collaboration agreement with Astellas, effective June 1, 2005, the initiation of the first Phase 3 trial in Japan triggered a \$10.0 million milestone payment that we expect to receive by July, 2016

# Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

Description

99.1 Press Release titled "FibroGen Announces Initiation by Astellas of Phase 3 Clinical Study in Japan of Roxadustat/ASP1517 for the Treatment of Anemia of Chronic Kidney Disease, Triggering \$10.0 Million Milestone Payment" dated June 9, 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: June 9, 2016

By: /s/ Michael Lowenstein

Michael Lowenstein Chief Legal Counsel

## INDEX TO EXHIBITS

Exhibit No. Description

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# **FIBROGEN**

## **Press Release**

FibroGen Announces Initiation by Astellas of Phase 3 Clinical Study in Japan of Roxadustat/ASP1517 for the Treatment of Anemia of Chronic Kidney Disease Triggering \$10.0 Million Milestone Payment

San Francisco - June 9, 2016

FibroGen, Inc. (FibroGen), announced today that it will receive a \$10.0 million milestone payment from Astellas Pharma Inc. (Astellas). This payment, which FibroGen expects to receive by July 2016, was triggered by the initiation by Astellas of the first Phase 3 clinical study in Japan of roxadustat (ASP1517 or FG-4592) for treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis. Roxadustat, an orally administered small molecule inhibitor of hypoxia-inducible factor prolyl hydroxylase (HIF-PHI), is the most clinically advanced candidate in this new class of potential anemia therapeutic agents.

Under the exclusive license and collaboration agreement with Astellas, Astellas is responsible for the development costs of roxadustat in Japan, and makes payments to FibroGen for certain development, regulatory, and commercial-based milestones.

"We are pleased with the progress that our collaboration partner Astellas has made in moving roxadustat, our first in class HIF-PHI, into Phase 3 in Japan." said Thomas B. Neff, President and Chief Executive Officer of FibroGen. "Based on Phase 2 data generated in multiple settings, roxadustat has the potential to provide a safer, more effective and more convenient alternative to erythropoiesis stimulating agents for Japanese CKD patients."

### **About Roxadustat**

Roxadustat is currently in Phase 3 development as a potential therapy for anemia associated with chronic kidney disease 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.

AstraZeneca and FibroGen are collaborating on the development and commercialization of roxadustat (FG-4592) for the treatment of anemia in patients with CKD in the U.S., China, and other markets. Astellas and FibroGen are collaborating on the development and commercialization of roxadustat in Europe, Japan, the Commonwealth of Independent States, the Middle East, and Africa.

For information about roxadustat studies that are currently recruiting patients, please visit clinicaltrials.gov at this link: <a href="https://clinicaltrials.gov/ct2/results?term=roxadustat&Search=Search">https://clinicaltrials.gov/ct2/results?term=roxadustat&Search=Search</a>

### About Chronic Kidney Disease (CKD)

Chronic kidney disease (CKD) affects more than 200 million people worldwide and more than 30 million adults in the U.S. Although the disease can occur at any age, it becomes more common in aging populations and its prevalence is increasing. Anemia is a common complication of CKD and is associated with significant morbidity and mortality in both the 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 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 (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 (DMD). For more information please visit: www.fibrogen.com.

### **Contact Information**

FibroGen: Leanne Price, (415) 978-1200, lprice@fibrogen.com

### **Forward-Looking Statements**

This release contains forward-looking statements, including statements regarding the clinical and commercial potential of roxadustat, the potential ability of roxadustat to be a safer, more effective and more convenient alternative to current standard of care, future financial results, and the roxadustat Phase 3 program.

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.