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): December 2, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	FGEN	The Nasdaq Global Select Market

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 7.01 Regulation FD Disclosure

On December 2, 2019, FibroGen, Inc. issued a press release announcing that roxadustat has been included on the updated National Reimbursement Drug List ("NRDL") released by China's National Healthcare Security Administration. Roxadustat is included on the NRDL for the treatment of anemia in chronic kidney disease covering patients who are both dialysis-dependent and non-dialysis-dependent.

A copy of such press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Item 7.01 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

Exhibit No.	Description
99.1	Press Release titled "FibroGen Announces Roxadustat Inclusion in China's National Reimbursement Drug List" dated December 2, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: December 2, 2019

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

FibroGen Announces Roxadustat Inclusion in China's National Reimbursement Drug List

SAN FRANCISCO, December 2, 2019 -- FibroGen, Inc. (NASDAQ: FGEN) today reported roxadustat has been included on the updated National Reimbursement Drug List (NRDL) released by China's National Healthcare Security Administration (NHSA). Roxadustat is included on the NRDL for the treatment of anemia in chronic kidney disease (CKD), covering patients who are non-dialysis-dependent (NDD) as well as those who are dialysis-dependent (DD).

"Inclusion on the NRDL is a significant milestone and inflection point for the growth trajectory for roxadustat, as reimbursement provides affordability and access for patients on a national basis," said Jim Schoeneck, Interim CEO, FibroGen. "We are grateful to the NHSA for recognizing the unmet medical need in the treatment of anemia associated with CKD, and the compelling value proposition of roxadustat."

"The timing of inclusion of roxadustat in NRDL is significant in that it underscores the Chinese government's commitment to making innovative medicines accessible on an accelerated basis," said Chris Chung, Managing Director, FibroGen China. "FibroGen and AstraZeneca will work diligently with provincial governments and hospitals to make this new treatment option available to patients. Roxadustat was among 97 drugs that were included on the updated NRDL list through negotiations, the highest number in history. Implementation will begin at the provincial level, starting January 2020."

Roxadustat is the first hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) to be approved anywhere in the world. HIF-PHIs are a brand-new class of drugs developed based on the groundbreaking science on the body's oxygen-sensing mechanism and adaptation to hypoxia which was awarded the 2019 Nobel Prize in Physiology or Medicine. Results from the two pivotal China roxadustat Phase 3 clinical trials were published in the New England Journal of Medicine earlier in 2019.[1,2]

The dialysis patient population in China, exceeding 600,000 patients, is the largest single-country cohort in the world and is growing. China also has the largest peritoneal dialysis population in the world,

standing at approximately 14-15% of all dialysis patients, or 100,000 patients. Roxadustat, with its oral administration, is particularly well-suited for this population, as patients receive treatment at home. The addressable anemic non-dialysis population in China is equally sizable, estimated to be in excess of 2 million.

FibroGen and AstraZeneca are collaborating on the development and commercialization of roxadustat in China. Following market approval, FibroGen China, the Beijing-based subsidiary of FibroGen, Inc. and the marketing authorization holder of roxadustat in China, is responsible for commercial manufacturing, medical affairs, pharmacovigilance, and regulatory affairs. AstraZeneca China is responsible for promotional activities including marketing, market access, key accounts and sales.

About Anemia Associated with Chronic Kidney Disease in China
Anemia commonly develops in association with chronic kidney disease and is linked to significant morbidity and mortality in both the dialysis and non-dialysis populations. Although chronic kidney disease (CKD) may occur at any age, it is more common in aging populations, and its prevalence is increasing. CKD can be both a cause and a consequence of cardiovascular disease and is a critical healthcare issue. There is no treatment available that is curative or can stop kidney deterioration. In China, 120 million people have chronic kidney disease.[3] Anemia is a complication of chronic kidney disease, is associated with morbidity and mortality[4,5] and remains undertreated in non-dialysis chronic kidney disease patients worldwide due to delayed nephrology referral[6] and concerns over erythropoiesis stimulating agent safety.[7-9]

About Roxadustat
Roxadustat (FG-4592) is a first-in-class, orally administered small molecule HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, improving iron regulation, and overcoming the negative impact of inflammation on hemoglobin syntheses and red blood cell production by downregulating hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of chronic kidney disease (CKD) patients, including in the presence of inflammation and without a need for supplemental intravenous iron. Roxadustat is currently approved in China for the treatment of anemia in CKD patients on dialysis and patients not on dialysis and approved in Japan for the treatment of anemia in CKD patients on dialysis. 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), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia 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 the U.S., China, and other markets in the Americas and in Australia/New Zealand as well as Southeast Asia.

About FibroGen

FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, 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) and 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, is an oral small molecule inhibitor of HIF prolyl hydroxylase (HIF-PH) activity, completing worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), is approved by the National Medical Products Administration (NMPA) in China for CKD patients on dialysis and not on dialysis and by the Ministry of Health, Labour and Welfare (MHLW) in Japan for CKD patients on dialysis. 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), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in 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.

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 candidates, the potential safety and efficacy profile of our product candidates, 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, 2018 and our quarterly report on 10-Q for the fiscal quarter ended September 30, 2019 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.

Contact

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