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): August 8, 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 2.02 Results of Operations and Financial Condition.

On August 8, 2019, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended June 30, 2019. 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 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in Exhibit 99.1 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by FibroGen, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Reports Second Quarter 2019 Financial Results," dated August 8, 2019

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: August 8, 2019

By: /s/ Pat Cotroneo
Pat Cotroneo
Senior Vice President, Finance and Chief Financial Officer

Exhibit 99.1

FIBROGEN REPORTS SECOND QUARTER 2019 FINANCIAL RESULTS

- On Track to Submit U.S. NDA for Roxadustat in October -
- Initiated ZEPHYRUS Phase 3 Study of Pamrevlumab in IPF -

Conference Call Today at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time

SAN FRANCISCO, August 8, 2019 -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the second quarter of 2019 and provided an update on the company's recent developments.

"This has been a very productive quarter with the achievement of multiple regulatory and clinical milestones. We had a positive pre-NDA meeting with the FDA on roxadustat. Supported by positive efficacy and safety data, including compelling MACE and MACE+ results, we look forward to submitting our U.S. NDA in October. In IPF, the first patient was dosed in our Phase 3 pamrevlumab program," said Thomas B. Neff, Chief Executive Officer. "We are pleased to see the publication of two articles in the *New England Journal of Medicine* on our pivotal roxadustat Phase 3 studies in China."

Recent Developments and Upcoming Milestones

Roxadustat for Anemia in Chronic Kidney Disease (CKD) in the U.S. and Europe

- Positive pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA)
    - Reached agreement on the content of the NDA, including cardiovascular safety analyse
- On-track to submit U.S. NDA in October 2019
- Astellas anticipates the submission of Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) within the second half of their 2019 fiscal year, ending March 2020

Roxadustat for Anemia in CKD in China

- Two articles on the China Phase 3 studies were published in the *New England Journal of Medicine* (NEJM)
- Commercial manufacturing plant certified; commercial product manufactured and shipped
- Regulatory decision for treatment of anemia in non-dialysis-dependent CKD anticipated in the third quarter of 2019

Roxadustat for Anemia in CKD in Japan

- Regulatory decision for treatment of anemia in dialysis-dependent CKD anticipated in the second half of 2019

Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)

- Initiated dosing in the ZEPHYRUS Phase 3 randomized, double-blind, placebo-controlled study

Pamrevlumab for Locally Advanced Pancreatic Cancer (LAPC)

- Screening patients in the LAPIS Phase 3 randomized, double-blind, placebo-controlled study of pamrevlumab as a neoadjuvant therapy in combination with gemcitabine and nab-paclitaxel

Pamrevlumab for Duchenne Muscular Dystrophy (DMD)

- Reported positive one-year Phase 2 preliminary clinical findings at the Parent Project Muscular Dystrophy (PPMD) 2019 Annual Conference in June
    - Relative to previously published data of DMD patients, our single-arm study of pamrevlumab showed:
        - Less than expected decline in pulmonary function tests
        - Increase in cardiac function measured by mean change of left ventricular ejection fraction from baseline
        - Increase in grip-strength score in both dominant and non-dominant hands
        - Less than expected decline in the performance of the upper limb test

Corporate and Financial

- Net income for the second quarter of 2019 was $116.0 million, or $1.34 net income per basic share and $1.26 net income per diluted share, compared to a net loss of $23.4 million, or $0.28 net loss per basic and diluted share one year ago
- In accordance with U.S. GAAP, in the second quarter, we are including in our revenue recognition methodology a total of $180 million, in anticipated milestone payments related to the filing of the U.S. NDA and EU MAA, of which $171.1 million was recognized in the current quarter and the remaining balance will be recognized in future periods [1]
- At June 30, 2019, FibroGen had $686.1 million in cash, restricted time deposits, cash equivalents, investments, and receivables

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Thursday, August 8, 2019, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time) to discuss financial results and provide a business update. A live audio webcast of the call may be accessed in the investor section of the company's website, www.fibrogen.com. To participate in the conference call by telephone, please dial 1 (800) 708-4540 (U.S. and Canada) or 1 (847) 619-6397 (international), reference the FibroGen second quarter 2019 financial results conference call, and use confirmation number 48879852. A replay of the webcast will be available shortly after the call for a period of two weeks. To access the replay, please dial (888) 843-7419 (domestic) or (630) 652-3042 (international), and use passcode 4887 9852.

About Roxadustat

Roxadustat (FG-4592), discovered by FibroGen, is a first-in-class, orally administered small molecule currently approved in China for the treatment of anemia in CKD patients on dialysis. Roxadustat is a 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 CKD patients, including in the presence of inflammation and without a need for supplemental intravenous iron.

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 Pamrevlumab

Pamrevlumab is a first-in-class antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and has been granted Orphan Drug Designation (ODD) in these indications as well as in Duchenne muscular dystrophy (DMD). Pamrevlumab has also received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with IPF and for patients with locally advanced unresectable pancreatic cancer. Pamrevlumab is currently in a Phase 2 trial for DMD. Across all trials, pamrevlumab has consistently demonstrated a good safety and tolerability profile to date. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

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[1] Under U.S. GAAP revenue recognition guidelines, we are required to include estimated consideration from milestones in the determination of revenue recognition in the period that milestone achievement becomes probable. Receipt of milestone payments is dependent on the occurrence of the triggering event.

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), 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 (HIF-PH) activity. Together with our collaboration partners Astellas and AstraZeneca, preparation for regulatory submissions for the treatment of anemia in chronic kidney disease (CKD) to the U.S. FDA, the EMA, and other competent authorities is underway. In China, a New Drug Application (NDA) was approved by the National Medical Products Administration (NMPA) in December 2018. Our partner Astellas submitted an NDA for the treatment of anemia in CKD patients on dialysis in Japan in September 2018, which is currently under review by the Pharmaceuticals and Medical Devices Agency (PMDA). 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 in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and for the treatment of pancreatic cancer. Pamrevlumab is also 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 pamrevlumab and roxadustat, our interpretation of the pooled safety analyses and other analyses of the global Phase 3 program for roxadustat, the potential for and timing of an NDA submission to the FDA and an MAA submission to the EMA for potential marketing approval for roxadustat, the potential safety and efficacy profile of our product candidates, and our clinical, regulatory 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 June 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.

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Condensed Consolidated Balance Sheets
(In thousands)

	June 30, 2019	December 31, 2018 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 74,587	$ 89,258
Short-term investments	586,174	532,144
Accounts receivable	6,453	63,684
Inventory	1,981	—
Prepaid expenses and other current assets	136,596	4,929
Total current assets	805,791	690,015
Restricted time deposits	4,145	4,145
Long-term investments	10,915	55,820
Property and equipment, net	44,865	127,198
Finance lease right-of-use assets	44,536	—
Other assets	4,814	3,420
Total assets	$ 915,066	$ 880,598
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 4,060	$ 9,139
Accrued and other liabilities	66,545	66,123
Deferred revenue	136	13,771
Finance lease liabilities, current	12,071	—
Total current liabilities	82,812	89,033
Long-term portion of lease obligations	1,342	97,157
Product development obligations	16,846	16,798
Deferred rent	—	3,038
Deferred revenue, net of current	102,926	136,109
Finance lease liabilities, non-current	43,780	—
Other long-term liabilities	19,058	9,993
Total liabilities	266,764	352,128
Total stockholders' equity	629,031	509,199
Non-controlling interests	19,271	19,271
Total equity	648,302	528,470
Total liabilities, stockholders' equity and non-controlling interests	$ 915,066	$ 880,598

(1) The condensed consolidated balance sheet amounts at December 31, 2018 are derived from audited financial statements.

Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(Unaudited)			
Revenue:				
License revenue	$ 150,581	$ 14,323	$ 150,581	$ 14,323
Development and other revenue	40,985	29,629	64,848	61,553
Total revenue	191,566	43,952	215,429	75,876
Operating expenses:				
Research and development	52,008	52,138	102,505	109,112
Selling, general and administrative	26,739	15,055	48,948	30,605
Total operating expenses	78,747	67,193	151,453	139,717
Income (loss) from operations	112,819	(23,241)	63,976	(63,841)
Interest and other, net:				
Interest expense	(736)	(2,750)	(1,507)	(5,519)
Interest income and other, net	4,125	2,645	8,303	4,717
Total interest and other, net	3,389	(105)	6,796	(802)
Income (loss) before income taxes	116,208	(23,346)	70,772	(64,643)
Provision for income taxes	205	75	180	174
Net income (loss)	$ 116,003	$ (23,421)	$ 70,592	$ (64,817)
Net income (loss) per share				
Basic	$ 1.34	$ (0.28)	$ 0.82	$ (0.78)
Diluted	$ 1.26	$ (0.28)	$ 0.77	$ (0.78)
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	86,445	83,750	86,077	83,309
Diluted	91,728	83,750	92,069	83,309

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