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 7, 2018

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 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 7, 2018, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended June 30, 2018. 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 2018 Financial Results," dated August 7, 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: August 7, 2018

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

FIBROGEN REPORTS SECOND QUARTER 2018 FINANCIAL RESULTS

Roxadustat U.S. Phase 3 Topline Clinical Data Readout on Track for Fourth Quarter of 2018

Feedback from FDA on Pamrevlumab Pivotal Programs in IPF and in Locally Advanced Unresectable Pancreatic Cancerr

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

SAN FRANCISCO, August 7, 2018 -- FibroGen, Inc. (NASDAQ: FGEN), a biopharmaceutical company, today reported financial results for the second quarter of 2018 and provided an update on the company's recent developments.

"We are encouraged by the progress of our discussions with the FDA in advancing the development of pamrevlumab in IPF and locally advanced pancreatic cancer into pivotal Phase 3 clinical trials, including with the potential for accelerated approval in LAPC," said Thomas B. Neff, FibroGen's Chief Executive Officer. "Meanwhile, we are on track with timelines for regulatory submission of roxadustat for the treatment of CKD anemia in multiple regions, as we have made significant progress toward approval in China, and our studies for US approval are completing and will read out in the fourth quarter of this year."

Recent Developments and Highlights

Roxadustat for Anemia in Chronic Kidney Disease (CKD) in the U.S./EU

- U.S. Phase 3 trial enrollment completed
- Topline Phase 3 clinical data readout on target for the fourth quarter of 2018
- Pooled MACE safety data anticipated in early 2019
- New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) on target for the first half of 2019
- In its most recent and final review, the data safety monitoring board recommended Phase 3 clinical studies continue under current protocols with no changes

Roxadustat for Anemia in CKD in China

- NDA approval decision by the State Drug Administration (SDA) anticipated by year-end 2018

Roxadustat for Anemia Associated with MDS in China

- Patient dosing underway in Phase 2/3 study

Roxadustat for Anemia in CKD in Japan

- Astellas and FibroGen announced positive topline results from double-blind Phase 3 study in hemodialysis CKD patients in May 2018
- Astellas plans to submit NDA for anemia associated with dialysis-dependent CKD in 2018
- Astellas expects to announce topline data readout from the first of two ongoing non-dialysis-dependent CKD Phase 3 studies in the fourth quarter of 2018

Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)

- Positive Phase 2b efficacy and safety results (improvements in lung function (FVC), quantitative measure of fibrosis (HRCT) and quality of life (SGRQ)) reported in multiple poster presentations at the 2018 American Thoracic Society (ATS) Conference in May 2018
- Met with the FDA on IPF Phase 3 design; Phase 3 study planned to begin in early 2019

Pamrevlumab for Pancreatic Cancer

- Positive Phase 1/2 clinical results showing higher rates of eligibility for surgical resection and tumor resection rates in patients treated with roxadustat, presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2018
- Agreement with the FDA on pivotal trial design with approximately 260 patients; trial planned to begin in early 2019

Corporate and Financial

- Net loss for the second quarter was $23.4 million, or ($0.28) per share, compared to $31.9 million, or ($0.46) per share, primarily due to recognition of a milestone payment for an upcoming Japan NDA submission
- At June 30, 2018, FibroGen had $733.7 million of cash, cash equivalents, investments, restricted time deposits, and receivables
- The weighted average number of common shares used to calculate net loss per share was 83.8 million shares and 69.6 million shares for the second quarters of 2018 and 2017, respectively. Total shares outstanding as of June 30, 2018 were 84.2 million shares

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Tuesday, August, 7, 2018, 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 (888) 771-4371 (U.S. and Canada) or 1 (847) 585-4405 (international), reference the FibroGen second quarter 2018 financial results conference call, and use passcode 47339190#. A replay of the webcast will be available shortly after the call for a period of two weeks. To access the replay, please dial 1 (888) 843-7419 (domestic) or 1 (630) 652-3042 (international), and use passcode 47339190#.

About Roxadustat

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule currently in global Phase 3 clinical development as a potential therapy for anemia associated with chronic kidney disease (CKD). Roxadustat is a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) that promotes erythropoiesis through increasing endogenous erythropoietin, improving iron regulation, and reducing 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 patients with CKD 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 patients with CKD in the U.S., China, and other markets.

Roxadustat is advancing through Phase 3 clinical trials worldwide, with multiple trials completed. The Phase 3 program is supported by extensive Phase 2 clinical data demonstrating correction and maintenance of hemoglobin levels in multiple subpopulations of CKD anemia patients. Globally, the Phase 3 program encompasses a total of 15 Phase 3 studies to support independent regulatory approvals of roxadustat in both non-dialysis-dependent and dialysis-dependent CKD patients in the U.S., Europe, Japan, and China. Roxadustat is currently in Phase 3 clinical development for the treatment of anemia associated with myelodysplastic syndrome (MDS) in the U.S. and in Phase 2/3 development for MDS in China.

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 advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer and has been granted Orphan Drug Designation (ODD) in each of these indications, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). Pamrevlumab has received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with locally advanced unresectable pancreatic cancer. 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.

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.

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, 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.

Condensed Consolidated Balance Sheets
(In thousands)

	June 30, 2018	December 31, 2017 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 643,803	$ 673,658
Short-term investments	28,094	62,060
Accounts receivable	30,189	8,452
Prepaid expenses and other current assets	17,997	4,800
Total current assets	720,083	748,970
Restricted time deposits	5,181	5,181
Long-term investments	10,587	10,506
Property and equipment, net	128,829	129,476
Other assets	5,239	4,517
Total assets	$ 869,919	$ 898,650
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 3,222	$ 5,509
Accrued liabilities	49,492	63,781
Deferred revenue	37,845	16,670
Total current liabilities	90,559	85,960
Long-term portion of lease financing obligations	97,473	97,763
Product development obligations	16,981	17,244
Deferred rent	3,350	3,657
Deferred revenue, net of current	137,436	138,241
Other long-term liabilities	9,318	8,047
Total liabilities	355,117	350,912
Total stockholders' equity	495,531	528,467
Non-controlling interests	19,271	19,271
Total equity	514,802	547,738
Total liabilities, stockholders' equity and non-controlling interests	$ 869,919	$ 898,650

(1) The condensed consolidated balance sheet amounts at December 31, 2017 are recast from audited financial statements to reflect the adoption of the new revenue standards as of January 1, 2018.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017 (1)	2018	2017 (1)
	(Unaudited)		(Unaudited)	(1)
Revenue:				
License revenue	$ 14,323	$ —	$ 14,323	$ -
Development and other revenue	29,629	30,268	61,553	59,710
Total revenue	43,952	30,268	75,876	59,710
Operating expenses:				
Research and development	52,138	46,981	109,112	93,713
General and administrative	15,055	13,425	30,605	24,955
Total operating expenses	67,193	60,406	139,717	118,668
Loss from operations	(23,241)	(30,138)	(63,841)	(58,958)
Interest and other, net:				
Interest expense	(2,750)	(2,757)	(5,519)	(5,132)
Interest income and other, net	2,646	1,031	4,717	1,677
Total interest and other, net	(104)	(1,726)	(802)	(3,455)
Loss before income taxes	(23,345)	(31,864)	(64,643)	(62,413)
Provision for income taxes	75	48	174	109
Net loss	$ (23,420)	(31,912)	$ (64,817)	$ (62,522)
Net loss per share - basic and diluted	$ (0.28)	$ (0.46)	$ (0.78)	$ (0.94)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	83,750	69,638	83,309	66,853

(1) The condensed consolidated statements of operations amounts for the three and six months ended June 30, 2017 are recast from unaudited financial statements to reflect the adoption of the new revenue standards as of January 1, 2018.

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Contact
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