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): November 8, 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 November 8, 2018, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended September 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 Third Quarter 2018 Financial Results," dated November 8, 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: November 8, 2018

By: /s/ Pat Cotroneo

Pat Cotroneo

Senior Vice President, Finance and Chief Financial Officer

Exhibit 99.1

FIBROGEN REPORTS THIRD QUARTER 2018 FINANCIAL RESULTS

—Roxadustat New Drug Applications under Review in China and Japan—
— Phase 3 Clinical Trials in IPF and Pancreatic Cancer to Initiate in First Quarter 2019—
— Conference Call Today at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time—

SAN FRANCISCO, November 8, 2018 -- FibroGen, Inc. (NASDAQ: FGEN), a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics, today reported financial results for the third quarter of 2018 and provided an update on the company's recent developments.

"With new drug applications for roxadustat in anemia associated with chronic kidney disease supported by positive Phase 3 results and under review in China and Japan, we look forward to the upcoming reporting of topline clinical results, pooled safety data and submitting our U.S. NDA." said Thomas B. Neff, FibroGen's Chief Executive Officer. "For pamrevlumab, our proprietary anti-fibrotic and anti-fibroproliferative therapeutic candidate, we are initiating Phase 3 studies in idiopathic pulmonary fibrosis, and in unresectable locally advanced pancreatic cancer, in the first quarter of 2019."

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

- Topline Phase 3 clinical results anticipated for the fourth quarter of this year
- Pooled MACE analysis results and submission of New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) anticipated in the first half of 2019
- Astellas reported positive topline efficacy and safety results from the first global trial, ALPS, a Phase 3 placebo-controlled study evaluating roxadustat in non-dialysis-dependent CKD anemia patients in September 2018
- Astellas also completed its global trial, PYRENEES, a Phase 3 study in dialysis patients

Roxadustat for Anemia in CKD in China

- Roxadustat NDA approval for the treatment of dialysis-dependent CKD is anticipated by year-end 2018, followed by approval in CKD non dialysis
- Clinical results from two Phase 3 studies conducted in China were presented at the American Society of Nephrology (ASN) Kidney Week 2018 annual meeting in October

Roxadustat for Anemia in CKD in Japan

- Astellas NDA for roxadustat was filed with the Pharmaceuticals and Medical Devices Agency (PMDA) for anemia associated with dialysis-dependent CKD, triggering a $15 million milestone payment to FibroGen
- Astellas announced positive topline results from the four Phase 3 dialysis-dependent studies that support the Japan NDA
- Clinical results from two of the four Japan Phase 3 trials in dialysis-dependent patients were presented at the ASN Kidney Week 2018:
  - A Phase 3 trial in peritoneal dialysis patients was presented in an oral session
  - A Phase 3 darbepoetin alfa controlled study in stable hemodialysis patients previously treated with ESA was presented in a clinical late-breaking poster session
- One of two non-dialysis-dependent Phase 3 studies supporting approval for non-dialysis is now completed

Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)

- Clinical and preclinical data presented at the European Respiratory Society International Congress (ERS) 2018 and 20th International Colloquium on Lung and Airway Fibrosis (ICLAF) 2018
- Fast Track designation received from the FDA
- Plan to start a randomized, double-blind, placebo-controlled Phase 3 clinical trial with a primary endpoint of change in forced vital capacity (FVC) from baseline in approximately 500 patients, in the first quarter of 2019

Pamrevlumab for Pancreatic Cancer

- On track to start a randomized, double-blind, placebo-controlled Phase 3 study evaluating pamrevlumab in combination with gemcitabine and nab-paclitaxel as a neoadjuvant therapy for unresectable locally advanced pancreatic cancer (LAPC) in approximately 260 patients in the first quarter of 2019

Corporate and Financial

- Net loss for the third quarter was $42.6 million, or ($0.50) per share, compared to $24.5 million, or ($0.32) per share, for the same period in 2017
- At September 30, 2018, FibroGen had $722.6 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 84.5 million shares and 75.9 million shares for the third quarters of 2018 and 2017, respectively
- Total shares outstanding as of September 30, 2018 were 84.8 million shares

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Thursday, November, 8, 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 third quarter 2018 financial results conference call, and use passcode 47780296. 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 4778 0296#.

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.

FibroGen and collaboration partners are pursuing four approval pathways in major jurisdictions to prepare for commercialization worldwide:

- 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.

FibroGen and its partners have completed 35 Phase 1 and Phase 2 studies. The Phase 2 clinical studies have consistently demonstrated anemia correction and maintenance of hemoglobin levels in multiple subpopulations across a wide spectrum of CKD patients.

Globally, the Phase 3 program encompasses a total of 15 Phase 3 studies of roxadustat in both non-dialysis-dependent and dialysis-dependent CKD patients to support independent regulatory approvals in the U.S., Europe, Japan, and China. To date, positive topline results have been announced for seven of the Phase 3 studies, with two supporting the China NDA for treatment of anemia in CKD patients on dialysis and not on dialysis, four supporting the Japan NDA for treatment of anemia in CKD patients on dialysis, and one supporting the U.S./EU submissions. The China and Japan NDAs are both under review by the respective regulatory agencies.

Roxadustat is currently in Phase 3 clinical development for the treatment of anemia associated with myelodysplastic syndromes (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, 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, 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 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 by the National Medical Products Administration (NMPA) in China. Our partner Astellas submitted a NDA for the treatment of anemia in CKD patients on dialysis in Japan and 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 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 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 September 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)

	September 30, 2018	December 31, 2017 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 566,722	$ 673,658
Short-term investments	86,009	62,060
Accounts receivable	23,187	8,452
Prepaid expenses and other current assets	2,865	4,800
Total current assets	678,783	748,970
Restricted time deposits	5,181	5,181
Long-term investments	40,602	10,506
Property and equipment, net	127,908	129,476
Other assets	3,167	4,517
Total assets	$ 855,641	$ 898,650
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 10,131	$ 5,509
Accrued liabilities	52,598	63,781
Deferred revenue	37,697	16,670
Total current liabilities	100,426	85,960
Long-term portion of lease financing obligations	97,323	97,763
Product development obligations	16,948	17,244
Deferred rent	3,197	3,657
Deferred revenue, net of current	136,874	138,241
Other long-term liabilities	10,291	8,047
Total liabilities	365,059	350,912
Total stockholders' equity	471,311	528,467
Non-controlling interests	19,271	19,271
Total equity	490,582	547,738
Total liabilities, stockholders' equity and non-controlling interests	$ 855,641	$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017 (1)	2018	2017 (1)
	(Unaudited)			
Revenue:				
License revenue	$ —	$ 9,933	$ 14,323	$ 9,933
Development and other revenue	29,027	30,617	90,580	90,327
Total revenue	29,027	40,550	104,903	100,260
Operating expenses:				
Research and development	56,443	50,336	165,555	144,049
General and administrative	15,356	12,953	45,961	37,908
Total operating expenses	71,799	63,289	211,516	181,957
Loss from operations	(42,772)	(22,739)	(106,613)	(81,697)
Interest and other, net:				
Interest expense	(2,739)	(2,769)	(8,257)	(7,901)
Interest income and other, net	3,079	1,106	7,796	2,783
Total interest and other, net	340	(1,663)	(461)	(5,118)
Loss before income taxes	(42,432)	(24,402)	(107,074)	(86,815)
Provision for income taxes	124	57	299	166
Net loss	$ (42,556)	(24,459)	$ (107,373)	$ (86,981)
Net loss per share - basic and diluted	$ (0.50)	$ (0.32)	$ (1.28)	$ (1.24)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	84,508	75,891	83,713	69,899

(1) The condensed consolidated statements of operations amounts for the three and nine months ended September 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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