
**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, 2017

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)

(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, 2017, FibroGen, Inc. (“FibroGen”) issued a press release announcing financial results for the quarter ended September 30, 2017. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release titled “FibroGen Reports Third Quarter 2017 Financial Results,” dated November 8, 2017

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, 2017

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

FIBROGEN REPORTS THIRD QUARTER 2017 FINANCIAL RESULTS

Roxadustat NDA Filing Accepted for CFDA Review; Positive Pamrevlumab Phase 2 IPF Results Reported

Conference Call and Webcast to be Held Today at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time

SAN FRANCISCO, November 8, 2017 -- FibroGen, Inc. (NASDAQ: FGEN), a science-based biopharmaceutical company, today reported financial results for the third quarter of 2017 and provided an update on the company's recent developments.

"We have achieved significant clinical and regulatory progress in FibroGen's product development programs. With the reporting of positive data from our placebo-controlled Phase 2 study of pamrevlumab for the treatment of moderate-to-severe idiopathic pulmonary fibrosis, we are very excited about the potential for pamrevlumab to help IPF patients who currently have few options. These results position us well on the path towards Phase 3 clinical development in IPF, as we continue to advance pamrevlumab in additional indications, where there is critical need for new therapies," said Thomas B. Neff, FibroGen's Chief Executive Officer. "With respect to roxadustat, the filing of our new drug application with the China Food and Drug Administration for the treatment of anemia associated with chronic kidney disease marks several important firsts for FibroGen, the HIF-PHI class of drugs, and towards the registration of a new chemical entity in China."

Recent Developments and Highlights

Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)

- Announced positive results from a randomized, placebo-controlled, double-blind Phase 2 study of pamrevlumab, a first-in-class fully human antibody targeting connective tissue growth factor (CTGF)
- Presented Phase 2 findings in an oral presentation at the European Respiratory Society (ERS) International Congress in September 2017
 - Results also presented at the ERS meeting from a preclinical mouse radiation-induced lung fibrosis model showed that pamrevlumab monotherapy reduced fibrosis to a greater extent than either pirfenidone or nintedanib monotherapy, and that the results of combination therapy with either standard-of-care were not statistically significantly better than those for pamrevlumab alone
- Clinical and preclinical data has been accepted for presentation in November 2017 at Pulmonary Fibrosis Foundation (PFF) Summit 2017 in Nashville, TN

Pamrevlumab for Pancreatic Cancer

- We expect to define a registrational strategy in the first half of 2018

Roxadustat for Anemia in Chronic Kidney Disease (CKD)

- New drug application (NDA) filing with the U.S. Food and Drug Administration targeted for 2018
- Positive topline results reported from the first completed Japan roxadustat Phase 3 CKD trial, for the treatment of anemia in peritoneal dialysis patients in October 2017
- In November 2017, the independent data safety monitoring board, which reviews the U.S. and European Phase 3 programs quarterly, recommended that all trials continue without modification to current protocols

Roxadustat for Anemia in Myelodysplastic Syndromes (MDS)

- Phase 3 U.S. clinical trial anticipated to start in the fourth quarter of 2017

Roxadustat for Anemia in CKD in China

- NDA accepted for review by the China Food and Drug Administration (CFDA) for anemia associated with CKD in dialysis-dependent and non-dialysis-dependent patients in October 2017
 - Twenty-six week data from the two Phase 3 trials showed correction of anemia and maintenance of hemoglobin levels, and comparable results with or without inflammation
 - Data from the fifty-two week safety extension study showed durability of effect
 - No safety signals were identified

Roxadustat for Anemia in MDS in China

- Initiation of Phase 2/3 clinical study is planned for the fourth quarter of 2017/first quarter of 2018
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Corporate and Financial Highlights

- Appointed Gerald Lema to the company's Board of Directors, adding extensive experience to FibroGen's leadership in commercialization, finance, and strategy in the Asia Pacific region, as well as in Europe/Middle East and Africa, U.S., and Latin America
- Earned \$15.0 million milestone from partner AstraZeneca for the submission of the NDA for roxadustat in CKD to the CFDA in October 2017, which will be received and recognized as license and milestone revenue in the fourth quarter of 2017
- Closed an equity financing in August 2017 that generated \$356.2 million in net proceeds
- Net loss per basic and diluted share for the quarter ended September 30, 2017 was \$0.50, as compared to a net loss per based and diluted share of \$0.38 a year ago
- At September 30, 2017, FibroGen had \$762.7 million of cash, restricted time deposits, cash equivalents, investments, and receivables

Conference Call Details

FibroGen will host a conference call and webcast today, November 8, 2017, 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 2017 conference call, and use the confirmation number 45903141. 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 the passcode 45903141#.

About Pamrevlumab

Pamrevlumab is a proprietary therapeutic antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in chronic fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. FibroGen recently completed Phase 2 clinical studies of pamrevlumab in idiopathic pulmonary fibrosis (IPF), and is conducting Phase 2 trials in pancreatic cancer and Duchenne muscular dystrophy (DMD). In desmoplastic or fibrotic cancers, such as pancreatic cancer, CTGF promotes abnormal proliferation of stromal and tumor cells. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

About Roxadustat

Roxadustat is a first-in-class, orally administered small molecule in global Phase 3 clinical development as a treatment for anemia associated with chronic kidney disease (CKD) with the potential to offer a safer, and more effective, convenient, and accessible treatment than the current therapies. A hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), roxadustat promotes erythropoiesis, or the production of red bloods, by increasing endogenous erythropoietin, improving iron regulation, and reducing hepcidin, including in the presence of inflammation without need for supplemental intravenous iron.

The roxadustat Phase 3 program is the largest Phase 3 clinical program in anemia to date, and is supported by extensive Phase 2 results demonstrating correction and maintenance of hemoglobin levels in multiple subpopulations of CKD anemia patients. A total of 15 roxadustat studies are underway supporting four independent regulatory approval pathways for both non-dialysis and dialysis CKD patients in the U.S., Europe, Japan, and China. With a New Drug Application (NDA) currently under review in China by the CFDA, FibroGen anticipates filing a U.S. NDA for roxadustat in 2018. In the next stage of its development program, roxadustat will be starting a Phase 2/3 clinical trial in China and a Phase 3 clinical trial in the U.S. for the treatment of anemia in patients with myelodysplastic syndromes (MDS). For information about roxadustat studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen, Inc.

FibroGen, Inc., headquartered in San Francisco, CA with subsidiary offices in Beijing and Shanghai, PRC, is a leading science-based 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, and fibrotic disease and cancer. Roxadustat, the company's most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase activity in worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD) with the exception of China, where a new drug application is currently under review by the CFDA for regulatory approval. Roxadustat is also entering Phase 3 development for anemia in myelodysplastic syndromes (MDS). Pamrevlumab, a fully-human monoclonal anti-CTGF antibody, is in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), pancreatic cancer, and 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. 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," "should," "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, 2016, and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, 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)

	<u>September 30, 2017</u> (Unaudited)	<u>December 31, 2016</u> (1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 651,373	\$ 173,782
Short-term investments	78,599	79,397
Accounts receivable	8,628	10,448
Prepaid expenses and other current assets	2,856	2,889
Total current assets	<u>741,456</u>	<u>266,516</u>
Restricted time deposits	6,217	6,217
Long-term investments	16,767	71,010
Property and equipment, net	126,643	123,657
Other assets	3,809	2,152
Total assets	<u>\$ 894,892</u>	<u>\$ 469,552</u>
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	\$ 6,407	\$ 6,223
Accrued liabilities	54,117	50,914
Deferred revenue	7,974	7,988
Total current liabilities	<u>68,498</u>	<u>65,125</u>
Long-term portion of lease financing obligations	97,370	97,352
Product development obligations	16,922	14,854
Deferred rent	3,799	4,212
Deferred revenue, net of current	110,844	106,709
Other long-term liabilities	6,690	6,191
Total liabilities	<u>304,123</u>	<u>294,443</u>
Total stockholders' equity	571,498	155,838
Non-controlling interests	19,271	19,271
Total equity	<u>590,769</u>	<u>175,109</u>
Total liabilities, stockholders' equity and non-controlling interests	<u>\$ 894,892</u>	<u>\$ 469,552</u>

(1) The condensed consolidated balance sheet amounts at December 31, 2016 are derived from audited financial statements.

Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(Unaudited)			
Revenue:				
License and milestone revenue	\$ 19,997	\$ 20,867	\$ 60,930	\$ 113,802
Collaboration services and other revenue	7,275	9,235	22,230	33,863
Total revenue	27,272	30,102	83,160	147,665
Operating expenses:				
Research and development	50,336	40,558	144,049	136,599
General and administrative	12,953	11,646	37,908	33,440
Total operating expenses	63,289	52,204	181,957	170,039
Loss from operations	(36,017)	(22,102)	(98,797)	(22,374)
Interest and other, net:				
Interest expense	(2,769)	(2,760)	(7,901)	(7,975)
Interest income and other, net	1,106	866	2,783	2,411
Total interest and other, net	(1,663)	(1,894)	(5,118)	(5,564)
Loss before income taxes	(37,680)	(23,996)	(103,915)	(27,938)
Provision for (benefit from) income taxes	57	158	166	(260)
Net loss	\$ (37,737)	\$ (24,154)	\$ (104,081)	\$ (27,678)
Net loss per share - basic and diluted	\$ (0.50)	\$ (0.38)	\$ (1.49)	\$ (0.44)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	75,891	62,858	69,899	62,543

Contact

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