
**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): February 27, 2018

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 February 27, 2018, FibroGen, Inc. (“FibroGen”) issued a press release announcing financial results for the quarter and full year ended December 31, 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 Fourth Quarter and Full Year 2017 Financial Results,” dated February 27, 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: February 27, 2018

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

FIBROGEN REPORTS FOURTH QUARTER AND FULL YEAR 2017 FINANCIAL RESULTS

Roxadustat U.S. Phase 3 Program in CKD Anemia Enrollment Completion and Data Readout in 2018 Pamrevlumab Phase 2 IPF Study Achieves Statistically Significant Attenuation of Lung Fibrosis as Measured by Quantitative HRCT

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

SAN FRANCISCO, February 27, 2018 -- FibroGen, Inc. (NASDAQ: FGEN), a science-based biopharmaceutical company, today reported financial results for the fourth quarter and full year 2017 and provided an update on the company's recent developments.

"In 2017, we continued to make significant progress on key clinical and regulatory milestones. Our first NDA submission for roxadustat was accepted for review by the China Food and Drug Administration. With our partners, we are advancing the roxadustat Phase 3 CKD anemia programs to completion with plans to file for market approvals in the U.S., Europe, and Japan. In our fibrosis program, pamrevlumab has demonstrated tremendous potential in multiple indications. In a randomized double-blind, placebo-controlled Phase 2b study in IPF, pamrevlumab was well-tolerated and achieved statistical significance in the primary endpoint of FVC % predicted, in FVC, and in the secondary endpoints of quantitative changes of lung fibrosis, disease progression, and patient-reported outcomes," said Thomas B. Neff, FibroGen's Chief Executive Officer. "We are intensely focused on the execution of critical activities for our CKD anemia, idiopathic pulmonary fibrosis, and pancreatic cancer programs as these approach important new milestones in 2018."

Recent Developments and Highlights

Roxadustat for CKD Anemia in U.S./ROW

- With our partner AstraZeneca, we have agreed to a timeline for Phase 3 enrollment completion in the second quarter of 2018 and data readout in the fourth quarter of 2018 to support U.S. regulatory submission in the first half of 2019
- DSMB recommended Phase 3 clinical studies to continue under current protocols with no changes

Roxadustat for CKD Anemia in China

- Positive efficacy and safety results reported from two Phase 3 trials
- New Drug Application accepted for filing by the CFDA

Roxadustat for CKD Anemia in Japan

- Our partner Astellas has completed three of six Phase 3 trials
- Topline positive Phase 3 results reported in peritoneal dialysis study

Roxadustat for MDS Anemia

- Enrollment commenced in our first U.S./Europe Phase 3 study for the treatment of anemia in myelodysplastic syndromes (MDS)

Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)

- Statistically significant high-resolution computed tomography (HRCT) results achieved in our randomized double-blind, placebo-controlled Phase 2b study
- Positive Phase 2b study results presented at European Respiratory Society (ERS) International Congress 2017

Pamrevlumab for Pancreatic Cancer

- Reported positive interim Phase 2 open-label results at 2017 ASCO-GI conference showing a majority of pamrevlumab-treated patients converted from unresectable to resectable cancer; all resection evaluations complete and results continue to be favorable for pamrevlumab
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Corporate and Financial

- Net loss for the fourth quarter of 2017 was \$22.1 million, or \$0.27 per share, compared to \$34.0 million, or \$0.54 per share one year ago
- Net loss for the year ended December 31, 2017 was \$126.2 million, or \$1.73 per share, compared to \$61.7 million, or \$0.98 per share one year ago
- At December 31, 2017, FibroGen had \$762.2 million in cash, restricted time deposits, cash equivalents, investments, and receivables
 - Received a \$15.0 million milestone payment from AstraZeneca in the fourth quarter of 2017 upon roxadustat NDA submission to CFDA
 - Completed financings in April 2017 and in August 2017 with net proceeds of \$115.1 million and \$356.2 million, respectively

2018 Outlook

- U.S. Phase 3 CKD anemia enrollment completion in the second quarter of 2018
- U.S. Phase 3 CKD anemia data readout in the fourth quarter of 2018 to support U.S. regulatory submission in the first half of 2019
- NDA approval decision expected in China for CKD anemia by the end of 2018
- Expect to confirm plans with our partner Astellas for regulatory submissions in Europe and Japan
- Anticipate data readout from two Japan Phase 3 hemodialysis studies, a long-term conversion study and a correction (ESA-naïve) study, in the first quarter of 2018
- Anticipate initiation of roxadustat Phase 2/3 clinical study in China for anemia associated with MDS in first half of 2018
- Expect to present HRCT and health-related quality-of-life results from the IPF Phase 2b trial at an upcoming scientific conference
- Design pivotal trials for IPF and locally advanced pancreatic cancer

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, February 27, 2018, at 5:00 p.m. Eastern (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 fourth quarter and full year 2017 Financial Results conference call, and use passcode 46307822#. 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 46307822#.

About Roxadustat

Roxadustat is a first-in-class oral therapeutic 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 current therapies. Roxadustat, a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), promotes erythropoiesis, or the production of red bloods, by increasing endogenous erythropoietin, improving iron regulation, and reducing hepcidin, including in the presence of inflammation and 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 anemia in multiple subpopulations of CKD dialysis and non-dialysis patients. A New Drug Application (NDA) has been accepted for review by the China Food and Drug Administration (CFDA), and enrollment completion and data readout for the Phase 3 program are expected in 2018. Roxadustat is also in Phase 3 clinical development in the U.S. and Europe, and expected to shortly enter Phase 2/3 development in China, for anemia associated with myelodysplastic syndromes (MDS). For information about roxadustat studies currently recruiting patients, please visit www.clinicaltrials.gov.

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 is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). Pamrevlumab has been well tolerated in a number of Phase 2 clinical studies to date, with a good safety and tolerability profile. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen

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, 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 in Phase 3 clinical development in the U.S. and Europe, and expected to shortly enter Phase 2/3 development in China, for anemia associated with myelodysplastic syndromes (MDS). Pamrevlumab, a fully-human monoclonal anti-CTGF 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," "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, 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>December 31, 2017</u> (Unaudited)	<u>December 31, 2016</u> (1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 673,658	\$ 173,782
Short-term investments	62,060	79,397
Accounts receivable	8,452	10,448
Prepaid expenses and other current assets	4,800	2,889
Total current assets	<u>748,970</u>	<u>266,516</u>
Restricted time deposits	5,181	6,217
Long-term investments	10,506	71,010
Property and equipment, net	129,476	123,657
Other assets	4,517	2,152
Total assets	<u>\$ 898,650</u>	<u>\$ 469,552</u>
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	\$ 5,509	\$ 6,223
Accrued liabilities	63,781	50,914
Deferred revenue	7,968	7,988
Total current liabilities	<u>77,258</u>	<u>65,125</u>
Long-term portion of lease financing obligations	97,763	97,352
Product development obligations	17,244	14,854
Deferred rent	3,657	4,212
Deferred revenue, net of current	112,231	106,709
Other long-term liabilities	8,047	6,191
Total liabilities	<u>316,200</u>	<u>294,443</u>
Total stockholders' equity	563,179	155,838
Non-controlling interests	19,271	19,271
Total equity	<u>582,450</u>	<u>175,109</u>
Total liabilities, stockholders' equity and non-controlling interests	<u>\$ 898,650</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 December 31,		Years Ended December 31,	
	2017	2016	2017	2016
	(Unaudited)		(Unaudited)	(1)
Revenue:				
License and milestone revenue	\$ 35,126	\$ 23,551	\$ 96,056	\$ 137,352
Collaboration services and other revenue	7,383	8,362	29,612	42,225
Total revenue	42,509	31,913	125,668	179,577
Operating expenses:				
Research and development	52,469	50,607	196,517	187,206
General and administrative	13,851	12,585	51,760	46,025
Total operating expenses	66,320	63,192	248,277	233,231
Loss from operations	(23,811)	(31,279)	(122,609)	(53,654)
Interest and other, net:				
Interest expense	(1,806)	(2,750)	(9,706)	(10,725)
Interest income and other, net	3,651	217	6,433	2,628
Total interest and other, net	1,845	(2,533)	(3,273)	(8,097)
Loss before income taxes	(21,966)	(33,812)	(125,882)	(61,751)
Provision for (benefit from) income taxes	156	189	321	(71)
Net loss	\$ (22,122)	\$ (34,001)	\$ (126,203)	\$ (61,680)
Net loss per share - basic and diluted	\$ (0.27)	\$ (0.54)	\$ (1.73)	\$ (0.98)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	82,151	63,345	72,987	62,744

(1) The condensed consolidated statements of operations amounts for the year ended December 31, 2016 are derived from audited financial statements.

Contact

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