
**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 12, 2015

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))
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Item 2.02 Results of Operations and Financial Condition.

On November 12, 2015, FibroGen, Inc. (FibroGen) issued a press release announcing financial results for the quarter ended September 30, 2015. 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 Announces Third Quarter 2015 Financial Results,” dated November 12, 2015

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 12, 2015

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

INDEX TO EXHIBITS

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99.1	Press Release titled "FibroGen Announces Third Quarter 2015 Financial Results," dated November 12, 2015

FibroGen Announces Third Quarter 2015 Financial Results

FibroGen Share of US / EU Roxadustat Development Cost Obligations Expected to Be Reached in Fourth Quarter

SAN FRANCISCO—November 12, 2015-- FibroGen, Inc. (NASDAQ: FGEN) (“FibroGen”), a research-based biopharmaceutical company, today reported financial results for the quarter ended September 30, 2015.

“The timing of regulatory submissions for our potential first-in-class anemia treatment, roxadustat, remains on track for 2016 in China and 2018 in the United States,” said Thomas B. Neff, chief executive officer of FibroGen. “FibroGen is responsible for three of the seven Phase 3 registrational studies of roxadustat that we and our partners, AstraZeneca and Astellas, are currently conducting. In our three roxadustat studies, FibroGen has reached more than 80% of combined target enrollment.”

“In our development program for FG-3019, an investigational anti-fibrotic drug that targets connective tissue growth factor (CTGF), we continue to evaluate potential therapeutic uses in multiple disease areas. Our Phase 2 study of FG-3019 in patients with idiopathic pulmonary fibrosis and our Phase 2 study in Stage 3 unresectable pancreatic cancer patients both continue to advance. We plan to start a Phase 2 study of FG-3019 in non-ambulatory patients with Duchenne muscular dystrophy by year-end.”

Financial Highlights

- Net loss per basic and diluted share for the quarter ended September 30, 2015 was \$0.74.
- At September 30, 2015, FibroGen had \$365.6 million of cash, cash equivalents, investments, and receivables.
- Under an agreement between FibroGen and AstraZeneca, FibroGen’s total funding obligations for roxadustat development in chronic kidney disease (CKD) outside China are limited to \$116.5 million, of which \$11.8 million remained at the end of the third quarter of 2015. Based on current internal and partner projections, FibroGen expects that its funding obligation will be met before December 2015. Thereafter, Astellas and AstraZeneca will be responsible for funding all roxadustat development in CKD through launch for all territories, excluding China.

Program Updates

Anemia in Chronic Kidney Disease (CKD) - Roxadustat (FG-4592)

- In October 2015, the roxadustat data safety monitoring board (DSMB) completed its scheduled review of the data from all active Phase 3 roxadustat clinical trials and recommended that the program proceed with no protocol changes.
- FibroGen remains on track to achieve its target enrollment goals as agreed upon with its partners. The company confirms prior guidance to meet the stretch goal in one trial by year-end 2015 and meet the base goal to enroll two studies by March-April 2016.
- Two Phase 3 studies required for regulatory approval in China are expected to begin patient enrollment by the end of fourth quarter of 2015.
- In October 2015, the *Journal of the American Society of Nephrology* published results from a Phase 2 study of roxadustat in chronic kidney disease patients with anemia who recently initiated dialysis.

FG-3019 (anti-CTGF)

- FibroGen continues to expand the scope of its Phase 2 randomized, double-blind placebo-control study of idiopathic pulmonary fibrosis (IPF) patients. The company is activating sites in Canada, New Zealand, India, and South Africa, with additional sites pending in Australia, Bulgaria and Romania.
- FibroGen is evaluating the potential of FG-3019 to convert inoperable pancreatic cancer to operable cancer in a randomized Phase 2 open-label study. FibroGen expects to present then-current available data from this study at the 2016 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO GI) in January 2016.
- FibroGen has begun activating clinical sites for a Phase 2 study of FG-3019 in non-ambulatory patients with DMD.
- FibroGen met with the FDA to define a clinical development path for FG-3019 treatment of patients with liver fibrosis due to non-alcoholic steatohepatitis (NASH).

Conference Call Details

FibroGen will host a conference call and webcast today, November 12, 2015 at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time), to discuss financial results and provide a business update. Interested parties may access a live audio webcast of the conference call via the investor section of the FibroGen website, www.fibrogen.com. To access the conference call by telephone, please dial (800) 708-4540

(U.S. and Canada) or (847) 619-6397 (international), reference the FibroGen Third Quarter 2015 conference call, and use the confirmation number 40946951. It is recommended that listeners register 15 minutes before the scheduled start time to ensure a timely connection. A replay of the webcast will be archived on the FibroGen website and accessible approximately two hours after the event.

About FibroGen

FibroGen is a research-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. We have capitalized on our extensive experience in fibrosis and hypoxia-inducible factor (HIF) biology to generate multiple programs targeting various therapeutic areas. Our most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases (HIF-PHs), in Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD). Our second product candidate, FG-3019, is a monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), pancreatic cancer, Duchenne muscular dystrophy (DMD), and liver fibrosis.

Forward Looking Statements

This release contains forward-looking statements, including statements regarding our milestones, clinical plans and financial projections. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties, including the continued progress and timing of our various clinical programs, including the timing of enrollment of the Phase 3 clinical trials for roxadustat in CKD and the initiation and enrollment in ongoing and planned clinical trials for FG-3019 in idiopathic pulmonary fibrosis, pancreatic cancer, Duchenne muscular dystrophy, and NASH; the continued progress of our plans and programs in China; and other matters that are described in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission ("SEC") and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015 filed with the SEC, including the risk factors set forth in that filing, as well as the Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, which we expect to file on November 12, 2015 with the SEC. 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)

	<u>September 30, 2015</u>	<u>December 31, 2014</u>
	<u>(Unaudited)</u>	<u>(1)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 208,650	\$ 165,455
Short-term investments	12,873	14,364
Accounts receivable	7,373	13,453
Prepaid expenses and other current assets	3,677	4,966
Total current assets	<u>232,573</u>	<u>198,238</u>
Restricted cash	7,254	7,254
Long-term investments	127,974	144,269
Property and equipment, net	129,607	132,171
Other assets	1,839	1,596
Total assets	<u>\$ 499,247</u>	<u>\$ 483,528</u>
Liabilities and equity		
Current liabilities:		
Accounts payable	\$ 4,234	\$ 4,551
Accrued liabilities	41,774	48,985
Deferred revenue	12,980	9,218
Total current liabilities	<u>58,988</u>	<u>62,754</u>
Long-term portion of lease financing obligations	96,990	96,818
Product development obligations	15,433	16,465
Deferred rent	4,814	5,131
Deferred revenue, net of current	85,720	60,988
Other long-term liabilities	747	696
Total stockholders' equity	217,284	221,405
Non-controlling interests	19,271	19,271
Total equity	<u>236,555</u>	<u>240,676</u>
Total liabilities and equity	<u>\$ 499,247</u>	<u>\$ 483,528</u>

(1) The condensed consolidated balance sheet amounts at December 31, 2014 are derived from audited financial statements.

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

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
License and milestone revenue	\$ 13,045	\$ 9,027	\$ 131,430	\$ 106,175
Collaboration services and other revenue	6,493	4,635	24,956	15,321
Total revenue	19,538	13,662	156,386	121,496
Operating expenses:				
Research and development	52,071	40,617	154,165	99,536
General and administrative	11,237	10,140	31,399	24,088
Total operating expenses	63,308	50,757	185,564	123,624
Loss from operations	(43,770)	(37,095)	(29,178)	(2,128)
Interest expense	(2,758)	(2,723)	(8,278)	(8,174)
Interest and other income, net	1,458	283	3,008	1,358
Loss before income taxes	(45,070)	(39,535)	(34,448)	(8,944)
Provision (benefit) from income taxes	28	-	(38)	-
Net loss	\$ (45,098)	\$ (39,535)	\$ (34,410)	\$ (8,944)
Net loss per basic and diluted share:	\$ (0.74)	\$ (2.93)	\$ (0.57)	\$ (0.67)
Weighted average number of common shares used to calculate net loss per basic and diluted share:	60,767	13,503(2) (3)	59,926	13,355(2) (3)

(2) On November 10, 2014, we effected a 1-for-2.5 reverse split of our common stock. All of the outstanding common stock share numbers (including shares of common stock which our outstanding preferred stock shares were convertible into), common stock warrants have been adjusted on a retroactive basis, to reflect this 1-for-2.5 reverse stock split for the quarter and nine months ended September 30, 2014.

(3) For purposes of reconciling GAAP weighted average shares outstanding pre- and post- offering.

Reconciliation of Non-GAAP Financial Measures
(In thousands, except per share data, unaudited)

	Quarter Ended September 30, 2014	Nine Months Ended September 30, 2014
GAAP weighted average shares outstanding	13,503	13,355
Shares sold in initial public offering	9,315	9,315
Concurrent private placement - AstraZeneca	1,111	1,111
Conversion of preferred shares upon initial public offering	33,920	33,920
Conversion of European subsidiary shares	959	959
Non-GAAP weighted average shares outstanding	<u>58,808</u>	<u>58,660</u>
GAAP net loss	\$ (39,535)	\$ (8,944)
Non-GAAP net loss per basic and diluted share	\$ (0.67)	\$ (0.15)

About Non-GAAP Financial Measures

To supplement our condensed consolidated financial statements, which are prepared and presented in accordance with U.S. generally accepted accounting principles (“GAAP”), we present non-GAAP weighted average shares outstanding and non-GAAP net loss per basic and diluted share for the quarter and nine months ended September 30, 2014. The presentation of this financial information is not intended to be considered in isolation or as a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP.

We define non-GAAP net loss per basic and diluted share as GAAP net loss for the quarter and nine months ended September 30, 2014 divided by the non-GAAP weighted average shares outstanding for the quarter and nine months ended September 30, 2014. Non-GAAP weighted average shares outstanding is based on GAAP weighted average shares outstanding plus the issuance of and conversion into shares of our common stock upon the closing of our initial public offering. This includes issuance of 9.3 million shares in our initial public offering, issuance of 1.1 million shares in our concurrent private placement, conversion of all outstanding shares of our preferred stock into 33.9 million shares and conversion of FibroGen Europe preferred stock into 1.0 million shares. We believe the presentation of non-GAAP net loss per basic and diluted share provides useful information to investors regarding comparability of net loss per basic and diluted share amounts between periods.

Contact

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