# 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): May 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)

 $\begin{tabular}{ll} (415) \ 978-1200 \\ (Registrant's telephone number, including area code) \end{tabular}$ 

 $\begin{tabular}{ll} Not Applicable \\ (Former name or former address, if changed since last report.) \end{tabular}$ 

| 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)) |  |  |  |  |  |
|   |  |  |  |  |  |  |

#### Item 2.02 Results of Operations and Financial Condition.

On May 12, 2015, FibroGen, Inc. (FibroGen) issued a press release announcing financial results for the quarter ended March 31, 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

Exhibit No. Description

99.1 Press Release titled "FibroGen Announces First Quarter 2015 Financial Results," dated May 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.

Dated: May 12, 2015

FIBROGEN, INC.

By: /s/ Pat Cotroneo

Pat Cotroneo

Vice President, Finance, and Chief Financial Officer

## INDEX TO EXHIBITS

Exhibit No. Description

99.1 Press Release titled "FibroGen Announces First Quarter 2015 Financial Results," dated May 12, 2015

#### FibroGen Announces First Quarter 2015 Financial Results

SAN FRANCISCO, Calif., May 12, 2015 – FibroGen, Inc. (NASDAQ: FGEN) ("FibroGen"), a research-based biopharmaceutical company, today reported financial results for the quarter ended March 31, 2015.

"FibroGen and its partners, AstraZeneca and Astellas, continue to make excellent progress in the global development of roxadustat for the treatment of anemia in patients with chronic kidney disease," said Thomas B. Neff, chief executive officer of FibroGen. "Patient enrollment in the seven Phase 3 studies required for approval in the U.S. and Europe is advancing as planned. In China, we expect to begin patient enrollment in both Phase 3 studies required for regulatory approval in the fourth quarter of 2015. In April 2015, the roxadustat data safety monitoring board completed its scheduled quarterly review of the data collected to date from the seven active Phase 3 roxadustat studies and recommended that the program proceed with no protocol changes. We expect to submit roxadustat regulatory filings in China in 2016 and in the U.S. in 2018."

#### **Other Program Updates**

#### FG-3019

- In idiopathic pulmonary fibrosis, we continue to enroll patients in a 136 patient Phase 2 placebo controlled study in the U.S. and expect to open additional clinical sites outside of the U.S. in the third quarter of 2015.
- In pancreatic cancer, we are evaluating in an open-label Phase 2 study the ability of FG-3019, in combination with gemcitabine and nab-paclitaxel, to convert inoperable pancreatic cancer to operable cancer.
- In Duchenne muscular dystrophy, following an expert advisory panel review completed in March 2015, we plan to file an IND, and to commence a Phase 2 study in non-ambulatory patients in the second half of 2015.

#### FG-5200 (Corneal Implant)

• A pilot study of a corneal implant containing our proprietary human collagen Type III is entering its seventh year with study patients having undergone successful replacement surgery and continuing to have vision regain. We plan to advance the development of our FG-5200 corneal implant in China and expect to receive responses from China regulatory authorities regarding the development priority status in the coming months.

#### **Financial Highlights**

- The final audited reports of two long-term roxadustat pre-clinical carcinogenicity studies were completed, further supporting the safety profile of roxadustat, and triggering a \$15.0 million milestone payment by AstraZeneca.
- Revenue was \$16.3 million and operating expenses were \$61.0 million for the first quarter of 2015. Net loss per share for the first quarter of 2015 was \$(0.78) based on 59.2 million shares outstanding compared to net loss per share of \$(0.27) for the first quarter of 2014 based on the same number of shares outstanding on a pro-forma basis.
- On March 31, 2015, we had \$296.4 million of cash, cash equivalents, investments, and receivables. In addition to the milestone payment of \$15.0 million received last week, we expect to receive a non-contingent license payment of \$120.0 million from AstraZeneca in the second quarter of 2015.

Under the agreement with AstraZeneca, our total funding obligations for roxadustat development in chronic kidney disease (CKD) outside China are limited to \$116.5 million, of which \$52.1 million remained at the end of the first quarter of 2015. Based on current internal and partner projections, we continue to expect that our funding obligation will be met by the fourth quarter of 2015. Thereafter, Astellas and AstraZeneca will be responsible for funding roxadustat development in CKD through launch for all territories, excluding China.

#### 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 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 IND filing for planned clinical trials for FG-3019 in idiopathic pulmonary fibrosis and pancreatic cancer, and Duchenne muscular dystrophy, respectively; the potential to achieve and receive approximately \$120 million in non-contingent license payments from AstraZeneca in the second quarter of 2015; 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 on March 26, 2015, including the risk factors set forth in that filing. 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)

|   | March 31,<br>2015<br>(Unaudited) | December 31,<br>2014<br>(1) |
|---|----------------------------------|-----------------------------|
| Assets  |                                  | , ,                         |
| Current assets:   |                                  |                             |
| Cash and cash equivalents                                       | \$ 128,369                       | \$ 165,455                  |
| Short-term investments  | 14,322                           | 14,364                      |
| Accounts receivable   | 6,963                            | 13,453                      |
| Prepaid expenses and other current assets                       | 5,746                            | 4,966                       |
| Total current assets  | 155,400                          | 198,238                     |
| Restricted cash   | 7,254                            | 7,254                       |
| Long-term investments   | 139,518                          | 144,269                     |
| Property and equipment, net                                     | 131,660                          | 132,171                     |
| Other assets  | 1,708                            | 1,596                       |
| Total assets  | \$ 435,540                       | \$ 483,528                  |
| Liabilities, stockholders' equity and non-controlling interests |                                  |                             |
| Current liabilities:  |                                  |                             |
| Accounts payable  | \$ 2,433                         | \$ 4,551                    |
| Accrued liabilities   | 42,466                           | 48,985                      |
| Deferred revenue  | 9,058                            | 9,218                       |
| Total current liabilities                                       | 53,957                           | 62,754                      |
| Long-term portion of lease financing obligations                | 96,873                           | 96,818                      |
| Product development obligations                                 | 14,774                           | 16,465                      |
| Deferred rent   | 5,024                            | 5,131                       |
| Deferred revenue, net of current                                | 60,326                           | 60,988                      |
| Other long-term liabilities                                     | 699                              | 696                         |
| Total stockholders' equity                                      | 184,616                          | 221,405                     |
| Non-controlling interests                                       | 19,271                           | 19,271                      |
| Total equity  | 203,887                          | 240,676                     |
| Total liabilities and equity                                    | \$ 435,540                       | \$ 483,528                  |

<sup>(1)</sup> 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)

|   | Three Months Ended March 31, |          |                   |
|---|------------------------------|----------|-------------------|
|   |                              | 2015     | 2014              |
| Revenue:  |                              |          |                   |
| License and milestone revenue   | \$                           | 11,506   | \$<br>14,685      |
| Collaboration services and other revenue  |                              | 4,792    | 3,191             |
| Total revenue   |                              | 16,298   | 17,876            |
| Operating expenses:   |                              |          |                   |
| Research and development  |                              | 50,539   | 25,650            |
| General and administrative  |                              | 10,482   | <br>6,432         |
| Total operating expenses  | ·                            | 61,021   | <br>32,082        |
| Loss from operations  |                              | (44,723) | (14,206)          |
| Interest expense  |                              | (2,758)  | (2,726)           |
| Interest and other income, net  |                              | 843      | <br>692           |
| Loss before income taxes  |                              | (46,638) | <br>(16,240)      |
| Benefit from income taxes   |                              | 271      | _                 |
| Net loss  | \$                           | (46,367) | \$<br>(16,240)    |
| Net loss per basic and diluted share  | \$                           | (0.78)   | \$<br>(1.23)      |
| Weighted average number of common shares used in net loss per basic and diluted share |                              | 59,197   | 13,210 <b>(2)</b> |

(2) On a pro-forma basis, the 13.2 million weighted shares would be reported as 59.2 million shares based on the following:

|   | Common Shares<br>(In Millions) |
|---|--------------------------------|
| Weighted average shares as of March 31, 2014                | 13.2                           |
| Shares sold in initial public offering                      | 9.3                            |
| Concurrent private placement — AstraZeneca                  | 1.1                            |
| Conversion of preferred shares upon initial public offering | 33.9                           |
| Conversion of European subsidiary shares                    | 1.0                            |
| Option exercises  | 0.7                            |
| Weighted average shares as of March 31, 2015                | 59.2                           |

#### 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 net loss per share for the first quarter of 2014 on a pro-forma basis. 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 share as GAAP net loss for the three months ended March 31, 2014 divided by the weighted average number of common shares outstanding for the same period in 2015. Weighted average common shares as of March 31, 2015 were 59.2 million. With a starting point of 13.2 million weighted shares as of March 31, 2014, we sold 9.3 million shares in our initial public offering in November 2014, concurrent private placement of 1.1 million shares with AstraZeneca. The resulting automatic conversion of the Company's outstanding convertible preferred stock into 33.9 million shares of common stock, plus the resulting exchange of our European subsidiary's preferred shares into 1.0 million shares of common stock, and 0.7 million shares related to option exercises, resulted in 35.4 million converted shares. The total of the above results in 59.2 million weighted average common shares at March 31, 2015, compared to 13.2 million common shares as of March 31, 2014.

#### Contact

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