

FIBROGEN INC
Form 8-K
December 07, 2018

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 30, 2018

FibroGen, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-36740
(Commission

File Number)
FibroGen, Inc.

77-0357827
(IRS Employer

Identification No.)

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 1.01 Entry into a Material Definitive Agreement.

On November 30, 2018, FibroGen, Inc. and Astellas Pharma Inc. entered into an amendment to the collaboration agreement dated as of June 1, 2005 (the "Japan Agreement") that will allow Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Japan Amendment"). Under this amendment, FibroGen would continue to manufacture and deliver to Astellas roxadustat active pharmaceutical ingredient ("API"). The commercial terms of the Japan Agreement relating to the transfer price for roxadustat for commercial use remain substantially the same, reflecting an adjustment for the manufacture of drug product by Astellas rather than FibroGen. This amendment obligates Astellas to purchase a total of net \$62.7 million of API, of which a net \$20.9 million was delivered to Astellas in the second quarter of 2018 under a material transfer agreement to conduct commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan. This \$20.9 million was recorded as deferred revenue in Q2 2018 but is expected to be recognized as revenue upon execution of the Japan Amendment. The remaining net \$41.8 million of API will be delivered to Astellas in 2018.

A corresponding memorandum of understanding for the Anemia License and Collaboration Agreement by and between FibroGen and Astellas, dated April 28, 2006 as amended ("EU Agreement"), which references the Japan Agreement manufacturing terms, was executed effective the same day, reflecting that the Japan Amendment does not apply to the EU Agreement.

The foregoing description of the Japan Amendment is not a complete description of the agreement and is qualified in its entirety by reference to the full text of the Japan Amendment, which will be filed with the Securities and Exchange Commission as an exhibit to FibroGen, Inc.'s Annual Report on Form 10-K for the year ending December 31, 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: December 7, 2018

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Officer