# 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 06, 2024**

# FIBROGEN, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-36740** | **77-0357827** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |
| **409 Illinois Street**<br>**San Francisco, California** | | **94158** |
| **(Address of Principal Executive Offices)** | | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: 415 978-1200**

**(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))

**Securities registered pursuant to Section 12(b) of the Act:**

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, $0.01 par value | FGEN | The Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company 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 May 6, 2024, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended March 31, 2024. 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, 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 Reports First Quarter 2024 Financial Results," dated May 6, 2024 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**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 thereunto duly authorized.

**FIBROGEN, INC.**

Date: May 6, 2024

By: /s/ Juan Graham

Juan Graham
Senior Vice President and Chief Financial Officer

**Exhibit 99.1**

# FibroGen Reports First Quarter 2024 Financial Results

- ***Topline data from the Pancreatic Cancer Action Network (PanCAN) Precision Promise[SM] Phase 2/3 study in metastatic pancreatic cancer anticipated in mid-2024***
- ***Topline data from LAPIS Phase 3 study in locally advanced unresectable pancreatic cancer anticipated in 3Q 2024***
- ***Reported compelling data from Phase 1 monotherapy study of FG-3246, a CD46 targeted antibody drug conjugate, in metastatic castration-resistant prostate cancer***
- ***First quarter net revenue growth of 55% year over year, driven by roxadustat China performance and one-time drug product revenue recognized from US/RoW AstraZeneca agreement termination***
- ***Robust year over year roxadustat volume growth of 39% in China***
- ***Cash, cash equivalents, investments, and accounts receivable balance of $214.7 million; cash runway projected into 2026***

SAN FRANCISCO, May 6, 2024 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the first quarter 2024 and provided an update on the company's recent developments.

"We are off to a strong start in 2024 marked by the recent release of compelling Phase 1 data on FG-3246, our CD46 targeted antibody drug conjugate, in metastatic castration-resistant prostate cancer and continued robust growth of our roxadustat business in China," said Thane Wettig, Chief Executive Officer, FibroGen. "Looking ahead, we expect to report topline data from our two late-stage clinical trials of pamrevlumab in pancreatic cancer in the coming months. In addition, we have a strong balance sheet and reaffirm our cash runway into 2026."

**Upcoming Milestones:**

**Pamrevlumab**

- Topline data from the PanCAN Precision Promise[SM] Phase 2/3 study of pamrevlumab in metastatic pancreatic cancer expected in mid-2024, reflecting PanCAN's updated timing to complete database lock and subsequent analysis of the topline results by the independent Statistical Monitoring Committee.
- Topline data from the LAPIS Phase 3 study of pamrevlumab in locally advanced unresectable pancreatic cancer (LAPC) expected in 3Q 2024, due to the current trend in reported blinded overall survival events needed to complete the study.

**Roxadustat**

- Expect approval decision for roxadustat in chemotherapy-induced anemia (CIA) in China in the second half of 2024. If approved, FibroGen will receive a $10 million milestone payment from AstraZeneca.

**Oncology Pipeline**

- Initial data from Phase 1 investigator-initiated combination study of FG-3246 with enzalutamide in metastatic castration-resistant prostate cancer (mCRPC) to be presented at ASCO 2024.
- Anticipate initiation of Phase 2 monotherapy dose optimization study of FG-3246 in mCRPC in 2H 2024.
- Anticipate filing of an IND for FG-3175 (anti-CCR8 mAb) in 2025.

**Recent Developments:**

**Oncology Pipeline**

- Additional data from a total of 56 biomarker unselected and heavily pre-treated patients in a Phase 1 monotherapy study of FG-3246 in mCRPC reported.
  - Efficacy analysis (includes adenocarcinoma patients receiving doses ≥ 1.2 mg/kg):
    - The median radiographic progression free survival (rPFS) in this patient population was 8.7 months.
    - For RECIST evaluable patients, 20% met the criteria of a partial response, or measurable tumor reduction in size of ≥ 30%, with a median duration of response of 7.5 months.
    - PSA reductions of ≥ 50% were observed in 36% of PSA evaluable patients
  - Safety analysis:
    - The most frequent adverse events were consistent with other MMAE-based antibody drug conjugates and included infusion-related reactions, fatigue, weight loss, neutropenia, and peripheral neuropathy.
- IND submitted for FG-3165 (Galectin-9 targeting mAb) for solid tumors in April 2024.

**Corporate**

- Appointed Deyaa Adib, MD as Chief Medical Officer.

**China:**

- First quarter FibroGen net product revenue under U.S. GAAP from the sale of roxadustat in China was $30.5 million compared to $24.2 million in the first quarter of 2023, an increase of 26% year over year.
- First quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca (JDE) was $79.4 million, compared to $64.1 million in the first quarter of 2023, an increase of 24% year over year, driven by a 39% increase in volume.
- Roxadustat continues to be the number one brand based on value share in the anemia of CKD market in China.
- For 2024, we reiterate FibroGen's full year net product revenue under U.S. GAAP to range between $120 million to $135 million, representing full year roxadustat net sales in China[1] by FibroGen and the JDE to range between $300 million to $340 million.

**Financial:**

- Total revenue for the first quarter of 2024 was $55.9 million, as compared to $36.2 million for the first quarter of 2023, an increase of 55% year over year. Total revenue increase was driven by net product revenue in China and one-time drug product revenue of $25.7 million recognized due to the termination of US/RoW AstraZeneca agreement.
- Net loss for the first quarter of 2024 was $32.9 million, or $0.33 net loss per basic and diluted share, compared to a net loss of $76.7 million, or $0.81 net loss per basic and diluted share one year ago.
- At March 31, 2024, FibroGen reported $214.7 million in cash - defined as cash, cash equivalents, investments, and accounts receivable.
- We expect our cash, cash equivalents, investments, and accounts receivable to be sufficient to fund our operating plans into 2026.

[1] Total roxadustat net sales in China includes sales made by the distribution entity as well as FibroGen China's direct sales, each to its own distributors. The distribution entity jointly owned by AstraZeneca and FibroGen is not consolidated into FibroGen's financial statements.

**Conference Call and Webcast Details**
FibroGen will host a conference call and webcast today, Monday, May 6, 2024, at 5:00 PM Eastern 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 Relations” page of the Company’s website at www.fibrogen.com.To access the call by phone, please go to this link (registration link), and you will be provided with dial in details. To avoid delays, we encourage participants to dial into the conference call fifteen minutes ahead of the scheduled start time. A replay of the webcast will also be available for a limited time at the following link (webcast replay).

**About Pamrevlumab**
Pamrevlumab is a potential first-in-class antibody being developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF). Pamrevlumab is in Phase 3 clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC) and in Phase 2/3 for the treatment of metastatic pancreatic cancer. The U.S. Food and Drug Administration has granted Orphan Drug Designation, and Fast Track designation to pamrevlumab for the treatment of patients with LAPC. Pamrevlumab has demonstrated a safety and tolerability profile that has supported ongoing clinical investigation in LAPC and metastatic pancreatic cancer. Pamrevlumab is an investigational drug and not approved for marketing by any regulatory authority. For information about our pamrevlumab studies please visit www.clinicaltrials.gov.

**About Roxadustat**
Roxadustat, an oral medication, is the first in a new class of medicines comprising HIF-PH inhibitors that promote erythropoiesis, or red blood cell production, through increased endogenous production of erythropoietin, improved iron absorption and mobilization, and downregulation of hepcidin. Roxadustat is in clinical development for chemotherapy-induced anemia (CIA) and a Supplemental New Drug Application (sNDA) has been accepted by the China Health Authority.

Roxadustat is approved in China, Europe, Japan, and numerous other countries for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). Several other licensing applications for roxadustat have been submitted by partners, Astellas and AstraZeneca, to regulatory authorities across the globe, and are currently under review. Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in territories including Japan, Europe, Turkey, Russia, and the Commonwealth of Independent States, the Middle East, and South Africa. AstraZeneca and FibroGen continue to collaborate on the development and commercialization of roxadustat in China.

**About FibroGen**
FibroGen, Inc. is a biopharmaceutical company focused on accelerating the development of novel therapies at the frontiers of cancer biology. Pamrevlumab, a fully human anti-CTGF monoclonal antibody, is in clinical development for the treatment of metastatic pancreatic cancer and locally advanced unresectable pancreatic cancer (LAPC). Roxadustat (爱瑞卓®, EVRENZO™) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease (CKD) patients on dialysis and not on dialysis. Roxadustat is in clinical development for chemotherapy-induced anemia (CIA) and a Supplemental New Drug Application (sNDA) has been accepted for review by the China Health Authority. FG-3246 (also known as FOR46), a first-in-class antibody-drug conjugate (ADC) targeting CD46 is in development for the treatment of metastatic castration-resistant prostate cancer. This program also includes the development of an associated CD46-targeted PET biomarker. In addition, FibroGen has expanded its research and development portfolio to include two immuno-oncology product candidates for the treatment of solid tumors. For more information, please visit www.fibrogen.com. www.fibrogen.com.

**Forward-Looking Statements**

This release contains forward-looking statements regarding FibroGen's strategy, future plans and prospects, including statements regarding its clinical programs and those of its collaboration partners Fortis, UCSF, and the Pancreatic Cancer Action Network. These forward-looking statements include, but are not limited to, statements regarding the efficacy, safety, and potential success of FibroGen product candidates, and statements about FibroGen's plans and objectives and typically are identified by use of terms such as "may," "will", "should," "on track," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. FibroGen's 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 its various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in FibroGen's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as 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 FibroGen undertakes 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)

| | March 31, 2024 (Unaudited) | December 31, 2023 (1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 105,734 | $ 113,688 |
| Short-term investments | 71,865 | 121,898 |
| Accounts receivable, net | 37,083 | 12,553 |
| Inventory | 27,335 | 41,565 |
| Prepaid expenses and other current assets | 36,150 | 41,855 |
| Total current assets | 278,167 | 331,559 |
| | | |
| Restricted time deposits | 1,658 | 1,658 |
| Property and equipment, net | 12,166 | 13,126 |
| Equity method investment in unconsolidated variable interest entity | 5,776 | 5,290 |
| Operating lease right-of-use assets | 64,751 | 68,093 |
| Other assets | 3,350 | 3,803 |
| **Total assets** | $ 365,868 | $ 423,529 |
| | | |
| **Liabilities, stockholders' equity and non-controlling interests** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,353 | $ 17,960 |
| Accrued and other liabilities | 164,286 | 172,891 |
| Deferred revenue | 12,863 | 12,740 |
| Operating lease liabilities, current | 15,231 | 14,077 |
| Total current liabilities | 196,733 | 217,668 |
| | | |
| Product development obligations | 17,446 | 17,763 |
| Deferred revenue, net of current | 147,118 | 157,555 |
| Operating lease liabilities, non-current | 62,511 | 66,537 |
| Senior secured term loan facilities, non-current | 72,213 | 71,934 |
| Liability related to sale of future revenues, non-current | 52,216 | 51,413 |
| Other long-term liabilities | 3,786 | 2,858 |
| Total liabilities | 552,023 | 585,728 |
| | | |
| Redeemable non-controlling interests | 21,480 | 21,480 |
| Total stockholders' deficit attributable to FibroGen | (228,122) | (204,166) |
| Nonredeemable non-controlling interests | 20,487 | 20,487 |
| Total deficit | (207,635) | (183,679) |
| **Total liabilities, redeemable non-controlling interests and deficit** | $ 365,868 | $ 423,529 |

**(1)** The condensed consolidated balance sheet amounts at December 31, 2023 are derived from audited financial statements.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2024 | 2023 |
| | (Unaudited) | |
| **Revenue:** | | |
| License revenue | $ — | $ 6,000 |
| Development and other revenue | 878 | 3,891 |
| Product revenue, net | 30,538 | 24,161 |
| Drug product revenue, net | 24,486 | 2,109 |
| Total revenue | 55,902 | 36,161 |
| | | |
| **Operating costs and expenses:** | | |
| Cost of goods sold | 25,753 | 3,491 |
| Research and development | 38,392 | 74,486 |
| Selling, general and administrative | 22,820 | 34,275 |
| Total operating costs and expenses | 86,965 | 112,252 |
| **Loss from operations** | (31,063) | (76,091) |
| | | |
| **Interest and other, net:** | | |
| Interest expense | (4,996) | (2,372) |
| Interest income and other income (expenses), net | 2,570 | 1,036 |
| Total interest and other, net | (2,426) | (1,336) |
| | | |
| **Loss before income taxes** | (33,489) | (77,427) |
| Provision for income taxes | 33 | 74 |
| Investment income in unconsolidated variable interest entity | 589 | 796 |
| **Net loss** | $ (32,933) | $ (76,705) |
| | | |
| Net loss per share - basic and diluted | $ (0.33) | $ (0.81) |
| | | |
| Weighted average number of common shares used to calculate net loss per share - basic and diluted | 98,982 | 94,691 |

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**Contacts:**
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