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): August 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 **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 August 6, 2024, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended June 30, 2024 and providing business update. 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 Second Quarter 2024 Financial Results and Provides Business Update," dated August 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: August 6, 2024

By: /s/ Juan Graham

Juan Graham
Senior Vice President and Chief Financial Officer

Exhibit 99.1

FibroGen Reports Second Quarter 2024 Financial Results and Provides Business Update

- ***Company implementing significant cost reduction plan in the U.S. due to results in late-stage pamrevlumab pancreatic cancer trials, including a reduction of U.S. workforce by approximately 75%***
- ***Focus R&D investment on FG-3246 and PET46, a first-in-class anti-CD46 antibody-drug conjugate and companion PET imaging agent for metastatic castration-resistant prostate cancer (mCRPC)***
- ***Presented compelling preliminary data from dose escalation portion of Phase 1b/2 investigator-sponsored study of FG-3246, in combination with enzalutamide, in patients with mCRPC at the 2024 American Society of Clinical Oncology Annual Meeting***
  - ***Topline results from Phase 2 portion of the study expected in 1H 2025***
- ***Anticipate initiation of Phase 2 monotherapy dose optimization study of FG-3246 in mCRPC in 1Q 2025***
- ***Second quarter net revenue growth of 14% year over year, driven by strong performance of roxadustat in China, with robust year over year volume growth of 33%***
  - ***Raising full year net product revenue guidance to $135 million to $150 million, representing full year total roxadustat net sales in China[1] between $320 million to $350 million***
- ***Cash, cash equivalents and accounts receivable balance of $147.1 million; cash runway projected into 2026***

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

"While we are disappointed with the results from the pamrevlumab pancreatic cancer trials, we continue to be very excited about the prospects of FG-3246 and PET46, our CD46 targeted antibody-drug conjugate and companion PET imaging agent. We have released compelling Phase 1 data on FG-3246 as a monotherapy and in combination with enzalutamide in metastatic castration-resistant prostate cancer. In addition, roxadustat continues its strong momentum in China, exceeding $92 million in net sales in the second quarter," said Thane Wettig, Chief Executive Officer, FibroGen. "Looking ahead, we expect topline data from the Phase 2 portion of the FG-3246 + enzalutamide combination study in mCRPC in the first half of 2025 and plan on initiating our Phase 2 monotherapy study in mCRPC in the first quarter of 2025 with a more focused and streamlined organization. I would like to express my deepest gratitude to our FibroGen colleagues who have dedicated so much of their time and energy for the prospect of bringing much needed therapies to some of the most challenging and deadly diseases affecting humanity."

Recent Developments and Key Events of Second Quarter 2024:

- Implementing significant cost reduction plan in the U.S.
  - Headcount in the U.S. will be reduced by approximately 75%.
- Focusing R&D investment on FG-3246 and PET46, a first-in-class antibody-drug conjugate and companion PET imaging agent for mCRPC.
- Announced positive interim results from the dose escalation portion of the investigator-sponsored Phase 1b/2 study conducted by the University of California San Francisco of FG-3246 (FOR46), a potential first-in-class anti-CD46 antibody drug conjugate (ADC) with a MMAE-containing payload, in combination with enzalutamide in patients with metastatic castration resistant prostate cancer (mCRPC) at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.
  - The presentation included data from 17 biomarker unselected patients in the dose escalation portion of the trial. Over 70% of the patients in the study received at least two prior ARSIs, which included prior enzalutamide treatment.

[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.

- The primary endpoint was determination of the maximally tolerated dose (MTD) of FG-3246 in combination with enzalutamide. The MTD was established at 2.1 mg/kg ABW, with primary G-CSF prophylaxis, in combination with enzalutamide 160 mg/day. The combination treatment demonstrated an encouraging preliminary estimate of median radiographic progression free survival (rPFS) of 10.2 months with prostate-specific antigen (PSA) declines observed in 71% (12/17) of evaluable patients.

- 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.
- Reported topline results from the pamrevlumab arm of PanCAN Precision Promise Phase 2/3 adaptive platform trial for the treatment of metastatic pancreatic ductal adenocarcinoma (mPDAC), in which the trial did not meet the primary endpoint.
- Reported topline results from the LAPIS Phase 3 study of pamrevlumab in patients with locally advanced, unresectable pancreatic cancer (LAPC), in which the trial did not meet the primary endpoint.

Upcoming Milestones:

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

- Topline results from the Phase 2 portion of the investigator-sponsored Phase 1b/2 study conducted by the University of California San Francisco of FG-3246 in combination with enzalutamide in patients with mCRPC expected in 1H 2025.
- Anticipate initiation of Phase 2 monotherapy dose optimization study of FG-3246 in mCRPC in 1Q 2025.

China:

- Second quarter FibroGen net product revenue under U.S. GAAP from the sale of roxadustat in China was $49.6 million compared to $23.9 million in the first quarter of 2023, an increase of 108% year over year.
- Second quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca (JDE) was $92.3 million, compared to $76.4 million in the second quarter of 2023, an increase of 21% year over year, driven by a 33% 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, FibroGen's expected full year net product revenue under U.S. GAAP is raised to a range between $135 million to $150 million, representing expected full year roxadustat net sales in China[1] by FibroGen and the JDE of $320 million to $350 million, due to continued strong performance in China.

[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.

Financial:

- Total revenue for the second quarter of 2024 was $50.6 million, as compared to $44.3 million for the second quarter of 2023, an increase of 14% year over year. Total revenue increase was driven by strong performance of roxadustat in China and changes in net product revenue assumptions under U.S. GAAP.
- Net loss for the second quarter of 2024 was $15.5 million, or $0.16 net loss per basic and diluted share, compared to a net loss of $87.7 million, or $0.90 net loss per basic and diluted share one year ago.
- At June 30, 2024, FibroGen reported $147.1 million in cash, cash equivalents and accounts receivable.
- We expect our cash, cash equivalents and accounts receivable to be sufficient to fund our operating plans into 2026.

Conference Call and Webcast Details
FibroGen management will host a conference call and webcast today, Tuesday, August 6, 2024, at 5:00 PM Eastern Time to discuss financial results and provide a business update. Interested parties may access the conference call by dialing 1-877-300-8521 (in the U.S.) or 1-412-317-6026 (outside the U.S.). The call will be available via webcast by clicking here or on the "Events and Presentation" page on the FibroGen website.

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. 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.

Forward-Looking Statements

This release contains forward-looking statements regarding FibroGen's strategy, future plans and prospects, including statements regarding its commercial products and clinical programs and those of its collaboration partners Fortis and UCSF. These forward-looking statements include, but are not limited to, statements regarding the efficacy, safety, and potential clinical or commercial success of FibroGen products and product candidates, statements under the caption "Upcoming Milestones", statements regarding the expectation that cash, cash equivalents and accounts receivable will be sufficient to fund FibroGen's operating plans into 2026, and statements about FibroGen's plans and objectives. These forward-looking statements are typically 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, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, each 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)

	June 30, 2024 (Unaudited)	December 31, 2023 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 140,714	$ 113,688
Short-term investments	-	121,898
Accounts receivable, net	6,412	12,553
Inventory	25,397	41,565
Prepaid expenses and other current assets	36,936	41,855
Total current assets	209,459	331,559
Restricted time deposits	1,658	1,658
Property and equipment, net	10,917	13,126
Equity method investment in unconsolidated variable interest entity	6,912	5,290
Operating lease right-of-use assets	61,212	68,093
Other assets	3,045	3,803
Total assets	$ 293,203	$ 423,529
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 9,938	$ 17,960
Accrued and other liabilities	113,574	172,891
Deferred revenue	9,546	12,740
Operating lease liabilities, current	15,531	14,077
Total current liabilities	148,589	217,668
Product development obligations	17,397	17,763
Deferred revenue, net of current	131,192	157,555
Operating lease liabilities, non-current	58,376	66,537
Senior secured term loan facilities, non-current	72,478	71,934
Liability related to sale of future revenues, non-current	54,532	51,413
Other long-term liabilities	1,012	2,858
Total liabilities	483,576	585,728
Redeemable non-controlling interests	21,480	21,480
Total stockholders' deficit attributable to FibroGen	(232,340)	(204,166)
Nonredeemable non-controlling interests	20,487	20,487
Total deficit	(211,853)	(183,679)
Total liabilities, redeemable non-controlling interests and deficit	$ 293,203	$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)			
Revenue:				
License revenue	$ —	$ 1,000	$ —	$ 7,000
Development and other revenue	269	5,158	1,147	9,050
Product revenue, net	49,643	23,889	80,181	48,049
Drug product revenue, net	729	14,272	25,216	16,381
Total revenue	50,641	44,319	106,544	80,480
Operating costs and expenses:				
Cost of goods sold	5,178	5,708	30,931	9,199
Research and development	34,106	95,478	72,498	169,964
Selling, general and administrative	22,276	31,181	45,097	65,455
Total operating costs and expenses	61,560	132,367	148,526	244,618
Loss from operations	(10,919)	(88,048)	(41,982)	(164,138)
Interest and other, net:				
Interest expense	(4,783)	(3,069)	(9,779)	(5,441)
Interest income and other income (expenses), net	(1,281)	2,652	1,289	3,687
Total interest and other, net	(6,064)	(417)	(8,490)	(1,754)
Loss before income taxes	(16,983)	(88,465)	(50,472)	(165,892)
Benefit from income taxes	(262)	(235)	(229)	(161)
Investment income in unconsolidated variable interest entity	1,177	550	1,766	1,346
Net loss	$ (15,544)	$ (87,680)	$ (48,477)	$ (164,385)
Net loss per share - basic and diluted	$ (0.16)	$ (0.90)	$ (0.49)	$ (1.71)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	99,835	97,729	99,408	96,218

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