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 07, 2023

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 7, 2023, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended June 30, 2023. 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 2023 Financial Results," dated August 7, 2023
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 7, 2023

By: /s/ Juan Graham

Juan Graham
Senior Vice President and Chief Financial Officer

Exhibit 99.1

FibroGen Reports Second Quarter 2023 Financial Results

- ***Topline data from three late-stage pamrevlumab trials expected through 1H 2024, including the Pancreatic Cancer Action Network (PanCAN) Precision PromiseSM Phase 2/3 study in metastatic pancreatic cancer***
- ***Robust roxadustat volume growth of over 40% in China***
- ***Entered into exclusive license for FOR46, a first-in-class CD46-targeting antibody-drug conjugate (ADC) for the treatment of metastatic castration-resistant prostate cancer***
- ***Implemented cost reduction plan extending cash runway into 2026***
- ***Thane Wettig appointed Interim CEO***

SAN FRANCISCO, August 7, 2023 (GLOBE NEWSWIRE) - FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the second quarter 2023 and provided an update on the Company's recent developments.

"We saw another record quarter of roxadustat sales in China, and we recently submitted the sNDA to the China Health Authority for chemotherapy-induced anemia," said Thane Wettig, Interim Chief Executive Officer, FibroGen. "As I assume the leadership role, I am very optimistic about our future. Within the next year, we have three pamrevlumab read-outs and key milestones for our early-stage pipeline, which combined with our deeply experienced team and strong cash position, set us up well for delivering value to patients and shareholders."

Recent Developments and Key Events of Second Quarter 2023:

- Appointed Thane Wettig as Interim Chief Executive Officer.
- Entered into exclusive license for FOR46 (now FG-3246), a first-in-class CD46-targeting ADC for the treatment of metastatic castration-resistant prostate cancer (mCRPC).
- Reported positive topline data from Company's Phase 3 clinical study of roxadustat for treatment of anemia in patients receiving concurrent chemotherapy treatment for non-myeloid malignancies in China.
- Filed Supplemental New Drug Application (sNDA) with China Health Authority for roxadustat in patients with chemotherapy-induced anemia.
- Announced a non-dilutive term loan facility with investment funds managed by Morgan Stanley Tactical Value (MSTV), which resulted in proceeds to FibroGen of $75 million.
- Reported negative topline results from MATTERHORN Phase 3 clinical study of roxadustat for treatment of anemia in patients with transfusion-dependent lower risk myelodysplastic syndromes (MDS).
- Reported negative topline results from the LELANTOS-1 Phase 3 study of pamrevlumab for the treatment of non-ambulatory patients with Duchenne muscular dystrophy (DMD).
- Reported negative topline results from the ZEPHYRUS-1 Phase 3 study of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF). Discontinued ZEPHYRUS-2 Phase 3 study of pamrevlumab in patients with IPF.
- Implemented a cost reduction plan, resulting in an expected reduction of total annualized U.S. GAAP expenses of $100-120 million.

China Performance:

- Achieved second quarter net product revenue under U.S. GAAP from the sale of roxadustat in China of $23.9 million compared to $23.3 million in the second quarter of 2022.
- Achieved second quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca of $76.4 million, compared to $53.1 million in the second quarter of 2022, an increase of 44%, driven by over 40% growth in volume.
- Roxadustat continues to be the number one brand based on value share in the anemia of chronic kidney disease market in China.

Upcoming Milestones:

Pamrevlumab

- Topline data from the LELANTOS-2 Phase 3 study of pamrevlumab in ambulatory DMD patients expected in 3Q 2023.
- Topline data from the LAPIS Phase 3 study of pamrevlumab in locally advanced unresectable pancreatic cancer (LAPC) expected in 1Q 2024.
- Topline data from the PanCAN Precision Promise^{SM} Phase 2/3 study of pamrevlumab in metastatic pancreatic cancer expected in 1H 2024.

Early-Stage Oncology Pipeline

- Anticipate the initiation of a Phase 2 trial of FG-3246, a first-in-class ADC targeting a novel epitope on CD46 for mCRPC in 2H 2024.
- Anticipate the filing of two INDs: FG-3165 (anti-Gal9 antibody) in 1Q 2024 and FG-3175 (anti-CCR8 antibody) in 2H 2024.

Financial:

- Total revenue for the second quarter of 2023 was $44.3 million, as compared to $29.8 million for the second quarter of 2022, an increase of 49%.
- Net loss for the second quarter of 2023 was $87.7 million, or $0.90 net loss per basic and diluted share, compared to a net loss of $72.6 million, or $0.78 net loss per basic and diluted share one year ago.
- Research and development expenses for the second quarter of 2023 included a one-time, non-cash charge of acquired in-process research and development expenses of $24.6 million, or $0.25 impact to net loss per basic and diluted share, resulting from the recent exclusive license for FG-3246 from Fortis Therapeutics.
- At June 30, 2023, cash – defined as cash, cash equivalents, investments, and accounts receivable – was$361.3 million, including proceeds received during the quarter from the Company's use of its at-the-market equity facility and the closing of the recently announced term loan.
- 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, August 7, 2023, 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 in to 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), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is in Phase 3 clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), ambulatory Duchenne muscular dystrophy (DMD), 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 DMD and LAPC. The U.S. Food and Drug Administration has also granted Rare Pediatric Disease Designation to pamrevlumab for the treatment of patients with DMD. Pamrevlumab has demonstrated a safety and tolerability profile that has supported ongoing clinical investigation in DMD, 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) in China.

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. FibroGen and AstraZeneca are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in the U.S., China, and other markets not licensed to Astellas.

About FibroGen
FibroGen, Inc. is a biopharmaceutical company committed to discovering, developing, and commercializing a pipeline of first-in-class therapeutics. The Company applies its pioneering expertise in connective tissue growth factor (CTGF) biology and hypoxia-inducible factor (HIF) to advance innovative medicines for the treatment of unmet needs. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), metastatic pancreatic cancer, and ambulatory Duchenne muscular dystrophy (DMD). Roxadustat (®, EVRENZO™) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in CKD patients on dialysis and not on dialysis. Roxadustat is in clinical development for chemotherapy-induced anemia (CIA) in China. FibroGen recently expanded its research and development portfolio to include product candidates in the immuno-oncology space along with an exclusive license for FG-3246. 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 the development and commercialization of the company's product candidates, the potential safety and efficacy profile of its product candidates, and its clinical programs. These forward-looking statements include, but are not limited to, statements under the caption "Upcoming Milestones", statements regarding the expected cost reduction savings, the statement that FibroGen expects its cash, cash equivalents, investments, and accounts receivable to be sufficient to fund its operating plans into 2026, 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, 2022, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, 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.

Condensed Consolidated Balance Sheets
(In thousands)

	June 30, 2023 (Unaudited)	December 31, 2022 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 152,585	$ 155,700
Short-term investments	183,131	266,308
Accounts receivable, net	25,599	16,299
Inventory	41,179	40,436
Prepaid expenses and other current assets	8,863	14,083
Total current assets	411,357	492,826
Restricted time deposits	2,072	2,072
Long-term investments	—	4,348
Property and equipment, net	16,829	20,605
Equity method investment in unconsolidated variable interest entity	6,112	5,061
Operating lease right-of-use assets	74,404	79,893
Other assets	4,353	5,282
Total assets	$ 515,127	$ 610,087
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 12,802	$ 30,758
Accrued and other liabilities	162,769	219,773
Deferred revenue	7,490	12,739
Operating lease liabilities, current	11,011	10,292
Total current liabilities	194,072	273,562
Product development obligations	17,365	16,917
Deferred revenue, net of current	165,416	185,722
Operating lease liabilities, non-current	73,813	79,593
Senior secured term loan facilities, non-current	71,408	—
Liability related to sale of future revenues, non-current	48,399	49,333
Other long-term liabilities	4,961	6,440
Total liabilities	575,434	611,567
Redeemable non-controlling interests	21,480	—
Total stockholders' deficit attributable to FibroGen	(102,274)	(21,447)
Nonredeemable non-controlling interests	20,487	19,967
Total deficit	(81,787)	(1,480)
Total liabilities, redeemable non-controlling interests and deficit	$ 515,127	$ 610,087

(1) The condensed consolidated balance sheet amounts at December 31, 2022 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,	
	2023	2022	2023	2022
	(Unaudited)			
Revenue:				
License revenue	$ 1,000	$ —	$ 7,000	$ 22,590
Development and other revenue	5,158	5,457	9,050	17,219
Product revenue, net	23,889	23,256	48,049	42,137
Drug product revenue, net	14,272	1,093	16,381	8,687
Total revenue	44,319	29,806	80,480	90,633
Operating costs and expenses:				
Cost of goods sold	5,708	6,809	9,199	11,048
Research and development	95,478	70,963	169,964	159,981
Selling, general and administrative	31,181	30,258	65,455	60,820
Total operating costs and expenses	132,367	108,030	244,618	231,849
Loss from operations	(88,048)	(78,224)	(164,138)	(141,216)
Interest and other, net:				
Interest expense	(3,069)	(141)	(5,441)	(238)
Interest income and other income (expenses), net	2,652	5,199	3,687	4,876
Total interest and other, net	(417)	5,058	(1,754)	4,638
Loss before income taxes	(88,465)	(73,166)	(165,892)	(136,578)
Provision for income taxes	(235)	23	(161)	136
Investment income in unconsolidated variable interest entity	550	565	1,346	885
Net loss	$ (87,680)	$ (72,624)	$ (164,385)	$ (135,829)
Net loss per share - basic and diluted	$ (0.90)	$ (0.78)	$ (1.71)	$ (1.46)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	97,729	93,475	96,218	93,260

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