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 06, 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 November 6, 2023, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended September 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 Third Quarter 2023 Financial Results," dated November 6, 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: November 6, 2023

By: /s/ Juan Graham
Juan Graham
Senior Vice President and Chief Financial Officer

FibroGen Reports Third Quarter 2023 Financial Results

- ***Topline data from two pivotal pamrevlumab pancreatic cancer trials on track to read out in 1H 2024, including the Pancreatic Cancer Action Network (PanCAN) Precision Promise℠ Phase 2/3 study in metastatic pancreatic cancer***
- ***Third quarter net revenue of $40.1 million, an increase of 155% year over year***
- ***Roxadustat sNDA accepted in China for chemotherapy-induced anemia***
- ***Robust roxadustat volume growth of 37% in China***
- ***Strong execution of cost reduction plan reaffirming cash runway into 2026***

SAN FRANCISCO, November 6, 2023 (GLOBE NEWSWIRE) - FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the third quarter 2023 and provided an update on the Company's recent developments.

"Today, we reported another quarter of strong roxadustat volume growth in China, achieving the highest ever value share, at 42%, in the anemia of CKD category," said Thane Wettig, Chief Executive Officer, FibroGen. "The continued strength of our China business, sooner than expected realization of our corporate cost reduction efforts and our strong balance sheet provide us a cash runway into 2026. Over the next 12 months, we will obtain data read-outs from our two late-stage pancreatic cancer trials, start a Phase 2 metastatic castrate-resistant prostate cancer trial, and file two immuno-oncology INDs. These unique and exciting programs, combined with the quality of our talented colleagues, provide a strong foundation to create significant value for shareholders relative to our current valuation."

Recent Developments and Key Events of Third Quarter 2023:

- Appointed Thane Wettig as Chief Executive Officer.
- Supplemental New Drug Application (sNDA) accepted by the China Health Authority for roxadustat for the treatment of patients with chemotherapy-induced anemia (CIA). Expect approval decision of CIA in China in mid-2024.
- Successful implementation of cost reduction plan, now resulting in an expected reduction of total annualized expenses of $120 million.
- Reported negative topline results from the LELANTOS-2 Phase 3 study of pamrevlumab for the treatment of ambulatory patients with Duchenne muscular dystrophy (DMD).
- Presented Phase 3 data of roxadustat for CIA in patients with non-myeloid malignancies in an oral presentation at the *European Society for Medical Oncology Congress 2023*.
- FibroGen and its partners presented five roxadustat abstracts, including four poster presentations and one late-breaker poster presentation, at the recent *American Society of Nephrology (ASN) Kidney Week 2023* conference.
- Presented preclinical data for the FG-3165 anti-Gal9 antibody program at the *Society for Immunotherapy of Cancer Annual Meeting 2023*.

China Performance:

- Achieved third quarter net product revenue under U.S. GAAP from the sale of roxadustat in China of $29.4 million compared to $17.4 million in the third quarter of 2022, an increase of 69% year over year.
- Achieved third quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca of $77.1 million, compared to $59.0 million in the third quarter of 2022, an increase of 31% year over year, driven by 37% 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.

[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.

Upcoming Milestones:

Pamrevlumab

- 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.

Oncology Pipeline

- Expect topline clinical trial results from Phase 1 monotherapy trial of FG-3246, a first-in-class antibody-drug conjugate (ADC) targeting a novel epitope on CD46 for metastatic castration-resistant prostate cancer (mCRPC) by 1Q 2024.
- Anticipate the initiation of a Phase 2 trial of FG-3246 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 third quarter of 2023 was $40.1 million, as compared to $15.7 million for the third quarter of 2022, an increase of 155% year over year.
- Net loss for the third quarter of 2023 was $63.6 million, or $0.65 net loss per basic and diluted share, compared to a net loss of $91.7 million, or $0.98 net loss per basic and diluted share one year ago.
- Restructuring charge for the third quarter of 2023 was $12.6 million, or $0.13 impact to net loss per basic and diluted share, resulting from the reduction in U.S. workforce announced in July 2023.
- At September 30, 2023, cash – defined as cash, cash equivalents, investments, and accounts receivable – was $283.0 million.
- We expect our cash, cash equivalents, investments, and accounts receivable to be sufficient to fund our operating plans into 2026.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, November 6, 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). 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. 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) and metastatic pancreatic cancer. 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) and a Supplemental New Drug Application (sNDA) has been accepted by the China Health Authority. FibroGen recently expanded its research and development portfolio to include product candidates in oncology. 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 company's financial performance, 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 September 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)

	September 30, 2023 (Unaudited)	December 31, 2022 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 120,914	$ 155,700
Short-term investments	130,426	266,308
Accounts receivable, net	31,694	16,299
Inventory	40,696	40,436
Prepaid expenses and other current assets	40,378	14,083
Total current assets	364,108	492,826
Restricted time deposits	2,072	2,072
Long-term investments	—	4,348
Property and equipment, net	14,512	20,605
Equity method investment in unconsolidated variable interest entity	4,534	5,061
Operating lease right-of-use assets	71,248	79,893
Other assets	3,952	5,282
Total assets	$ 460,426	$ 610,087
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 19,220	$ 30,758
Accrued and other liabilities	170,986	219,773
Deferred revenue	7,325	12,739
Operating lease liabilities, current	11,884	10,292
Total current liabilities	209,415	273,562
Product development obligations	16,942	16,917
Deferred revenue, net of current	154,206	185,722
Operating lease liabilities, non-current	70,035	79,593
Senior secured term loan facilities, non-current	71,666	—
Liability related to sale of future revenues, non-current	49,109	49,333
Other long-term liabilities	4,255	6,440
Total liabilities	575,628	611,567
Redeemable non-controlling interests	21,480	—
Total stockholders' deficit attributable to FibroGen	(157,169)	(21,447)
Nonredeemable non-controlling interests	20,487	19,967
Total deficit	(136,682)	(1,480)
Total liabilities, redeemable non-controlling interests and deficit	$ 460,426	$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(Unaudited)			
Revenue:				
License revenue	$ 2,649	$ —	$ 9,649	$ 22,590
Development and other revenue	6,775	2,453	15,825	19,672
Product revenue, net	29,390	17,359	77,439	59,495
Drug product revenue, net	1,320	(4,077)	17,701	4,610
Total revenue	40,134	15,735	120,614	106,367
Operating costs and expenses:				
Cost of goods sold	4,243	4,308	13,441	15,355
Research and development	61,194	75,182	231,158	235,163
Selling, general and administrative	25,573	29,902	91,029	90,722
Restructuring charge	12,606	—	12,606	—
Total operating costs and expenses	103,616	109,392	348,234	341,240
Loss from operations	(63,482)	(93,657)	(227,620)	(234,873)
Interest and other, net:				
Interest expense	(5,022)	(84)	(10,464)	(321)
Interest income and other income (expenses), net	4,296	1,798	7,984	6,672
Total interest and other, net	(726)	1,714	(2,480)	6,351
Loss before income taxes	(64,208)	(91,943)	(230,100)	(228,522)
Provision for (benefit from) income taxes	84	114	(77)	250
Investment income in unconsolidated variable interest entity	677	407	2,023	1,293
Net loss	$ (63,615)	$ (91,650)	$ (228,000)	$ (227,479)
Net loss per share - basic and diluted	$ (0.65)	$ (0.98)	$ (2.35)	$ (2.43)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	98,245	93,767	96,901	93,431

# # #

Contacts:
FibroGen, Inc.

Investors:
David DeLucia, CFA
Vice President of Corporate FP&A / Investor Relations
ddelucia@fibrogen.com

Media:
Meichiel Keenan
Director, Investor Relations and Corporate Communications
mkeenan@fibrogen.com