FibroGen Reports Fourth Quarter and Full Year 2023 Financial Results

February 26, 2024

- ***Topline data from two pivotal pamrevlumab pancreatic cancer trials anticipated in 2Q 2024***
- ***Additional data from Phase 1 monotherapy study of FG-3246 in metastatic castration-resistant prostate cancer (mCRPC) expected in 1Q 2024***
- ***FibroGen regains rights to roxadustat from AstraZeneca in the United States and other AstraZeneca territories, except China and South Korea***
- ***FY 2023 total net revenue of $147.8 million, an increase of 5% year over year***
- ***Robust roxadustat volume growth of 41% in China in FY 2023 compared to FY 2022***
- ***Successful execution of cost reduction plan; $248.1 million in cash provides cash runway into 2026***

SAN FRANCISCO, Feb. 26, 2024 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the fourth quarter and full year 2023 and provided an update on the company's recent developments.

"We are extremely excited about the company's prospects in 2024," said Thane Wettig, Chief Executive Officer, FibroGen. "In this year alone, we will obtain data read-outs from our two late-stage pancreatic cancer trials, start a Phase 2 metastatic castration-resistant prostate cancer trial, file an immuno-oncology IND, and potentially receive approval for roxadustat in chemotherapy-induced anemia in China. Furthermore, the continued strength of our China business, accelerated realization of our corporate cost reduction program, and our strong balance sheet provide us a cash runway into 2026. 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."

Upcoming Milestones:

Pamrevlumab

- Topline data from the PanCAN Precision Promise℠ Phase 2/3 study of pamrevlumab in metastatic pancreatic cancer expected in 2Q 2024.
- Topline data from the LAPIS Phase 3 study of pamrevlumab in locally advanced unresectable pancreatic cancer (LAPC) expected in 2Q 2024.

Roxadustat

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

Oncology Pipeline

- Additional data from Phase 1 monotherapy study of FG-3246 in metastatic castration-resistant prostate cancer (mCRPC) expected in 1Q 2024.
- Anticipate the initiation of a Phase 2 study of FG-3246 in 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 2025.

Recent Developments and Key Highlights of 2023:

Pamrevlumab

- Announced graduation and completion of the pamrevlumab arm in Precision Promise℠, Pancreatic Cancer Action Network's Phase 2/3 adaptive platform trial for metastatic pancreatic cancer.
  - Pamrevlumab, in Stage 1 of the trial, achieved a protocol pre-specified ≥ 35% predictive probability of success for the primary endpoint of overall survival at the completion of the trial.

Roxadustat

- Regained all rights to roxadustat from AstraZeneca in the United States and other AstraZeneca territories, except China

and South Korea.
- Presented data from Phase 3 MATTERHORN study of roxadustat in patients with anemia of lower risk transfusion-dependent myelodysplastic syndromes at American Society of Hematology Annual Meeting.

Corporate

- Thane Wettig appointed Chief Executive Officer.
- Successful execution of cost reduction plan, resulting in a reduction of total annualized expenses of $120 million.

China:

- Fourth quarter FibroGen's net product revenue under U.S. GAAP from the sale of roxadustat in China was $23.5 million compared to $23.4 million in the fourth quarter of 2022.
- Full year 2023 FibroGen's net product revenue under U.S. GAAP from the sale of roxadustat in China was $100.9 million compared to $82.9 million in the full year 2022, an increase of 22%.
- Fourth quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca (JDE) was $66.5 million, compared to $53.1 million in the fourth quarter of 2022, an increase of 25%.
- Full year 2023 total roxadustat net sales in China[1] by FibroGen and the JDE was $284.1 million, compared to $208.8 million in the full year 2022, an increase of 36%, driven by over 41% growth in volume.
- Roxadustat continues to be the number one brand based on value share in the anemia of CKD market in China and has secured renewal on the National Reimbursement Drug List.
- For 2024, we anticipate 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 fourth quarter of 2023 was $27.1 million, as compared to $34.4 million for the fourth quarter of 2022. Reduction primarily driven by the change in net product revenue assumptions under U.S. GAAP and drug product revenue shipment timing.
- Total revenue for full year 2023 was $147.8 million as compared to $140.7 million in 2022.
- Net loss for the fourth quarter of 2023 was $56.2 million, or $0.57 net loss per basic and diluted share, compared to a net loss of $66.2 million, or $0.70 net loss per basic and diluted share one year ago.
- Net loss for the year was $284.2 million, or $2.92 net loss per basic and diluted share, compared to a net loss of $293.7 million, or $3.14 net loss per basic and diluted share one year ago.
- At December 31, 2023, FibroGen had $248.1 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.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, February 26, 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, an anti-CTGF fully human 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. FibroGen recently expanded its research and development portfolio to include antibody-drug conjugate (ADC) and 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 the development and commercialization of roxadustat, including its commercial potential, and the potential safety and efficacy profile of roxadustat. These forward-looking statements include but are not limited to 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.

Condensed Consolidated Balance Sheets
(In thousands)

	December 31, 2023 (Unaudited)	December 31, 2022 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 113,688	$ 155,700
Short-term investments	121,898	266,308
Accounts receivable, net	12,553	16,299
Inventory	41,565	40,436
Prepaid expenses and other current assets	41,855	14,083
Total current assets	331,559	492,826
Restricted time deposits	1,658	2,072
Long-term investments	—	4,348
Property and equipment, net	13,126	20,605
Equity method investment in unconsolidated variable interest entity	5,290	5,061
Operating lease right-of-use assets	68,093	79,893
Other assets	3,803	5,282
Total assets	$ 423,529	$ 610,087
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 17,960	$ 30,758
Accrued and other liabilities	172,891	219,773
Deferred revenue	12,740	12,739
Operating lease liabilities, current	14,077	10,292
Total current liabilities	217,668	273,562
Product development obligations	17,763	16,917

Deferred revenue, net of current	157,555	185,722
Operating lease liabilities, non-current	66,537	79,593
Senior secured term loan facilities, non-current	71,934	—
Liability related to sale of future revenues, non-current	51,413	49,333
Other long-term liabilities	2,858	6,440
Total liabilities	585,728	611,567
Redeemable non-controlling interests	21,480	—
Total stockholders' deficit attributable to FibroGen	(204,166)	(21,447)
Nonredeemable non-controlling interests	20,487	19,967
Total deficit	(183,679)	(1,480)
Total liabilities, redeemable non-controlling interests and deficit	$ 423,529	$ 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 December 31,		Years Ended December 31,	
	2023	**2022**	**2023**	**2022**
	(Unaudited)		**(Unaudited)**	**(1)**
Revenue:				
License revenue	$ —	$ —	$ 9,649	$ 22,590
Development and other revenue	2,575	4,517	18,401	24,189
Product revenue, net	23,510	23,374	100,949	82,869
Drug product revenue, net	1,052	6,476	18,753	11,086
Total revenue	27,137	34,367	147,752	140,734
Operating costs and expenses:				
Cost of goods sold	5,406	4,924	18,848	20,280
Research and development	51,702	61,628	282,861	296,791
Selling, general and administrative	24,224	33,966	115,252	124,688
Restructuring charge	—	—	12,606	—
Total operating costs and expenses	81,332	100,518	429,567	441,759
Loss from operations	(54,195)	(66,151)	(281,815)	(301,025)
Interest and other, net:				
Interest expense	(5,068)	(1,119)	(15,532)	(1,440)
Interest income and other income (expenses), net	2,496	923	10,480	7,596
Total interest and other, net	(2,572)	(196)	(5,052)	6,156
Loss before income taxes	(56,767)	(66,347)	(286,867)	(294,869)
Provision for (benefit from) income taxes	80	108	3	358
Investment income in unconsolidated variable interest entity	615	280	2,638	1,573
Net loss	$ (56,232)	$ (66,175)	$ (284,232)	$ (293,654)
Net loss per share - basic and diluted	$ (0.57)	$ (0.70)	$ (2.92)	$ (3.14)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	98,496	94,032	97,303	93,582

(1) The condensed consolidated statement of operations amounts for the year ended December 31, 2022 are derived from audited financial statements.

Contacts:
FibroGen, Inc.

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

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

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[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.

Source: FibroGen, Inc.