FibroGen Reports Fourth Quarter and Full Year 2020 Financial Results

March 1, 2021

• Strong Fourth Quarter China Roxadustat Net Sales of $29.2 Million and 2020 full-year Net Sales of $72.5 Million

• FDA to hold Advisory Committee Meeting on Roxadustat New Drug Application

SAN FRANCISCO, March 01, 2021 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the fourth quarter and full year 2020 and provided an update on the company's recent developments.

"While disappointed with the news today, FibroGen and AstraZeneca remain confident in the efficacy and safety profile of roxadustat based on positive results from a global Phase 3 program encompassing more than 8,000 patients," said Enrique Conterno, Chief Executive Officer, FibroGen. "With strong roxadustat commercial results in China, we continue to drive forward in our three main areas of focus: ensuring the regulatory and commercial success of roxadustat; accelerating the development of pamrevlumab in the three high-value indications of locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF); and building our research capabilities in both hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology while adding to our clinical development pipeline."

Key Events in 2020 and Other Developments

Roxadustat

- **Regulatory:**
  - The Cardiovascular and Renal Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) will hold an advisory committee (AdCom) meeting to review the new drug application (NDA) for roxadustat in the U.S. The companies have not received a confirmed AdCom meeting date from the FDA.
  - In November 2020, Japan's Ministry of Health, Labour and Welfare (MHLW) approved EVRENZO® (roxadustat) for the treatment of anemia of CKD in adult patients not on dialysis.
  - The Marketing Authorization Application (MAA) for roxadustat for the treatment of anemia in adult patients with CKD was accepted for regulatory review by the European Medicines Agency (EMA) in May 2020, with an expected decision by mid-2021.

- **Clinical:**
  - Enrollment was completed in the WHITNEY US Phase 2 roxadustat clinical trial in chemotherapy-induced anemia (CIA) in 4Q 2020.
  - Enrollment continued in the MATTERHORN Phase 3 roxadustat clinical trial in anemia associated with myelodysplastic syndromes (MDS).
  - Enrollment was completed in the ASPEN and DENALI Phase 3b roxadustat clinical trials in dialysis patients with anemia of CKD.

- **Publications / Presentations:**
  - Roxadustat data was presented at the following scientific meetings in 2020:
    - The National Kidney Foundation Spring Clinical Meeting
    - The 57th European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) Virtual Congress
    - The American Society of Nephrology (ASN) Kidney Week 2020 Reimagined
    - The 62nd American Society of Hematology (ASH) Annual Meeting and Exposition
  - Roxadustat Phase 3 manuscripts on the treatment of anemia of CKD were published in peer-reviewed medical journals:
    - Pooled Analysis of Roxadustat for Anemia in Patients with Kidney Failure Incident to Dialysis *Kidney International Reports*
    - Roxadustat for Chronic Kidney Disease-related Anemia in Non-dialysis Patients *Kidney International Reports*
    - Roxadustat for Treating Anemia in Patients with CKD Not on Dialysis: Results from a Randomized Phase 3 Study *Journal of the American Society of Nephrology*
    - Roxadustat for the Treatment of Anemia in Chronic Kidney Disease (CKD) Patients Not on Dialysis: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study (ALPS) *Nephrology Dialysis Transplantation*
    - Roxadustat for anemia in patients with end-stage renal disease incident to dialysis *Nephrology Dialysis Transplantation*

Pamrevlumab

- Enrollment continued in the LAPIS Phase 3 clinical trial of pamrevlumab in patients with locally advanced unresectable pancreatic cancer (LAPC).
- Enrollment continued in the LELANTOS Phase 3 clinical trial of pamrevlumab in non-ambulatory patients with Duchenne muscular dystrophy (DMD).
- Enrollment continued in the ZEPHYRUS Phase 3 clinical trial of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF).
- In December, we initiated a second Phase 3 clinical trial of pamrevlumab, ZEPHYRUS-2, in patients with idiopathic pulmonary fibrosis (IPF).

Upcoming Data Catalysts

- Data from the Phase 2 WHITNEY study of roxadustat in chemotherapy-induced anemia (CIA) expected 2H 2021.
- Data from the Phase 3 MATTERHORN study of roxadustat in anemia of myelodysplastic syndromes (MDS) expected 1H 2022.
- Resection data from the Phase 3 LAPIS study of pamrevlumab in locally advanced pancreatic cancer (LAPC) expected 2H 2022.
- Data from the Phase 3 LELANTOS study of pamrevlumab in Duchenne muscular dystrophy (DMD) expected 2H 2022.

2020 Key Executive Additions

- Percy Carter, Ph.D., was appointed to the newly created position of Chief Scientific Officer.
- Mark Eisner, M.D., M.P.H., was appointed as Chief Medical Officer.
- Thane Wettig was appointed to the newly created position of Chief Commercial Officer.

Financial

- Total revenue for the fourth quarter of 2020 was $65.0 million, as compared to $8.0 million for the fourth quarter of 2019. The current quarter revenue consists of net product revenues of $29.2 million for roxadustat sales in China, $21.5 million in development revenue, and $14.3 million in license revenue related to NDD approval in Japan. Total net roxadustat sales in China for 2020 were $72.5 million.
- Net loss for the fourth quarter of 2020 was $58.6 million, or $0.64 net loss per basic and diluted share, compared to a net loss of $98.1 million, or $1.12 net loss per basic and diluted share one year ago.
- Net loss for the year was $189.3 million, or $2.11 net loss per basic and diluted share, compared to a net loss of $77.0 million, or $0.89 net loss per basic and diluted share one year ago.
- At December 31, 2020, FibroGen had $732.1 million in cash, restricted time deposits, cash equivalents, investments, and receivables.
- Based on our latest forecast, we estimate our 2021 ending cash to be in the range of $660 to $670 million.
- The China Agreement with AstraZeneca was amended in July 2020 to maximize the economic value of the roxadustat franchise for both parties with more predictable economics and profitability for FibroGen.

Conference Call and Webcast Details
FibroGen will host a conference call and webcast today, Monday, March 1, 2021, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time) to discuss financial results and provide a business update. A live audio webcast of the call may be accessed in the investor section of the company's website, www.fibrogen.com. To participate in the conference call by telephone, please dial 1 (877) 658-9081 (U.S. and Canada) or 1 (602) 563-8732 (international), reference the FibroGen fourth quarter and full year 2020 financial results conference call, and use confirmation number **3055327**. A replay of the webcast will be available shortly after the call for a period of four weeks. To access the replay, please dial 1 (855) 859-2056 (domestic) or 1 (404) 537-3406 (international), and use passcode **3055327.**

About Roxadustat
Roxadustat, an oral medicine, is the first in a new class of medicines, 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 also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA).

Roxadustat is approved in China, Japan, and Chile for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). In Europe, the Marketing Authorization Application for roxadustat for the treatment of anemia of CKD in patients both on dialysis and not on dialysis was filed by our partner Astellas and accepted by the European Medicines Agency for review on May 2020. Several other licensing applications for roxadustat have been submitted by Astellas and AstraZeneca to regulatory authorities across the globe, and are currently in 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, other markets in the Americas, in Australia/New Zealand, and Southeast Asia.

About Pamrevlumab
Pamrevlumab is a first-in-class antibody developed by FibroGen that inhibits the activity of connective tissue growth factor (CTGF), an important biological mediator in fibrotic and proliferative disorders. Pamrevlumab is in Phase 3 clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

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 hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines for the treatment of unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD). Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA). Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). For more information, please visit www.fibrogen.com.

Forward-Looking Statements

This release contains forward-looking statements regarding our 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 our product candidates, our clinical programs and regulatory events, and those of our partners. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts 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. Our 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 our various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and our Quarterly Report on Form 10-Q for quarter ended September 30, 2020 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 we undertake 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, 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 678,393	$ 126,266
Short-term investments	8,144	407,491
Accounts receivable, net	41,883	28,455
Inventory	16,530	6,887
Prepaid expenses and other current assets	10,160	133,391
Total current assets	755,110	702,490
Restricted time deposits	2,072	2,072
Long-term investments	244	61,118
Property and equipment, net	33,647	42,743
Finance lease right-of-use assets	29,606	39,602
Equity method investment in unconsolidated variable interest entity	2,728	—
Other assets	3,433	9,372
Total assets	$ 826,840	$ 857,397
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 24,789	$ 6,088
Accrued and other liabilities	119,521	83,816
Deferred revenue	6,547	490
Finance lease liabilities, current	12,330	12,351

Total current liabilities	163,187	102,745
Product development obligations	18,697	16,780
Deferred revenue, net of current	138,474	99,449
Finance lease liabilities, non-current	25,391	37,610
Other long-term liabilities	39,642	65,407
Total liabilities	385,391	321,991
Total stockholders' equity	422,178	516,135
Non-controlling interests	19,271	19,271
Total equity	441,449	535,406
Total liabilities, stockholders' equity and non-controlling interests	$ 826,840	$ 857,397

(1) The condensed consolidated balance sheet amounts at December 31, 2019 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,	
	2020	**2019**	**2020**	**2019**
	(Unaudited)		**(Unaudited)**	**(1)**
Revenue:				
License revenue	$ 14,323	$ 14,569	$ 14,323	$ 177,086
Development and other revenue	21,527	28,607	80,592	114,115
Product revenue, net	29,165	1,122	72,498	1,700
Drug product revenue	(17)	(36,324)	8,906	(36,324)
Total revenue	64,998	7,974	176,319	256,577
Operating costs and expenses:				
Cost of goods sold	2,615	905	8,869	1,147
Research and development	78,133	56,797	252,924	209,265
Selling, general and administrative	42,249	50,708	106,406	135,479
Total operating costs and expenses	122,997	108,410	368,199	345,891
Loss from operations	(57,999)	(100,436)	(191,880)	(89,314)
Interest and other, net:				
Interest expense	(538)	(668)	(2,402)	(2,876)
Investment loss in unconsolidated variable interest entity	(190)	—	(202)	—
Interest income and other, net	264	3,053	5,553	15,548
Total interest and other, net	(464)	2,385	2,949	12,672
Loss before income taxes	(58,463)	(98,051)	(188,931)	(76,642)
Provision for income taxes	171	72	360	328
Net loss	$ (58,634)	$ (98,123)	$ (189,291)	$ (76,970)
Net loss per share - basic and diluted	$ (0.64)	$ (1.12)	$ (2.11)	$ (0.89)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	91,166	87,352	89,854	86,633

(1) The condensed consolidated statement of operations amounts for the year ended December 31, 2019 are derived from audited financial statements.

Contacts:
FibroGen, Inc.

Investors:
Michael Tung, M.D.

Corporate Strategy / Investor Relations
415.978.1434
mtung@fibrogen.com

Media:
Jennifer Harrington
610.574.9196
Jennifer.Harrington@gcihealth.com

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