



FibroGen Reports Fiscal 2016 Financial Results

March 1, 2017

Conference Call and Webcast to be Held Today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time

SAN FRANCISCO, March 01, 2017 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ:FGEN), a science-based biopharmaceutical company, today reported financial results for the year ended December 31, 2016, and provided an update on the company's recent developments.

"We are pleased with the topline results reported from our two China Phase 3 trials, which are the first Phase 3 readouts for roxadustat, and bring us closer to completing our new drug application submission in China. With our partners AstraZeneca and Astellas, we are making steady progress in Phase 3 clinical development worldwide for roxadustat in CKD anemia, and continue to expect filing of our U.S. NDA in 2018," said Thomas B. Neff, FibroGen's Chief Executive Officer. "This year, we are expanding development activities for roxadustat into oncology-related anemias. We are also anticipating important clinical milestones for pamrevlumab, or FG-3019. We began the year with the presentation and publication of promising clinical results in pancreatic cancer, and expect to report data from our placebo-controlled Phase 2 trial in idiopathic pulmonary fibrosis in the third quarter of this year."

Recent Developments

U.S. and Europe Roxadustat (FG-4592) Anemia in Chronic Kidney Disease (CKD)

- Met initial target enrollment for three FibroGen-sponsored Phase 3 trials supporting U.S. and EU approvals and are continuing to enroll patients to meet overall enrollment goals among the partners
- The independent data safety monitoring board (DSMB), which reviews the U.S. and European Phase 3 program quarterly, recommended in February that trials continue without modification to current protocols

China Roxadustat Anemia in Chronic Kidney Disease

- Completed the controlled portion of our two Phase 3 trials in 2016
- These studies met their primary endpoints for the treatment of anemia in non-dialysis and dialysis patients
 - In non-dialysis patients, roxadustat achieved a significantly greater increase in mean Hb and a significantly greater Hb response rate, as compared to patients in the placebo arm
 - In dialysis patients, roxadustat met the predefined non-inferiority criteria for the primary efficacy endpoint. In the pre-specified sequential analysis, roxadustat was also shown to be superior to 利血宝® (Li Xue Bao) epoetin alfa (Kirin EPO) in mean Hb increase

Japan Roxadustat Anemia in Chronic Kidney Disease

- All six Phase 3 trials are now underway
- Presented Phase 2 study results in non-dialysis-dependent patients in a clinical late-breaker session of the November 2016 American Society of Nephrology (ASN) Kidney Week

U.S. Roxadustat Oncology-Related Anemias

- Phase 3 investigational new drug application was approved by the FDA for the treatment of anemia in myelodysplastic syndromes (MDS) in the fourth quarter of 2016

China Roxadustat Oncology-Related Anemias

- Submitted a clinical trial application (CTA), which is under review by the China Food and Drug Administration (CFDA), for a Phase 2/3 clinical study of anemia in MDS

Pamrevlumab in Idiopathic Pulmonary Fibrosis (IPF)

- Completed enrollment of the Phase 2 double-blind, placebo-controlled -067 study
- Results from Study -049 were published in the *European Respiratory Journal*, accompanied by an editorial, and the corresponding open-label extension results were presented at the 19th International Colloquium on Lung and Airway Fibrosis (ICLAF)
 - No safety issues reported with long-term treatment
 - Trend towards improved or stable pulmonary function and stable fibrosis continued in second year of treatment

Pamrevlumab in Pancreatic Cancer

- Presented findings at the 2017 Gastrointestinal Cancers Symposium (ASCO-GI) from an ongoing open-label, randomized Phase 1/2 study in locally advanced pancreatic cancer -069 showing improvement in survival among patients in the combination arm, as compared to chemotherapy alone
- Published Phase 1/2 trial results in the *Journal of Cancer Clinical Trials* reporting statistically significant dose-related increase in survival and that pamrevlumab can be safely combined with chemotherapy standard-of-care in advanced pancreatic cancer

Corporate and Financial Highlights

- Net loss per basic and diluted share for the year ended December 31, 2016 was \$0.98, as compared to \$1.42 a year ago
- At December 31, 2016, FibroGen had \$342.2 million of cash, restricted time deposits, cash equivalents, investments, and receivables

Outlook

- Report pamrevlumab topline Phase 2 IPF data, placebo-controlled and combination treatment sub-study results, in the third quarter
- Submit new drug application in China in the third quarter
- Expect to complete enrollment of pamrevlumab open-label, randomized Phase 2 trial in locally advanced pancreatic cancer patients in the first half of the year, and to complete the patient treatment period by year-end
- On track to submit the NDA for roxadustat in the U.S. in 2018

Conference Call Details

FibroGen will host a conference call and webcast today, March 1, 2017, at 4:30 p.m. Eastern Time (1:30 p.m. Pacific 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 section of the FibroGen website, www.fibrogen.com. To access the conference call by telephone, please dial (888) 771-4371 (U.S. and Canada) or (847) 585-4405 (international), reference the FibroGen Year-End 2016 conference call, and use the confirmation number 44252209. It is recommended that listeners register 15 minutes before the scheduled start time to ensure a timely connection. A replay of the webcast will be available shortly after the call for a period of two weeks. To access the replay, please dial (888) 843-7419 (domestic) or (630) 652-3042 (international), and use the confirmation number 44252209#.

About Roxadustat

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule currently in global Phase 3 clinical development as a potential therapy for anemia associated with chronic kidney disease (CKD). Roxadustat is a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) that promotes erythropoiesis through increasing endogenous erythropoietin, improving iron regulation, and reducing hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis – increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of CKD patients – including in the presence of inflammation and without a need for supplemental intravenous iron.

Roxadustat is currently advancing through Phase 3 clinical trials worldwide, supported by extensive Phase 2 clinical data demonstrating correction and maintenance of hemoglobin levels in multiple subpopulations of CKD anemia patients. To date, roxadustat has been evaluated in Phase 1 and Phase 2 studies, involving more than 1,400 subjects. Globally, a total of 15 Phase 3 studies, with target enrollment of about 10,000 patients worldwide, are currently being conducted to support independent regulatory approvals of roxadustat in both NDD-CKD and DD-CKD patients in the U.S., Europe, Japan, and China. Roxadustat is also entering a Phase 3 clinical trial in the U.S. for treatment of anemia in patients with myelodysplastic syndrome (MDS). In China, a roxadustat MDS Phase 2/3 clinical trial application (CTA) is currently under review by the China Food and Drug Administration (CFDA). For information about roxadustat studies currently recruiting patients, please visit www.clinicaltrials.gov.

About Pamrevlumab

Pamrevlumab (FG-3019) is an investigational therapeutic antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in chronic fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. FibroGen is currently conducting clinical studies of pamrevlumab in idiopathic pulmonary fibrosis, pancreatic cancer, and Duchenne muscular dystrophy (DMD). In desmoplastic or fibrotic cancers, such as pancreatic cancer, CTGF in the extensive fibrous stroma associated with the tumor promotes abnormal proliferation of stromal cells and tumor cells. Studies in a transgenic mouse model of pancreatic cancer indicate that treatment with pamrevlumab in combination with chemotherapy may enhance the efficacy of chemotherapy and improve survival. For information about roxadustat studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen, Inc.

FibroGen, Inc., headquartered in San Francisco with subsidiary offices in Beijing and Shanghai, is a leading science-based biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in fibrosis and hypoxia-inducible factor (HIF) biology and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat (FG-4592), the company's most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase activity in Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD). Pamrevlumab (FG-3019), a fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor (CTGF), is in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF),

pancreatic cancer, and Duchenne muscular dystrophy (DMD). FibroGen is also developing a biosynthetic cornea in China. 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 of the Company's product candidates, roxadustat and pamrevlumab, the potential safety and efficacy profile of our product candidates, the timelines for reporting of our clinical data reporting, potential milestones, and regulatory submissions, our clinical plans and our financial projections. 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 non-clinical and clinical programs, including enrollment of our Phase 3 trials, and our collaboration partners' clinical trials for roxadustat in anemia associated with CKD, the continued progress of our plans and programs in China, clinical development of and regulatory filing outcomes for anemia associated with myelodysplastic syndrome, the enrollment and results from ongoing clinical trials for pamrevlumab in IPF, and pancreatic cancer, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, 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, 2016	December 31, 2015
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 173,782	\$ 153,324
Short-term investments	79,397	27,847
Accounts receivable	10,448	15,405
Prepaid expenses and other current assets	2,889	3,988
Total current assets	266,516	200,564
Restricted time deposits	6,217	7,254
Long-term investments	71,010	131,720
Property and equipment, net	123,657	129,020
Other assets	2,152	2,016
Total assets	\$ 469,552	\$ 470,574
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	\$ 6,223	\$ 6,521
Accrued liabilities	50,914	47,932
Deferred revenue	7,988	12,728
Total current liabilities	65,125	67,181
Long-term portion of lease financing obligations	97,352	97,042
Product development obligations	14,854	15,085
Deferred rent	4,212	4,702
Deferred revenue, net of current	106,709	85,132
Other long-term liabilities	6,191	4,607
Total liabilities	294,443	273,749
Total stockholders' equity	155,838	177,554
Non-controlling interests	19,271	19,271
Total equity	175,109	196,825
Total liabilities, stockholders' equity and non-controlling interests	\$ 469,552	\$ 470,574

(1) The condensed consolidated balance sheet amounts at December 31, 2015 are derived from audited financial statements.

Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Years Ended December 31,	
	2016	2015
	(Unaudited)	(1)
Revenue:		
License and milestone revenue	\$ 137,352	\$ 148,093
Collaboration services and other revenue	42,225	32,735
Total revenue	179,577	180,828
Operating expenses:		
Research and development	187,206	214,089
General and administrative	46,025	44,364
Total operating expenses	233,231	258,453
Loss from operations	(53,654)	(77,625)
Interest and other, net:		
Interest expense	(10,725)	(11,033)
Interest income and other, net	2,628	3,121
Total interest and other, net	(8,097)	(7,912)
Loss before income taxes	(61,751)	(85,537)
Provision for (benefit from) income taxes	(71)	242
Net loss	<u>\$ (61,680)</u>	<u>\$ (85,779)</u>
Net loss per share - basic and diluted	\$ (0.98)	\$ (1.42)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	62,744	59,926

(1) The condensed consolidated statements of operations amounts for the year ended December 31, 2015 are derived from audited financial statements.

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