



FibroGen Announces Fiscal 2015 Financial Results

February 29, 2016

Webcast Conference Call Scheduled for 4:30pm EST Today

SAN FRANCISCO, Feb. 29, 2016 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ:FGEN) ("FibroGen"), a research-based biopharmaceutical company, today reported financial results for the year ended December 31, 2015.

"2015 was a year that marked significant progress for FibroGen and our clinical-stage programs in anemia, idiopathic pulmonary fibrosis, pancreatic cancer, and Duchenne muscular dystrophy," said Thomas B. Neff, chief executive officer of FibroGen. "In partnership with Astellas and AstraZeneca, our roxadustat Phase 3 development program has strong momentum and remains on track, with regulatory submissions expected in 2016 for China and in 2018 for the United States. Additionally, now that we have reached the cap on FibroGen's development cost contributions for roxadustat, our partners will cover all development costs through product launch outside of China."

Program Updates

Anemia in Chronic Kidney Disease (CKD) - Roxadustat (FG-4592)

- Timelines for roxadustat remain on track. The company expects to file regulatory submissions for roxadustat in 2016 for China and in 2018 for the U.S.
- FibroGen and partners AstraZeneca and Astellas are conducting a total of seven Phase 3 trials for registration in the U.S., EU, and other territories. FibroGen is conducting three of those seven trials and, as of today, has enrolled approximately 90 percent of the sum of the target enrollment for these three studies.
- An independent data safety monitoring board (DSMB) oversees all of roxadustat Phase 3 studies and convenes regularly to review the roxadustat safety data. In January 2016, the DSMB confirmed that the trials should proceed with current Phase 3 protocols without modification.

Anti-Connective Tissue Growth Factor (CTGF) – (FG-3019)

- In pancreatic cancer, encouraging early data were presented at the January 2016 ASCO-GI Meeting (American Society of Clinical Oncology Gastrointestinal Cancers Symposium). A Phase 2 study in patients with inoperable, Stage 3 pancreatic cancer is underway. Subjects were randomized to two treatment arms: chemotherapy or FG-3019 plus chemotherapy. In the FG-3019 plus chemotherapy treatment arm, the tumors in three of the first four evaluable subjects were converted from inoperable to operable, i.e., upon rescoring, the tumors were deemed resectable and the subjects eligible for surgery. The fourth subject discontinued therapy due to an adverse event unrelated to study drug. In comparison, only one of the first four evaluable subjects receiving chemotherapy alone was considered a candidate for surgery after rescoring.
- In idiopathic pulmonary fibrosis (IPF), the company's Phase 2 placebo-controlled trial of FG-3019 as first-line therapy in IPF is ongoing, with over two-thirds of the requisite 90 patients enrolled.
- In Duchenne muscular dystrophy (DMD), an open-label Phase 2 study of FG-3019 in DMD has been initiated. This is an open-label study for non-ambulatory patients. The first few subjects were treated last month, and enrollment is ongoing.

Financial Highlights

- Net loss per basic and diluted share for the year ended December 31, 2015 was \$1.42 per share.
- At December 31, 2015, FibroGen had \$336.9 million of cash, cash equivalents, investments, receivables and restricted cash.
- Under an agreement between FibroGen and AstraZeneca, FibroGen's total funding obligations for roxadustat development in chronic kidney disease ("CKD") outside China are limited to \$116.5 million. As of the fourth quarter of 2015, the \$116.5 million cap on our share of development costs for roxadustat has been reached. As such, Astellas and AstraZeneca are now responsible for funding future development and commercialization costs for roxadustat in CKD through launch for all territories, excluding China, where AstraZeneca pays 50 percent of development costs.

Conference Call Details

FibroGen will host a conference call and webcast today, February 29, 2016, 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 2015 conference call, and use the confirmation number 41794315. 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 four weeks. To access the replay,

please dial (888) 843-7419 (domestic) or (630) 652-3042 (international), and use the confirmation number 41794315.

About FibroGen

FibroGen is a research-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. We have capitalized on our extensive experience in fibrosis and hypoxia-inducible factor (HIF) biology to generate multiple programs targeting various therapeutic areas. Our most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule HIF prolyl hydroxylase (HIF-PH) inhibitor in Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD). Our second product candidate, FG-3019, is a monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), pancreatic cancer, and Duchenne muscular dystrophy. For more information about FibroGen, please visit www.fibrogen.com.

Forward-Looking Statements

This release contains forward-looking statements, including statements regarding our milestones, clinical plans and financial projections. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties, including the continued progress and timing of our various clinical programs, including the timing of enrollment of the Phase 3 clinical trials for roxadustat in CKD and the initiation and enrollment in ongoing and planned clinical trials for FG-3019 in IPF, pancreatic cancer, DMD, and liver fibrosis; the continued progress of our plans and programs in China; and other matters that are described in our Annual Report on Form 10-K for the year ended December 31, 2015, 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, 2015	December 31, 2014
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 153,324	\$ 165,455
Short-term investments	27,847	14,364
Accounts receivable	15,405	13,453
Prepaid expenses and other current assets	3,988	4,966
Total current assets	200,564	198,238
Restricted cash	7,254	7,254
Long-term investments	131,720	144,269
Property and equipment, net	129,020	132,171
Other assets	2,016	1,596
Total assets	\$ 470,574	\$ 483,528
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	\$ 6,521	\$ 4,551
Accrued liabilities	47,932	48,985
Deferred revenue	12,728	9,218
Total current liabilities	67,181	62,754
Long-term portion of lease financing obligations	97,042	96,818
Product development obligations	15,085	16,465
Deferred rent	4,702	5,131
Deferred revenue, net of current	85,132	60,988
Other long-term liabilities	4,607	696
Total liabilities	273,749	242,852
Total stockholders' equity	177,554	221,405
Non-controlling interests	19,271	19,271
Total equity	196,825	240,676

Total liabilities, stockholders' equity and non-controlling interests \$ 470,574 \$ 483,528

(1) The condensed consolidated balance sheet amounts at December 31, 2014 are derived from audited financial statements.

Condensed Consolidated Statements of Operations

(In thousands, except per share data, unaudited)

	Years Ended December 31,	
	2015	2014
	(Unaudited)	(1)
Revenue:		
License and milestone revenue	\$ 148,093	\$ 117,191
Collaboration services and other revenue	32,735	20,410
Total revenue	180,828	137,601
Operating expenses:		
Research and development	214,089	150,794
General and administrative	44,364	36,909
Total operating expenses	258,453	187,703
Loss from operations	(77,625)	(50,102)
Interest and other, net:		
Interest expense	(11,033)	(11,108)
Interest income and other, net	3,121	1,706
Total interest and other, net	(7,912)	(9,402)
Loss before income taxes	(85,537)	(59,504)
Provision for income taxes	242	-
Net loss	<u>\$ (85,779)</u>	<u>\$ (59,504)</u>
Net loss per share - basic and diluted	\$ (1.42)	\$ (3.17)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	60,337	18,775 (2)

(1) The condensed consolidated statement of operations amounts at for the year ended December 31, 2014 are derived from audited financial statements.

(2) For purposes of reconciling GAAP weighted average shares outstanding pre- and post- offering.

Reconciliation of Non-GAAP Financial Measures

(In thousands, except per share data, unaudited)

	Year Ended December 31,
	2014
GAAP weighted average shares outstanding	18,775
Shares sold in initial public offering	8,218
Concurrent private placement - AstraZeneca	980
Conversion of preferred shares upon initial public offering	29,924
Conversion of European subsidiary shares	846
Non-GAAP weighted average shares outstanding	<u>58,743</u>
GAAP net loss	\$ (59,504)
Non-GAAP net loss per basic and diluted share	\$ (1.01)

About Non-GAAP Financial Measures

To supplement our condensed consolidated financial statements, which are prepared and presented in accordance with U.S. generally accepted accounting principles ("GAAP"), we present non-GAAP weighted average shares outstanding and non-GAAP net loss per basic and diluted share for the year ended December 31, 2014. The presentation of this financial information is not

intended to be considered in isolation or as a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP.

We define non-GAAP net loss per basic and diluted share as GAAP net loss for the year ended December 31, 2014 divided by the non-GAAP weighted average shares outstanding for the year ended December 31, 2014. Non-GAAP weighted average shares outstanding is based on GAAP weighted average shares outstanding plus the impacts from reflecting full year weight for the issuance of and conversion into shares of our common stock upon the closing of our initial public offering on November 19, 2014. This includes 8.2 million additional weighted shares related to issuance of 9.3 million shares in our initial public offering, 1.0 million additional weighted shares related to issuance of 1.1 million shares in our concurrent private placement, 29.9 million additional weighted shares related to conversion of all outstanding shares of our preferred stock into 33.9 million shares, and 0.8 million additional weighted shares related to conversion of FibroGen Europe preferred stock into 1.0 million shares. We believe the presentation of non-GAAP net loss per basic and diluted share provides useful information to investors regarding comparability of net loss per basic and diluted share amounts between periods presented.

Contact ☐

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The logo for FibroGen, featuring the word "FIBROGEN" in a bold, blue, sans-serif font.

FibroGen, Inc.