



FibroGen Reports First Quarter 2018 Financial Results

May 9, 2018

Pamrevlumab Data to be Presented at ATS 2018 and ASCO 2018

Roxadustat U.S. Phase 3 Clinical Studies on Track to Readout in Fourth Quarter 2018

Conference Call Today at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time

SAN FRANCISCO, May 09, 2018 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ:FGEN), a science-based biopharmaceutical company, today reported financial results for the first quarter of 2018 and provided an update on the company's recent developments.

"FibroGen and AstraZeneca are preparing to complete patient enrollment in five Phase 3 roxadustat CKD anemia trials this quarter. We look forward to reporting topline data in the fourth quarter of this year. With our partners, we are continuing to see positive data from our global roxadustat Phase 3 programs, most recently in Japan from Astellas," said Thomas B. Neff, FibroGen's Chief Executive Officer. "Pamrevlumab continues to reveal its potential in the treatment of fibrotic and fibro-proliferative diseases. We are working towards achieving regulatory alignment with the FDA on pivotal study designs for both IPF and pancreatic cancer. We will be presenting data at the ATS conference in May from our placebo-controlled Phase 2 study in IPF representing the first known significant attenuation of fibrosis progression as measured by quantitative HRCT, and we will report Phase 2 data at ASCO in June showing that a majority of unresectable locally advanced pancreatic cancer patients treated with pamrevlumab and chemotherapy were assessed as resectable after six months of treatment. We will also report that there appears to be a survival benefit in this study for patients who have undergone tumor resection. Patients continue to be followed in this study for survival."

Recent Developments and Highlights

Roxadustat for Anemia in Chronic Kidney Disease (CKD) in the U.S. and ROW

- Phase 3 trial enrollment to complete in the second quarter of 2018
- Topline Phase 3 clinical studies data expected in the fourth quarter of 2018
- In its most recent review in March, the DSMB recommended Phase 3 clinical studies continue under current protocols with no changes

Roxadustat for Anemia in CKD in China

- NDA review by the State Drug Administration, or SDA (formerly the China Food and Drug Administration, or CFDA) is ongoing; anticipate regulatory approval by year-end 2018

Roxadustat for Anemia in CKD in Japan

- Positive topline data from two Phase 3 studies in dialysis-dependent CKD patients with anemia, a long-term ESA conversion study and an ESA-naïve correction study, were reported in April 2018 by our partner Astellas
- Astellas expects to submit a NDA for anemia associated with dialysis-dependent-CKD in Japan in 2018
- Astellas expects data readout in one of the Japan Phase 3 studies in non-dialysis-dependent CKD anemia patients in the fourth quarter of 2018

Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)

- Multiple abstracts accepted for presentation at the 2018 American Thoracic Society (ATS) Conference in May
 - Results from our Phase 2 IPF clinical trial
 - HRCT quantitative imaging of lung fibrosis;
 - Health-related quality of life assessments; and
 - PK/PD modeling
 - Preclinical results from a highly predictive animal model of lung fibrosis.

Pamrevlumab for Pancreatic Cancer

- Fast Track designation granted by the FDA for the treatment of patients with locally advanced unresectable pancreatic cancer in the first quarter of 2018
- Phase 2 clinical trial results have been accepted for presentation at the 2018 American Society of Clinical Oncology

Pamrevlumab for Duchenne Muscular Dystrophy

- Completed clinical trial enrollment in the first quarter of 2018

Corporate and Financial

- Net loss for the first quarter was \$41.4 million, or (\$0.50) per share, compared to \$30.6 million, or (\$0.48) per share, for the first quarter of 2017, primarily due to ongoing investments in our research and development and general and administrative initiatives
- We recast our condensed consolidated statement of operations and condensed balance sheet from the amounts previously reported upon the adoption of the new revenue guidance under Accounting Standards Codification 606 as of January 1, 2018. The impact for the first quarter 2017 was a \$2.6 million increase in revenue. The cumulative reduction in revenue of \$34.7 million through 2017 for all years impacted on a fully retrospective basis, will be recognized over the future remaining development periods.
- At March 31, 2018, FibroGen had \$730.4 million of cash, restricted time deposits, cash equivalents, investments, and receivables
- The weighted average number of common shares used to calculate net loss per share was 82.9 million shares and 64.0 million shares for the first quarters of 2018 and 2017, respectively, reflecting equity offerings completed in 2017. Total shares outstanding as of March 31, 2018 were 83.4 million shares.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Wednesday, May 9, 2018, 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 (888) 771-4371 (U.S. and Canada) or 1 (847) 585-4405 (international), reference the FibroGen first quarter 2018 financial results conference call, and use passcode 46778299#. 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 passcode 46778299#.

About Roxadustat

Roxadustat is a first-in-class oral therapeutic in global Phase 3 clinical development as a treatment for anemia associated with chronic kidney disease (CKD) with the potential to offer a safer and more effective, convenient, and accessible treatment than current therapies. Roxadustat, a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), promotes erythropoiesis, or the production of red blood cells, by increasing endogenous erythropoietin, improving iron regulation, and reducing hepcidin, including in the presence of inflammation and without need for supplemental intravenous iron.

The roxadustat Phase 3 program is the largest Phase 3 clinical program in anemia to date, and is supported by extensive Phase 2 results demonstrating correction and maintenance of hemoglobin levels in anemia in multiple subpopulations of CKD dialysis and non-dialysis patients. A New Drug Application (NDA) has been accepted for review by the State Drug Administration, or SDA (formerly the China Food and Drug Administration, or CFDA). In the U.S., data readout for the Phase 3 program is expected in the fourth quarter of 2018. Roxadustat is also in Phase 3 clinical development in the U.S. and Europe, and expected to shortly enter Phase 2/3 development in China, for anemia associated with myelodysplastic syndromes (MDS). For information about roxadustat studies currently recruiting patients, please visit www.clinicaltrials.gov.

About Pamrevlumab

Pamrevlumab is a first-in-class antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). Pamrevlumab has been well tolerated in multiple Phase 2 clinical studies, with a good safety and tolerability profile. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen

FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, is a leading science-based biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor (HIF), connective tissue growth factor (CTGF) biology, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, the company's most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase activity in worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), except in China, where a New Drug Application is currently under review by the State Drug Administration, or SDA (formerly the China Food and Drug Administration, or CFDA). Roxadustat is in Phase 3 clinical development in the U.S. and Europe, and expected to shortly enter Phase 2/3 development in China, for anemia associated with myelodysplastic syndromes (MDS). Pamrevlumab, a human monoclonal anti-CTGF antibody, is advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for 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 pamrevlumab and roxadustat, the potential safety and efficacy profile of our product candidates, and our clinical, regulatory, and commercial plans, 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, 2017, and our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2018 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)

	March 31, 2018	December 31, 2017 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 659,007	\$ 673,658
Short-term investments	44,761	62,060
Accounts receivable	9,975	8,452
Prepaid expenses and other current assets	3,420	4,800
Total current assets	717,163	748,970
Restricted time deposits	5,181	5,181
Long-term investments	10,506	10,506
Property and equipment, net	129,880	129,476
Other assets	4,881	4,517
Total assets	\$ 867,611	\$ 898,650
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	\$ 3,549	\$ 5,509
Accrued liabilities	62,859	63,781
Deferred revenue	16,934	16,670
Total current liabilities	83,342	85,960
Long-term portion of lease financing obligations	97,620	97,763
Product development obligations	17,824	17,244
Deferred rent	3,503	3,657
Deferred revenue, net of current	137,972	138,241
Other long-term liabilities	8,561	8,047
Total liabilities	348,822	350,912
Total stockholders' equity	499,518	528,467
Non-controlling interests	19,271	19,271
Total equity	518,789	547,738
Total liabilities, stockholders' equity and non-controlling interests	\$ 867,611	\$ 898,650

(1) The condensed consolidated balance sheet amounts at December 31, 2017 are recast from audited financial statements to reflect the adoption of the new revenue standards as of January 1, 2018.

Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended March 31,	
	2018	2017 (1)
	(Unaudited)	
Revenue:		
License and milestone revenue	\$ -	\$ -
Collaboration services and other revenue	31,925	29,442
Total revenue	31,925	29,442
Operating expenses:		
Research and development	56,974	46,732
General and administrative	15,550	11,530
Total operating expenses	72,524	58,262
Loss from operations	(40,599)	(28,820)
Interest and other, net:		
Interest expense	(2,769)	(2,375)
Interest income and other, net	2,071	645
Total interest and other, net	(698)	(1,730)
Loss before income taxes	(41,297)	(30,550)
Provision for income taxes	99	60
Net loss	<u>\$ (41,396)</u>	<u>\$ (30,610)</u>
Net loss per share - basic and diluted	\$ (0.50)	\$ (0.48)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	82,863	64,037

(1) The condensed consolidated statements of operations amounts for the three months ended March 31, 2017 are recast from unaudited financial statements to reflect the adoption of the new revenue standards as of January 1, 2018.

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