



FibroGen Announces First Quarter 2015 Financial Results

May 12, 2015

SAN FRANCISCO--(BUSINESS WIRE)--May 12, 2015-- FibroGen, Inc. (NASDAQ:FGEN) ("FibroGen"), a research-based biopharmaceutical company, today reported financial results for the quarter ended March 31, 2015.

"FibroGen and its partners, AstraZeneca and Astellas, continue to make excellent progress in the global development of roxadustat for the treatment of anemia in patients with chronic kidney disease," said Thomas B. Neff, chief executive officer of FibroGen. "Patient enrollment in the seven Phase 3 studies required for approval in the U.S. and Europe is advancing as planned. In China, we expect to begin patient enrollment in both Phase 3 studies required for regulatory approval in the fourth quarter of 2015. In April 2015, the roxadustat data safety monitoring board completed its scheduled quarterly review of the data collected to date from the seven active Phase 3 roxadustat studies and recommended that the program proceed with no protocol changes. We expect to submit roxadustat regulatory filings in China in 2016 and in the U.S. in 2018."

Other Program Updates

FG-3019

- In idiopathic pulmonary fibrosis, we continue to enroll patients in a 136 patient Phase 2 placebo controlled study in the U.S. and expect to open additional clinical sites outside of the U.S. in the third quarter of 2015.
- In pancreatic cancer, we are evaluating in an open-label Phase 2 study the ability of FG-3019, in combination with gemcitabine and nab-paclitaxel, to convert inoperable pancreatic cancer to operable cancer.
- In Duchenne muscular dystrophy, following an expert advisory panel review completed in March 2015, we plan to file an IND, and to commence a Phase 2 study in non-ambulatory patients in the second half of 2015.

FG-5200 (Corneal Implant)

- A pilot study of a corneal implant containing our proprietary human collagen Type III is entering its seventh year with study patients having undergone successful replacement surgery and continuing to have vision regain. We plan to advance the development of our FG-5200 corneal implant in China and expect to receive responses from China regulatory authorities regarding the development priority status in the coming months.

Financial Highlights

- The final audited reports of two long-term roxadustat pre-clinical carcinogenicity studies were completed, further supporting the safety profile of roxadustat and triggering a \$15.0 million milestone payment by AstraZeneca.
- Revenue was \$16.3 million and operating expenses were \$61.0 million for the first quarter of 2015. Net loss per share for the first quarter of 2015 was \$(0.78) based on 59.2 million shares outstanding compared to net loss per share of \$(0.27) for the first quarter of 2014 based on the same number of shares outstanding on a pro-forma basis.
- On March 31, 2015, we had \$296.4 million of cash, cash equivalents, investments, and receivables. In addition to the milestone payment of \$15.0 million received last week, we expect to receive a non-contingent license payment of \$120.0 million from AstraZeneca in the second quarter of 2015.
- Under the agreement with AstraZeneca, our total funding obligations for roxadustat development in chronic kidney disease (CKD) outside China are limited to \$116.5 million, of which \$52.1 million remained at the end of the first quarter of 2015. Based on current internal and partner projections, we continue to expect that our funding obligation will be met by the fourth quarter of 2015. Thereafter, Astellas and AstraZeneca will be responsible for funding roxadustat development in CKD through launch for all territories, excluding China.

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 inhibitor of HIF prolyl hydroxylases (HIF-PHs), 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 liver fibrosis.

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 IND filing for planned clinical trials for FG-3019 in idiopathic pulmonary fibrosis and pancreatic cancer, and Duchenne muscular dystrophy, respectively; the potential to achieve and receive approximately \$120 million in non-contingent license payments from AstraZeneca in the second quarter of 2015; 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, 2014 filed with the Securities and Exchange Commission on March 26, 2015, including the risk factors set forth in that filing. 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, 2015 (Unaudited)	December 31, 2014 (1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 128,369	\$ 165,455
Short-term investments	14,322	14,364
Accounts receivable	6,963	13,453
Prepaid expenses and other current assets	5,746	4,966
Total current assets	155,400	198,238
Restricted cash	7,254	7,254
Long-term investments	139,518	144,269
Property and equipment, net	131,660	132,171
Other assets	1,708	1,596
Total assets	<u>\$ 435,540</u>	<u>\$ 483,528</u>
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	\$ 2,433	\$ 4,551
Accrued liabilities	42,466	48,985
Deferred revenue	9,058	9,218
Total current liabilities	53,957	62,754
Long-term portion of lease financing obligations	96,873	96,818
Product development obligations	14,774	16,465
Deferred rent	5,024	5,131
Deferred revenue, net of current	60,326	60,988
Other long-term liabilities	699	696
Total stockholders' equity	184,616	221,405
Non-controlling interests	19,271	19,271
Total equity	203,887	240,676
Total liabilities and equity	<u>\$ 435,540</u>	<u>\$ 483,528</u>

(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)

	Three Months Ended March 31,	
	2015	2014
Revenue:		
License and milestone revenue	\$ 11,506	\$ 14,685
Collaboration services and other revenue	4,792	3,191
Total revenue	16,298	17,876
Operating expenses:		
Research and development	50,539	25,650
General and administrative	10,482	6,432
Total operating expenses	61,021	32,082
Loss from operations	(44,723)	(14,206)
Interest expense	(2,758)	(2,726)
Interest and other income, net	843	692
Loss before income taxes	(46,638)	(16,240)
Benefit from income taxes	271	-
Net loss	<u>\$ (46,367)</u>	<u>\$ (16,240)</u>
Net loss per basic and diluted share	\$ (0.78)	\$ (1.23)
Weighted average number of common shares used in net loss per basic and diluted share	59,197	13,210 (2)

(2) On a pro-forma basis, the 13.2 million weighted shares would be reported as 59.2 million shares based on the following:

	Common Shares (In Millions)
Weighted average shares as of March 31, 2014	13.2
Shares sold in initial public offering	9.3
Concurrent private placement - AstraZeneca	1.1
Conversion of preferred shares upon initial public offering	33.9
Conversion of European subsidiary shares	1.0
Option exercises	0.7
Weighted average shares as of March 31, 2015	<u>59.2</u>

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 net loss per share for the first quarter of 2014 on a pro-forma basis. 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 share as GAAP net loss for the three months ended March 31, 2014 divided by the weighted average number of common shares outstanding for the same period in 2015. Weighted average common shares as of March 31, 2015 were 59.2 million. With a starting point of 13.2 million weighted shares as of March 31, 2014, we sold 9.3 million shares in our initial public offering in November 2014, concurrent private placement of 1.1 million shares with AstraZeneca. The resulting automatic conversion of the Company's outstanding convertible preferred stock into 33.9 million shares of common stock, plus the resulting exchange of our European subsidiary's preferred shares into 1.0 million shares of common stock, and 0.7 million shares related to option exercises, resulted in 35.4 million converted shares. The total of the above results in 59.2 million weighted average common shares at March 31, 2015, compared to 13.2 million common shares as of March 31, 2014.



Source: FibroGen, Inc.

FibroGen, Inc.
Greg Mann, 415-978-1433
gmann@fibrogen.com