



FibroGen Announces Second Quarter 2015 Financial Results

August 13, 2015

SAN FRANCISCO, Aug. 13, 2015 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ:FGEN) ("FibroGen"), a research-based biopharmaceutical company, today reported financial results for the quarter ended June 30, 2015.

"FibroGen continues to make advancements across multiple programs, including anemia, idiopathic pulmonary fibrosis, pancreatic cancer, and Duchenne muscular dystrophy," said Thomas B. Neff, chief executive officer of FibroGen. "Through FibroGen's joint effort with our partners, AstraZeneca and Astellas, the Phase 3 development of roxadustat remains on track. We continue to expect to file the roxadustat regulatory submissions in 2016 for China and 2018 for the United States."

"As previously announced, our first roxadustat Phase 2 publication appeared on line last week. The article breaks new ground as the first peer-reviewed article ever to feature clinical evidence of hemoglobin correction by a hypoxia inducible factor prolyl hydroxylase inhibitor in anemic patients. Additional manuscripts on roxadustat Phase 2 studies have been submitted for editorial review. We expect this body of scientific literature will reinforce the first-in-class and best-in-class potential of roxadustat for the treatment of anemia in patients with chronic kidney disease."

"In our fibrosis programs, the FDA cleared our Investigational New Drug application for the study of FG-3019 in Duchenne muscular dystrophy. We plan to begin evaluating the potential anti-fibrotic activity of FG-3019 in non-ambulatory boys with this disease later this year. In addition, we are evaluating expansion of enrollment in our Phase 2 idiopathic pulmonary fibrosis study to include FG-3019 as a combination treatment with approved therapy. Our open label study of FG-3019 in pancreatic cancer continues to advance and we look forward to evaluating potential program expansion once we have sufficient preliminary data from the study."

Financial Highlights

- At June 30, 2015, FibroGen had \$408.0 million of cash, cash equivalents, investments, and receivables.
- Net income per basic share for the second quarter of 2015 was \$0.95, and \$0.83 on a per diluted share basis.

Program Updates

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

- Patient enrollment is advancing as planned in the seven Phase 3 clinical trials required for regulatory approval in the U.S. and Europe.
- In July 2015, the roxadustat data safety monitoring board (DSMB) completed its scheduled review of the data from all active Phase 3 roxadustat clinical trials and recommended that the program proceed with no protocol changes.
- Patient enrollment in FibroGen's three studies, ANDES (non-dialysis, NCT01750190), HIMALAYAS (incident dialysis, NCT02052310), and SIERRAS (stable dialysis, NCT02273726) are on track. For the three studies, the base plan is to meet target enrollment in March to April 2016. FibroGen expects to achieve this goal in two studies, and in the third study potentially to reach target enrollment ahead of plan by end of year 2015.
- Two Phase 3 studies required for regulatory approval in China are expected to begin enrollment in the fourth quarter of 2015.
- Regulatory filings are planned for 2016 in China and 2018 in the U.S.
- First manuscript of a roxadustat Phase 2 study was published in a peer reviewed journal; five additional articles submitted for editorial review.
- FibroGen continues to expect to reach the end of its cost-sharing obligations under its agreement with AstraZeneca in December 2015.

Idiopathic Pulmonary Fibrosis - FG-3019

- FibroGen continues to advance its 48-week Phase 2 randomized, double-blind placebo-control study in patients with idiopathic pulmonary fibrosis (IPF).
- In addition to enrolling subjects at research sites in the United States, FibroGen recently opened sites in Canada and South Africa, and plans to open additional sites in Eastern Europe, India, Australia, and New Zealand this year. The expansion of research sites targets territories in which there currently are no approved therapies for IPF or approved therapies have limited market penetration.
- FibroGen is evaluating the expansion of the Phase 2 placebo-control study to add a group of patients receiving approved therapy in order to assess FG-3019's efficacy in combination therapy.
- Meeting our patient enrollment targets is expected to be dependent on our success in enrolling patients in the expanded

territories.

Pancreatic Cancer – FG-3019

- In pancreatic cancer, FibroGen is evaluating the potential of FG-3019 in combination with gemcitabine and nab-paclitaxel to convert inoperable pancreatic cancer to operable cancer in a Phase 2 open label study of up to 40 patients.
- FibroGen plans to review preliminary data, including tumor biopsy data, to determine whether FG-3019 appears to increase the proportion of patients eligible for resection in hope of extending survival. If the data warrant, FibroGen would consider expanding the study.

Duchenne Muscular Dystrophy – FG-3019

- In July 2015, the FDA completed its review of FibroGen's investigational new drug (IND) application for the study of FG-3019 in patients with Duchenne muscular dystrophy (DMD) and allowed FibroGen to proceed with the trial.
- FibroGen plans to begin enrolling non-ambulatory patients with DMD in a Phase 2 study in the fourth quarter of 2015.
- In 2016, FibroGen expects to discuss with the FDA plans for a clinical study of FG-3019 in ambulatory DMD patients.

Other Financial Highlights

- FibroGen received a non-contingent license payment of \$120.0 million from AstraZeneca in the second quarter of 2015.
- FibroGen received a \$15.0 million milestone payment from AstraZeneca in the second quarter of 2015 for the completion of final audited reports of two long-term roxadustat pre-clinical carcinogenicity studies.
- Revenue was \$120.6 million and operating expenses were \$61.2 million for 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 \$33.1 million remained at the end of the second quarter of 2015. Based on current internal and partner projections, we expect that our funding obligation will be met in December 2015. Thereafter, Astellas and AstraZeneca will be responsible for funding roxadustat development in CKD through launch for all territories, excluding China.

Conference Call Details

FibroGen will host a conference call and webcast today, August 13, 2015 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 (800) 708-4540 (U.S. and Canada) or (847) 619-6397 (international), reference the FibroGen Second Quarter 2015 conference call, and use the confirmation number 40444300. To ensure timely connection, it is recommended that listeners register 15 minutes before the scheduled start time. A replay of the webcast will be archived on the FibroGen website and accessible approximately two hours after the event.

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 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 ("SEC") on March 26, 2015 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 filed with the SEC on May 12, 2015, including the risk factors set forth in that filing, as well as the Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, which we expect to file on August 13, 2015 with the SEC. 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)

	<u>June 30, 2015</u>	<u>December 31, 2014</u>
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 236,536	\$ 165,455
Short-term investments	12,129	14,364
Accounts receivable	12,183	13,453
Prepaid expenses and other current assets	<u>2,731</u>	<u>4,966</u>
Total current assets	263,579	198,238
Restricted cash	7,254	7,254
Long-term investments	138,310	144,269
Property and equipment, net	130,451	132,171
Other assets	<u>1,801</u>	<u>1,596</u>
Total assets	<u>\$ 541,395</u>	<u>\$ 483,528</u>
Liabilities and equity		
Current liabilities:		
Accounts payable	\$ 3,915	\$ 4,551
Accrued liabilities	46,240	48,985
Deferred revenue	<u>13,347</u>	<u>9,218</u>
Total current liabilities	63,502	62,754
Long-term portion of lease financing obligations	96,929	96,818
Product development obligations	15,186	16,465
Deferred rent	4,917	5,131
Deferred revenue, net of current	87,273	60,988
Other long-term liabilities	702	696
Total stockholders' equity	253,615	221,405
Non-controlling interests	<u>19,271</u>	<u>19,271</u>
Total equity	<u>272,886</u>	<u>240,676</u>
Total liabilities and equity	<u>\$ 541,395</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)

<u>Quarter Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>

Revenue:

License and milestone revenue	\$ 106,879	\$ 82,463	\$ 118,385	\$ 97,148
Collaboration services and other revenue	<u>13,671</u>	<u>7,495</u>	<u>18,463</u>	<u>10,686</u>
Total revenue	120,550	89,958	136,848	107,834

Operating expenses:

Research and development	51,555	33,269	102,094	58,919
General and administrative	<u>9,680</u>	<u>7,516</u>	<u>20,162</u>	<u>13,948</u>
Total operating expenses	<u>61,235</u>	<u>40,785</u>	<u>122,256</u>	<u>72,867</u>
Income from operations	59,315	49,173	14,592	34,967
Interest expense	(2,762)	(2,725)	(5,520)	(5,451)
Interest and other income, net	<u>707</u>	<u>383</u>	<u>1,550</u>	<u>1,075</u>
Income before income taxes	57,260	46,831	10,622	30,591
Provision (benefit) from income taxes	<u>205</u>	<u>--</u>	<u>(66)</u>	<u>--</u>
Net income	<u>\$ 57,055</u>	<u>\$ 46,831</u>	<u>\$ 10,688</u>	<u>\$ 30,591</u>

Net income per share:

Basic	\$ 0.95	\$ 1.36	\$ 0.18	\$ 0.74
Diluted	0.83	0.58	0.15	0.46

Weighted average number of common shares used to calculate net income per share:

Basic	59,798	13,347 (2)	59,499	13,279 (2)
Diluted	68,752	37,106 (2)	69,354	21,639 (2)

(2) On November 10, 2014, we effected a 1-for-2.5 reverse split of our common stock. All of the outstanding common stock share numbers (including shares of common stock which our outstanding preferred stock shares were convertible into), common stock warrants have been adjusted on a retroactive basis, to reflect this 1-for-2.5 reverse stock split for the quarter and six months ended June 30, 2014.

Reconciliation of Non-GAAP Financial Measures

	<u>Quarter Ended June 30, 2014</u>	<u>Six Months Ended June 30, 2014</u>
GAAP weighted average shares outstanding - basic	13,347	13,279
Shares sold in initial public offering	9,315	9,315
Concurrent private placement - AstraZeneca	1,111	1,111
Conversion of preferred shares upon initial public offering	33,920	33,920
Conversion of European subsidiary shares	959	959
Effect of potentially dilutive securities	<u>8,022</u>	<u>7,959</u>
Non-GAAP weighted average shares outstanding - diluted	<u>66,674</u>	<u>66,543</u>

GAAP net income	\$ 46,831	\$ 30,591
Non-GAAP net income per diluted share	\$ 0.70	\$ 0.46

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 – diluted and non-GAAP net income per diluted share for the quarter and six months ended June 30, 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 income per diluted share as GAAP net income for the quarter and six months ended June 30, 2014 divided by the non-GAAP weighted average shares outstanding – diluted for the quarter and six months ended June 30, 2014. Non-GAAP weighted average shares outstanding – diluted is based on GAAP weighted average shares outstanding – basic plus the issuance of and conversion into shares of our common stock upon the closing of our initial public offering. This includes issuance of 9.3 million shares in our initial public offering, issuance of 1.1 million shares in our concurrent private placement, conversion of all outstanding shares of our preferred stock into 33.9 million shares and conversion of FibroGen Europe preferred stock into 1.0 million shares. Non-GAAP weighted average shares outstanding – diluted also includes the effect of any potentially dilutive securities during the periods. We believe the presentation of non-GAAP net income per diluted share provides useful information to investors regarding comparability of net income per diluted share amounts between periods.

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