FibroGen Reports Financial Results for the Second Quarter of 2016

August 8, 2016

Enrollment Completed in Placebo-Controlled Study of FG-3019 (Pamrevlumab) in IPF
China Phase 3 Top Line Data Expected by Year-End 2016

–Webcast Conference Call Scheduled for 4:30pm EDT Today–

SAN FRANCISCO, Aug. 08, 2016 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ:FGEN) ("FibroGen"), a research-based biopharmaceutical company, today reported financial results for the quarter ended June 30, 2016.

"We continue to develop our multiple key programs across focused therapeutic areas," said Thomas B. Neff, chief executive officer of FibroGen. "Working jointly with our partners, Astellas and AstraZeneca, we have advanced global clinical development for roxadustat for treatment of anemia in chronic kidney disease patients to Phase 3 in four independent regulatory pathways − the U.S., Europe, China, and Japan − and remain on track to initiate new drug application submissions in 2016 in China, and in 2018 in the U.S. We have completed enrollment in the placebo-controlled portion of our Phase 2 study of FG-3019 (now known as pamrevlumab) for treatment of idiopathic pulmonary fibrosis, and expect to report data from this study in the middle of next year, and our Phase 2 studies in pancreatic cancer and Duchenne muscular dystrophy continue to progress."

Program Updates

Anemia of Chronic Kidney Disease (CKD): roxadustat (FG-4592)

- China Phase 3 enrollment on track: Completed enrollment in a 300-patient dialysis study, one of two Phase 3 pivotal trials in China; expect to complete enrollment in the second study, a 150-patient non-dialysis study now over 70% enrolled, in Q3 of this year. We expect first reportable data in each of the Phase 3 studies by the end of the year.
- The independent data safety monitoring board overseeing roxadustat U.S and Europe Phase 3 studies met in July 2016 to review the roxadustat safety data, and confirmed that the trials should proceed with current Phase 3 protocols without modification.
- Continue to expect to initiate new drug application submissions for roxadustat in 2016 for China and in 2018 for the U.S.

Fibrosis and Other Fibroproliferative Diseases: pamrevlumab (FG-3019)

- Completed enrollment in the 48-week main study portion of a placebo-controlled Phase 2 trial for treatment of IPF. We plan to report topline data for the entire study in mid-2017, including the six month combination therapy sub-study in which patients will receive pamrevlumab in combination with pirfenidone or nintedanib, which will continue to enroll until the end of the year.
- Continue to advance our Phase 2 trial in patients with unresectable, locally advanced pancreatic cancer, and anticipate that we will present available findings early next year.
- Enrollment continues in our open-label Phase 2 study of pamrevlumab in non-ambulatory Duchenne muscular dystrophy (DMD) patients.

Financial Highlights

- Net income per basic share for the quarter ended June 30, 2016, was $0.39, and $0.35 on a per diluted share basis.
- At June 30, 2016, FibroGen had $368.6 million of cash, cash equivalents, investments, receivables, and restricted cash.
- During the quarter ended June 30, 2016, we received a $62.0 million upfront payment under the AstraZeneca Agreement. We also recognized $10.0 million milestone revenue under the Astellas Agreement, which payment was received in early July 2016.

Conference Call Details

FibroGen will host a conference call and webcast today, August 8, 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 Q2 2016 conference call, and use the passcode 43075857. 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 (U.S. and Canada) or (630) 652-3042 (international), reference the FibroGen Q2 2016 conference call, and use the passcode 43075857#.

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. The company utilizes its extensive experience in fibrosis and hypoxia-inducible factor (HIF) biology to generate development programs in multiple therapeutic areas. Its most advanced product candidate, roxadustat (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 CKD. A second product candidate, pamrevlumab (FG-3019), our fully-human monoclonal antibody that inhibits the activity of CTGF, is in Phase 2 clinical development for the treatment of IPF, pancreatic cancer, and DMD. For more information please visit: www.fibrogen.com.

Forward-Looking Statements

This release contains forward-looking statements, including statements regarding our clinical data reporting, potential milestones, clinical plans, regulatory submissions, and 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 clinical programs, including enrollment of the Phase 3 clinical trials for roxadustat in CKD, the continued progress of our plans and programs in China, the outcome of regulatory filings for anemia associated with myelodysplastic syndrome, the enrollment and results from ongoing clinical trials for pamrevlumab in IPF, pancreatic cancer, and DMD, 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 March 31, 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)

	June 30, 2016	December 31, 2015
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 190,411	$ 153,324
Short-term investments	40,105	27,847
Accounts receivable	18,088	15,405
Prepaid expenses and other current assets	3,705	3,988
Total current assets	252,309	200,564
Restricted cash	7,254	7,254
Long-term investments	111,540	131,720
Property and equipment, net	126,264	129,020
Other assets	1,762	2,016
Total assets	$ 499,129	$ 470,574
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 3,474	$ 6,521
Accrued liabilities	47,942	47,932
Deferred revenue	15,027	12,728
Total current liabilities	66,443	67,181
Long-term portion of lease financing obligations	97,395	97,042
Product development obligations	15,515	15,085
Deferred rent	4,461	4,702
Deferred revenue, net of current	97,947	85,132
Other long-term liabilities	4,991	4,607
Total liabilities	286,752	273,749
Total stockholders’ equity	193,106	177,554

Non-controlling interests	19,271	19,271
Total equity	212,377	196,825
Total liabilities, stockholders' equity and non-controlling interests	$ 499,129	$ 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
			(Unaudited)	
Revenue:				
License and milestone revenue	$ 73,197	$ 106,879	$ 92,935	$ 118,385
Collaboration services and other revenue	16,083	13,671	24,628	18,463
Total revenue	89,280	120,550	117,563	136,848
Operating expenses:				
Research and development	52,392	51,555	96,041	102,094
General and administrative	10,376	9,680	21,794	20,162
Total operating expenses	62,768	61,235	117,835	122,256
Income (loss) from operations	26,512	59,315	(272)	14,592
Interest and other, net:				
Interest expense	(2,438)	(2,762)	(5,215)	(5,520)
Interest income and other, net	129	707	1,545	1,550
Total interest and other, net	(2,309)	(2,055)	(3,670)	(3,970)
Income (loss) before income taxes	24,203	57,260	(3,942)	10,622
Provision for (benefit from) income taxes	(113)	205	(418)	(66)
Net income (loss)	$ 24,316	$ 57,055	$ (3,524)	$ 10,688
Net income (loss) per share				
Basic	$ 0.39	$ 0.95	$ (0.06)	$ 0.18
Diluted	$ 0.35	$ 0.83	$ (0.06)	$ 0.15
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	62,582	59,798	62,383	59,499
Diluted	69,022	68,752	62,383	69,354

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