# FibroGen Announces Third Quarter 2015 Financial Results

November 12, 2015

**FibroGen Share of US / EU Roxadustat Development Cost Obligations Expected to be Reached in Fourth Quarter**

SAN FRANCISCO, Nov. 12, 2015 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ:FGEN) ("FibroGen"), a research-based biopharmaceutical company, today reported financial results for the quarter ended September 30, 2015.

"The timing of regulatory submissions for our potential first-in-class anemia treatment, roxadustat, remains on track for 2016 in China and 2018 in the United States," said Thomas B. Neff, chief executive officer of FibroGen. "FibroGen is responsible for three of the seven Phase 3 registrational studies of roxadustat that we and our partners, AstraZeneca and Astellas, are currently conducting. In our three roxadustat studies, FibroGen has reached more than 80% of combined target enrollment."

"In our development program for FG-3019, an investigational anti-fibrotic drug that targets connective tissue growth factor (CTGF), we continue to evaluate potential therapeutic uses in multiple disease areas. Our Phase 2 study of FG-3019 in patients with idiopathic pulmonary fibrosis and our Phase 2 study in Stage 3 unresectable pancreatic cancer patients both continue to advance. We plan to start a Phase 2 study of FG-3019 in non-ambulatory patients with Duchenne muscular dystrophy by year-end."

**Financial Highlights**

- Net loss per basic and diluted share for the quarter ended September 30, 2015 was $0.74.
- At September 30, 2015, FibroGen had $365.6 million of cash, cash equivalents, investments, and receivables.
- 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, of which $11.8 million remained at the end of the third quarter of 2015. Based on current internal and partner projections, FibroGen expects that its funding obligation will be met before December 2015. Thereafter, Astellas and AstraZeneca will be responsible for funding all roxadustat development in CKD through launch for all territories, excluding China.

**Program Updates**

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

- In October 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.
- FibroGen remains on track to achieve its target enrollment goals as agreed upon with its partners. The company confirms prior guidance to meet the stretch goal in one trial by year-end 2015 and meet the base goal to enroll two studies by March-April 2016.
- Two Phase 3 studies required for regulatory approval in China are expected to begin patient enrollment by the end of fourth quarter of 2015.
- In October 2015, the *Journal of the American Society of Nephrology* published results from a Phase 2 study of roxadustat in chronic kidney disease patients with anemia who recently initiated dialysis.

**FG-3019 (anti-CTGF)**

- FibroGen continues to expand the scope of its Phase 2 randomized, double-blind placebo-control study of idiopathic pulmonary fibrosis (IPF) patients. The company is activating sites in Canada, New Zealand, India, and South Africa, with additional sites pending in Australia, Bulgaria and Romania.
- FibroGen is evaluating the potential of FG-3019 to convert inoperable pancreatic cancer to operable cancer in a randomized Phase 2 open-label study. FibroGen expects to present then- current available data from this study at the 2016 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO GI) in January 2016.
- FibroGen has begun activating clinical sites for a Phase 2 study of FG-3019 in non-ambulatory patients with DMD.
- FibroGen met with the FDA to define a clinical development path for FG-3019 treatment of patients with liver fibrosis due to non-alcoholic steatohepatitis (NASH).

**Conference Call Details**

FibroGen will host a conference call and webcast today, November 12, 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 Third Quarter 2015 conference call, and use the confirmation number 40946951. 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 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, Duchenne muscular dystrophy (DMD), 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 planned clinical trials for FG-3019 in idiopathic pulmonary fibrosis, pancreatic cancer, Duchenne muscular dystrophy, and NASH; 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") and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015 filed with the SEC, including the risk factors set forth in that filing, as well as the Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, which we expect to file on November 12, 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)

| | September 30, 2015 (Unaudited) | December 31, 2014 (1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 208,650 | $ 165,455 |
| Short-term investments | 12,873 | 14,364 |
| Accounts receivable | 7,373 | 13,453 |
| Prepaid expenses and other current assets | 3,677 | 4,966 |
| Total current assets | 232,573 | 198,238 |
| Restricted cash | 7,254 | 7,254 |
| Long-term investments | 127,974 | 144,269 |
| Property and equipment, net | 129,607 | 132,171 |
| Other assets | 1,839 | 1,596 |
| Total assets | $ 499,247 | $ 483,528 |
| **Liabilities and equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,234 | $ 4,551 |
| Accrued liabilities | 41,774 | 48,985 |
| Deferred revenue | 12,980 | 9,218 |
| Total current liabilities | 58,988 | 62,754 |
| Long-term portion of lease financing obligations | 96,990 | 96,818 |
| Product development obligations | 15,433 | 16,465 |
| Deferred rent | 4,814 | 5,131 |
| Deferred revenue, net of current | 85,720 | 60,988 |
| Other long-term liabilities | 747 | 696 |

| | | |
|---|---|---|
| Total stockholders' equity | 217,284 | 221,405 |
| Non-controlling interests | 19,271 | 19,271 |
| Total equity | 236,555 | 240,676 |
| Total liabilities and equity | $ 499,247 | $ 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)

| | Quarter Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2015** | **2014** | **2015** | **2014** |
| Revenue: | | | | |
| License and milestone revenue | $ 13,045 | $ 9,027 | $ 131,430 | $ 106,175 |
| Collaboration services and other revenue | 6,493 | 4,635 | 24,956 | 15,321 |
| Total revenue | 19,538 | 13,662 | 156,386 | 121,496 |
| Operating expenses: | | | | |
| Research and development | 52,071 | 40,617 | 154,165 | 99,536 |
| General and administrative | 11,237 | 10,140 | 31,399 | 24,088 |
| Total operating expenses | 63,308 | 50,757 | 185,564 | 123,624 |
| Loss from operations | (43,770) | (37,095) | (29,178) | (2,128) |
| Interest expense | (2,758) | (2,723) | (8,278) | (8,174) |
| Interest and other income, net | 1,458 | 283 | 3,008 | 1,358 |
| Loss before income taxes | (45,070) | (39,535) | (34,448) | (8,944) |
| Provision (benefit) from income taxes | 28 | - | (38) | - |
| Net loss | $ (45,098) | $ (39,535) | $ (34,410) | $ (8,944) |
| Net loss per basic and diluted share: | $ (0.74) | $ (2.93) | $ (0.57) | $ (0.67) |
| Weighted average number of common shares used to calculate net loss per basic and diluted share: | 60,767 | 13,503 **(2)(3)** | 59,926 | 13,355 **(2)(3)** |

**(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 nine months ended September 30, 2014.

**(3)** 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)

| | Quarter Ended September 30, 2014 | Nine Months Ended September 30, 2014 |
|---|---|---|
| GAAP weighted average shares outstanding | 13,503 | 13,355 |
| 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 |
| Non-GAAP weighted average shares outstanding | 58,808 | 58,660 |

| | | | | |
|---|---|---|---|---|
| GAAP net loss | $ | (39,535) | $ | (8,944) |
| Non-GAAP net loss per basic and diluted share | $ | (0.67) | $ | (0.15) |

**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 quarter and nine months ended September 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 loss per basic and diluted share as GAAP net loss for the quarter and nine months ended September 30, 2014 divided by the non-GAAP weighted average shares outstanding for the quarter and nine months ended September 30, 2014. Non-GAAP weighted average shares outstanding is based on GAAP weighted average shares outstanding 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. 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.

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