FibroGen Reports First Quarter 2020 Financial Results

May 7, 2020

- Roxadustat U.S. NDA review and E.U. MAA filing on track -

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

SAN FRANCISCO, May 07, 2020 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the first quarter of 2020 and provided an update on the company's recent developments.

"During this difficult time, we continue to be inspired by our unique opportunity to leverage world-class science to benefit patients," said Enrique Conterno, Chief Executive Officer, FibroGen. "The COVID-19 pandemic has presented a number of unprecedented challenges, including in the conduct and enrollment of our clinical trials. Nevertheless, I want to reassure patients, healthcare providers, and stakeholders of our continued commitment to bring to patients our potential first-in-class medicines for the treatment of chronic and life-threatening conditions. Our strong financial position gives us sufficient runway to navigate this storm."

"We remain focused on ensuring the regulatory and commercial success of roxadustat, a potentially transformational oral medicine in anemia therapy, first demonstrated in patients with chronic kidney disease. With pamrevlumab, our monoclonal antibody targeting connective tissue growth factor (CTGF), we are implementing a comprehensive plan to accelerate development across the three indications of idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), and Duchenne muscular dystrophy (DMD) once the situation with COVID-19 improves. Finally, we continue to advance the innovation of our hypoxia-inducible factor (HIF) and CTGF platforms."

Key Events in Recent Months and Other Developments

Roxadustat

- U.S. NDA for roxadustat for the treatment of anemia of chronic kidney disease (CKD), in non-dialysis-dependent and dialysis-dependent patients, is under review with a Prescription Drug User Fee Act (PDUFA) date of December 20, 2020.
- Japan sNDA for roxadustat for the treatment of anemia of chronic kidney disease (CKD) in non-dialysis-dependent patients is under review.
- Presented new analyses from our Phase 3 roxadustat trials at the annual National Kidney Foundation Spring Clinical meeting which demonstrated:
    - Roxadustat corrected and maintained hemoglobin in non-dialysis dependent patients with anemia using similar doses regardless of iron status at baseline.
    - Roxadustat reduced the risk of red blood cell transfusions and IV iron rescue compared to placebo in non-dialysis CKD patients, regardless of iron status at baseline.
    - Roxadustat reduced the risk of red blood cell transfusion during anemia treatment in dialysis dependent CKD patients vs. epoetin alfa.

Pamrevlumab

- To minimize the risk of exposure to COVID-19 in the vulnerable patient population with compromised lung function from idiopathic pulmonary fibrosis (IPF), paused near-term enrollment of ZEPHYRUS Phase 3 clinical trial of pamrevlumab in patients with IPF.
- Continue to enroll the LAPIS Phase 3 clinical trial of pamrevlumab in patients with locally advanced unresectable pancreatic cancer (LAPC).

Upcoming Events

- In Europe, the Marketing Authorization Application filing for roxadustat for the treatment of anemia in both dialysis- and non-dialysis-dependent patients with CKD is expected in the second quarter of 2020.
- Plan to initiate ZEPHYRUS 2, a second IPF Phase 3 clinical trial similar in size and design to ZEPHYRUS, as COVID-19 conditions improve.
- Plan to initiate LELANTOS, a Phase 3 global clinical trial of pamrevlumab in DMD in the second half 2020. This trial will enroll approximately 90 patients randomized 1:1 to placebo and have a treatment period of 52 weeks.

Corporate and Financial

- Total revenue for the first quarter of 2020 was $24.4 million, as compared to $23.9 million for the first quarter of 2019. The current quarter revenue consisted of $19.4 million in development revenue, and $5.0 million in net roxadustat sales in China.
- Net loss for the first quarter of 2020 was $78.3 million, or $0.89 net loss per basic and diluted share, compared to a net income of $45.4 million, or $0.53 net loss per basic and diluted share one year ago.
- At March 31, FibroGen had $598.4 million in cash, cash equivalents, restricted time deposits, investments, and receivables.
- Based on our latest forecast, we reiterate our year end 2020 estimate to be in the range of $720 million to $730 million in cash, cash equivalents, restricted time deposits, investments, and receivables.

Conference Call and Webcast Details
FibroGen will host a conference call and webcast today, Thursday, May 7, 2020, 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 (877) 658-9081 (U.S. and Canada) or 1 (602) 563-8732 (international), reference the FibroGen first quarter 2020 financial results conference call, and use passcode 9946439. A replay of the webcast will be available shortly after the call for a period of two weeks. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and use passcode 9946439.

About Roxadustat
Roxadustat is a first-in-class, orally administered small molecule HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, and improved iron absorption, transport and mobilization. Roxadustat is approved in China for the treatment of anemia in CKD patients on dialysis and patients not on dialysis, and is approved in Japan for the treatment of anemia in CKD patients on dialysis, and a supplemental NDA for the treatment of anemia in CKD patients not on dialysis is under regulatory review. The roxadustat NDA for the treatment of anemia in CKD is under review by the U.S. FDA with a Prescription Drug User Fee Act date of December 20, 2020. Our partner Astellas expects the Marketing Authorization Application filing for roxadustat for the treatment of anemia in CKD in the second quarter of 2020. Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia in territories including Japan and Europe. AstraZeneca and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia in the U.S., China, and other markets.

About Pamrevlumab
Pamrevlumab is a first-in-class antibody developed by FibroGen that inhibits the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders. Pamrevlumab is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and locally advanced unresectable pancreatic cancer (LAPC), and in Phase 2 clinical development for the treatment of Duchenne muscular dystrophy (DMD). For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen
FibroGen, Inc. is a biopharmaceutical company committed to discovering, developing and commercializing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines to treat unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD). Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer, and Duchenne muscular dystrophy (DMD). 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 and commercialization of the company's product candidates, our financial results, the potential safety and efficacy profile of our product candidates, our clinical programs and regulatory events, 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, 2019 and our Quarterly Report on Form 10-Q for quarter ended March 31, 2020 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, 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 121,560	$ 126,266
Short-term investments	413,869	407,491
Accounts receivable, net	58,540	28,455
Inventory	8,408	6,887
Prepaid expenses and other current assets	134,028	133,391
Total current assets	736,405	702,490
Restricted time deposits	2,072	2,072
Long-term investments	223	61,118
Property and equipment, net	40,058	42,743
Finance lease right-of-use assets	37,017	39,602
Other assets	8,602	9,372
Total assets	$ 824,377	$ 857,397
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 2,865	$ 6,088
Accrued and other liabilities	42,309	83,816
Deferred revenue	8,531	490
Finance lease liabilities, current	12,396	12,351
Total current liabilities	66,101	102,745
Long-term portion of lease obligations	1,040	1,141
Product development obligations	16,536	16,780
Deferred revenue, net of current	139,404	99,449
Finance lease liabilities, non-current	34,545	37,610
Other long-term liabilities	89,122	64,266
Total liabilities	346,748	321,991
Total stockholders' equity	458,358	516,135
Non-controlling interests	19,271	19,271
Total equity	477,629	535,406
Total liabilities, stockholders' equity and non-controlling interests	$ 824,377	$ 857,397

(1) The condensed consolidated balance sheet amounts at December 31, 2019 are derived from audited financial statements.

Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Revenue:		
License revenue	$ —	$ —
Development and other revenue	19,446	23,863
Product revenue, net	4,955	—
Total revenue	24,401	23,863
Operating costs and expenses:		

Cost of goods sold	970	—
Research and development	54,902	50,496
Selling, general and administrative	49,603	22,210
Total operating costs and expenses	105,475	72,706
Loss from operations	(81,074)	(48,843)
Interest and other, net:		
Interest expense	(633)	(770)
Interest income and other, net	3,165	4,177
Total interest and other, net	2,532	3,407
Loss before income taxes	(78,542)	(45,436)
Benefit from income taxes	(194)	(25)
Net loss	$ (78,348)	$ (45,411)
Net loss per share - basic and diluted	$ (0.89)	$ (0.53)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	88,219	85,704

(1) The condensed consolidated statement of operations amounts for the year ended December 31, 2019 are derived from audited financial statements.

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