# FibroGen Reports Fourth Quarter and Full Year 2021 Financial Results

February 28, 2022

- ***Completed enrollment in LAPIS Phase 3 study of pamrevlumab in locally advanced unresectable pancreatic cancer***
- ***Completed enrollment in LELANTOS-1 Phase 3 study of pamrevlumab in Duchenne muscular dystrophy***
- ***Total company revenue increased from $176.3 million in 2020 to $235.3 million in 2021***

SAN FRANCISCO, Feb. 28, 2022 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the fourth quarter and full year 2021 and provided an update on the company's recent developments.

"We are excited to advance pamrevlumab in three high value indications - completing enrollment in our LAPIS and LELANTOS-1 Phase 3 studies, and expecting to complete enrollment of the ZEPHYRUS-1 Phase 3 study in idiopathic pulmonary fibrosis in the next few weeks," said Enrique Conterno, Chief Executive Officer, FibroGen. "In China, roxadustat had a strong 2021 performance and after inclusion in the updated NRDL, we are off to a good start in 2022."

**Recent Developments and Key Events:**

- Following the European Commission approval of EVRENZO™ (roxadustat) for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease (CKD), Astellas has launched EVRENZO™ in Germany, the United Kingdom, Netherlands, Austria, and the Nordic countries.
- Completed enrollment of the LAPIS Phase 3 clinical trial of pamrevlumab in patients with locally advanced unresectable pancreatic cancer (LAPC).
- Completed enrollment of the LELANTOS-1 Phase 3 clinical trial of pamrevlumab in patients with Duchenne muscular dystrophy (DMD).
- Exercised option to exclusively license HiFiBiO's CCR8 drug program to advance next-generation therapies for patients with solid tumors.

**China:**

- Roxadustat net transfer price from sales to the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca was $12.2 million for the fourth quarter. From the net transfer price, FibroGen defers a certain portion for revenue recognition purposes under U.S. GAAP. FibroGen reported $5.5 million in roxadustat net product revenue for the quarter.
  - In the fourth quarter of 2021, China's National Healthcare Security Administration renewed the listing of roxadustat on the National Reimbursement Drug List (NRDL).
  - Due to the price reduction associated with the NRDL listing renewal, we have updated our estimates and reflected a cumulative adjustment in our revenue in the fourth quarter.
- Fourth quarter total roxadustat net sales in China[1] of $32.0 million[2] by FibroGen and the JDE compared to $29.2 million in the fourth quarter of 2020.
- Full year 2021 total roxadustat net sales in China[1] of $186.1 million by FibroGen and the JDE compared to $72.5 million in the full year 2020.
- Roxadustat continues to be the number one brand based on value share in the anemia of CKD market in China.

**Upcoming Milestones:**

- Expect to complete enrollment in the ZEPHYRUS-1 Phase 3 study of pamrevlumab in idiopathic pulmonary fibrosis (IPF) in the next few weeks.
- Interim analysis of event free survival of the LAPIS Phase 3 study of pamrevlumab in LAPC expected to be conducted in 2Q 2022.
- Topline data from the LELANTOS-1 Phase 3 study of pamrevlumab in DMD expected 1H 2023.
- Topline data from the ZEPHYRUS-1 Phase 3 study of pamrevlumab in IPF expected mid-2023.
- Topline data from the MATTERHORN Phase 3 study of roxadustat in anemia of myelodysplastic syndromes (MDS) expected 2H 2022 / 1H 2023.

**Corporate:**

- Implemented a plan to reduce our projected expenses by approximately $100 million per year, for each of the next 3 years, compared to our previous internal plans.

**Financial:**

- Total revenue for the fourth quarter of 2021 was $16.5 million, as compared to $65.0 million for the fourth quarter of 2020.
- Total revenue for 2021 was $235.3 million as compared to $176.3 million in 2020.
- Net loss for the fourth quarter of 2021 was $134.1 million, or $1.45 net loss per basic and diluted share, compared to a net loss of $58.6 million, or $0.64 net loss per basic and diluted share one year ago.
- Net loss for the year was $290.0 million, or $3.14 net loss per basic and diluted share, compared to a net loss of $189.3 million, or $2.11 net loss per basic and diluted share one year ago.
- At December 31, 2021, FibroGen had $590.4 million in cash - defined as cash, cash equivalents, investments, and accounts receivable.
- Based on our latest forecast, we estimate our 2022 ending cash to be in the range of $270 to $300 million.

[1] Total roxadustat net sales in China includes sales made by the distribution entity as well as FibroGen China's direct sales, each to its own distributors. The distribution entity jointly owned by AstraZeneca and FibroGen is not consolidated into FibroGen's financial statements.
[2] As a result of the price reduction associated with the NRDL listing renewal, the roxadustat net sales for the fourth quarter of 2021 reflected a one-time adjustment driven by a revaluation of channel inventory.

**Conference Call and Webcast Details**
FibroGen will host a conference call and webcast today, Monday, February 28, 2022, 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 fourth quarter 2021 financial results conference call, and use confirmation number 1795663. A replay of the webcast will be available shortly after the call for a period of 7 days. To access the replay, please dial 1 (855) 859-2056 (domestic) or 1 (404) 537-3406 (international) and use passcode 1795663.

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

**About Roxadustat**
Roxadustat, an oral medication, is the first in a new class of medicines comprising HIF-PH inhibitors that promote erythropoiesis, or red blood cell production, through increased endogenous production of erythropoietin, improved iron absorption and mobilization, and downregulation of hepcidin. Roxadustat is in clinical development for anemia of chronic kidney disease (CKD) and anemia associated with myelodysplastic syndromes (MDS), and for chemotherapy-induced anemia (CIA).

Roxadustat is approved in European Union (EU) member states, including the European Economic Area (EEA) countries, as well as in Japan, China, Chile, and South Korea for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). Several other licensing applications for roxadustat have been submitted by partners, Astellas and AstraZeneca to regulatory authorities across the globe, and are currently under review.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in territories including Japan, Europe, Turkey, Russia and the Commonwealth of Independent States, the Middle East, and South Africa. FibroGen and AstraZeneca are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in the U.S., China, other markets not licensed to Astellas.

**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 connective tissue growth factor (CTGF) biology and hypoxia-inducible factor (HIF) to advance innovative medicines for the treatment of unmet needs. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), and Duchenne muscular dystrophy (DMD). 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), anemia associated with myelodysplastic syndromes (MDS), and for chemotherapy-induced anemia (CIA). FibroGen recently expanded its research and development portfolio to include product candidates in the immuno-oncology and autoimmune space. 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, 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, 2021 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)

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| | (Unaudited) | (1) |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 171,223 | $ 678,393 |
| Short-term investments | 233,967 | 8,144 |
| Accounts receivable, net | 17,401 | 41,883 |
| Inventory | 31,015 | 16,530 |
| Prepaid expenses and other current assets | 20,453 | 10,160 |
| Total current assets | 474,059 | 755,110 |
| Restricted time deposits | 2,072 | 2,072 |
| Long-term investments | 167,796 | 244 |
| Property and equipment, net | 28,277 | 33,647 |
| Finance lease right-of-use assets | 761 | 29,606 |
| Equity method investment in unconsolidated variable interest entity | 3,825 | 2,728 |
| Operating lease right-of-use assets | 91,112 | 2,043 |
| Other assets | 5,919 | 1,390 |
| **Total assets** | $ 773,821 | $ 826,840 |
| **Liabilities, stockholders' equity and non-controlling interests** | | |
| Current liabilities: | | |
| Accounts payable | $ 26,097 | $ 24,789 |
| Accrued and other liabilities | 172,588 | 118,333 |
| Deferred revenue | 15,857 | 6,547 |
| Finance lease liabilities, current | 11 | 12,330 |
| Operating lease liabilities, current | 10,944 | 1,188 |
| Total current liabilities | 225,497 | 163,187 |
| Product development obligations | 17,613 | 18,697 |
| Deferred revenue, net of current | 186,801 | 138,474 |
| Finance lease liabilities, non-current | 3 | 25,391 |
| Operating lease liabilities, non-current | 88,776 | 853 |
| Other long-term liabilities | 26,018 | 38,789 |
| Total liabilities | 544,708 | 385,391 |
| Total stockholders' equity | 209,146 | 422,178 |
| Non-controlling interests | 19,967 | 19,271 |
| Total equity | 229,113 | 441,449 |
| **Total liabilities, stockholders' equity and non-controlling interests** | $ 773,821 | $ 826,840 |

**(1)** The condensed consolidated balance sheet amounts at December 31, 2020 are derived from audited financial statements.

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

| | Three Months Ended December 31, | | Years Ended December 31, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | (Unaudited) | | (Unaudited) | (1) |
| **Revenue:** | | | | |
| License revenue | $ — | $ 14,323 | $ 116,434 | $ 14,323 |
| Development and other revenue | 9,951 | 21,527 | 70,275 | 80,592 |
| Product revenue, net | 5,463 | 29,167 | 47,638 | 72,498 |
| Drug product revenue | 1,129 | (17) | 962 | 8,906 |
| Total revenue | 16,543 | 65,000 | 235,309 | 176,319 |
| **Operating costs and expenses:** | | | | |
| Cost of goods sold | 3,125 | 2,615 | 12,871 | 8,869 |
| Research and development | 113,920 | 78,132 | 387,043 | 252,924 |
| Selling, general and administrative | 34,739 | 42,249 | 123,925 | 106,406 |
| Total operating costs and expenses | 151,784 | 122,996 | 523,839 | 368,199 |
| **Loss from operations** | (135,241) | (57,996) | (288,530) | (191,880) |
| **Interest and other, net:** | | | | |
| Interest expense | (110) | (538) | (1,075) | (2,402) |
| Interest income and other income (expenses), net | 1,042 | 261 | (1,078) | 5,553 |
| Total interest and other, net | 932 | (277) | (2,153) | 3,151 |
| **Loss before income taxes** | (134,309) | (58,273) | (290,683) | (188,729) |
| Provision for income taxes | 112 | 171 | 347 | 360 |
| Investment income (loss) in unconsolidated variable interest entity | 342 | (190) | 1,007 | (202) |
| **Net loss** | $ (134,079) | $ (58,634) | $ (290,023) | $ (189,291) |
| Net loss per share - basic and diluted | $ (1.45) | $ (0.64) | $ (3.14) | $ (2.11) |
| Weighted average number of common shares used to calculate net loss per share - basic and diluted | 92,774 | 91,166 | 92,349 | 89,854 |

**(1)** The condensed consolidated statement of operations amounts for the year ended December 31, 2020 are derived from audited financial statements.

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