UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 7, 2017

FibroGen, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36740**	**77-0357827**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
(Address of principal executive offices, including zip code)

(415) 978-1200
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

A transcript of FibroGen, Inc.'s Earnings Call on August 7, 2017 is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of FibroGen, Inc.'s Earnings Call on August 7, 2017

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FIBROGEN, INC.

Dated: August 11, 2017

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Counsel

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Transcript of FibroGen, Inc.’s Earnings Call on August 7, 2017

Q2 2017 FibroGen Inc Earnings Call

SAN FRANCISCO Aug 7, 2017 (Thomson StreetEvents) — Preliminary Transcript of FibroGen Inc earnings conference call or presentation Monday, August 7, 2017 at 9:00:00pm GMT

TEXT version of Transcript

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Corporate Participants

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* Elias Kouchakji
  FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance
* K. Peony Yu
  FibroGen, Inc.—Chief Medical Officer
* Karen L. Bergman
  FibroGen, Inc.—VP of IR & Corporate Communications
* Pat Cotroneo
  FibroGen, Inc.—VP of Finance & CFO
* Seth Porter
  FibroGen, Inc.—VP of Fibrosis Therapeutics
* Thomas B. Neff
  FibroGen, Inc.—Founder, Chairman & CEO

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Conference Call Participants

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* Geoffrey Craig Porges
  Leerink Partners LLC, Research Division—MD, Biotechnology, Director of Therapeutics Research and Senior Biotechnology Analyst
* Joel Lawrence Beatty
  Citigroup Inc, Research Division—VP and Analyst
* Michael Jonathan Yee
  Jefferies LLC, Research Division—Equity Analyst
* Terence C. Flynn
  Goldman Sachs Group Inc., Research Division—MD
* Thomas Shrader
  Stifel, Nicolaus & Company, Incorporated, Research Division—Analyst
* Tsan-Yu Hsieh
  William Blair & Company L.L.C., Research Division—Senior Research Analyst

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Presentation

Operator [1]

Welcome to the FibroGen, Inc. Second Quarter 2017 Financial Results Conference Call. My name is Ally, and I will be your operator today. (Operator Instructions)

Please note that this conference is being recorded. A webcast of this call will be available on the company website 2 weeks from today’s date. For opening remarks and introduction, I’ll now turn the call over to Karen Bergman, Vice President, Investor Relations and Corporate Communications. Please go ahead.

Karen L. Bergman, FibroGen, Inc.—VP of IR & Corporate Communications [2]

Thank you, Ally, and again this is Karen Bergman. Good afternoon, everyone, and welcome to FibroGen’s financial results and corporate update call for the second quarter of 2017. The call will be led

by Tom Neff, our Chief Executive Officer. Tom will kick off the call today with our top line Phase II results for pamrevlumab in idiopathic pulmonary fibrosis and later will discuss progress and milestones for our product development programs.

We are joined today by Dr. Peony Yu, Chief Medical Officer, and she will discuss top line efficacy results from our Phase II placebo-controlled clinical study assessing the efficacy of pamrevlumab in the treatment of IPF and the two comparator controlled sub-studies using pamrevlumab in combination with approved IPF therapies as well as our anemia program in China and recent clinical results related to the down regulation of hepcidin.

Dr. Elias Kouchakji, Vice President, Clinical Development, Drug Safety and Pharmacovigilance and the clinical team leader for the pamrevlumab program, will discuss the safety results from our IPF Phase II study.

Dr. Seth Porter, Vice President and project team leader for fibrosis therapeutics, will provide pamrevlumab program updates.

Mr. Pat Cotroneo, Chief Financial Officer, will review financial performance in the second quarter.

Also joining us for the Q&A portion of the call is Dr. Eduard Gorina, Executive Director of Clinical Development.

On this call, we expect to make forward-looking statements regarding our business, including our collaborations with AstraZeneca and Astellas; financial guidance; the initiation, enrollment, design, conduct and results of clinical trials; research and development activities; and certain other business matters.

For risks and uncertainties regarding our business and statements made on the call today as well as factors beyond our control that may cause differences between current expectations and actual results, we refer you to our Form 10-K for the fiscal year ended December 31, 2016, and quarterly reports, including our Form 10-Q for the period ended March 31, 2017, filed with the Securities and Exchange Commission. Copies of these filings can be found in the Investors section of our website. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise.

The format for today's call will include remarks from FibroGen's management team, and then we'll open the lines to take your questions. A webcast of this conference call will be available for replay again on the Investors page on FibroGen's website, www.fibrogen.com.

And now, it is my pleasure to turn the call over to our CEO, Tom Neff.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [3]

Thank you, Karen. Good afternoon, everyone. Thank you for joining us today. This is an exciting time for FibroGen, and we look forward to sharing with you recent advances across our pipeline and in multiple therapeutic indications.

First, with pamrevlumab, we are pleased to report to you topline results from our randomized placebo-controlled double-blind Phase II study of pamrevlumab and IPF, and our combination sub-studies with the approved drugs. We view these data as an important milestone for the company and for the program, and we believe the results of this study enable us to move into Phase III with IPF.

Study 067 includes a main study and 2 sub-studies: first the 48-week placebo-controlled study; second, two combination 24-week safety sub-studies. In the double-blind placebo-controlled study, 103 patients were randomized in one-to-one ratio to receive either pamrevlumab or placebo for 48 weeks.

In terms of FVC percent predicted, the primary endpoint of the study, the decline in FVC percent predicted from baseline to week 48 was 2.85 in the pamrevlumab arm, as compared to a decline of 7.17 in the placebo arm, a statistically significant result. In terms of FVC, as measured in volume, the pamrevlumab-treated patients had an average decrease of FVC of 129 ml at week 48 as compared to an average decrease of 308 ml in the patients receiving placebo, a difference that was also statistically significant.

For clarity, I should point out that we chose to use of the random coefficient linear regression model similar to the methodology employed by Boehringer Ingelheim in their Phase III U.S. study in nintedanib. We chose this method because the published FDA clinical and statistical review or comments after the Phase III made it clear that this approach is acceptable and not controversial.

Turning to safety. Pamrevlumab continued to be well tolerated as monotherapy and IPF patients consistent with previous clinical studies and was also well tolerated when administered in combination

with either pirfenidone or nintedanib. We did not see any synergistic or unexpected safety result when pamrevlumab was combined with either of the approved drugs. Dr. Kouchakji will further describe later on in this call. We will present additional data regarding these studies from — by Dr. Yu and Dr. Kouchakji immediately after my remarks.

We continue to believe IPF will be a significant value generator for pamrevlumab due to severe unmet medical need and limited life expectancy at the time of diagnosis. Pamrevlumab may represent a valuable option to treat IPF patients as our results suggest improvements in both standard measurements in lung function, improved safety and quantitative measurement of fibrosis.

We will also be showing further results from the 067 study in an oral presentation at the European Respiratory Society International Congress in Milan, Italy next month. We'll also be presenting interesting preclinical data comparing pamrevlumab to the approved therapies in the highly predictive radiation-induced fibrosis model. It was in this model that we demonstrated the ability of pamrevlumab to reverse lung remodeling and to improve pulmonary function.

The results in this model demonstrate superior performance of pamrevlumab for inhibition of fibrosis and reversal of gene expression associated with fibrosis.

With respect to pamrevlumab development for treatment of unresectable locally advanced pancreatic cancer, the U.S. Food and Drug Administration recently granted orphan drug designation status to pamrevlumab for the treatment of pancreatic cancer. We had previously received orphan drug designation for pamrevlumab for the treatment of IPF. In our ongoing Phase II study, we continue to see favorable differences in resectability and trends in the overall survival between patients in the pamrevlumab-treated and the control arm. We expect to report results at the end of this year or early next year at a scientific conference.

We continue to enroll patients in our Phase II open-label study of pamrevlumab in non-ambulatory Duchenne muscular dystrophy, or DMD patients. Pamrevlumab has the potential to be a disease-modifying therapy for DMD by countering the activity of elevated CTGF and the harmful effects of fibrosis in muscle tissue.

Following remarks on our IPF data reported today, Dr. Peony Yu will also provide a status report on our roxadustat program and Pat Cotroneo will summarize our second quarter results. Then I will wrap up our remarks today with an update on milestones followed by your questions.

With that said, I would now like to turn the call over to Dr. Peony Yu to discuss today's IPF results. Peony?

K. Peony Yu, FibroGen, Inc.—Chief Medical Officer [4]

Thank you, Tom.

The 067 main study was a Phase II, randomized double-blind placebo-controlled clinical trial to evaluate the safety and efficacy of FG-3019 in 103 patients with idiopathic pulmonary fibrosis, with most of the patients in the U.S.

IPF is a chronic progressive fatal disease characterized by fibrosis in the lungs resulting in loss of lung function and exercise capacity. Despite the availability of new drugs for IPF within the last few years, there remains a need for better and safer treatment options.

After a screening period of up to 6 weeks, study subjects received 30 milligrams per kilogram of pamrevlumab or placebo intravenously every 3 weeks for 48 weeks. Lung function assessments were conducted at baseline and at weeks 12, 24, 36 and 48.

The IPF diagnostic criteria utilized for patient selection was based on the current international guidelines.

The key function assessment of IPF progression is pulmonary function. The primary efficacy of assessment is forced vital capacity or FVC. The FVC change from baseline to 48 weeks was analyzed both in FVC (measured in ml) and in FVCpercent predicted, adjusted for age, race, sex and height. This latter parameter, FVC percent predicted, was designated as the primary endpoint.

In the Intent to Treat population, pamrevlumab had a statistically significant lower rate of decline than placebo in FVC volume and FVC percent predicted when analyzed using the predefined method of linear slope model, also known as the random coefficient linear regression model. The absolute decline in FVC percent predicted from baseline to week 48 was 2.85% in the pamrevlumab arm as compared to a decline of 7.17% in placebo, an absolute difference of 4.33%. Thus, the relative decline was 60% less than placebo, with a P value of 0.0331.

The mean decline in FVC volume from baseline to week 48 in pamrevlumab-treated patients of 129 milliliters was statistically less than placebo of 308 ml, with a difference of 178 ml, or a relative decline of 58% lower than the placebo arm, with a significant p-value of 0.0249.

The findings in this placebo-controlled study are consistent with and additive to earlier completed open- label Phase II study in IPF, study 049.

Dr. Kouchakji will now present the safety results.

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [5]

Thank you, Peony. I would now like to share with you safety result of our studies with placebo-controlled 103 patients in 48-weeks main study, followed by safety results from the two 48-weeks combination safety study.

In these studies, pamrevlumab was well-tolerated. In the main study, the treatment emergent adverse events were comparable between pamrevlumab and placebo. Adverse events in the pamrevlumab arm of this study were consistent with the known safety profile of pamrevlumab. While in IPF which is known as a fatal disease, there were lower numbers of death in the treatment emergent serious adverse events leading to discontinuation reported in the pamrevlumab arm compared to the placebo arm.

For the death, there were three deaths in the pamrevlumab versus six in the placebo. The treatment emergent serious adverse event, there were the 3 treatment emergent serious adverse events in pamrevlumab versus 7 in the placebo arm.

In the 2 sub-studies, were randomized as double-blind trials with standard of care as a background therapy. Study subject had been on stable doses of either pirfenidone or nintedanib for at least 3 months and randomized to 2:1 to receive 30 mg/kg pamrevlumab with standard of care or standard of care alone every 3 weeks for 24 weeks. 36 subjects were on pirfenidone or pirfenidone in combination with pamrevlumab, 21 patients and 15, in the pirfenidone with pamrevlumab and 6 in the combination.

Pamrevlumab was well-tolerated when dosed in combination with either pirfenidone or nintedanib. No safety signal was detected in the respective combination arm compared to either pirfenidone or nintedanib alone.

We shall be presenting this data and additional analyses at the upcoming 2017 European Respiratory Society Meeting on September 12 in Milan.

Thank you for your time today, and now I will turn the call to. Seth Porter. Dr. Porter.

Seth Porter, FibroGen, Inc.—VP of Fibrosis Therapeutics [6]

Thank you, Elias. Just a few program updates to round out the special news on pamrevlumab. With regard to our IPF-based trial, we have — much work to remains to be done in analyzing our pharmacokinetic data as well as HRCT data. As in the previous Phase II study, we analyzed changes in fibrosis by qualitative HRCT at baseline, week 24 and week 48.

Moving to pancreatic cancer, we expect to complete the assessment of surgical resection of pancreatic tumors by the end of this year, or perhaps early next year, and so we look forward to those results.

In muscular dystrophy, we are now enrolling in that trial and at a much better pace, and we’re excited about that.

And then one other further development is we are moving forward for our process finalization and scale up for the manufacture of pamrevlumab so that we are in a position to support Phase III programs.

With that, I’ll turn it back to Tom.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [7]

Thank you, Seth. Dr. Peony Yu will now talk about continued progress in our Phase III program for roxadustat including new hepcidin results from our recently completed roxadustat Phase 3 anemia trials in China. Dr. Yu?

K. Peony Yu, FibroGen, Inc.—Chief Medical Officer [8]

Thank you, Tom.

Our large global roxadustat anemia program is progressing well. We are on track to submit the new drug application or NDA to the U.S. FDA in 2018 for roxadustat, our small molecule inhibitor of hypoxia-inducible factor prolyl hydroxylase activity for treatment of anemia associated with chronic kidney disease.

As we progress through the studies, we continue to get a green light from the independent data safety monitoring board, or DSMB, which reviews our U.S. and European Phase III program on a quarterly basis. In the most recent review in August, the DSMB recommended that our trials continue without modification to current protocols.

In China anemia program on the other side of the globe, we reported positive clinical results from our 2 Phase III pivotal trials earlier this year in CKD anemia and expect to complete the submission of our NDA to the Chinese FDA in the third quarter of this year.

Hepcidin, the key hormone that regulates iron metabolism, is generally elevated and contributory to EPO hyporesponsiveness in patients with inflammation. Consistent with previously reported Phase II CKD data from the U.S. and China, a reduction of serum hepcidin levels was observed in our 2 Phase III studies in China in roxadustat and CKD anemia. In the Phase III dialysis study, the mean decrease in serum hepcidin levels from baseline to the end of 26 weeks of treatment with 30.2 nanograms per ml in the roxadustat arm versus 2.2 nanograms per ml in the EPO comparator arm. In the Phase III non-dialysis study, the mean decrease in hepcidin level at the end of 8 weeks of double-blind treatment was 56.1 nanograms per ml in the roxadustat arm versus 15.1 nanograms per ml in the placebo arm. P-value was — has 7 zeros followed by a 5. These results are consistent with the mechanism of action of roxadustat, which not only increases the level of endogenous EPO transiently, but also decreases the elevated hepcidin levels in patients with inflammation, often seen in CKD and MDS.

We look forward to keeping you updated on clinical and regulatory events for roxadustat in 2017. I'd like to turn the call back to Tom. Tom?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [9]

Thank you, Peony. Pat Cotroneo, our Chief Financial Officer, will now walk through financial highlights for the second quarter of the year. Pat?

Pat Cotroneo, FibroGen, Inc.—VP of Finance & CFO [10]

Thanks, Tom. As announced today, total revenue for the quarter ended June 30, 2017, was $29 million. For the same period, operating expenses were $60 million and net loss was $33.2 million or $0.48 per basic and diluted share. Included in operating expenses for the quarter ended June 30, 2017, was an aggregate noncash portion totaling $11.5 million, of which $9.6 million was a result of stock-based compensation expense. As of June 30, FibroGen had $414.7 million, as compared to $342.2 million at the end of 2016.

As previously communicated, the cash balance includes a financing closed on April 11, 2017, which resulted in net proceeds of $115.1 million. For these purposes total cash refers to cash, including cash, cash equivalents, receivables, investments, consisting primarily of investment-grade corporate debt and restricted time deposits related to our building lease. On our balance sheet, the category of long-term investments consists entirely of investment-grade corporate debt, with remaining maturities of fewer than 2 years.

We are currently projecting year-end cash of $370 million.

I will now turn the call back over to Tom.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [11]

Thank you, Pat.

I would like to reiterate how pleased we are with the results reported to you today in our Phase II study of pamrevlumab in IPF and the combination sub-studies. Based on the work today, we view these data as Phase III enabling and a significant can step forward in both our IPF program and overall fibrosis program. We look forward to reporting additional analyses from these studies as soon as the data become available.

We are heading to the second half of the year with a number of upcoming milestones for both our lead programs.

Milestones for roxadustat include completion of our NDA submission for CKD anemia in China, anticipated by the end of Q3 2017; and initiation of our U.S. Phase III clinical study in anemia of MDS or myelodysplasia, followed by initiation of a Phase II/III study in China before the end of the year in the same indication.

For pamrevlumab, following today's announcement of positive results in our IPF Phase II trial, we look forward to reporting further data reports at the European Respiratory Society International Congress in Milan next month. We will also be reporting preclinical data comparing pamrevlumab to approved therapies in the validated mouse model of radiation-induced lung fibrosis. After having received orphan drug designation from the FDA for pamrevlumab and pancreatic cancer, we are looking forward to surgical assessment data by early 2018 or possibly sooner.

We can now turn to your questions. Operator?

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Questions and Answers

Operator [1]

(Operator Instructions) And our first question comes from Michael Yee of Jefferies.

Michael Jonathan Yee, Jefferies LLC, Research Division—Equity Analyst [2]

Thank you and congrats. This has been a long time coming. You have been talking about this for a long time. A couple of quick questions. Number 1, what can you say about the next steps, how fast can you go to the FDA? Talk about that. Would you run a mono pivotal study combo? Talk a little bit about that. Number 2, what do the combination show after 6 months? What type of FVC declines? And then number 3, what do you see on HRCT?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [3]

Michael, thank you for your comments. For the next steps, we are actively considering 2 or 3 different trial designs and looking forward to talking to FDA about protocol design and getting some alignment there. In addition, we will be speaking with partners in the next couple of months, so this will be a dynamic going-forward process. The near-term focus is the ERS presentations in Milan. But all these things are planned out in various scenarios. The team will get right back to work now that they have the definitive data and will help us choose between the various pathways that we have mapped out. With regard to the sub- study, there was no endpoint measured for the FVC percent predicted at 24 weeks. This is the safety study, and so the safety characterizations were where the focus was and we did not expect to see benefit or lack benefit in terms of FVC liters, FVC percent predicted, so to my knowledge that's not calculated to this point. With respect to HRCT, there are several things that we're doing and I'll also include the PK studies in this category where we have very interesting data but we have experts also that help us with interpreting the data and when we unblinded the study last week, we just haven't had enough time to go get those experts in place and get everybody, have a chance to look at the data and make sure the interpretations are correct. So HRCT is on our list of things to do in the very near term, but we have not done a computation yet purposefully. We — draw the lines if things require third-party assistance because of the shortage of time.

Operator [4]

Our next question comes from Terence Flynn from Goldman Sachs.

Terence C. Flynn, Goldman Sachs Group Inc., Research Division—MD [5]

Maybe a couple on pamrevlumab for me as well. Can you tell us what percentage of patients discontinued in each arm for any reason? And how were any missing data imputed particularly the patients that died? And then I have 1 follow-up on that?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [6]

So, Elias, do you want to take that?

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [7]

I can start by answering the question of the imputed patient— process. In the linear slope, as mentioned, the method we used there is…; no imputation has been used, so there is no imputation… for the patients who completed this study...

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [8]

…Discontinuation. How many was the question. Give us just a second, Terence. I think we can get this information but nobody has it right off the tip of their tongue.

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [9]

So for the completed patients in the pamrevlumab arm, there is 40 patients completed the study. In the placebo arm, there's 39 patients who completed the study.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [10]

Thank you. Terence, do you have other question?

Terence C. Flynn, Goldman Sachs Group Inc., Research Division—MD [11]

Yes. So just to be clear though, what — how if a patient died, how was their last FVC measurement calculated? Like what do you assume for that? Again, if a patient died, they couldn't come in obviously for the 48-week measurement, so how was that data point accessed, I guess, is my question?

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [12]

So there is no assumption that is being made. We're using the linear projection and that been linear projection is computed to assess the final results. It's not manual computation or any imputation methodology is used.

Terence C. Flynn, Goldman Sachs Group Inc., Research Division—MD [13]

So it's their last observation carried forward essentially? Or is it an average of the prior? Sorry, I'm just not...

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [14]

No. It's not carryforward. I will ask Dr. Yu to answer.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [15]

Dr. Yu, you want to add something?

K. Peony Yu, FibroGen, Inc.—Chief Medical Officer [16]

Yes. So, Terence, the statistical method we use a similar to that used in nintedanib, where there is some linear model that you use all the available time points for projecting in this model, so therefore, you do not need to — so for example —

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [17]

(inaudible)

K. Peony Yu, FibroGen, Inc.—Chief Medical Officer [18]

So for example, if a patient has all available time points available for FVC except for week 48, then the slope for the individual patient will be based on all the available time points. This is what's described in the New England Journal of 2014 publication on the pirfenidone. 1 of pirfenidone alternative — analysis as well as in the nintedanib primary publication.

Terence C. Flynn, Goldman Sachs Group Inc., Research Division—MD [19]

Okay, and just with the P value one-sided or 2 sided?

K. Peony Yu, FibroGen, Inc.—Chief Medical Officer [20]

2 sided.

Operator [21]

We do have Michael Yee from Jefferies back on with a question.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [22]

Michael, sorry, I think we are cut off there.

Michael Jonathan Yee, Jefferies LLC, Research Division—Equity Analyst [23]

So my other question was in regarding the safety analysis. Can you just talk about anything you saw there other than just deaths? And then how many were completers were there in the drug war versus placebo? How many completers not just discontinuations? So side effects, safety and completers?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [24]

So, Mike, I'm going to ask Dr. Kouchakji to answer part of this question. But the completers in the past population, right, there are a total of 95. Completers were 40 and 39, 44 active and 39 for placebo. So you can do the numbers from there, right, 89 versus 95. Okay. Now Elias will answer the next part of the question.

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [25]

I think I will answer part of the question by saying, first of all, the treatment adverse events at 96% to 98%, respectively, pamrevlumab to placebo. And serious EAE as I mentioned is leading to treatment discontinuation that was 3 to 7. And there was no unique characteristic that shows that any new risk is identified, and it is as we've seen in the previous published in the 049 studies, we see similar event that is reported in this study that is what's reported in the study so...

Operator [26]

Our next question comes from Andy Hsieh from William Blair.

Tsan-Yu Hsieh, William Blair & Company L.L.C., Research Division—Senior Research Analyst [27]

I have a couple. One is really on the potential Phase III structure so I believe the other 2 approved agents were approved based on about 1200 to 1300 patients. Would that be a fair number for the Phase III program? Related to that, curious to hear your thoughts about the potential for an overall survival benefit. Would that — maybe comment on the potential for that on the label? And also from a partner perspective, maybe lay out a couple of factors that you're looking for in a potential partnership for pamrevlumab and that's it for my questions.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [28]

So for purposes of responding to you, I think the Phase III design and the number of patients, I will let Dr. Kouchakji answer there. And also I think you're asking given the trend we've seen with death and progression in both 049 and 067, would we expect some sort of survival benefit? I'll ask Dr. Kouchakji to address that as well. And then I'll take the part on partner. Go ahead, Elias.

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [29]

For the design of the study, there will be multiple design as has been discussed as we continued to discuss and the size of this study will be based on the results of this study. So that is would be very active discussion with the regulators. And we cannot at this time define exactly what the size of these studies. We would not anticipate that the studies (inaudible) for we cannot speculate at this time. You asked the question about the mortality assessment. Now we've done some assessment on mortality using the GAP score and at same time with the expected mortality for 1 year in this patient population. The expected mortality in this patient population is 13.2%, which is in the — sorry, will higher than this is 13 subject is expected to die in the study. Our total death is 9. And if we do this by arm in pamrevlumab, we expected death to be 6.4, which was around 6, and we have seen only 3 patients in the pamrevlumab arm. Placebo, the rate will be 6.5 subject could die according to this expected rate from 1 known published data and 6 patients died with the rate of 92.3% of expected. We can see in this assessment a rather reduction versus placebo of 51%. One of the things that was not pointed out, that is the mortality in the pamrevlumab arm was only at 40% of expected rate.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [30]

So again, we're seeing really interesting data that comparison of 40s for pamrevlumab and 90s for placebo relative to expected. This is suggestive and, we need to do bigger studies, obviously, as the next step. As it relates to partners, there are a couple things that will matter a lot in our analysis. One,is how much time independent of all the factors, partnering negotiations will take for us generally immediate capital needs as it relates to scaling up are something that's important to address and to secure appropriate financing. And with respect to partners, we would not want to be waiting around for partners to provide that money where we're losing time overall as a critical path matter, and so that kind of idea how much the stipulation of interference with or demanding Phase III participation and protocol design will be another factor. All these things really relate to time and getting encumbered by things to slow us down. The other major issue, obviously, is what the overall business proposition is. We believe we have the first active factor in fibrosis, anti-fibrotic, you can call it. It's a huge category in medicine depending on the statistics either the first or second, or third largest killer of humans, and there is never been any therapies. And so obviously want a partnership that is anticipating the breadth of opportunity both in straight fibrosis and in the cancer arena where fibrosis is important and in combination with things like the PD-L1 medicines. So the vision of what the ideas are and then the proposals by geography, so we are very interested in the U.S. and in China, obviously, in the other territories not. So we will look to a partner to be

responsive in a manner we're net better off strategically in those things. And these are the factors that come to mind as the important ones for now, though I'm sure there will be more as we get into it. But as far as the time issues we will be very sensitive to these things. We don't want to lose critical path time over bargaining back and forth with very elaborate organizations that have to do a lot of diligence. We want to make sure we stay on our critical path. I hope that helps.

Operator [31]

And our next question comes from Geoff Porges from Leerink Partners.

Geoffrey Craig Porges, Leerink Partners LLC, Research Division—MD, Biotechnology, Director of Therapeutics Research and Senior Biotechnology Analyst [32]

A couple of questions. First, about the data. Could you comment on any differences in hospitalizations between the 2 arms and placebo-controlled phase? Secondly, any laboratory differences? And then third, could you tell us what the baseline percent and actual FVC were for the patients? And then lastly, I apologize for all the questions, Tom, could you talk a bit more about manufacturing because it looks to me as though you need to about 35 kilograms of antibody per 1000 patients, which is going to be a substantial scale up exercise. And when do you think you'll have a final process? When do you think that you will have a facility and what kind of investment do you think you will need to make to get to the capacity that supply the market for this?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [33]

Thank you. Let me do the manufacturing part first so the people can find the data you're looking for in the other categories. We have been working on manufacturing plant very carefully for the past 2 or 3 years. There are several manufacturers who are highly skilled that are interested in working with us. The people that we have been working with to date have expressed a high interest in staying involved, and we have made the decision to finish process optimization and the upscaling of the new method of producing the comparability testing there to that with the people that are involved now. Now we anticipate at some point anywhere from 18 to 24 months from now, there will be a second partner brought in because we are mindful of capacity issues and scale issues, and we're also mindful that and some of these areas of therapy, we are having a meaningful effect on disease so we had to be sure we can supply the market that we're entering appropriately. Fortunately, it is the case that the people we're talking to have a scale that they're willing to commit as well as new scale coming online in the next 12 to 24 months that would be available as an additive proposition. And we have gotten to the point with the providers that people are agreeing to essentially work together because of instead of trying to argue for exclusivity people are seeing the need for us to have 2 producers, at least 2 producers of the antibody in short order. So all these things are happening. I think that the scale of opportunity for something like IPF once you to start looking at the non-U.S. but as a global matter, that's a lot of antibody obviously. And with respect to pancreatic cancer, at the other end of the spectrum, because of how severe the disease is and what the dire circumstances are for patients, there aren't that many patients out there relative to something like IPF so it's much easier to see coverage for pancreatic, for instance, than IPF and so we're focused on making sure that as it relates to the U.S. and Europe as your first likely approval markets on IPF that we will have enough antibody to be responsive to the known demand. So I think that's sort of the picture there. Now let's turn to the other questions. You asked about hospitalizations and any laboratory differences and the FVC entry as I understood it. So, Elias, you want to go ahead and address?

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [34]

Yes, can address just talking with answering the question onthe hospitalization that was in the pamrevlumab arm, there was 5 hospitalizations. And placebo arm, there was 7. For the FVC percent predicted, pamrevlumab was at 73.4% and the placebo at 71%. The gap score was a balance between...

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [35]

Laboratory differences is the other question? go ahead.

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [36]

There was no differences in the laboratory —

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [37]

No discernible.

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [38]

No discernible differences. And I guess the GAAP score was similar between the 2 study arms.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [39]

So let me qualify there that we're learning this data very, very rapidly right now in the top line statistics. I agree, there is no discernible difference but as we dig into it there may be some further modification. And if that happens, we'll get back to you and let you know.

Operator [40]

And our next question comes from Tom Shrader of Stifel.

Thomas Shrader, Stifel, Nicolaus & Company, Incorporated, Research Division—Analyst [41]

All I can say is, wow, with 100 patients, good for you. To follow up a little bit on the previous question, looking at placebo arm, your drop was quite a bit less than pirfenidone so are these quite mild patients you treated? Would this be mild IPF or just your sense of the entry patients.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [42]

So we're not comparing the pirfenidone in our study so I'm not sure I'm quite following what you have...

Thomas Shrader, Stifel, Nicolaus & Company, Incorporated, Research Division—Analyst [43]

Just the drop in FVC in the placebo arms was quite a lot higher in the pirfenidone on trial the curves tend to bend down with time in IPF.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [44]

I think understand the question. I think we can provide some light on this. Dr. Yu, do you want to go ahead on this?

K. Peony Yu, FibroGen, Inc.—Chief Medical Officer [45]

Yes, I think it depends on which pirfenidone analyses that we're talking about. The primary analyses in the pirfenidone Phase III was a method that is co-rank and — our methods of, our prespecified method of statistical analyses, the slope analysis, is like more like the nintedanib primary analysis. Yet pirfenidone did do a sensitivity analysis and published it and put it in the appendix portion of the New England Journal in 2014. And in that analysis, if you would like to compare this to pirfenidone in that analysis, the decline in the FVC volume in that study was minus, I mean, the change was minus 164 ml in the pirfenidone group. The placebo was minus 280 ml in that model. And you're right, our placebo and pirfenidone

placebo were not exactly the same but I would just like to compare the like with the like and the treatment difference between pirfenidone and placebo in using that model was 116-milliliter and their treatment, relative treatment benefits was 41.4%. By comparison — now that study was based on a 52-week. Now the numbers that I reported to you with the treatment difference of 178 ml was based on our 48-week data. Using the same model, if we were to project to 52 weeks, the treatment difference is 180 ml and the treatment difference is would be also 57% relative to placebo.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [46]

Tom, is that clear enough?

Thomas Shrader, Stifel, Nicolaus & Company, Incorporated, Research Division—Analyst [47]

Yes, I think I was looking at one of the pirfenidone trials and you're right. By your analysis, the groups are much closer so. And then what other quick question. Was reversal of fibrosis, is that a hard endpoint? And do you think that's the basis for breakthrough designation given nothing else does that? Have you talked at all with the FDA about that?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [48]

So we're not in a position to comment on our discussions with FDA about any priority or accelerated type review discussions. It is a matter of history that we used HRCT as primary focus in 049, and it is the case that have been told repeatedly that the only people that have generated any results in HRCT. In this study, we also did HRCT and we need to do the work with our CROs that have worked with us in the past, and we have a lot of gravitas and reputation in this field to assess of the data we have. How important it is in the overall picture for first approval, we don't have a preset notion. We are perfectly fine with FVC liters or FVC percent predicted as endpoints. At the same time, we do believe from our prior study that and the extension studies that patients got benefit in terms of what occurred on treatment versus what they would have expected otherwise. And we continue to look very closely at both the impact on matrix from the antibody but also let me point out that we've been doing PK studies in parallel. And so if you recall in our pancreatic cancer program, the notion of having a continuous minimum antibody at 150 nanograms per milliliter was something that we've shown have mortality benefits. We've now found independently in study 067 that there is a Cmin level, which is just a little bit higher than that. I won't go into it now because we are going to publish a patent, but there is a Cmin level. If we attain it, all the patients that have been treated have benefited. And so we're very, very excited about applying this in the next trial design to have a Cmin concept in the IPF program. You might ask in 067 why we didn't do this and the answer is actual pretty simple. We started in 067 before the approval of the 2 drugs in America and we tried very hard to get enrolled ahead of the rollouts. We're not able to do it, but we started in 2013. And the work that was done in by pancreatic cancer on the Cmin really was 2015, 2016 and got published right at the beginning of 2017. And so this is something that we are seeing very compelling data with an idea that we know has relevance in another disease area, and we would seek to modify dose. So for example, one way we could get to the levels that have been seen instead of 30 mg per k every 3 weeks. If we did 30 mg per kg every 2 weeks, we would get up to the kinds of PK levels where you would be looking for the Cmin level I describe and expect to see. So that kind of adjustment is in the offing and we are very excited about it so (inaudible)

Operator [49]

And our next question comes from Joel Beatty from Citigroup.

Joel Lawrence Beatty, Citigroup Inc, Research Division—VP and Analyst [50]

A couple questions on pamrevlumab. The first is on the combination therapies sub-study. I know the data is not available yet but would you expect a similar magnitude of benefit in sub-study as was seen in the main study even though –the powering may not be there? And then the second question is on the ERS

conference coming up in September, is it possible there'll be additional data there beyond what was presented today such as the HRCT data and sub-study results?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [51]

Dr. Beatty, thank you. Let me try to address this question. We do not have an expectation at 24 weeks of FVC results with the antibody. We simply have not studied as performance endpoint to date and the sub-studies are only 24 weeks in duration. So the focus and the sub-studies was is there any unexpected safety event or any synergistic effect of the 2 drugs that occurs in a manner which might be dangerous for patients that is not seen previously. And so we really haven't tried to turn it into a backdoor look into more data to this point. I'm not saying we might not do it someday but it's not in protocol, and so that's the situation there. As it relates to ERS, I do to expect that there will be more data presented. I do want to front run anything but we've heard about the radiation-induced liver or lung fibrosis model. This rodent model that we used in the past and proved reversal. We now have a comparison of each of the 2 approved drugs and pamrevlumab 1 by 1 each, each 1, properly powered and then studies where one of those drugs is added to pamrevlumab and then to another study where the others added. And then finally, a study where all 3 are added, and we think that data are very interesting in that study and worth looking at because it shows where the statistical significance emanates from, and that's all I can really say right now about that. We may have something on PK to talk about at ERSI'm not sure yet about that but we're certainly trying to get there. For HRCT, I also am not quite sure on the timeline to get everything done because it depends on third-party advisers being available and this summer time particularly in the next 3 weeks is the only part of the summer that most people get off at all in this part of the U.S. so I think we have to be mindful but we're going to do what we can as fast as we can to get data to everybody.

Operator [52]

And we have Terence Flynn with Goldman Sachs back on with a question.

Terence C. Flynn, Goldman Sachs Group Inc., Research Division—MD [53]

I just wanted to follow-up again on the question, just wondering if you excluded the deaths from each of the 2 arms. If you could tell us what the delta would be. Does the delta narrow at all or does it stay pretty similar to what you saw? Just want a kind of sensitivity around the deaths with respect to the FVC delta?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [54]

So, Terence, thank you for coming back with another question. I'm looking at my MDs here to see if they actually got this data right now.

Elias Kouchakji, FibroGen, Inc.—VP of Clinical Development, Drug Safety & Pharmacovigilance [55]

So we have not yet analyzed this data. This is in this part of our continuous effort, and we are looking as Tom said additional analysis with the ongoing.

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [56]

So that's what we are, Terence, and we'll get it out as soon as we can.

Karen L. Bergman, FibroGen, Inc.—VP of IR & Corporate Communications [57]

Operator, I think we're ready to conclude the call. Thank you, everyone.

Operator [58]

Any further final remarks?

Thomas B. Neff, FibroGen, Inc.—Founder, Chairman & CEO [59]

To everyone on the call, thank you for joining our call today. We are very pleased to be able to share our top line IPF results with you today. We are very excited about them, and we look forward to reporting additional progress across our pipeline in coming quarters. I'd like to wish everyone a good afternoon and evening and a good August, summer, restful vacation time, hopefully. Thank you all for attending.

Operator [60]

Thank you, ladies and gentlemen. This concludes today's call. Thank you for participating. You may now disconnect.