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): June 7, 2018

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 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 7.01 Regulation FD Disclosure

On June 7, 2018, FibroGen, Inc. (the "Company") conducted a fireside chat at the Jefferies 2018 Global Health Care Conference.

A copy of the transcript of the chat is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this Item 7.01 is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Item 7.01 of this report will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by the Company that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of Fireside Chat at Jefferies 2018 Global Health Care Conference, dated June 7, 2018

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: June 8, 2018

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

MY (Michael Yee, Jefferies)
TN (Thomas B. Neff, FibroGen)
PY (K. Peony Yu, FibroGen)
SP (Seth Porter, FibroGen)

MY: Thank you for joining us for this afternoon session. Michael Yee, Managing Director and Senior Biotechnology Analyst here at Jefferies, and really happy to have one of the companies that I cover up here, FibroGen. With us on the podium to my left here is the Chief Medical Officer, Peony Yu. In the middle is the founder, chairman, and CEO, Tom Neff, and to his right is VP of Fibrosis Therapeutics, Seth Porter.

And there is not a breakout session, but I'll ask all the good questions.

I guess I just wanted to start off – Tom, maybe open it up to you. Obviously, this is perhaps the most transformative year in Fibro- … potential most transformative year for FibroGen. Maybe you could talk about your two programs and specifically this year what are we going to get from roxa? And what are you looking for, and what's good data from roxa this year?

TN: OK. So roxadustat is at a stage where we are closing 15 Phase 3 studies around the world – I think we've just gotten to number eight being closed. Approvals are slated for China, Japan, European Authority on the continent, and U.S. The Chinese and Japanese studies are not involving MACE cardiovascular evaluations, and China will – is ahead of the others now, so we expect China and then Japan, and then the filing for the MACE pools will affect both the U.S. and Europe, so the– so the contemporaneous filings for Astellas which is the license holder in Europe and FibroGen in the U.S. with AstraZeneca, and so you know best case, we will have in China an approval for dialysis CKD and non-dialysis CKD, in Japan in dialysis CKD – the non-dialysis is one year out – and then in Europe it's a MACE+ endpoint, so it's a MACE evaluation, cardiovascular MACE but a MACE+ endpoint, and Astellas will be on the basic calendar that we committed to in the U.S., which is to say, in the 4th quarter we expect to have individual studies read out, and, as soon as those studies are all read out, we will bring together the non-dialysis pooling and the dialysis pooling, which are the two big reportable outcomes for U.S. and Europe, and we've given ourselves part of next year to get that done. Internal goal is three months [for] our partners so that would mean, like, March, but I think we've said mid-year for full filing just to be careful about the timing. So we expect individual studies to readout in November-December and from there the others, and so that's the picture in roxadustat.

MY: And so my point is that investors are certainly keenly looking forward to the efficacy data in November-December, I think you implied. What is a good outcome – non-inferiority in dialysis on efficacy, superiority on efficacy like in non-dialysis, what's a good outcome?

TN: Let me ask Peony to take that one on.

MY: What should we expect, Peony? What's good data?

PY: OK, so we are … so when we look at non-dialysis, we are comparing against placebo; we fully expect to be able to demonstrate superiority in the three U.S./EU global studies totaling 4300 patients. And I'm … I have that confidence because we've seen this drug work, work very well, in non-dialysis in China with 150 patients, we have 14 zeros in the p-value. And in terms of efficacy, in dialysis, we also have full confidence this drug will work well based on the extensive Phase 2 data as well as China dialysis study where we … the criteria for meeting efficacy was just to show non-inferiority and we ended up demonstrating superiority, especially in the patients with inflammation measured by elevated

C-reactive protein. So we expect that in the global program there will be patients on dialysis with inflammation and we expect that to occur in about 30% of the patients, and that is where we will have most advantage over EPO but at the same time, our regulatory hurdle is to show non-inferiority in change in hemoglobin from baseline in comparison to EPO in these Phase 3 studies.

MY: So in dialysis, non-inferiority to EPO, it certainly means you're least as good as it, as an oral pill?

PY: Correct.

MY: And non-dialysis against placebo, you would certainly expect superiority with lots of zeroes on it. So after we get efficacy, I know Tom you suggested it would take some time to pull together all of the data for a MACE analysis because you want to show that the drug is not going to cause worst cardiovascular side-effects than EPO or placebo, can you talk to what you would expect in the MACE analysis a few months after the efficacy analysis in November-December – so, in spring? Do you expect non-inferiority in MACE and non-inferiority in dialysis/MACE – do you expect non-inferiority and that's a good result?

TN: So I think the way to answer this question is that ... let's just go through each of non-dialysis and dialysis and think about what's happening. We have studies in the U.S. that will be combined with the study in Europe – it's Astellas's study, their 608 study – and we would expect that in the MACE filings that we would have numerical advantage in MACE in the non-dialysis setting; that's certainly the goal for how we've been thinking about it. And of course the MACE is really a safety readout in many ways and so I'll just stick to that here. In dialysis there's two different pools: one is ESA switch which is to say how ESAs been used previously in dialysis for the past fifteen years, and that population are people that are on dialysis coming into the study and they are randomized either to more EPO or roxadustat, 1:1. And then in the population of incident dialysis patients – this is part of our effort to address a fundamental unmet medical need in dialysis. So CMS informed us a few years ago that their analysis indicated that they felt 30 to 40% of patients did not have adequate standard of care with current medicines and as such particularly in inflammation, so … in inflammation typically EPO studies don't work and roxa does work without modification or increased dose. So in that kind of environment if the results bear out, they're willing to talk to us outside the bundle, OK? And so that incident pool's about 1500 patients and will be done by FibroGen and AstraZeneca for U.S. filing. It's not a key issue in Europe, but it's a very key issue in the U.S., and, of course, as it relates to reimbursement, one of the things they'll want to see is that the patients that are in the incident pool were properly handled and you know had incremental benefit as expected so that they can believe that there is not a need for EPO to be used first in that population. So you are essentially trying to segue into first-line therapy in the EPO hyporesponse population, and so that's the other comparison that will be done as part of the reporting, so …. Now that comparison, I need to make clear, that the shell of all of EPO includes the incidents – incident is a subgroup of the dialysis pool. But that's the strategy.

MY: So in non-dialysis again on MACE, non-inferiority with a potential positive trend, I presume that your drug has a positive effect on cardiovascular so this would be at safety with a numerical trend….

TBN: Well, again, I think what I can share is what we can … that this is a very innovative medicine – it turns on the body's machinery to make hemoglobin go up so there's a lot of things that happen coordinately. And, so, we have believed for a long time that our compound is really a hepcidin regulator, and when we started talking about this, hepcidin had barely been discovered, but it was soon shown that, with hepcidin that – this is 2005, approximately – that hepcidin was upregulated in conditions of inflammation and it served to block the channels through which red blood cells are made. So an absolute bar to production of red blood cells. And so with CMS, we actually briefed our compound as a hepcidin regulator. That allows them to look at it as new technology, because EPO doesn't do anything like this.

And so this kind of approach is something that we've thought about a lot, and all the data we've gotten so far we looked very carefully at what's going on to support what we think is going to happen, which is to say that we think that were going to find that the slope of eGFR will shift on treatment compared to placebo, and to us that's part and parcel of having positive MACE numbers, so that's how we're thinking about it.

MY: OK, so lowering hepcidin, lower in inflammation, novel mechanism that you think the FDA would view as potentially novel enough to be outside the bundle – that's what you have said?

TN: Well, not the FDA, CMS. CMS, yeah. So, at FDA, they're going to look at normal standards for safety and efficacy for approval, but what we're interested in as it relates to CMS is, do you see benefit here incrementally for the patients that do not have adequate standard of care now? And, if you do, are you willing to engage in the normal kinds of things CMS is empowered to do to encourage new technology, which is to say that we wouldn't be put into the bundle and be second-line therapy to EPO.

MY: Yes. OK, and then one last question on EPO and then I'm going to ask some fibrosis questions. Either for Peony or for Tom, there's been a lot of growing interest in a number of public stocks that have Chinese approvals coming, some of them have large market caps, you have I think a program that could get approved in China, you did say later this year, for roxa, not a lot of investors seem to talk about it. You know, what is the type of peak sales you think could be doable in China for roxa and, you know, what do you think could happen there?

TN: OK, so I think the easiest way to get at this: in China, it's a very different kind of market for anemia because, unlike in the West, China really can't use blood transfusion as a chronic therapy method. Because of the degree of contamination that exists from Hepatitis B and C. And so when discussing with the regulators, we're really talking about areas in which EPO itself – the recombinant protein or the knock-offs – were not approved, essentially stopped in 2008 after the safety events in the U.S. And, so, if it's not approved with EPO, there's no requirement for us to use … to have to use transfusion in the control arm, so from the perspective of how we and many people in China look at this, we are bringing a solution to a very challenging problem, which is to say with an EPO you have to have cold storage system, you have to have sterility and so on, and you have to figure out how to reimburse very poor people's usage of EPO or it's an expensive drug, and so we are approaching it with an oral therapy, we have a lot of these problems go away, and we expect that use will go throughout society. We are keeping pricing in a range which is considered very reasonable in China and it's a little bit of an explanation as to why we can do that, but there's – there are reasons, solid medical reasons that we are approaching it this way. And so the goal or the vision is really to have a brand – as more that, a brand than an agent – more like a brand because we're able to do several things at once … again in patients with high inflammation, it works where EPO doesn't, in dialysis or in non-dialysis settings in nephrology we can treat anyone and everyone, and so on. So it's very exciting in China.

MY: And you've gone to China, there's actually articles all over the web, on engaging with the regulators and the government, and you've had pretty high level conversations with them.

TN: Yes, and I'll have Peony here share a little bit of what she's seen about the business in China, she's in a position that she converses routinely in Cantonese or Mandarin, which I can't do…

MY: So, Peony, just anecdotally, you've been to Asia and talked with regulators and the government about this and what do they say?

PY: Well, there has been a great deal of interest from the regulator and the physician. Both, as Tom said, this is a public problem that we are trying to solve. In the U.S., if you … from surgery or any reason, if my

patient needs a couple units of blood, all I need to do is I put it on the doctor's orders and I know it will be done, In China, it's not the same, there is shortage in the blood bank and physicians have to apply for blood. The threshold for transfusion in the ... for example, for chemotherapy-induced anemia or MDS, patients' hemoglobin [inaudible] which is half of , less than half of the hemoglobin level of you sitting in the audience. So an agent, an oral agent which can increase the hemoglobin level, is very attractive for the Chinese patients.

MY: So we'll look to … formal guidance is by the end of the year, is that the formal guidance on potential approval – I don't think there's like a PDUFA filing?

TN: Yeah, I don't think sales numbers have been put out there just because there's so many variables in play thus far, but I think that, you know – numbers anywhere from three-quarters of a billion to a couple billion dollar, I've seen as a range of numbers.

MY: OK. I need to check my model – I need to check my model.

TN: And the number of users in China is a quite a bit larger than the number of users in the U.S., so in … currently, in China, the dialysis count for the patients that are doing not transplant but just dialysis is about 50% higher than in the U.S. – they surpassed the U.S. about three years ago and it looks like they're going to go to about a-million-and-a-half, the U.S. is about 400,000, so you're talking about much bigger markets and so as this stuff plays out there are some really interesting dynamics in terms of value creation.

MY: OK. So we'll look to that, and also we'll look forward to the global Phase 3 efficacy studies readouts in November-December, and then the MACE shortly thereafter, so that's going to be really important.

In the meantime, Seth, there's been a great deal of attention because you've had a lot of data now on your second drug, pamrevlumab, the fibrosis antibody, both in IPF as well as the data this weekend at ASCO in locally advanced pancreatic cancer. Maybe I guess briefly talk about some of the initial data from IPF and pancreatic cancer and what the next steps are for those programs because there's been a lot of data and you're going to move forward with this.

SP: I will try to summarize this briefly. So, we reported out the results from our Phase 2b randomized controlled IPF trial last year, and we continue to report out data because there's a lot of data that has come out of the study. So, we showed a very robust effect in terms of pulmonary function and slowing down the rate of pulmonary function measured as FVC or FVC % predicted. And, also, in terms of disease progression, that is those patients that have a decline in their FVC % predicted of 10 % or more or death, so that's a very real measure of disease progression, and so we showed a very strong signal in terms of improvement over placebo on that. And then just recently, a few weeks ago, at the American Thoracic Society meeting, we reported out results from our assessments of quantitative fibrosis, and we have been unique in that we used that assessment in both our first Phase 2 open-label study and then again in our randomized Phase 2 study, and we have shown by quantitative high resolution CT imaging a statistically significant slowing down of the rate of fibrosis compared to placebo. And we are, as far as I know, the only company who has been able to show that effect on fibrosis and as expected but never shown by others that the changes in fibrosis relate directly to the changes in pulmonary function so that makes sense biologically and I think we are unique in showing that effect. And, in addition, we also reported out a few weeks ago in terms of patient-reported outcomes the so-called St George's respiratory questionnaire, which is an assessment of quality of life in pulmonary patients and there, too, we saw a strong trend in our Phase 2 study in terms of patients who are feeling better, functioning better for those treated with pamrevlumab relative to placebo. So all of the signals, and including most particularly safety and tolerabililty –

remember, it's a monoclonal antibody and our safety profile has been very good all along – so with strong safety signals, positive safety signals, plus strong efficacy signals, we think we are very well positioned for a Phase 3 trial or trials in IPF. So we'll be meeting with FDA soon on that and hopefully come to an agreement on what that Phase 3 program will be.

MY: The question I get from everyone is, do you want to run a head-to-head study vs. standard of care, there are IPF drugs out there, do you want to run a placebo-controlled study – you know, there are people, who can't take the existing drugs or whatever. You know, what – how would you presume, why don't you run both? How would you position …?

TN: So we haven't taken a very absolutely firm stance on the question of trial design as much as we've been guided by our data. And the results we've seen in this measure of death and FVC minus 10% of functional lung capacity or more, so it effectively operates as death or something considered as a proxy for death, have been very striking,. And so the picture that's developed in our company over the past few years is that, IPF enrollments, you really have two pools of patients: ones that go into really rapid freefall and the others that have really slow decline over 3, 4, 5 years. And the ones with very rapid freefall, we think we actually have a medicine that can make a difference – where, you know, we've been seeing anywhere from 31 to 40% of patients in these studies be in the death and FVC minus 10% category, and the most recent study we did, study 067, the placebo is 30, 31 and change – 31-and-a-half % or something – and we were 10%. And we had a prior study, a somewhat larger study, that was informative about this as well, so we have a very high degree of confidence about what's happening there.

MY: 30% to 40% of these people fall off by more than 10% or they die, and your drug is basically cutting that down by two-thirds and that is pretty important for the regulators. That could be [inaudible]

TN: It was the best statistical result we had out of the entire package of IPF results this year. And so I think the way I put it is that we're really interested in that endpoint, that's really like a mortality endpoint kind of idea, and it remains to be seen if regulators see it the same way or not. We know that's the part we need to wait and find out.

MY: OK. So then at ASCO this weekend you had Phase 2 locally advanced pancreatic cancer data, this is a unique drug … this is in locally advanced – not metastatic, the traditional stuff – that we're looking at, so I guess briefly, can you explain the role of this drug and whether or not an end point like resection is a potential endpoint or do you have to show survival to get this stuff approved?

SP: So just to review those results briefly, the study was to look in patients with locally advanced non-resectable pancreatic cancer; that's about 30% of the pancreatic cancer population, and it's pretty well established, if you can resect the localized tumor, that gives the best advantage in terms of survival. So the study was to take these patients who were deemed to be locally advanced, non-resectable, and treat them with chemotherapy or chemotherapy plus pamrevlumab, and to compare the rate at which they are deemed to be evaluable for resection, then those who actually went on to a successful resection and ultimately survival. Small proof of concept study, but nonetheless, pretty clear signal that when we compared the two arms, in terms of those – after 6 months of a neoadjuvant kind of an approach or treatment, that … in those who got the chemotherapy, there was about 15% who were deemed to be evaluable for resection, whereas in the arm with pamrevlumab, it was more like 70%. And then when the surgery was actually conducted or attempted, 33% of the pamrevlumab plus chemotherapy patients had successful resection, compared to only 8%. So a very striking result, both in terms of assessment for eligibility for resection and those who actually got successful resection. So we think this is a very strong result, although it's a relatively small study. And so actually we met yesterday with FDA about this and I don't want to front-run that because we haven't gotten the notes from this meeting nor have we had time for internal discussions but we think that there's a path forward that can get us to a pivotal trial in a very near term.

MY: So you'll disclose the design of that, but you feel very confident based on general discussions that you're going to be able to come up with a design in Phase 3 and that, based on that data showing resection, and then ultimately looking at survival ….

TN: I think it's fair to say it's going to have elements of resectability or resection as well as survival elements in the design.

MY. OK. Fantastic. Ok, with that we're out of time on the clock and so I really appreciate your guys' discussion and dialogue about this and look forward to the update in the third quarter and the data later this year.

PY: Thank you.

TN: Michael, thank you very much for your support of our company. It's been fantastic, so thank you for inviting us here.