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): November 11, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	FGEN	The Nasdaq Global Select Market

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 2.02 Results of Operations and Financial Condition.

On November 11, 2019, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended September 30, 2019, and conducted an investor conference call to discuss financial results and provide a business update. A copy of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference. An approximate transcript of the investor conference call is furnished as Exhibit 99.2 to this report.

The information in this Item 2.02, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02, in Exhibit 99.1 and in Exhibit 99.2 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by FibroGen, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Reports Third Quarter 2019 Financial Results," dated November 11, 2019
99.2	Transcript of the Investor Conference Call, dated November 11, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 12, 2019

By: /s/ Pat Cotroneo
Pat Cotroneo
Senior Vice President, Finance and Chief Financial Officer

Exhibit 99.1

FibroGen Reports Third Quarter 2019 Financial Results

— ***Roxadustat Positive Pooled Phase 3 Efficacy and Cardiovascular Safety Data Presented Last Friday at American Society of Nephrology 2019 Kidney Week***
— ***Plan to Submit Roxadustat U.S. NDA This Quarter***

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

SAN FRANCISCO, Nov. 11, 2019 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the third quarter of 2019 and provided an update on the company's recent developments.

"The FibroGen team achieved many milestones over the past few months, culminating with the positive Phase 3 results for roxadustat reported at the American Society of Nephrology conference last week in Washington, D.C.," said Jim Schoeneck, Interim Chief Executive Officer, FibroGen. "This set of global studies covered the spectrum of chronic kidney disease anemia and is believed to be the largest and most comprehensive ever reported. We expect the positive cardiovascular safety data, comparing roxadustat to placebo in non-dialysis patients and to epoetin alfa in patients on dialysis, along with the superior efficacy results, can serve as the basis for regulatory approval in the U.S. and other jurisdictions. We plan to submit an NDA in the U.S. by the end of this quarter for both dialysis and non-dialysis patients with our partner AstraZeneca, and an MAA in Europe by the end of first quarter 2020 by our partner Astellas, followed by submissions to other regulatory authorities.

"In addition, roxadustat is now approved for CKD patients with anemia in China and was approved in Japan for anemia in CKD patients on dialysis. Our other clinical programs advanced, as we initiated our roxadustat Phase 2 study to treat anemia in patients receiving chemotherapy and enrolled the first patients in our pamrevlumab Phase 3 programs for both idiopathic pulmonary fibrosis (ZEPHYRUS) and locally advanced pancreatic cancer (LAPIS).

"These major accomplishments demonstrate our commitment to the vision set by FibroGen's founder and long-time CEO and Chairman, Tom Neff. We mourn his unexpected passing and are grateful for his leadership and rare ability to recognize and advance scientific innovation."

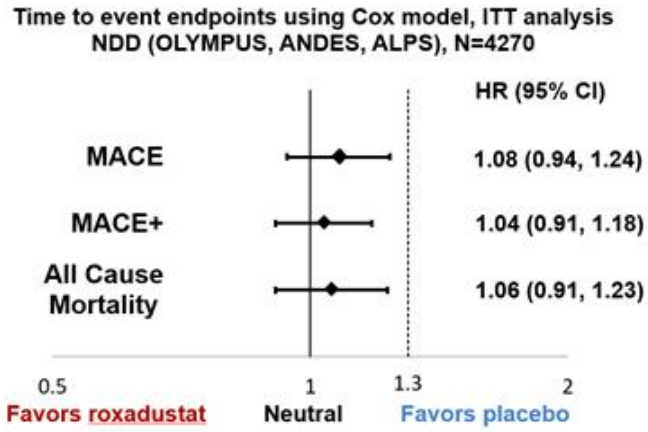
Recent Developments – Roxadustat

Roxadustat is a novel, oral, first-in-class treatment for chronic kidney disease (CKD) patients with anemia, discovered by FibroGen and developed globally in conjunction with our partners AstraZeneca and Astellas. Groundbreaking science on the body's oxygen-sensing mechanism and adaptation to hypoxia was awarded the 2019 Nobel Prize in Physiology or Medicine and serves as the foundation for the mechanism of action for roxadustat. Roxadustat increases hemoglobin by mimicking the body's natural response to low oxygen.

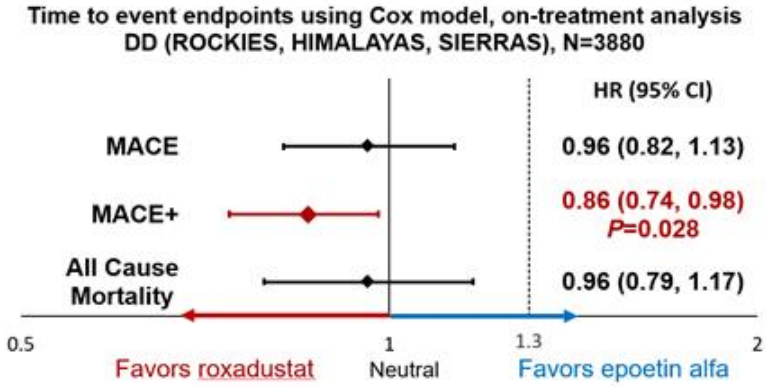
American Society of Nephrology Kidney Week Presentations – November 6-9, 2019

- Clinical results presented from six roxadustat Phase 3 studies comprising over 8,000 anemia patients with chronic kidney disease, as well as pooled results for patients not on dialysis and on dialysis, including an incident dialysis subgroup
  - *For additional data presented, please see our November 8, 2019 press release. Please also see our website for FibroGen's ASN presentations*

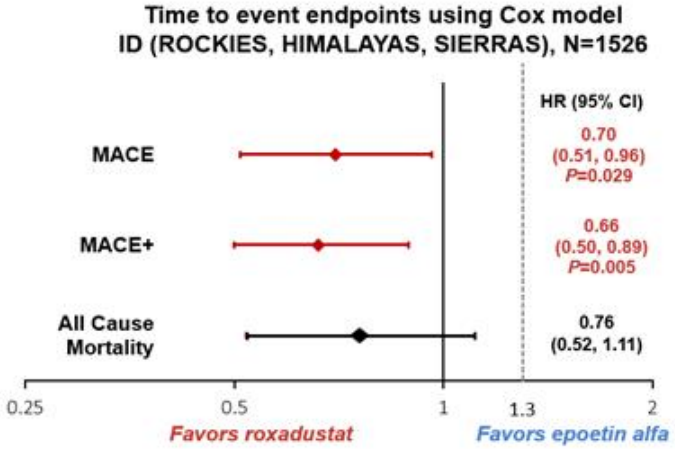
- **Cardiovascular Safety Confirmed:** In both non-dialysis dependent and dialysis dependent CKD anemia patients**:**
  - **Non-Dialysis Dependent (NDD)** (n=4270):
    - Risk of MACE, MACE+, and all-cause mortality in roxadustat patients was comparable to placebo based on a reference non-inferiority margin of 1.3
    - NDD results are based on ITT long-term follow-up analysis method agreed with the FDA



  - **Dialysis Dependent (DD)** (n=3880):
    - Risk of MACE and all-cause mortality in roxadustat patients were not increased compared to the active comparator, epoetin alfa
    - Roxadustat patients had a 14% lower risk of MACE+ than epoetin alfa patients



- **Incident Dialysis (ID) Subgroup** (n=1526): In the clinically important ID subgroup of patients, initiating dialysis within 4 months prior to randomization:
  - Roxadustat patients had a 30% lower risk of MACE than epoetin alfa
  - Roxadustat patients had a 34% lower risk of MACE+ than epoetin alfa
  - Roxadustat patients had a trend towards lower all-cause mortality compared to epoetin alfa



- Endpoint definitions, using centrally adjudicated events:
  - Time to first Major Adverse Cardiovascular Events (MACE), a composite endpoint including all-cause mortality, myocardial infarction, and stroke
  - Time to first MACE+, referring to MACE plus unstable angina and heart failure requiring hospitalization
  - Time to all-cause mortality

- **Primary Efficacy Endpoints Met in all Individual Studies and Pooled Analyses**
  - Met primary efficacy endpoint of mean change in hemoglobin (Hb) from baseline to average Hb weeks 28-52 in each of the six individual studies and in each of the two pooled efficacy analyses
  - Statistically superior to placebo in the NDD pool
  - Statistically superior to epoetin alfa in the DD pool

- **Other Pooled Efficacy Analyses**
  - Non-Dialysis Dependent
    - In the pooled analysis, roxadustat was superior to placebo, with significantly larger Hb increase than placebo regardless of *iron-repletion* status at baseline
    - Roxadustat treatment reduced the need for *rescue treatment* and *red blood cell transfusion* (RBC) compared to placebo
    - Roxadustat slowed *the decline in renal function* compared to placebo in patients eGFR >= 15
    - Roxadustat reduced *LDL cholesterol*
  - Dialysis Dependent
    - The larger Hb increase in patients treated with roxadustat vs. epoetin alfa was particularly notable in *patients with inflammation* (elevated CRP level)
    - Roxadustat treatment reduced the need for *RBC transfusion* compared to epoetin alfa
    - Less *IV iron* was required in patients receiving roxadustat versus patients receiving epoetin alfa

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Other Recent Developments, Recognition and Future Milestones

Roxadustat U.S. and EU Regulatory Timelines

- Expect to submit U.S. NDA for roxadustat for the treatment of anemia in CKD patients both on dialysis and not on dialysis this quarter
- Astellas expected to submit the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) within the second half of their 2019 fiscal year, ending March 2020

Roxadustat for Anemia in CKD – Approvals and Market Activity

- Expanded approval of roxadustat (China tradename: □□□®) in China to include the treatment of anemia in CKD patients who are not dialysis-dependent
- Roxadustat (Japan tradename: Evrenzo®) approved in Japan for the treatment of anemia associated with CKD in dialysis patients
- First prescriptions written for roxadustat for patients in China
- FibroGen booked commercial product revenue for the first time (China)
- Roxadustat received the 2019 Dushu Lake Prize □□□□ in China for "On-Market Innovative Drug with Highest Clinical Value"
- Results from the two China Phase 3 studies published in the *New England Journal of Medicine* (NEJM)

Development Programs

- **Roxadustat for Anemia in Oncology**
  - Myelodysplastic Syndromes (MDS)
    - Clinical proof-of-concept study accepted for oral presentation at the 2019 American Society of Hematology Annual Meeting
    - Randomized placebo-controlled portion of global Phase 3 study ongoing
  - Chemotherapy-Induced Anemia (CIA)
    - Initiated patient dosing in Phase 2 study

- **Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)**
  - Initiated dosing in the pivotal ZEPHYRUS Phase 3 randomized, double-blind, placebo-controlled study

- **Pamrevlumab for Locally Advanced Pancreatic Cancer (LAPC)**
  - Initiated dosing in the pivotal LAPIS Phase 3 randomized, double-blind, placebo-controlled study

- **Pamrevlumab for Duchenne Muscular Dystrophy (DMD)**
  - Expect to meet with the FDA this quarter to discuss clinical development plan

Corporate and Financial

- Net loss for the third quarter of 2019 was $49.4 million, or $0.57 net loss per basic and diluted share, compared to a net loss of $42.6 million, or $0.50 net loss per basic and diluted share one year ago
- At September 30, 2019, FibroGen had $666.5 million in cash, restricted time deposits, cash equivalents, investments, and receivables

Conference Call and Webcast Details
FibroGen will host a conference call and webcast today, Monday, November 11, 2019, 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 (888) 771-4371 (U.S. and Canada) or 1 (847) 585-4405 (international), reference the FibroGen third quarter 2019 financial results conference call, and use confirmation number 49132826. A replay of the webcast will be available shortly after the call for a period of four weeks. To access the replay, please dial 1 (888) 843-7419 (domestic) or 1 (630) 652-3042 (international), and use passcode **4132826.**

About Roxadustat
Roxadustat (FG-4592) is a first-in-class, orally administered small molecule HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, improving iron regulation, and overcoming the negative impact of inflammation on hemoglobin syntheses and red blood cell production by downregulating hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of chronic kidney disease (CKD) patients, including in the presence of inflammation and without a need for supplemental intravenous iron. Roxadustat is currently approved in China for the treatment of anemia in CKD patients on dialysis and patients not on dialysis and approved in Japan for the treatment of anemia in CKD patients on dialysis. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia in territories including Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa. 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 in the Americas and in Australia/New Zealand as well as Southeast Asia.

About Pamrevlumab
Pamrevlumab is a first-in-class antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and for the treatment of locally advanced unresectable pancreatic cancer (LAPC), and in Phase 2 clinical development for the treatment of Duchenne muscular dystrophy (DMD). The U.S. Food and Drug Administration has granted Orphan Drug Designation to pamrevlumab for the treatment of patients with IPF, LAPC, and DMD. Pamrevlumab has also received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with IPF and LAPC. Across all clinical studies, pamrevlumab has consistently demonstrated a good safety and tolerability profile to date. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen

FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, is a leading biopharmaceutical company discovering and developing 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, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, the company's most advanced product, is an oral small molecule inhibitor of HIF prolyl hydroxylase (HIF-PH) activity, completing worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), is approved by the National Medical Products Administration (NMPA) in China for CKD patients on dialysis and not on dialysis and by the Ministry of Health, Labour and Welfare (MHLW) in Japan for CKD patients on dialysis. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). FibroGen is also developing a biosynthetic cornea in China. 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 of the company's product candidates, the potential safety and efficacy profile of our product candidates, our interpretation of the pooled safety analyses and other analyses of the global Phase 3 program for roxadustat, the potential for our Phase 3 program data to form the basis of a regulatory approval, our clinical and regulatory plans, 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, 2018 and our quarterly report on 10-Q for the fiscal quarter ended September 30, 2019 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.

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Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2019	December 31, 2018 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 196,592	$ 89,258
Short-term investments	432,040	532,144
Accounts receivable	19,225	63,684
Inventory	4,908	—
Prepaid expenses and other current assets	133,715	4,929
Total current assets	786,480	690,015
Restricted time deposits	4,145	4,145
Long-term investments	10,999	55,820
Property and equipment, net	43,208	127,198
Finance lease right-of-use assets	42,064	—
Other assets	7,068	3,420
Total assets	$ 893,964	$ 880,598
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 4,055	$ 9,139
Accrued and other liabilities	70,825	66,123
Deferred revenue	257	13,771
Finance lease liabilities, current	12,149	—
Total current liabilities	87,286	89,033
Long-term portion of lease obligations	1,242	97,157
Product development obligations	16,256	16,798
Deferred rent	—	3,038
Deferred revenue, net of current	98,708	136,109
Finance lease liabilities, non-current	40,713	—
Other long-term liabilities	36,041	9,993
Total liabilities	280,246	352,128
Total stockholders' equity	594,447	509,199
Non-controlling interests	19,271	19,271
Total equity	613,718	528,470
Total liabilities, stockholders' equity and non-controlling interests	$ 893,964	$ 880,598

(1) The condensed consolidated balance sheet amounts at December 31, 2018 are derived from audited financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(Unaudited)			
Revenue:				
License revenue	$ 11,935	$ —	$ 162,517	$ 14,323
Development and other revenue	20,660	29,027	85,507	90,580
Product revenue	579	—	579	—
Total revenue	33,174	29,027	248,603	104,903
Operating costs and expenses:				
Cost of goods sold	242	—	242	—
Research and development	49,963	56,443	152,467	165,555
Selling, general and administrative	35,823	15,356	84,772	45,961
Total operating costs and expenses	86,028	71,799	237,481	211,516
Income (loss) from operations	(52,854)	(42,772)	11,122	(106,613)
Interest and other, net:				
Interest expense	(702)	(2,739)	(2,209)	(8,257)
Interest income and other, net	4,193	3,079	12,496	7,796
Total interest and other, net	3,491	340	10,287	(461)
Income (loss) before income taxes	(49,363)	(42,432)	21,409	(107,074)
Provision for income taxes	76	124	256	299
Net income (loss)	$ (49,439)	$ (42,556)	$ 21,153	$ (107,373)
Net income (loss) per share				
Basic	$ (0.57)	$ (0.50)	$ 0.24	$ (1.28)
Diluted	$ (0.57)	$ (0.50)	$ 0.23	$ (1.28)
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	87,007	84,508	86,390	83,713
Diluted	87,007	84,508	91,995	83,713

# # #

Contact
FibroGen, Inc.
Michael Tung, M.D.
Investor Relations
1.415.978.1433
ir@fibrogen.com

Exhibit 99.2

Welcome to the FibroGen Third Quarter 2019 Financial Results Conference Call. My name is Erin and I'll be your operator for today's call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session. During the question-and-answer session, if you have a question, please press star, then 1 on your touchtone phone. Please note that this conference is being recorded.

I will now turn the call over to Michael. Michael, you may begin.

Thank you, Erin, and good afternoon, everyone. Thank you for joining our call. Today, we'll be reporting financial results and corporate updates for the third quarter of 2019. Joining me today on the call are Jim Schoeneck, Interim Chief Executive Officer; Dr. Peony Yu, Chief Medical Officer; Ms. Chris Chung, Senior Vice President, China; Dr. Elias Kouchakji, Senior Vice President, Clinical Development, and Drug Safety and Pharmacovigilance; and Mr. Pat Cotroneo, Chief Financial Officer.

Following our prepared remarks, Jim will discuss upcoming milestones, and we will then open the call to Q&A. During this call, we may 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; our regulatory strategies and potential regulatory results; our 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2018, and to our quarterly report on Form 10-Q for the quarter ended September 30, 2019, filed with the Securities and Exchange Commission. Copies of these filings may 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 includes remarks from FibroGen's management team and then we'll open the lines to take your questions. The press release reporting our financial results and business update and a webcast of today's conference call can be found on the Investors section of the FibroGen website at www.fibrogen.com.

The webcast will be available for 30 days from today's date. And with that, I'd now like to turn the call over to our Interim CEO, Jim Schoeneck.

James A. Schoeneck

Thank you Mike and thank you all for joining us today. During today's call I will give you an overview of our third quarter results and recent accomplishments. Dr. Peony Yu will then give a review of the roxadustat data from the American Society of Nephrology meeting, which just wrapped up yesterday. Following that Chris Chung will update you on our China efforts. Dr. Elias Kouchakji, will give us a pamrevlumab update, and Pat Cotroneo will discuss our financials. Then, I'll provide some closing comments and open the call to questions.

Exhibit 99.2

First I want to take a moment to acknowledge with a great sense of loss, the recent and unexpected passing of FibroGen's Founder and long term Chairman and CEO, Tom Neff. Tom was a man of vision, determination and leadership and was deeply committed to innovation. We at FibroGen are deeply indebted to him. Tom founded FibroGen in 1993 with the vision of treating fibrosis at a time when there was no hope for the disease category. He led the company for over 25 years and established a culture and a team driven to support his vision motivated by his commitment to improve the lives of those suffering from conditions with no satisfactory therapeutic options. In founding FibroGen, Tom assembled global scientific leaders in areas critical to the understanding of fibrosis and the fibrotic disease mechanism, ultimately providing the basis for pamrevlumab and through the exploration of prolyl hydroxylase enzyme activity, the basis for roxadustat. Tom was intimately involved in the discovery and development of roxadustat and pamrevlumab, and position the company for great success given the breadth of the applications for both compounds. His contribution as a pioneer in the biotechnology industry will be measured by the lives that he has and will continue to touch as FibroGen continues to develop medicines for unmet medical needs. The FibroGen Board and management team are committed to fulfill and build upon Tom's vision.

As you all saw, last month, the 2019 Nobel Prize in Physiology or Medicine was awarded to three physician scientists for their research into how cells sense oxygen, and how they function in low-oxygen conditions or hypoxia. The collective contributions of Dr. Bill Kaelin of the Dana-Farber Cancer Institute; Sir Peter Ratcliffe of the University of Oxford; and Dr. Gregg Semenza of Johns Hopkins University School of Medicine, identified the pathway by which cells detect oxygen and respond to hypoxia. This seminal science has paved the way for promising new strategies to fight anemia, cancer and many other diseases.

FibroGen is fortunate to work closely with Bill Kaelin, a collaborator and member of the company's Scientific Advisory Board for nearly two decades. Today, roxadustat is the first medication in the world which applies this groundbreaking science. As Dr. Bob Provenzano stated at the American Society of Nephrology last week, this is a great example of cutting-edge science moving from bench to bedside. Roxadustat is already approved in China for the treatment of anemia associated with chronic kidney disease, and in Japan, for CKD patients on dialysis. We're also currently preparing regulatory submissions for the US and Europe.

Last week, during the American Society of Nephrology Kidney Week 2019, FibroGen and our partners, Astellas and AstraZeneca, presented roxadustat data from our Phase 3 program as well as pooled cardiovascular safety and efficacy results. The pooled data kicked off ASN's High-Impact Clinical Trials session with a packed room of almost 2,000 people. One nephrologist called it the largest crowd for an anemia presentation in well over a decade. This set of global studies covered the spectrum of chronic kidney disease anemia and is believed to be the largest and most comprehensive study population ever reported with over 8,000 patients. Details of the data presented can be found on our website and in our press release from last Friday. Our studies assessed cardiovascular safety in dialysis- and non-dialysis-dependent patients using endpoints of Major Adverse Cardiovascular Events known as MACE, and MACE+, which adds hospitalization due to unstable angina and congestive heart failure. The pooled results showed that roxadustat's cardiovascular safety was comparable to placebo in non-dialysis-dependent patients and in dialysis-dependent patients roxadustat did not increase the risk of MACE and reduced the risk of MACE+ compared to epoetin alfa, the leading product currently used to treat anemia in this population. Finally, in the subgroup of dialysis patients who recently started dialysis, referred to as incident dialysis patients, roxadustat reduced risk of MACE by 30% and MACE+ by 34% compared to epoetin alfa. Roxadustat achieved the primary hemoglobin efficacy endpoint in all of these groups. Of note, roxadustat was shown to raise hemoglobin levels, regardless of iron status at baseline, in patients who required no supplementary IV iron, and in patients with inflammation, a group that is difficult to treat with current therapies. Having an oral product with this safety and efficacy profile can offer patients with anemia of chronic kidney disease, and their doctors, a treatment unlike anything currently on the market in the US or Europe.

Let me briefly mention a few other highlights from the quarter. We initiated our Phase 3 pamrevlumab programs, enrolling the first patients in our idiopathic pulmonary fibrosis or IPF trial as well as our study in locally advanced pancreatic cancer. Our Phase 2 IPF trial was published in The Lancet Respiratory Medicine journal and, in the company editorial Professor Athol Wells, of the Royal Brompton Hospital, stated: “In *conclusion, it's difficult to imagine more encouraging Phase 2 results of* a *novel drug for IPF.*

In China, we booked our first roxadustat product revenue anywhere in the world and we continue to prepare for the full market launch with our 50/50 partner AstraZeneca. In September, FibroGen and roxadustat won the 2019 Dushu Lake Prize for Innovative Drug with the Highest Clinical Value in China.

I think you'll agree with me it's been a very, very accomplished quarter.

Now I'll turn it over to Peony, who will give you a more in-depth discussion of roxadustat and the data from the ASN meeting.

K. Peony Yu

Thank you, Jim. Last week, FibroGen and our partners presented roxadustat Phase 3 results at the annual American Society of Nephrology meeting which included over 13,000 kidney professionals. All the nephrologists share our excitement of a potential game changer in anemia therapy based on strong scientific foundation. Today, I would like to review the highlights.

The pooled analysis included data from six Phase 3 trials which included over 8,000 patients and encompassed over 13,000 patient exposure years.

Our studies evaluated three patient populations, non-dialysis-dependent, dialysis-dependent and then incident dialysis, which is a subgroup of patients who recently started dialysis within four months of study participation. We've reported on results of the following safety endpoints: Major Adverse Cardiovascular Events or MACE endpoints consist of death due to all causes, non-fatal myocardial infarction, and non-fatal stroke. MACE + consists of the three MACE events, plus hospitalization due to heart failure or unstable angina. All-cause mortality is simply all deaths due to any cause.

To maintain objectivity and consistency the events in these cardiovascular endpoints were adjudicated by independent adjudicators blinded to treatment assignment.

The time to event analyses are conducted based on pooling strategy and analytical approaches agreed with the FDA and the time to MACE is the primary safety endpoint in the US, supported by results of MACE+, which is recognized as an important endpoint in the nephrology community.

In non-dialysis where roxadustat was compared to placebo, which is the gold standard in safety assessment, roxadustat was comparable to placebo in MACE and MACE+ risk, using a commonly applied non-inferiority margin of 1.3.

In dialysis patients, roxadustat reduced the risk of MACE+ by 14percent compared to epoetin alfa and had no increased risk of MACE compared to EPO using a commonly applied NI margin of 1.3.%. In incident dialysis roxadustat, had a 30% lower risk of MACE and a 34% lower risk of MACE+ than EPO.

Let's discuss the rest of the efficacy and safety results, starting with non-dialysis. 4,270 plus CKD patients were enrolled into the three Phase 3 non-dialysis studies comparing roxadustat to placebo. In these studies, we included CKD Stage 3, 4, and 5 patients, of which 42% were CKD Stage 5. Their anemia tends to be more severe with their more advanced chronic kidney disease and they have been generally excluded from prior large CKD anemia studies of ESAs. Similarly, we included patients with a range of iron stores with 40% of study patients non-iron replete at baseline and thus they were ineligible for ESA treatment based on the current ESA label.

Roxadustat met the primary efficacy endpoint of mean change from baseline to average hemoglobin over weeks 28 to 52 in which -- I'm sorry-- in each of the three individual Phase 3 studies and in the pool analyses in which roxadustat was superior to placebo regardless of CKD severity, regardless of severity of anemia at baseline, and regardless of iron repletion status.

Roxadustat’s efficacy is accompanied by an 81% risk reduction in use of rescue treatment, which includes IV iron, ESA, and transfusion, and a 74% reduction in the risk of red blood cell transfusion, with P-value point 001 -- P-value less than.

Importantly in comparison to placebo, roxadustat patients also show a slower decline in eGFR which was a measure of kidney function. Patients were based in -- patients with baseline eGFR of 15 or higher during the first year of treatment.

The one year decline in eGFR in roxa patients was 2.8, which is significantly less than the decline in placebo patients of 4.4 with a treatment difference of 1.6 and has three zeroes in it. This represents a 38% reduction in eGFR decline relative to placebo.

Turning to cardiovascular safety, in the CKD non-dialysis pool, based on ITT analysis, roxadustat was comparable to placebo. For reference, here are the hazard ratios. MACE, hazard ratio of 1.08 with 95% confidence interval of 0.94 and 1.24., MACE+, hazard ratio of 1.04 with confidence interval of 0.91 and 1.18.

All-cause mortality, hazard ratio of 1.06 with confidence interval of 0.91 and 1.23.

We have received questions on the individual components of cardiovascular composite endpoint in non-dialysis, with the most interest in stroke, while this is most likely because of the TREAT study on darbepoetin that resulted in the ESA label restriction in its use in non-dialysis and dialysis patients.

I want to be clear from the outset. We believe the data from the individual components of MACE and MACE+ in the roxadustat program are consistent with the results in the overall analysis. Stated another way, we believe the results in the individual components are comparable to placebo in non-dialysis. This is also true for the dialysis pool.

Before we delve into details, I want to remind you that the roxadustat non-dialysis program was powered for assessing the MACE composite endpoint and not the individual components. To give a sense of magnitude in the roxadustat program stoke represents only 10% of the MACE events in the non-dialysis pool and the incidence of rate in roxadustat is comparable to placebo, which is 1.2 per 100 patient years in roxadustat versus 1.1 in placebo arm hazard ratio of 1.22, with 95% confidence interval of 0.80 and 1.86. As a reminder, in the TREAT study the incidence rate of stroke in darbepoetin was twice that of placebo, with hazard ratio of 1.92 and 95% confidence interval of 1.38 and 2.18.

The rest of the MACE+ components in our non-dialysis pool is as follows: all -cause mortality hazard ration of 1.06, confidence interval of 0.91 and 1.23, which we stated earlier. MI has a ratio of 1.28, confidence interval of 0.9 and 1.84. Unstable angina requiring hospitalization with hazard ratio a 0.49 and confidence interval of 0.19 and 1.27.

Finally, congestive heart failure requiring hospitalization, which is an important – which is important in CKD patients -- has hazard ratio of 0.89, confidence interval of 0.72 and 1.12. Based on the composite endpoints of time -to MACE, MACE+, all -cause mortality and the individual components, the overall cardiovascular safety of roxadustat is comparable to placebo.

The dialysis-dependent patient pool consists of 3,880 patients who were randomized 1:1 to receive roxadustat or epoetin alfa in three dialysis Phase 3 studies. The primary efficacy endpoint of mean change changing hemoglobin from baseline to week 28 to 52 was met in each individual study and in the pooled analyses. Roxadustat achieved higher hemoglobin level than active comparator of epoetin alfa. This result was seen in patients with or without inflammation as measured by CRP, with similar roxadustat dose requirements regardless of inflammation status, with roxadustat-treated patients receiving less IV iron than EPO patients, while transferrin saturation or TSAT, a measure of iron store in the body, were comparable between the two treatment arms. In addition, when compared with EPO, roxadustat-treated patients had a lower red blood cell transfusion risk than EPO-treated patients, hazard ratio of 0.82, p-value of 0.046. The combination of findings above reflects the benefits of coordinated erythropoiesis with roxadustat as resulted in more efficient iron utilization lower transfusion requirements and can potentially overcome ESA hypo-responsiveness.

Turning to cardiovascular endpoint analyses of the dialysis pool. In MACE and in all-cause mortality, roxadustat had no increase risk relative to EPO.

In MACE+, roxadustat had 14% reduction in risk compared to EPO. I would like to point out the incidence rate of each of the individual MACE+ components in dialysis are numerically lower in roxadustat than EPO.

Finally, let's talk about the exciting patient population incident dialysis, which is a sub-group of the dialysis-dependent pool.

Here we studied 1,526 new dialysis patients who commenced treatments within four months before study participation and were treated up to three years with an average treatment duration of 1.5 year.

In the incident dialysis pool, in comparison to epoetin alfa, roxadustat treatment resulted in a 30% reduction in the risk of MACE and a 34% reduction in the risk of MACE+ with a trend for lower risk of death. These results suggest the potential long-term safety benefits in selecting roxadustat when initiating anemia therapy in dialysis patients.

To evaluate the merits of roxadustat, it is important to put together an overall picture, taking into account efficacy and safety, and ask, if this drug has the potential to improve anemia treatment in CKD patients.

Our answer is yes. In non-dialysis, our Phase 3 program show roxadustat treatment corrected anemia effectively, regardless of iron repletion and reduce risk of rescue use of blood transfusion while also slowing down the decline in kidney function in patients with eGFR greater than or equal to 15 while MACE, MACE+ and all -cause mortality risk were comparable to placebo, the gold standard because of safety-related treatment restriction of ESA coupled with the iron repletion requirement and the inconvenience of parenteral administration requirement currently, there is little use of ESA in non-dialysis patients as US RDS reported that only 15% of patients entering dialysis had received prior ESA treatment.

If approved roxadustat could deliver the therapeutic benefits with the convenience of a pill unlike the ESA which requires frequent injection at the doctor's office. In addition to the favorable efficacy and safety characteristics, the convenient dosing of oral medication and removal of the financial and time burden from physicians need to stock and inject the medicine. We believe roxadustat has the potential to improve treatment access and patient compliance.

Therefore, we believe we have an unprecedented opportunity to expand anemia therapy to the millions of non-dialysis patients whose anemia goes unaddressed.

In dialysis currently the decision on the choice of anemia agent is generally made at the early periods of dialysis treatments. With a 30% reduction in MACE risk and a 34% reduction in MACE+ risk compared with epoetin alfa in incident dialysis patients, we believe roxadustat could be viewed as a safer option for patients initiating chronic dialysis, while benefiting from the robust efficacy in patients with or without inflammation with less IV iron use and lower transfusion rate compared to epoetin in the dialysis patients.

We are privileged to have an opportunity to potentially introduce a new standard for anemia therapy for CKD patients with roxadustat, a first -in -class agent based on Nobel winning science.

We believe these compelling efficacy results with demonstration of clinical benefits accompanied by the above safety results could serve as a strong basis for marketing approval in both the US, Europe and other countries in the world. Working with our partner AstraZeneca, we have made substantial progress in preparing NDA for CKD anemia in patients on dialysis and in patients not on dialysis. We plan to submit the NDA for both indications before year end. We're working closely with Astellas, our European partner and then – and expect to file the MAA for both indications in the first quarter of 2020.

Encouraged by the safety and efficacy results in CKD, we continue to expand treatment of anemia for other etiologies.

In MDS we have two ongoing clinical studies, a Phase 3 US global study in transfusion -dependent MDS patients, and a Phase 2/3 study in non-transfusion -dependent MDS patients in China. From Phase 3 global study results of the open label lead-in portion demonstrating efficacy in MDS patients will be presented in an oral session of the upcoming American Society of Hematology meeting in Orlando next month. We have also started a Phase 2 US study of roxadustat for treating chemotherapy-induced anemia, which we believe to have much opportunity to address the unmet need of a large patient population. Our founding CEO led pioneering HIF-PHI for anemia therapy. We are committed to carry on Tom Neff’s legacy to develop innovative medicine to improve patient care.

I now like to turn the call over to Chris Chung.

Christine L. Chung

Thanks, Peony. It has been an eventful quarter for us in China. Publication of data from the two China only Phase 3 studies in the New England Journal of Medicine was a landmark event, which was celebrated in China with much enthusiasm. The Chinese nephrology community envisions itself as leading the way internationally in the adoption of a transformative new paradigm for the treatment of anemia in CKD.

With the expansion of the China label to include non-dialysis, our partnership with AstraZeneca is serving us well. We're able to leverage the significant commercialization capability and launch experience of what is now the largest multinational pharma in China with coverage at over 6,000 hospitals that represent the vast majority of the potential market for roxadustat. FibroGen in China has responsibility from medical affairs and we too have expanded our key opinion leader coverage and evidence generation activities over the last few years from the original 30. Phase 3 clinical trial sites to now over 300 leading hospitals and counting. As a joint team, we continue to advance our efforts in market development, distribution, reimbursement and gaining listings in hospitals. China, as the first launch market for roxadustat, has given us some very encouraging early signals about prescriber and patient receptivity, indicators which are helping us calibrate the scale and scope of our ambitions for the market.

Looking at the different segments of the potential patient universe, in dialysis, the installed base of over 600,000 patients is now the single – the largest single country dialysis population of the world exceeding that of the United States. This is a substitution market for roxadustat. Treatment of anemia is well-established, but only one -fifth of patients are treated to the target hemoglobin of 11. There continues to be double -digit growth in dialysis. After accounting for deaths, nearly 100,000 new patients come onto dialysis each year. They represent new candidates for roxadustat and many have no prior ESA experience. Within dialysis is approximately 100,000 patients or 14% who are treated on peritoneal dialysis, PD, instead of hemodialysis, HD. We believe the segment is particularly well -suited for an oral therapeutic like roxadustat because patients receive PD treatment at home.

Finally, the non-dialysis segment is even bigger in patient count, but ease-of-use is much less established. We believe as an oral therapy, roxadustat has the opportunity to greatly expand the addressable market.

We expect to know by the end of 2019, roxadustat will be included in the updated national reimbursement drug list or NRDL. Inclusion would be an important inflection point for the business as it would greatly increase patient affordability, accelerate hospital listing and expand overall market adoption. This remains a stretch goal as, historically, the NRDL cycles were farther apart in time and drugs were on the market for a few years before inclusion. In the event roxadustat is not admitted in this round, reimbursement would be a top priority for us in 2020. We look forward to keeping you updated on the exciting market opportunity in front of us in China.

With this, I'll turn it over to Elias to discuss pamrevlumab. Elias Kouchakji

Thank you, Chris, and good afternoon. I'd like to start with some introduction of pamrevlumab. It is a – the first in class fully human monoclonal antibody that inhibits the activity of connective tissue growth factor, also known as CTGF. It's a critical mediator of the progression of fibrosis and fibrotic diseases. Pamrevlumab is currently in Phase 3 clinical development for the treatment of both idiopathic pulmonary fibrosis or IPF, and unresectable locally -advanced pancreatic cancer also known as LAPC. Pamrevlumab is in Phase 2 for the treatment of Duchenne muscular dystrophy in non-ambulatory patients. These diseases share a commonality of fibrosis involvement and each represents an area of significant unmet medical need in which these patients face a dire prognosis.

I'd like to start with an update on IPF. In July we dosed the first patient in the ZEPHYRUS Phase 3 clinical study pf Pamrevlumab in patients with IPF. We continue to activate additional sites in this study and engage with our investigators to enroll patients. We are redoubling our efforts and improving our processes to bring sites online and expect an acceleration over the next few months. Our focus now is to activate sites with the expectation that enrollment will accelerate in the year 2020.

In September, as Jim mentioned, we announced The Lancet Respiratory Medicine publication of positive results from the company's PRAISE Phase 2 clinical study in IPF, showing both significant improvement in the primary efficacy endpoints of FVC change from baseline and reduction in disease progression and quantitative lung fibrosis as measured by HRCT or high resolution CT scan. This paper was well -received by the medical community at the 2019 European Respiratory Society International Congress. We are very appreciative of and encouraged by this reception.

In this publication, the authors reported that pamrevlumab demonstrated the potential for stabilization of disease, and for the first time in human studies, the potential of reversal of lung fibrosis in some patients. I'd like to remind to everyone that pamrevlumab has received Orphan Drug and Fast Track Designation from the FDA for the treatment of IPF.

Moving to LAPC, our Phase 2 results showed the encouraging clinical evidence of the potential of pamrevlumab plus chemotherapy to transform unresectable LAPC patients into patients who are eligible for surgical resection. We recently announced that the first patient was dosed in LAPIS our pivotal Phase 3 randomized double-blind placebo controlled study evaluating pamrevlumab as a neoadjuvant therapy for unresectable LAPC patients. This study will enroll 260 patients, approximately, to receive chemotherapy of gemcitabine and nab-paclitaxel, and will be randomized to either pamrevlumab or placebo.

As you may know, this are very sick patient with limited options. With the primary endpoint of overall survival, at the end of the treatment period, we will be evaluating the rate of resection as a surrogate endpoint for a potential approval. Similar to IPF, pamrevlumab has received both Orphan Drug and Fast Track designation from the FDA for the treatment of this disease.

Turning to Duchenne muscular dystrophy, we will meet with the FDA this quarter to discuss the design of our pivotal Phase 3 program in DMD. We look forward to updating you in the future as this program advances. Also, we plan in the near future to publish additional data from patients who have completed one year of treatment in our Phase 2 study. Pamrevlumab has received Orphan Drug Designation from the FDA for the treatment of DMD.

In clinical studies in multiple indications, pamrevlumab has consistently shown positive efficacy results has demonstrated a good safety and tolerability profile. We are pleased to be progressing with the Phase 3 studies, to fulfill the vision of our late CEO Tom Neff whose goal in founding FibroGen was to treat fibrotic diseases. We look forward to updating you on the progress of the pamrevlumab program in the future.

I will turn over the call to our CFO Pat Cotroneo for the financial update. Pat?

Pat Cotroneo

Thank you, Elias.

As announced today, total revenue for the quarter ended September 30, 2019 was $33.2 million as compared to $29 million for the third quarter of 2018. For the same period operating costs and expenses were $86 million and net loss was $49.4 million or $0.57 per basic and diluted share as compared to operating costs and expenses of $71.8 million, and a net loss of $42.6 million or $0.50 per basic and diluted share for the third quarter last year.

Included in revenue for the quarter ended September 30, 2019 are first commercial sales of roxadustat drug product in China. The related net product revenue was $600,000 for the quarter.

Also included in operating costs and expenses for the quarter ended September 30, 2019 was an aggregate non-cash portion, totaling $19.6 million, of which $14.8 million was a result of stock-based compensation expense as compared to an aggregate non-cash portion of $16 million of which $14.3 million was a result of stock-based compensation expense for the same period in the prior year.

As stated in Q2 2019 in accordance with the US GAAP, we had included in our revenue recognition methodology a total of $180 million comprised of $50 million for an anticipated milestone from AstraZeneca relating to the filing of the US NDA and $130 million in anticipated milestones from Astellas in connection with the EU MAA filings, when such milestone achievements became probable. Included in our third quarter revenue recognition methodology is a $12.5 million milestone associated with the approval for CKD in dialysis patients in Japan.

The timing of when the payments related to these milestones will be remitted to FibroGen depends on when the milestones are actually achieved. As noted earlier on this call, our NDA submission is targeted for Q4 of this year and we expect the Astellas MAA submission to occur in the second half of the Astellas 2019 fiscal year, which ends March 31, 2020. Based on our latest forecasts, we estimate our 2019 ending cash to be in the range of $650 million to $660 million and this range includes a $50 million dollar US NDA milestone.

At September 30, 2019 FibroGen had $665.5 million in cash, restricted time deposits, cash equivalents, investments and receivables.

Thank you. And I would now like to turn the call back over to Jim.

James A. Schoeneck

As you have heard we've made significant progress over the past few months. Looking forward we'll continue to drive our products, programs, and organization. Here are some of our areas of focus. First FibroGen's Board and our Search Committee has initiated a search to find a truly exceptional leader to be FibroGen's permanent CEO. We'll update you as we have more news about selection.

For pamrevlumab we're enrolling in our Phase 3 studies for both IPF and locally advanced pancreatic cancer and we'll focus on opening additional study sites in increasing patient enrollment. We also look forward to discussions with the FDA to determine the next steps in our Duchenne muscular dystrophy program. In China our focus is on securing reimbursement and the upcoming roxadustat launch. We look forward to updating you on that progress in the coming months, as well.

For roxadustat we are completing our NDA submission in conjunction with AstraZeneca and plan to file by the end of this quarter followed by the European MAA submission through our partner Astellas by March of 2020. As Pat mentioned FibroGen is eligible to receive $180 million in filing milestones from our partners and we are also eligible to receive similar scope approval milestones.

Finally, we plan to submit the data just presented at the ASN for publication and we'll continue to seek out new indications for roxadustat with our programs in MDS and CIA.

At this point, I'd like to open up the call for questions.

Question and Answer Section

Operator

And your first question comes from Michael Yee. Michael, your line is open.

Q

Michael J. Yee

Thanks very much. I appreciate the questions, and congrats on the progress. I know Tom would have been proud, had he been there and congrats on the progress.

A

Thank you.

Q

Michael J. Yee

Two questions. One is for Peony, I would just like to understand since there seems to be some investor concern about FDA agreements and FDA signed off on statistical plans. How you are general impression-wise of your meeting with the FDA. And why do you feel confident about statistical protocols and their signing off of what you have from statics and why you feel good about that?

And my second question is for Jim; in your seat, although I appreciate you're the interim CEO, perhaps you could talk about what your priorities are, and what the board's priorities are at this point given where the stock is at, where things are, and I guess what you're thinking about in terms of priorities from here. I appreciate it. Thanks.

Peony Yu

Mike, thank you the good question. First of all, I wanted to share that we have been in dialogue with the FDA in the past six years.

And there has been a very good understanding about what the Phase 3 require study would look like and including the size of the study, how to power it and what the primary endpoint. And we agree on time to MACE as the primary endpoint, and that's how we power for the non-dialysis and the dialysis. And we've also had a very productive dialogue with the FDA on the analysis of cardiovascular safety as well as what the efficacy requirement needs to be for this submission.

And the most recent conversation with the FDA was at the end of July. And we had sent it to the FDA, a fairly comprehensive briefing package, and had a very productive meeting. And walking out of it, we thought that we had all the guidance from the FDA we needed to put together a winning submission. And that is about to be out the door this quarter.

Q

So, you feel no issue or no real concern about the hazard ratios and the upper bounds and all of the things that people are talking about. You look at diabetes programs and things like that, there is – you're well within that, so you don't feel any concern about that.

A

No, we have no concern about that. And, Mike, as you know, that a regulatory assessment is not based on one criterion, but instead, it is based on totality of evidence such as efficacy, safety, what is the medical need. And so based on our discussions and the historical precedents in this therapeutic area and the various conversations we've had with the agency we are very comfortable with our data, where it is now.

Q

Okay. Thanks. And Jim, just for that question for you.

A

And Mike, I think our focus is very clear as I mentioned through my closing remarks. I mean, first and foremost, it's filing of the NDA. Second, it's filing through Astellas, the MAA in Europe. Behind that is China and securing reimbursement along with the support and our participation in the China launch and with pamrevlumab it's around accelerating both the number of sites and the enrollment in our two Phase 3 studies and getting agree with the FDA on where we're taking the DMD program next. Beyond that, we're working with the rest of the Board, it's finding a very capable person to step in and lead the company longer term.

Q

Okay. Thank you.

Operator

And your next question that comes from Geoffrey Porges. Your line is open.

Q

Thank you. Thank you very much, and thanks everybody for participating in the call. I just want to also share my sadness and sympathy about Tom and particularly poignant given all the recognition and progress that you've made with roxadustat and pamrevlumab.

A

Thank you, Geoff.

Q

So one question for Peony, if I may, and one question for Chris. Peony, could you share the number of patients in the non-dialysis cohorts that progressed to dialysis and the difference in timing in the progression of dialysis and perhaps comment about whether the patients post-progression-to-dialysis presumably were treated with EPO and behaved in the same way as the incident dialysis patients and so is there a benefit from the comparison between ROXA and EPO in the patients who progressed. And then, Chris could you talk a little bit more about the NRDL listing, specifically, have you applied to both dialysis and non-dialysis, and what is the size of the non-dialysis patient population who are anemic enough to justify treatment with an innovative drug such as ROXA? Thanks.

A

Geoff, you asked a lot of -- noticed that the question is more than one. So, I think that – it is correct to expect that when 30% of the other than non-dialysis patient pool were indeed already had – already reached end stage kidney disease, meaning eGFR being below 15, than you do expect some patients to required dialysis treatment in this long-term outcome program. And so, we the – now the analysis of these patients is important because transition – that presents a transition to dialysis. And we have not had a chance – as you see, we have – we have presented a lot of data at the ASN. We have not had a chance to write this one up yet and we agree with you this is important that we should present in future medical conferences or publications. There's a little bit complicated to report that as a Q&A over here.

A

I'm sorry.

Q

Was there a benefit at least in time, was there a significant difference in the time to progression to dialysis between the two cohorts?

A

Based on the results from the eGFR change, we believe there should be, but the data needs further analysis, mainly because the time on treatments between roxadustat and placebo differ.

Q

Okay. Thanks. Chris, I'd love to hear from you about NRDL?

A

Hi, Geoff. So your first question I believe is whether roxadustat was invited by the Chinese Government to NRDL negotiations. So first of all you're absolutely right, a sponsor is invited, you don't proactively apply. So I think consistent with what AstraZeneca partners have said, the two companies are collectively putting a lot of effort in getting into NRDL, at this point in time we're not discussing if there is an invitation primarily because all invitations either to roxadustat or to other companies are considered confidential and the Chinese government has not published a list of companies invited to negotiate. So I would prefer to wait until the end of the year when the outcomes from NRDL is disclosed. I hope you understand.

Q

Sure.

A

With regard to the second question I believe the question was what is the size – potential market size of non-dialysis. So I had mentioned just now in my section of the script that there are over 600,000 dialysis patients in China 90% to 95% of them are anemic.

90% to 95% of them are anemic. In non-dialysis if you look at the CKD population exactly a 120 million of course mostly they are early stage and they're not necessarily anemic. If you look at Stage 3b it's about 50% anemic State 4 about 70%, Stage 5 non-dialysis it's about 90%. If we add those numbers up based on the real world evidence data that we have measuring hemoglobin 10 and below we believe the addressable market in China for non-dialysis patients but low hemoglobin 8 is close to 2 million patients. It's a substantial population. And, Geoff, we're very excited because we have an oral therapeutic with a safety profile that we think would greatly expand the addressable market.

Q

Great. Thank you very much for that, Chris.

Operator

And your next question comes from Adam Walsh. Your line is open.

Q

Edwin Zhang

Hi. This is Edwin on for Adam. Thanks for the question. First question maybe for Peony, for the individual MACE components in the NDD, I guess that events for myocardial infarction and the stroke, in the data set are small and FDA will focus on the MACE composite. Can you please further clarify on this NDDs MACE data set?

A

Yes. So I wanted to reiterate that in our conversation with the FDA, the primary safety endpoint was the composite MACE and there was never any requirement stated for us to -- on the individual component itself. And I also again remind ourselves that these numbers are fairly – the number of events are fairly small. And that – now, another thing to point out is that the lower of the 95% confidence interval on each of these individual components are below 1.0, which is very different than the stroke in TREAT. And we're looking at the overall picture and the overall safety profile off the drug, looking at efficacy, safety, as well as what – how little is on the market for treating the non-dialysis patients.

Q

Okay. My second question is, when are you going to talk [Technical Difficulty], I mean the statistical analysis plan, including the non-inferiority market? Is there – [Technical Difficulty] FDA meeting in the coming weeks?

A

I am sorry about the questions. Are you asking when we will publish these results? We do plan to write it up as soon as we can and put it in a scientific journal.

A

I think – Adam, I think the question is, when will we talk to the FDA about the statistics and the analytical plan, is the question.

Q

Right.

A

Do we plan to talk to them in the coming weeks?

A

Oh, okay. So, the answer to that question is that we had already talked with the FDA about analytical plan and we had a -- made the agreement on the analysis plan that that we have presented in high impact clinical session at the ASN and the numbers I had just presented were based on the agreed analysis plan that we have made with the FDA.

Q

So the non-inferiority margin of 1.3% is already in agreement or not?

A

So we are talking about the analysis plan meaning how do you prove you know what's the proven strategy and the analysis plan how to analyze the data. When you talk about NI margins, we're -- you're talking about the standard for assessment, right? And as I mentioned earlier that we expect that all regulators will assess the data based on very you know on the entire application of the NDA and based upon our dialogue with the FDA with the past six years and that data as we have shown, we are confident that we do have what it takes for this drug to be favorably evaluated.

Q

All right. Maybe another question for Chris regarding the China market, can you help us understand more of the safety market there and how do you -- and AstraZeneca book a revenue across China, is it 50-50? Thank you.

Thank you.

A

So, Edwin, with regard to the first question about the self-pay market. So the self-pay market is not large, and this is why getting into NRDL it's an important inflection point for the business. The self-pay market is basically people not getting reimbursement and choosing to pay a 100% out-of-pocket, at a price and you know it's visible to the market for a roxadustat drug that is higher than the standard of care. We have sales at this point in time, so there is a self-pay market, but we do not expect it to be substantial because of that differential in pricing.

With regard to revenue recognition, FibroGen is the marketing authorization holder of roxadustat in China. And under the two invoices rule it is the manufacturing, it's the marketing authorization holder that books revenues. We have a 50/50 profit share with AstraZeneca. So that is how the 50/50 works is not a 50/50 split of the top line, it's a 50/50 split of the profits.

Q

That's very helpful. Thank you.

A

You’re welcome.

Operator

And your next question comes from Danielle. Your line is open.

Q

Hi, thanks for taking my question and congratulation on the data. I just had a couple of questions. This is Nirav on for Danielle, by the way. I was just wondering, would you be able to talk a little about whether you're expecting priority review or normal review with the NDA and if you'd be willing to use a priority review voucher?

A

This is a very good question. And we believe that the basis for priority review could be because we have a new innovative drug that is potentially better than what is available, so treating diseases in patients was a serious condition. However, the decision whether to grant us power to review is that one of the FDA.

A

So, the second part of your question, I would not see us using a priority review voucher, but we will indeed request priority review.

Q

Okay. I see. Thank you. That's helpful. And I guess my second question would be, would you be able to give us just some color on the MDS study? Just how it's going? How the enrollment's going? And when we should expect data? And along with other agents that are currently in the pipeline for the indication as well, how do you see roxadustat sort of fitting in from a strategic standpoint?

A

Good question. We do – we are seeing encouraging data from the open label portion of our Phase 3 study, which is what we will be presenting in the upcoming ASH. And since the other -- so, in terms of -- of the competitive landscape, we believe that because MDS is such a – MDS anemia is a condition that there's so much need, and so, difficult to treat. We believe that there are – there is still opportunity for us to make a difference in these patients. And the moment is ongoing and we will come back with a – in the future with timeline on the when the study will be completed.

Q

Great. Thank you so much.

A

Thank you.

Operator

And your next question comes from Paul Choi. Your line is open.

Q

Hi, everyone, great to see everyone at the ASN meeting, and thanks for taking the question. My first question is for Peony and you did state earlier that -- that the non-dialysis population was not powered to individually assess the various components of MACE, but given the background of the patient population in terms of their eGFR level, can you give us, what is your understanding with regard to the FDA's position on the individual components with respect to when a trial is non-powered to show a statistical difference on those individual points, given the patients -- background population? And that I had a second commercial question on the NRDL.

A

So to you – we can share our view on the individual components and what that discussion with the FDA in terms of the requirement for our primary safety endpoints. And, as I stated earlier, there was never any explicit expectation on the individual components. Now, but I we do believe that the evaluations of the data have to take into account the overall benefit risk of the drug for a patient. So, I hope this answers the question.

Q

Oh, yes. Thank you. And then, on the NRDL, I know you stated you haven't – you won't formally communicate whether you – whether roxadustat is under invitation to be considered. But assuming -assuming it is under consideration, I guess as you think about you know potential reference price -pricing in the competitive landscape given the wide availability of EPO in China, can you maybe give us what you think of a reasonable range is potentially for pricing on the go forward given the – given the availability and pricing of EPO in the China market? Thank you very much.

A

Absolutely, Paul. So, the way we think about pricing in China is as follows. So, first of all, as value-based pricing, we evaluate the scope of unmet medical need and the pharmacoeconomic consequences of not treating or not treating optimally or not treating safely. We've then compared the clinical efficacy benefits of roxadustat based on the China Phase 3 studies over ESAs and then we'd looked at the safety advantages over ESAs and this is all about differentiation on a clinical basis. We also with AstraZeneca believe that roxadustat as a first-in-class drug and a patented first-in-class drug of course to state the obvious deserves that innovation premium because we are bringing a transformative new treatment paradigm to China debt above and beyond to clinical benefit to the patient in a quantifiable unmet medical need also supports the country's policy direction of encouraging innovation. So we're hopeful that roxadustat could become an example of companies bringing innovation to China and expecting a return for that delivery.

We do not see ourselves being benchmarked against locally manufactured ESA because we think we're a highly differentiated product with clinical benefits and we believe we deserve an innovation premium.

Obviously, Paul, at the end of the day it's about budgetary concerns and budgetary considerations of the Chinese government and affordability for the patient. So at the end of the day should there be an NRDL negotiations pricing would not just be what we would like to assert but what the country can actually afford. So, we'd be eager to see what that balance is should there be an NRDL negotiation but that is our pricing strategy in terms of what we will believe it's a fair pricing for roxadustat.

Q

Thanks for taking our questions.

Operator

Okay. And your next question comes from Joel Beatty. Your line is open. Joel perhaps you're muted on your end.

Q

Joel L. Beatty

Citigroup Global Markets, Inc.

Sorry about that. Okay. Can you hear me now?

A

We can, Joel.

Q

Joel L. Beatty

Citigroup Global Markets, Inc.

Hi. Okay. Oh great. So the first question is on quality of life benefit from the Phase 3 program. I believe that there were some initial data presented in the top line data but then I didn't see anything on quality-of-life ASN, should we still consider quality-of-life effect to be in line with the top line press release, and how important. Well quality-of-life data from the Phase 3 program for marketing the drug?

A

Joel, it is a great question. Yes, our data is consistent with what we had reported in top line. And we just have so much to put together for the ASN and we do look forward to present the results in future conferences and publications. As you know one of the manifestations of anemia is for patients' fatigue and loss in quality of life. Thank you.

Q

Okay. And maybe one other question, could you talk about the indications you plan to pursue for roxadustat? Thanks.

A

Yes. So we and our partners believe that roxadustat has the potential to become the anemia drug for various kinds of anemia beyond CKD. And as we have presented, we already have ongoing trials in MDS anemia and in chemotherapy induced anemia, and there are additional anemia types that are in consideration such as anemia in multiple myeloma patients and anemia of inflammation. There has been extensive effort to evaluate all these types of anemia and more.

Q

Thank you.

Operator

Okay. And there are no questions at this time.

James Schoeneck

On closing, I'd like to thank you for your attention and support. I also want to thank the senior management team and all the dedicated employees at FibroGen in the US and in China who are committed to bringing novel innovative medicines to patients around the world fulfilling the vision that Tom set for the company 25 years ago. Thank you.

Operator

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