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): January 7, 2019

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

Delaware (State or other jurisdiction of incorporation)

001-36740 (Commission File Number)

77-0357827 (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))

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

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

Emerging growth company $\ \square$

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. \Box

Item 7.01 Regulation FD Disclosure

Beginning January 7, 2019, FibroGen, Inc. (the Company) intends to conduct meetings with existing and prospective investors and analysts in which its corporate slide presentation will be presented. A copy of the presentation materials, including a slide setting forth certain cautionary statements intended to qualify the forward-looking statements therein, is attached as Exhibit 99.1 to this Current Report on Form 8-K 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 most 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 FibroGen, Inc. Presentation Materials dated January 7, 2019.

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: January 7, 2019

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

FibroGen, Inc. Corporate Presentation

January 2019





Forward-Looking Statements

This presentation contains "forward-looking" statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, business strategy, and plans, and objectives of management for future operations, are forward looking statements. These forward-looking statements can generally be identified by terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "contemplate," "intend," "target," "project," "should," "plan," "expect," "predict," "could," "or potentially," or by the negative of these terms or other similar expressions. Forward-looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses, or current expectations concerning, among other things, our ongoing and planned development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for roxadustat, pamrevlumab, and our other product candidates, the potential safety, efficacy, reimbursement, convenience, or clinical and pharmaco-economic benefits of our product candidates, including in China, the potential markets for any of our product candidates, our ability to develop commercial, spending of proceeds from our public offerings, financial condition, liquidity, prospects, growth, and strategies, the industry in which we operate, and the trends that may affect the industry or us.

Forward-looking statements involve known and unknown risks, uncertainties, assumptions, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Forward-looking statements represent our management's beliefs and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

FibroGen

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2019: A Transformational Year

TWO FIRST-IN-CLASS PRODUCT PLATFORMS ADDRESSING MAJOR MARKETS WITH SIGNIFICANT PATIENT NEED

ROXADUSTAT

Anemia associated with CKD

- Approved in China for dialysis in 2018
- NDA approval decisions expected in 2019:
 - Japan for dialysis
 - China for non-dialysis
- NDA submissions expected in 2019:
 - U.S., EU, other territories

Anemia Associated with MDS

• One U.S./EU Phase 3, one China Phase 2/3 trial ongoing

FibroGen



PAMREVLUMAB

IPF

Phase 3 study starting in 2019

Pancreatic Cancer

• Phase 3 study starting in 2019

DMD

· Phase 2 trial ongoing

Product Portfolio

HIF-PHI	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	APPROVED	Partnered
Roxadustat CKD Anemia						Wholly Owne
Inited States, Europe						
China ¹			•	•		
apan ²			1			
Roxadustat MDS Anemia						
Inited States, Europe						
China (Phase 2/3)						
ANTI-CTGF	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3		
Pamrevlumab						
Idiopathic Pulmonary Fibrosis						
Pancreatic Cancer						
Duchenne Muscular Dystrophy						
			Å			
Dialysis-dependent NDA approved; non-dialysis dependent Dialysis-dependent NDA filed in Japan; non-dialysis depend	NDA filed in China ent trials are ongoing					

• 4

Corporate and Financial

San Francisco headquarters with subsidiary in Beijing

\$722M cash as of September 30, 2018; no debt

- Well-managed financial position
- No debt •
- Year-end cash balance projection of • \$720M to \$730M



Appointed Maykin Ho, Ph.D., to Board of Directors in December 2018

465 employees worldwide

- 310 U.S. ٠
- 155 ex-U.S. •

Roxadustat

Anemia

Roxadustat: An Innovative Approach to Addressing Anemia

ROXADUSTAT HAS BEEN SHOWN TO BE MORE THAN AN ORAL ALTERNATIVE TO ESAs

- · Overcomes suppressive effects of inflammation on erythropoiesis
- · Coordinate iron mobilization, hepcidin reduction
- · Erythropoietin levels within or near physiological range
- Superiority to ESAs has been shown in hemoglobin change from baseline and reduction in risk of blood cell transfusion

>> INTERNALLY ADVANCED BY FIBROGEN FROM DISCOVERY THROUGH LATE-STAGE CLINICAL DEVELOPMENT AND APPROVAL*

- Dialysis-dependent and non-dialysis-dependent CKD patients
- · Anemia associated with MDS



PARTNERED WITH ASTRAZENECA AND ASTELLAS

- Astellas: Europe, Middle East, CIS, South Africa, Japan
- AstraZeneca: U.S./ROW; China



*First approved in China for anemia associated with CKD in dialysis-dependent patients on December 17, 2018.

Roxadustat: The Leader in Oral HIF-PHI Anemia Therapeutics

Anemia in CKD Patients

• U.S./EU

- Positive Phase 3 results from five trials announced by FibroGen and AstraZeneca December 2018
- Positive Phase 3 topline results announced by Astellas from first EU study
- All Phase 3 studies supporting U.S. NDA and EU MAA completed
- MACE pooled analysis readouts (DD, NDD) anticipated in 1H 2019
- U.S. NDA submission planned for 1H 2019
- China
 - NDA approved by the NMPA for dialysis-dependent patients in December 2018
 - NDA approval anticipated for non-dialysis in 1H 2019
 - Launch planned for 2H 2019
- Japan
 - NDA for dialysis-dependent patients submitted to PMDA in September, 2018
 - Astellas completed 1 of 2 CKD non-dialysis dependent Phase 3 studies needed for sNDA

Anemia Associated with MDS

• U.S. Phase 3 and China Phase 2/3 studies underway

Roxadustat in China



China is the first country to approve a HIF-PHI

FIRST TO MARKET

Commercialization Activities

FibroGen and AstraZeneca China working closely to prepare for 2H 2019 launch

- · FibroGen China to lead:
 - Medical Affairs
 - Pharmacovigilance
 - Regulatory Affairs
 - Commercial Manufacturing
 - Post-Approval Clinical Development

· AstraZeneca China to lead:

国家药品监督管理局

- Marketing
- Market Access
- Sales
- Commercial Operations

U.S. and China CKD Anemia Market Opportunity

ADDRESSING UNDERSERVED, GROWING, AND EMERGENT PATIENT POPULATIONS



>35M CKD patients

- · Linked to diabetes and hypertension
- Hepcidin modulation may benefit broader CKD anemia population

> 500K Dialysis patients¹

 AZ leads marketing, sales, and distribution with strong presence in diabetes and hypertension markets





>500K CKD dialysis patients

- Double-digit Y/Y growth rate
- · Large DD population significantly undertreated
- · "Severe disease" reimbursement classification
- AZ leads marketing and sales with strong and established presence

Global Registration Programs: Enrollment Summary

GLOBAL PHASE 3 STUDIES FOR U.S. NDA, EU MAA

	DD-CKD Stu	udies	N	Population, Comparator	Completed Chi	na Phase 3 Studies Support China NDA Approv	al	
Г	HIMALAYAS (FibroGen)	063	1,043	Incident dialysis, vs. epoetin α	China Studies	Population, Comparator	N	
	SIERRAS				806	Dialysis, vs. epoetin α	304	
	(FibroGen)	064	741	Stable/Incident dalysis, vs. epoetin α	808	Non-dialysis, vs. placebo	151	
	ROCKIES (AstraZeneca)	002	2,133	Stable/Incident dialysis, vs. epoetin $\boldsymbol{\alpha}$	China Phase 3	Total N	455	
	PYRENEES	CL-613	838	Stable dialysis, vs. epoetin α or	Completed Jap	an Phase 3 Dialysis Studies, NDA (DD) Submitt	ed Sept'18	
1	(Astellas)			darbepoetin	JPN Studies	Population, Comparator	N	
Studies Completed	Dialysis Total N		4,755		CL-307	ESA conversion, hemodialysis, vs. darbepoetin	303	
	NDD-CKD st	udies	N	Population, Comparator	CL-312	ESA conversion long-term, hemodialysis, open label	pel 164	
	ANDES	060	922	Non-dialysis ys placebo	CL-308	ESA naïve, hemodialysis, open label	75	
	(FibroGen)	000	322	Non-dialysis, vs. placebo	CL-302	Peritoneal dialysis, open label	56	
	OLYMPUS (AstraZeneca)	001	2,782	Non-dialysis, vs. placebo	Dialysis	Total N	598	
	ALPS (Astellas)	CL-608	597	Non-dialysis, vs. placebo	Japan Phase 3	CKD-NDD Studies for sNDA (NDD)		
	Non-Dialysis Tota	al	4,301		CL-314	ESA naive, non-dialysis, open label	100	
					CL-310	ESA conversion, non-dialysis, vs. darbepoetin	~325	
ski	DOLOMITES (Astellas)	CL-610	616	Non-dialysis, vs. darbepoetin, for EU reimbursement	Japan Non-Dia	lysis Total N	~425	

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ANDES Roxadustat Phase 3 CKD-NDD Study(060)

- · Randomized, double-blind, placebo-controlled study in U.S., APAC, S. America
- Chronic kidney disease (Stages 3, 4, or 5) not on dialysis, no prior ESA use
- N=922; roxadustat (n=616) vs. placebo (n=306)
 Treatment Duration: up to 4.5 years, mean=1.7 years

Ø



Wee



Tirst 52 weeks: 81% reduction in risk of rescue use (HR=0.19), p<0.0001
 Time to first blood transfusion during the first 52 weeks: 74% reduction in blood transfusion risk (HR=0.26), p<0.0001

Safety: An overall safety profile consistent with the results observed in prior roxadustat studies. The adverse events reported are consistent with those expected in these study populations with similar background diseases

HIMALAYAS Roxadustat Phase 3 Incident Dialysis Study (063)

Roxadustat Epoetin alfa

521

8.46

522

8.43

- Randomized, open-label, active-controlled global study (U.S., Asia Pacific, Europe, Russia, S. America)
- Anemic incident dialysis patients with baseline Hb <10 g/dL, minimal to no prior ESA use
- N=1043; roxadustat (n=522) vs. epoetin alfa (n=521)
- Treatment Duration: up to 4.4 years, mean=1.8 years

U.S. Primary Endpoint

- Mean Hb change from baseline to the average over Weeks 28-52 • Non-inferior: LS-means (LSM) difference=0.18; lower bound of the 95% CI of
- $(0.08, 0.29) \ge 0.75 \text{ g/dL}$ (NI margin);
- Superiority to epoetin alfa, p=0.0005
 <u>n</u>
 Baseline Hb (g/dL)



EU Primary Efficacy Endpoint (U.S. secondary endpoint)

% Hb Responder: 88.2% (roxadustat) vs. 84.5% (epoetin alfa)
Non-inferior: lower bound of the 95% CI (-0.9%, 7.6%) of the treatment difference is >-15% (NI margin)





Safety: An overall safety profile consistent with the results observed in prior roxadustat studies. The adverse events reported are consistent with those expected in these study populations with similar background diseases

SIERRAS Roxadustat Phase 3 Conversion Study in Dialysis Patients (064)

- · Randomized, open-label, active-controlled U.S. study
- N=741; roxadustat (n=370) vs. epoetin alfa (n=371)
- Stable dialysis patients with baseline Hb 9 12 g/dL, on stable doses of ESA
- Newly initiated dialysis patients with baseline Hb 8.5 12 g/dL
- Treatment Duration: up to 3.5 years, mean=1.9 years

U.S. Primary Endpoint

Mean Hb change from baseline to the average over <u>Weeks 28-52</u> Non-inferior to epoetin alfa: LSM difference = 0.48 g/dL Lower bound of the 95% Cl of (0.37, 0.59) ≥0.75 g/dL (NI margin) Superiority over epoetin alfa, p<0.0001

	Roxadustat	Epoetin alfa
n	370	371
Baseline Hb (g/dL)	10.30	10.31
mean Hb Wk 28-52 (g/dL)	10.69	10.22
change in Hb (g/dL)	0.39	-0.09



EU Primary Efficacy Endpoint (U.S. Secondary Endpoint)

Mean Hb change from baseline to the average over Wks 28-36

- Non-inferior
- LSM difference = 0.53 g/dL
 Lower bound of the 95% Cl of (0.39, 0.67) ≥0.75 g/dL (NI margin)
- Superiority over epoetin alfa, p<0.0001



Secondary Endpoint

Time to first blood transfusion during the first 52 weeks: 33% reduction in blood transfusion risk (HR=0.67), *p*=0.0337

Safety: An overall safety profile consistent with the results observed in prior roxadustat studies. The adverse events reported are consistent with those expected in these study populations with similar background diseases

Roxadustat Phase 3 Clinical Studies Topline Result (AstraZeneca Sponsored)

Olympus Phase 3 CKD-NDD Study Rockies Phase 3 CKD-DD Study Double-blind, placebo-controlled study in 26 countries Open-label, active-controlled study in 18 countries • CKD patients, non-dialysis (Stages 3, 4 or 5) with · ESRD patients, dialysis-dependent baseline Hb <10 g/dL N=2,133; randomized 1:1, roxadustat or epoetin alfa N=2,781; randomized 1:1, roxadustat or placebo • Primary Efficacy Endpoint Primary Efficacy Endpoint ٠ The trial met its primary efficacy endpoint by demonstrating a The trial met its primary efficacy endpoint by demonstrating statistically significant improvement in mean change from a statistically significant and clinically meaningful baseline in Hb levels averaged over Weeks 28 to 52 vs. epoetin improvement in mean change from baseline in Hb levels alfa averaged over Weeks 28 to 52 vs. placebo

Roxadustat Ongoing Pivotal MDS Anemia Studies

U.S. / EU Phase 3 MDS Study

- Patient population: transfusion-dependent, ESA-naïve, lower risk MDS patients
- Open-label lead-in: N up to 24
- Starting doses (8 each): 1.5 mg/kg, 2.0 mg/kg, 2.5 mg/kg
- Double-blind, placebo-controlled: N=160
- · 3:2 randomization, roxadustat vs. placebo
- Primary endpoint at 28 weeks:

Cumulative % patients achieved transfusion independence (over at least 8 weeks)

- Safety exposure: up to 52 weeks
- · Sites in U.S., EU, APAC

China Phase 2/3 MDS Study

- Patient population: non-transfusion dependent with baseline Hb of 6 to 10 g/dL, lower risk MDS patients
- Open-label: N up to 40
- Double-blind, placebo-controlled: N=135
- 2:1 randomization, roxadustat vs. placebo
- Primary endpoints at 26 weeks:
- % patients with Hb increased by 1.5 g/dL from baseline
- Treatment duration: 26 weeks
- ~30 sites in China

Pamrevlumab

Pamrevlumab: Three High-Value, High-Need Indications

Idiopathic Pulmonary Fibrosis (IPF)

- FDA Fast Track designation
- Phase 3 study planned to start in Q1 2019
- Randomized placebo-controlled, double-blind study similar to PRAISE Phase 2b study design
- · Primary endpoint will be change in forced vital capacity (FVC) from baseline

Pancreatic Cancer (LAPC)

- FDA Fast Track and Orphan Drug Designation
- Phase 3 study planned to start in Q1 2019
- Randomized double-blind, placebo-controlled study evaluating pamrevlumab in combination with gemcitabine and nab-paclitaxel as neoadjuvant treatment
- Assess resectability and resection rates with the primary endpoint of overall survival

Duchenne Muscular Dystrophy (DMD)

- Phase 2 trial fully enrolled
- All patients will have completed first of three years on trial in Q1 2019
- Initial data anticipated at end of Q1 2019

Pamrevlumab: Potential Innovative Treatment for Fibrosis and Fibroproliferative Diseases



Pamrevlumab

Idiopathic Pulmonary Fibrosis

IPF Patients Need New Therapeutic Options





- U.S. prevalence of ~44,000 to 135,000¹
- U.S. incidence of ~21,000 to 52,000¹ cases per year
- Incident and mortality are on the rise, and prevalence is expected to increase with the aging population²



- Leads to irreversible loss of lung function with high morbidity and mortality rates
- Median survival of 3-5 years following diagnosis



- · Slow pulmonary function loss
- Modest effect on slowing disease progression
- · No demonstration of reversal
- Require side effect management
- ~\$1.8B 2017 sales

¹ Raghu 2006 and United Nations Population Division ² https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3848422/



Pamrevlumab IPF Phase 3 Study Design

Patient Population

- · IPF patients who are not being treated with approved therapies
- IPF diagnosis according to ATS/ERS/JRS/ALAT guidelines*

Study Design

- · Placebo-controlled, double-blind
 - · Similar to PRAISE Phase 2b study
- Enroll ~500 patients
- Randomization 3:2 pamrevlumab or placebo

Primary Endpoint

• Change in forced vital capacity (FVC) from baseline

Secondary Endpoints

- · Composite clinical outcome of disease progression
- · Patient reported outcomes
- · Quantitative changes in lung fibrosis volume from baseline
- Others

FibroGen *Raghu, 2018



Pamrevlumab IPF Program: Positive Phase 2 Results

PRAISE Phase 2 double-blind, placebo-controlled study (n=103)

- Met primary endpoint of change in FVC % predicted from baseline to Week 48
 - Average decline in FVC by Week 48 was significantly less in pamrevlumab arm
- Significantly smaller proportion of patients in the pamrevlumab arm experienced disease progression (FVC % predicted decline ≥10% or death)
- Statistically significant attenuation of fibrosis change by qHRCT vs. placebo at Weeks 24 and 48
- Strong trends for improvement in health-related quality of life (HRQoL) relative to placebo

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Pamrevlumab

Pancreatic Cancer

LAPC Patient Population Lacks Treatment Options

ADDRESSING UNDERSERVED, GROWING, AND EMERGENT PATIENT POPULATIONS



55K new U.S. patients Dx annually¹

- ~27,700 (50%) present with no detectable metastases
- ~9,700 (15-20%) classified as resectable
- ~18,000 (30-35%) with locally advanced disease that precludes resection

12018 Estimates: http://seer.cancer.gov/statfacts/html/pancreas.html

FibroGen



Clinical significance of resection

Locally advanced disease

- 50% survive 8-12 months
 - ~8% survive 5 years
 - Survival rate similar to metastatic disease

Borderline and resectable disease

- 50% survive 17-27 months
- ~20% survive 5 years

LAPC Pivotal Phase 3 Study Design

Patient Population

- · Locally advanced, unresectable pancreatic cancer
- ECOG 0-1
- No prior therapy

Study Design

- · Double-blind, placebo-controlled
- · Enroll ~260 subjects at 40-60 sites globally
- Randomization 1:1 pamrevlumab + gemcitabine/nab-paclitaxel or placebo + gemcitabine/nab-paclitaxel
- 6 cycles of neoadjuvant treatment followed by evaluation for surgical eligibility and possible resection
- · Long-term follow-up for survival in all subjects

Primary Endpoint: Overall survival (OS)

• Interim Analysis: After 6 months treatment, if pamrevlumab arm shows improved resection rate over placebo arm, we may request FDA meeting to discuss Accelerated Approval

Secondary Endpoints: Progression-free survival, patient reported outcomes, and others

Pancreatic Cancer Program: Positive Clinical Results Reported from Phase 1/2 Studies

STUDY 069 IN LOCALLY ADVANCED UNRESECTABLE PANCREATIC CANCER*

- Resection results:
 - Higher proportion of patients in pamrevlumab arm:
 - Eligible for surgical exploration 70.8% vs.15.4% (pamrevlumab vs. control, respectively)
 - Achieved tumor resection 33.3% vs. 7.7% (pamrevlumab vs. control)
- · Survival results:
 - Statistically significant improvement of median survival in those who undergo resection
 - · Median survival for patients with non-resected tumors was 18.6 months
 - Median survival for patients with resected tumors was >40 months (median not reached)

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Pamrevlumab

Duchenne Muscular Dystrophy

DMD Background

- Affects ~1 in every 5,000 newborn boys
- · About 20,000 children are diagnosed with DMD globally each year
- The fatal disease is caused by genetic mutations leading to the absence or defect of dystrophin, a protein necessary for normal muscle function.
 - The absence of dystrophin results in muscle weakness, muscle loss, fibrosis, and inflammation
- Patients with DMD are often non-ambulatory before the age of 12, and their progressive muscle weakness may lead to serious medical problems relating to diminished function of respiratory and cardiac muscles



Pamrevlumab DMD Program

One-Year Data Anticipated in Q1 2019

Design

Open-label, single-arm study in 21 non-ambulatory boys, 12 years of age and older

Objective

· Efficacy, safety and tolerability, and PK

Endpoints

- Change from baseline in:
 - Pulmonary function tests
 - Upper body muscle function tests
 - Muscle and cardiac fibrosis by MRI imaging

Study Status

· Fully enrolled and treatment is ongoing

🔅 FibroGen



Upcoming Roxadustat Milestones

CKD Anemia U.S. / ROW

- Pooled MACE safety data analysis (dialysis, non-dialysis) anticipated in the first half of 2019
- NDA submission to FDA for the treatment of anemia in dialysis-dependent and non-dialysis-dependent CKD patients anticipated in the first half of 2019

CKD Anemia China

- Regulatory approval for CKD non-dialysis anticipated in the first half of 2019
- Roxadustat launch in CKD dialysis-dependent and non-dialysis dependent anticipated in the second half of 2019

Upcoming Pamrevlumab Milestones

Idiopathic Pulmonary Fibrosis

• Plan to commence Phase 3 clinical study in the first quarter of 2019

Locally Advanced Unresectable Pancreatic Cancer

• Initiate Phase 3 clinical study in the first quarter of 2019

Duchenne Muscular Dystrophy

• Anticipate completing first year of treatment and reporting topline data in the first quarter of 2019

990

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Thank you