### 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): October 22, 2018

## EIGER BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction incorporation) 001-36183 (Commission File Number) 33-0971591 (IRS Employer of Identification No.)

Eiger Biopharmaceuticals, Inc. 2155 Park Blvd. Palo Alto, California 94306 (Address of principal executive offices, including zip code)

(650) 272-6138

(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))

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

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

Emerging growth company ⊠

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

#### Item 8.01. Other Events.

Eiger BioPharmaceuticals, Inc. (the "Company") is filing the investor presentation slides attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company may use from time to time in conversations with investors and analysts.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Investor Presentation.

#### 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.

Eiger BioPharmaceuticals, Inc.

Dated: October 22, 2018

By: /s/ James Welch James Welch Chief Financial Officer



# FORWARD-LOOKING STATEMENTS

This presentation and the oral commentary contain "forward-looking" statements that involve substantial risks and uncertainties. All statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward looking statements include terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "include," "interdet," "target, "project, "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms. Forward looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, whether the FDA minutes confirm the understanding that existing data will support an NDA filing for lonafarnib in Progeria and the timing of the NDA filing; our ability to meet the quality and documentation requirements for potential approval of an NDA; our ongoing and planned clinical development, including whether the D-LIVR study will be supported by the FDA as a single, pivotal study to support registration; results of the Phase 3 D-LIVR study; the timing of and our ability to initiate or enroll clinical trials, including whether our D-LIVR study can be advanced by the end of this year; whether Phase 2 results in any of our clinical trial candidates to date will be indicative of larger, controlled Phase 3 clinical trial results; whether PREVENT Phase 2 study results will support for availide and our other product candidates; our intellectual property position; and the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates as well as the commercial opportunities, including potential market sizes and segments; our ability to finance the continued advancement of our development, including our results of operations, cash available, financial condition, liquidity, prospects, growth and st

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, including the risks described in the "Risk Factors" section in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, and subsequent filings with the Securities and Exchange Commission (SEC). Forward-looking statements represent our 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.

This presentation concerns products that have not yet been approved for marketing by the FDA. No representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

© 2017 Eiger BioPharmaceuticals, Inc., all rights reserved. All trademarks belong to their respective owners.

# LATE–STAGE PIPELINE TARGETING RARE DISEASES

3

**EIGER** is a late stage biopharmaceutical company focused on the development and commercialization of targeted therapies for multiple rare diseases.

ALL on-going programs have reported critical Phase 2b positive results using well-characterized drugs in targeted rare diseases.

LONAFARNIB is our lead compound advancing into:

- Phase 3 in a single, pivotal trial to treat hepatitis delta virus (HDV) infection by end of 2018
- NDA for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) in 2019





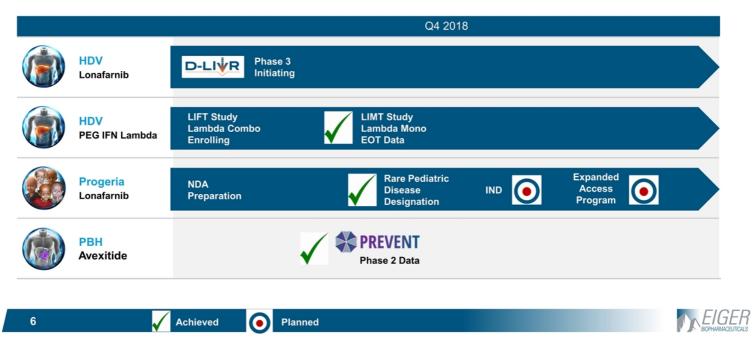
## Portfolio of Clinical Programs Targeting Diverse Rare Indications



NOVEL TARGETS VALIDATED	MATCHING DRUGS IDENTIFIED	
Faculty Inventors / Advisors		Partners / Licensors
Jeffrey Glenn, MD, PhD		
Leslie Gordon, MD, PhD*	Boston Children's Hospital Until every child is well"	
Tracey McLaughlin, MD, MPh	MEDICINE	Bristol-Myers Squibb
5 * volunteer		EIGER BICHHARMICEUTICALS

# 4Q 2018 MILESTONES

Analyst Day December 11th

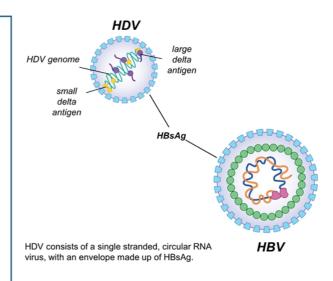




## OVERVIEW

- HDV is the most severe form of human viral hepatitis
- HDV is always a co-infection with HBV
  - HDV requires HBsAg to complete virion assembly
  - HBsAg acquired through protein prenylation
- · 4-6% of HBV infected patients co-infected with HDV
- HDV causes more rapid disease progression
  - Compared to HBV mono-infection
- No FDA approved Rx
- 15-20 M HDV infected patients worldwide
  - > 100K patients in US; > 200K patients in EU

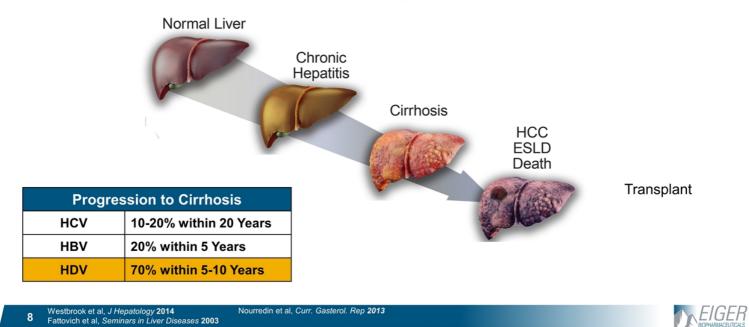






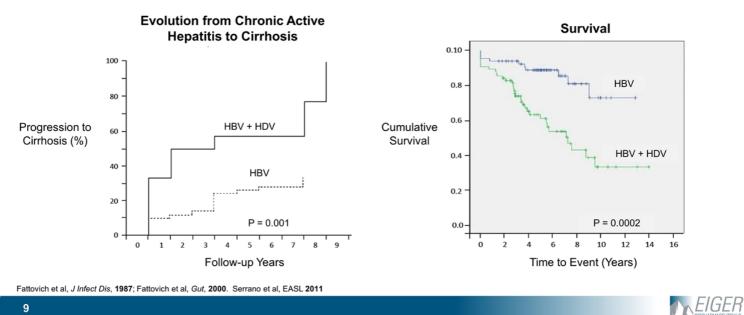
# HDV: MOST RAPID PROGRESSION OF VIRAL HEPATITIS

50% of HDV-Infected Patients are Cirrhotic at Diagnosis



# AT DIAGNOSIS, >50% OF HDV PATIENTS ARE CIRRHOTIC

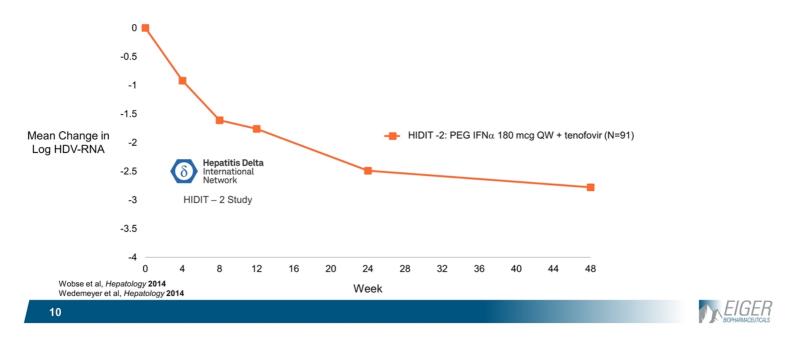
**Risk of Hepatocellular Carcinoma, Decompensation, Mortality Increase** 



# PEG IFN-ALFA REDUCED HDV RNA IN PATIENTS



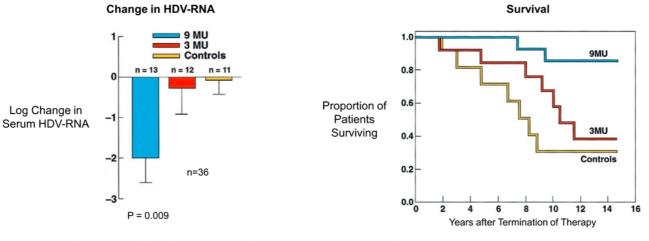
## **Not Approved for HDV**



## REDUCING HDV-RNA WITH IFN $\alpha$ IMPROVED SURVIVAL

## Improved Clinical Benefit without Clearance of HDV-RNA

#### Interferon- $\alpha$ for 48 weeks with 15 year Follow Up



EIGER

Farci et al, Gastroenterology 2004: Long-Term Benefit of Interferon-a Therapy of Chronic HDV: Regression of Advanced Hepatic Fibrosis

# HBV Rx APPROVALS AND REGISTRATION ENDPOINTS

## Viral Load Reduction, Biochemical Response, Histologic Improvement

Brand (generic)	Approved	Primary Endpoint(s)	Secondary Endpoints(s)
Intron A <sup>®</sup> (interferon alfa-2b)	1991	• HBeAg + HBV DNA	• HBsAg + ALT + Histology
Epivir HBV <sup>®</sup> (lamivudine)	1998	<ul><li>Histology*</li><li>HBeAg + HBV DNA</li></ul>	• ALT
Hepsera® (adefovir dipivoxil)	2002	<ul> <li>Histology*</li> </ul>	• HBV DNA + ALT + HBeAg
Baraclude <sup>®</sup> (entecavir)	2005	<ul> <li>Histology*</li> </ul>	• HBV DNA + ALT
Pegasys® (peginterferon alfa-2a)	2005	<ul><li>HBeAg</li><li>HBV DNA</li><li>ALT</li></ul>	• Histology
Tyzeka <sup>®</sup> (telbivudine)	2006	• HBV DNA + HBeAg or ALT	Histology + ALT
Viread® (tenofovir disoproxil fumurate)	2008	HBV DNA + Histology	• ALT
Vemlidy® (tenofovir alafenamide)	2016	• HBV DNA	• ALT + HBsAg + HBeAg

12

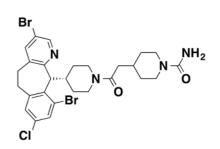
\* ≥ 2 point decrease in the Knodell necro-inflammatory score with no worsening of the Knodell fibrosis score



# LONAFARNIB FOR HDV

## Well-characterized Clinical Stage Lead Compound

- · Small molecule, oral, prenylation inhibitor
- Well-characterized through Phase 3
  - >2,000 patients dosed in oncology program by Merck (Schering)
  - Dose limiting toxicity is GI (class effect)
- · Over 120 HDV patients dosed across international sites
- HDV Orphan Designation in US & EU, Fast Track in US
- · Patent issued allowing broad range of lonafarnib + ritonavir doses and durations
- · Prenylation is a host target; potential barrier to resistance



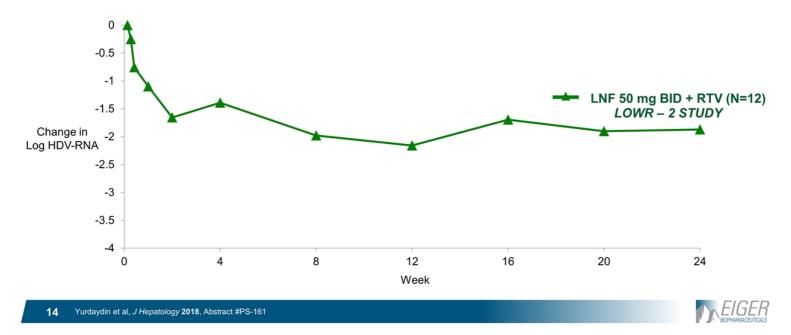


# 0

# **ALL-ORAL REGIMEN: IFN-FREE OPTION**



Lonafarnib 50 mg BID + Ritonavir 100 mg BID



#### Presented **ALL-ORAL REGIMEN: IFN-FREE OPTION** FAS 2018 Lonafarnib 50 mg BID + Ritonavir 100 mg BID 0 -0.5 -1 LNF 50 mg BID + RTV (N=12) -1.5 LOWR - 2 STUDY -Change in -2 Log HDV-RNA -2.5 PEG IFN-alfa-2a 180 mcg ± TDF (N=91) HIDIT - 2 -3 STUDY

12

Week

16

20

24

EIGER

8

15 LOWR 2 and HIDIT-1 enrolled comparable HDV patient populations: GT 1, well-compensated cirrhotics and non-cirrhotics, chronic HDV

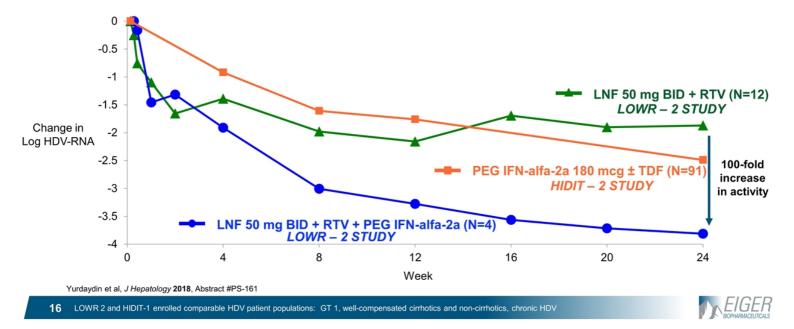
4

-3.5

-4 + 0

Yurdaydin et al, J Hepatology 2018, Abstract #PS-161

# **COMBO REGIMEN:** GREATEST OBSERVED DECLINE IN HDV-RNA



Lonafarnib 50 mg BID + Ritonavir 100 mg BID + PEG IFN-alfa-2a

# LONAFARNIB PHASE 2 HDV PROGRAM

## **Dose, Combinations and Endpoints Defined**

- · All-oral: Lonafarnib boosted with Ritonavir
  - 39% (7 of 18) patients ≥ 2 log decline or BLQ at Week 24
  - 60% patients normalized ALT at Week 24
- Combination: Lonafarnib boosted with Ritonavir + PEG IFN-alfa-2a
  - 89% (8 of 9) patients ≥ 2 log decline or BLQ at Week 24
  - 78% patients normalized ALT at Week 24
- Predominant AEs were GI-related (mild / moderate)

Yurdaydin et al, J Hepatology 2018, Abstract #PS-161

17 Most common reported AEs: nausea, diarrhea, fatigue, weight loss, anorexia, vomiting

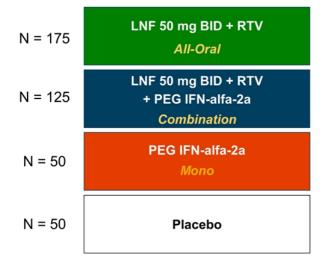






# D-LIVR : PHASE 3 STUDY INITIATING Q4 2018

## <u>Delta-Liver</u> Improvement and <u>Virologic</u> Response in HDV



#### **Primary Endpoint at Week 48**

- ≥ 2 log decline in HDV RNA
- Normalization of ALT

+

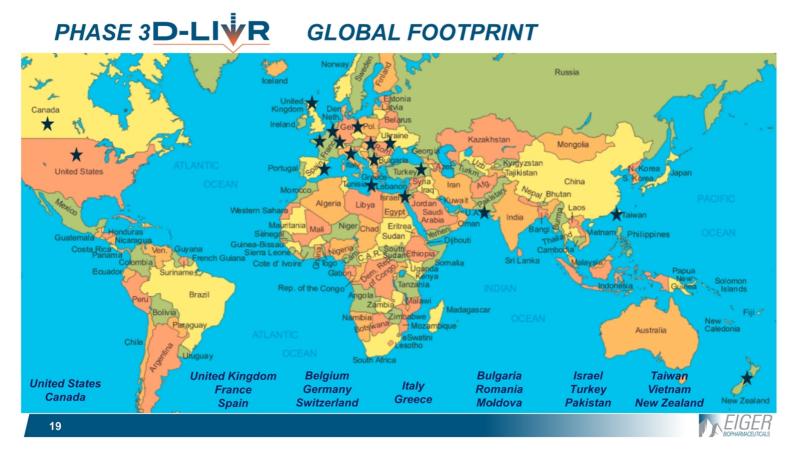
#### Secondary Endpoint at Week 48

- Histologic improvement
  - > 2 point improvement in HAI inflammatory score

EIGER

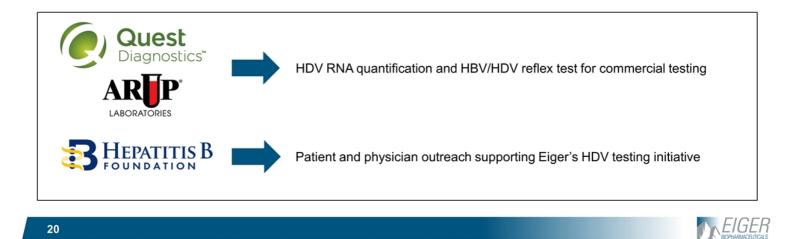
- o No progression in fibrosis
- Improvement of fibrosis

\* All patients will be run-in and maintained on background HBV nucleoside therapy



# **U.S. HDV PATIENT IDENTIFICATION PROGRAM**

- · 600,000 diagnosed HBV patients provide readily identifiable HDV market
- · HDV patients clustered in major metro hotspots



## U.S. MAJOR METRO HOTSPOTS IDENTIFIED

HDV Geographic Footprint is Growing



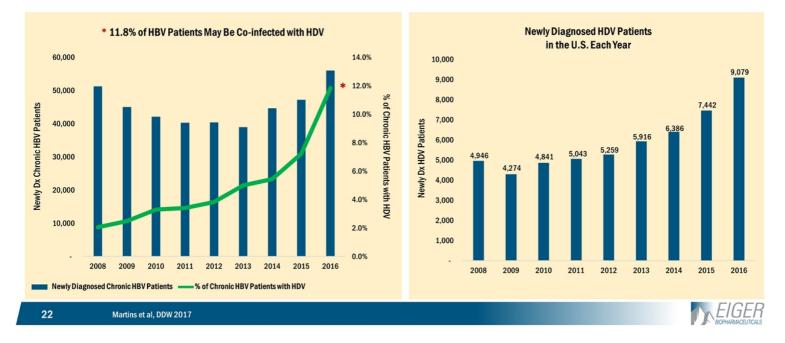
21 Martins et al, DDW 2017





## U.S. HDV PREVALENCE ~ 110,000

## Increased Screening Leads to Increased HBV and HDV Diagnosis



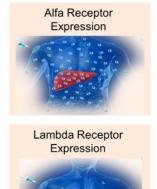
# **PEGYLATED INTERFERON LAMBDA**

## A Better Tolerated Interferon

- A novel first in class Type III interferon
- Binds to a unique receptor versus Type I interferons
  - Highly expressed on hepatocytes
  - Limited expression on hematopoietic cells and CNS cells
- · Uses similar downstream signaling pathway as Type I interferons
- Greater than 3,000 patients in 17 clinical trials (HCV / HBV)
- Comparable antiviral activity with less of the typical IFN alfa related side effects\*

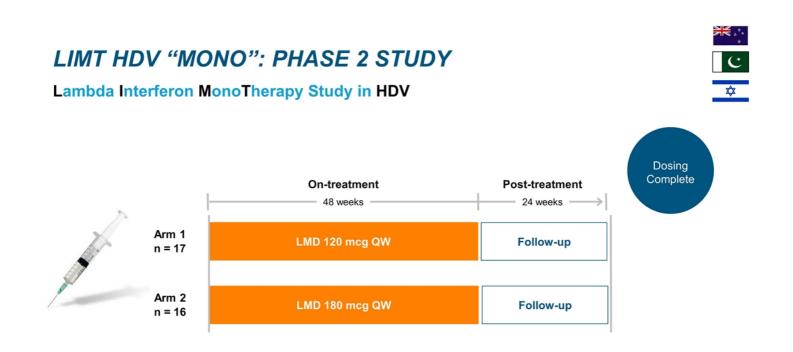
\*Chan, HLY et al, J Hepatology 2016

23



- Andrewsky

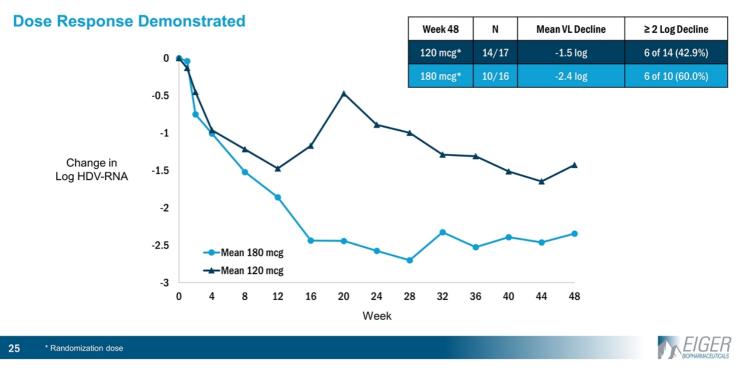
**NEIGER** 



EIGER

24

## HDV-RNA REDUCTION WITH LAMBDA THRU WEEK 48





EIGER

# LIMT HDV "MONO": PHASE 2 STUDY

## 48 Week End of Treatment Data

- · Lambda demonstrated comparable anti-HDV activity to historical PEG IFN-alfa-2a
- · Lambda was well tolerated in the majority of patients
- Lambda is a promising investigational agent, alone or in combination Rx in HDV

\*Hamid S et al, Hepatology 2017

26

# 

The ElGER

# LIFT: PHASE 2 LAMBDA COMBO STUDY

## Lambda InterFeron combination Therapy



- Open-label, Phase 2 study evaluating Lambda + LNF + RTV
- To be conducted at the NIH
- Enrollment and Dosing Ongoing

## \* biopsy

#### 27

### Primary Endpoint:

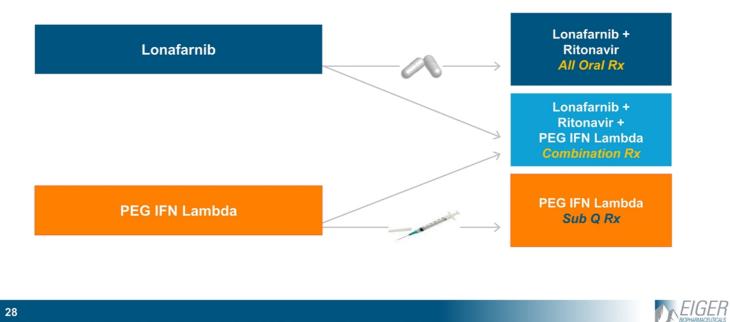
• ≥ 2 Log HDV RNA reduction at EOT

#### Secondary Endpoint:

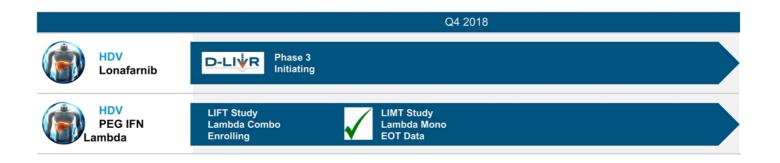
 Histological Improvement (biopsy confirmed)

# **COMPLEMENTARY DRUGS FOR HDV**

## **Multiple Treatment Options**



# HDV PROGRAM: DEVELOPING MULTIPLE TREATMENT OPTIONS





Achieved



## EIGER HDV PROGRAM UPDATES AT AASLD 2018

- Liver Institute and Foundation for Education and Research: The Search for HBV/HDV Cure, L.I.F.E.R. Meeting, November 9
- Eiger Phase 3 D-LIVR Study Investigator Reception, November 9
- Hepatitis Delta International Network (HDIN) Meeting, November 10



ASLD

NOVEMBER 9-13

ばしいとの MEETING® 2018 SAN FRANCISCO











#### Delta-Liver Improvement and Virologic Response in HDV

**D-LIVR** is the first-ever, Phase 3 study in Hepatitis Delta Virus (HDV) Infection.

**D-LIVR** will evaluate an "All-Oral" regimen of investigational drug **LONAFARNIB** boosted with **RITONAVIR** and a "Combination" regimen with **PEGYLATED INTERFERON-ALFA** in HDV-infected patients.

**D-LIVR** is a global study, currently activating clinical sites across 19 countries around the world.

Chronic Hepatitis Delta Virus Infection leads to the most severe form of human viral hepatitis and a growing unmet medical need in the United States and Western Europe.

Eiger BioPharmaceuticals is committed to developing treatments for HDV patients worldwide.

www.eigerbio.com

31



# HUTCHINSON-GILFORD PROGERIA SYNDROME (PROGERIA)

### **OVERVIEW**

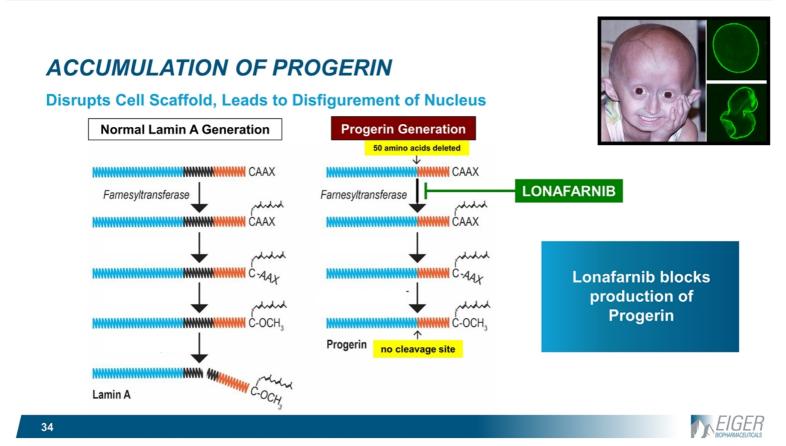
- · Ultra-rare, fatal, premature aging pediatric disease
- Point mutation in the Lamin A gene
  - Results in a farnesylated aberrant protein, Progerin
  - Disruption of scaffold structure of the nuclear membrane
- · Accelerated atherosclerosis with cardiovascular decline
- Average lifespan = 14.5 years
- Prevalence of 1 in 20 million (~400 worldwide)
  - 1 child born each year in the US
- No FDA approved Rx
- · >80 Children treated with lonafarnib

32 The Progeria Research Foundation









### W/W PREVALENCE ~ 400 CHILDREN WITH PROGERIA



EIGER

#### 147 Identified Across 47 Countries Worldwide with Progeria and Progeroid Laminopathies



- Progeria\* W/W = 114
- Progeroid Laminopathies\*\* W/W = 33

43 Patients Identified in US/EU

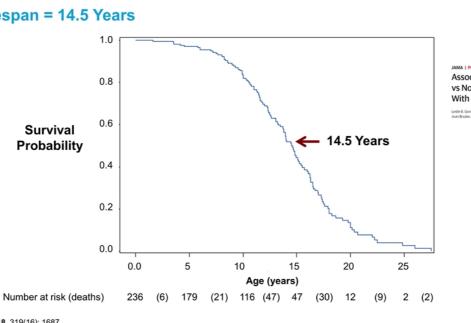
- Progeria\* US/EU = 32
- Progeroid Laminopathies\*\* US/EU = 11

\* Progeria (HGPS) patients have a progerin-producing mutation in the LMNA gene
\*\* Progeroid Laminopathies have a mutation in the lamin pathway but do not produce progerin



### SURVIVAL OF UNTREATED PROGERIA CHILDREN

#### Average Lifespan = 14.5 Years





Association of Lonafarnib Treatment vs No Treatment With Mortality Rate in Patients With Hutchinson-Gilford Progeria Syndrome

Leslie B. Gordon, MD, PhD; Heather Shappell, PhD; Joe Massaro, PhD; Ralph B. D'Agostino Sr, PhD; Joan Brazier, MS; Sosan E. Campbell, MA; Monica E. Kleinman, MD, Mark W. Kieran, MD, PhD

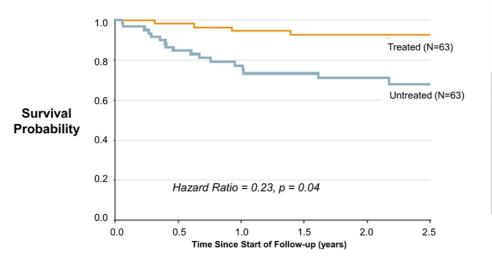
Gordon, L et al, JAMA, 2018, 319(16): 1687

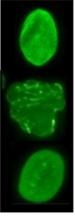
36



### LONAFARNIB IMPROVES SURVIVAL IN PROGERIA

77% Reduction in Risk of Mortality Compared to No Treatment





Normal Cell

JAMA

Progeria Cell

Progeria Cell After Treatment with Lonafarnib

Gordon, L et al, JAMA, 2018, 319(16): 1687

37 Average follow-up period of 2.2 years



#### NEXT STEPS FOR PROGERIA



# PROGERIA PROGRAM: PREPARING NDA

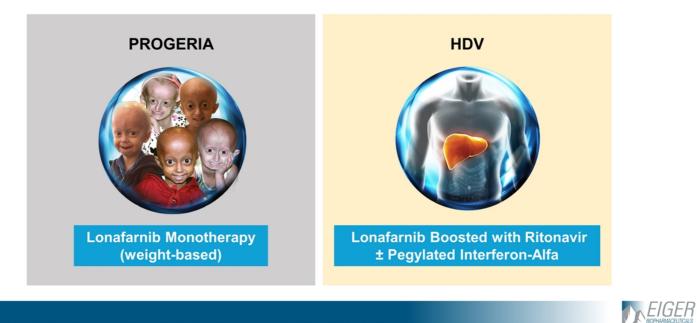
#### NDA Filing Planned in 2019

	Q4 2018			
HDV PEG IFN ambda	LIFT Study Lambda Combo Enrolling			
Progeria Lonafarnib	NDA Preparation	Rare Pediatric Disease IND Designation	Expanded Access Program	



### **PROGERIA AND HDV**

#### **Distinct Diseases, Distinct Treatment Regimens, Distinct Commercial Strategies**



### **POST-BARIATRIC HYPOGLYCEMIA (PBH)**



#### **OVERVIEW**

- · Bariatric Surgery Increasing due to Morbid Obesity
  - ~200K US / ~100K EU in 2015\*
  - Significant Impact: Weight Loss, Glycemic Control
  - Roux-en-Y Gastric Bypass ~35% of all procedures

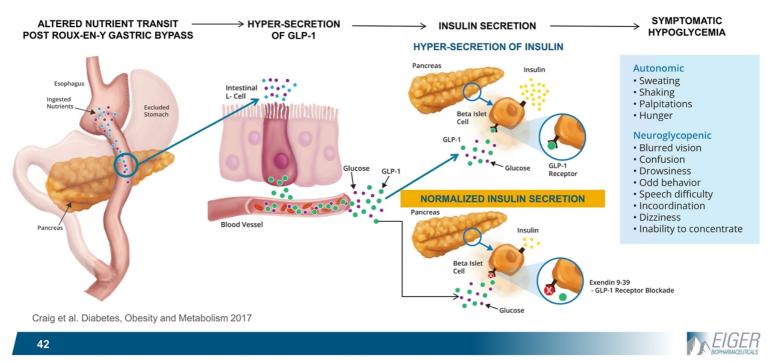
EIGER

- · Postprandial Hypoglycemia: Serious Complication
  - Dangerously low blood sugar after meals
  - Impacts 5-10% of Roux-en-Y patients
- PBH estimated prevalence ~70K in US / EU
- · No approved therapy

\* American Society for Metabolic and Bariatric Surgery 2015

### TARGETED BLOCKADE OF GLP-1

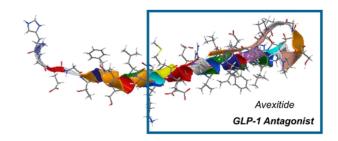
#### **Normalizes Insulin Secretion**

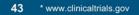


## AVEXITIDE: A GLP-1 ANTAGONIST

#### 31 Amino Acid Fragment of Byetta (exenatide), a GLP-1 Agonist

- Phase 2 Activity and Safety Demonstrated in 54 PBH Patients
  - Four clinical studies completed (POC, SAD, MAD, 28-day)
- Previous experience as investigational agent
   >300 patients reported dosed worldwide\*
- Proprietary Liquid Formulation Developed
- · Orphan Designation Granted in US and EU





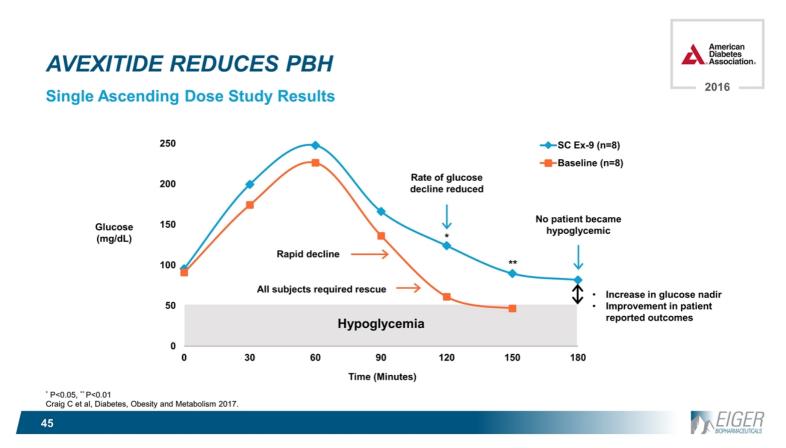


## PHASE 2 CLINICAL PROOF OF CONCEPT DEMONSTRATED

#### 54 Patients Dosed in 4 Completed Clinical Studies with Avexitide

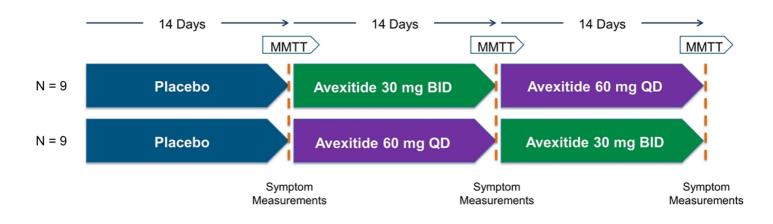
Study	# Patients	Duration of Dosing	Status
IV Infusion	8	Single dose	Published Diabetologia
Sub Q Injection SAD	8	Single dose	Presented at 2016 ADA American Diabetes Association. Published Diabetes, Obesity and Metabolism
Sub Q Injection MAD	20	Up to 3 days BID dosing	Presented at 2017 ADA American Diabetes Association.
Sub Q Injection; Durability of Effect	18	28 days QD / BID dosing	Topline data press released October 16, 2018

44



# **PREVENT** 28-DAY PHASE 2 OUTPATIENT STUDY

Goal: Demonstrate Durability of Effect, Define Dose, Safety, Tolerability



Primary Endpoint: Magnitude of postprandial hypoglycemia defined as the plasma glucose nadir occurring within 3 hours of mixed meal tolerance test (MMTT) Secondary Endpoints: Postprandial neuroglycopenic signs & symptoms; peak postprandial insulin response; require glucose rescue during MMTT

46 Liquid formulation of Avexitide (subcutaneous injection)

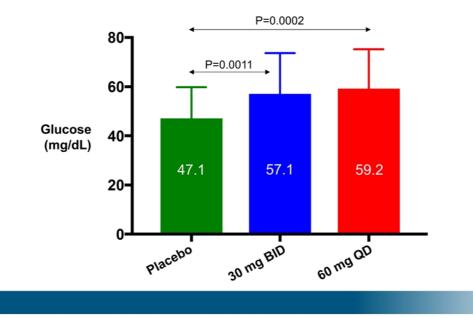




## IMPROVED POSTPRANDIAL GLUCOSE NADIR

#### **Primary Endpoint Achieved**

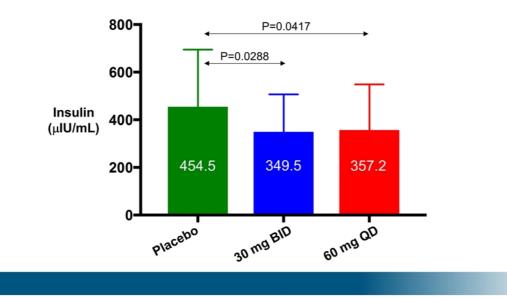
47





#### **REDUCED POSTPRANDIAL INSULIN PEAK**

#### **Secondary Endpoint Achieved**



#### FEWER EPISODES OF HYPOGLYCEMIA WITH AVEXITIDE



EIGER

**Exploratory Secondary Endpoints Achieved with CGM** 

- Metabolic and clinical improvements corroborated by continuous glucose monitoring (CGM)
- Fewer episodes of hypoglycemia (< 70 mg/dL)
- Fewer episodes of severe hypoglycemia (< 55 mg/dL)
- Fewer neuroglycopenic symptoms confirmed by CGM



# **PREVENT** PHASE 2 STUDY

**Clinically Meaningful Improvements Throughout 28-days of Avexitide Treatment** 

- · Improved postprandial glucose nadir
- Reduced postprandial insulin peak
- · Fewer episodes of hypoglycemia; less rescue required
- · Statistical significance achieved with QD and BID dosing
- · Well tolerated
- No approved therapy

Next Steps: Regulatory guidance in 2019

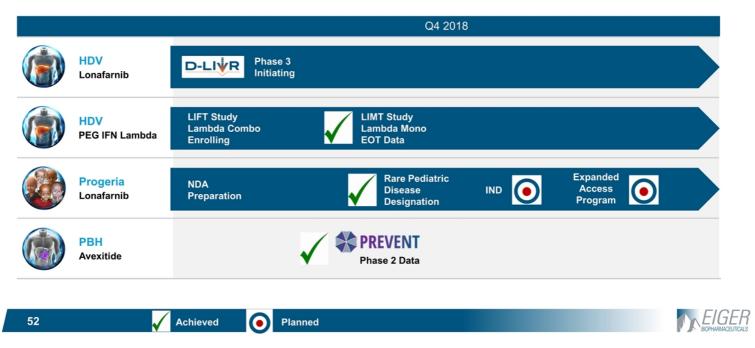
The ElGER

## **PBH PROGRAM: REGULATORY GUIDANCE IN 2019**

	Q4 2018				
		Phase 3 Initiating			
	Progeria Lonafarnib	NDA Preparation			
	PBH Avexitide	PREVENT Phase 2 Data			
51		Achieved			The El

# 4Q 2018 MILESTONES

Analyst Day December 11th



#### FINANCIAL SUMMARY

- \$73.5 million cash as of June 30, 2018
- 14.2 million shares outstanding as of June 30, 2018





# EXPERIENCED MANAGEMENT

DAVID CORY, RPH, MBA	President Chief Executive Officer
DAVID APELIAN, MD, PHD, MBA	Chief Operating Officer Executive Medical Officer
JIM WELCH, MBA	Chief Financial Officer
LISA PORTER, MD	Chief Medical Officer Metabolic Diseases
JIM SHAFFER, MBA	Chief Business Officer
INGRID CHOONG, PHD	Vice President Investor Relations and Corporate Development
JOHN FERRARO, MBA	Vice President Clinical Operations

## SEASONED BOARD

THOMAS DIETZ, PHD	Chairman
DAVID CORY, RPH, MBA	President and CEO
DAVID APELIAN, MD, PHD, MBA	COO and EMO
EVAN LOH, MD	Independent Director
JEFFREY GLENN, MD, PHD	Independent Director
ELDON MAYER, MBA	Independent Director

