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

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**FORM 8-K**

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**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 8, 2018**

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**EIGER BIOPHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36183**  
(Commission  
File Number)

**33-0971591**  
(IRS Employer  
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.)

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company

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

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**Item 7.01. Regulation FD Disclosure.**

Eiger BioPharmaceuticals, Inc. (the “*Company*”) plans to present the posters attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K to potential investors and analysts, including at The Liver Meeting® hosted by the American Association for the Study of Liver Diseases on November 9, 2018.

The information in this report is being furnished pursuant to Item 7.01 and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Growing Hepatitis Delta Virus (HDV) Infection Prevalence in the US: Under diagnosis in Foreign-bom Individuals.</u></a>
99.2	<a href="#"><u>End of Treatment Results from LIMT HDV Study: A Phase 2 randomized clinical study to evaluate the safety and efficacy of pegylated interferon Lambda monotherapy in patients with chronic HDV infection.</u></a>

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**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: November 8, 2018

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

A PHASE 2 RANDOMIZED CLINICAL STUDY TO EVALUATE THE SAFETY AND EFFICACY OF PEGYLATED INTERFERON LAMBDA MONOTHERAPY IN PATIENTS WITH CHRONIC HEPATITIS DELTA VIRUS INFECTION

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 1. Gastroenterology and Liver Disease Institute, Soroka University Medical Center, Beer-Sheva, Israel ; 2. Aga Khan University and Hospital, Karachi, Pakistan; 3. Shaare Zedek Medical Center, Jerusalem, Israel; 4. Auckland City Hospital, Auckland, New Zealand 5. Department of Gastroenterology, Ghulam Muhammad Mahar Medical College, Sukkur, Pakistan; 6. DILiSym<sup>®</sup>, USA; 7. Stanford University School of Medicine; 8. Eisai BioPharmaceuticals, Inc.  
 \*These authors share lead authorship

1. ABSTRACT

**Background and Aims:** Hepatitis Delta Virus (HDV) infection leads to the most aggressive form of human viral hepatitis. There is no approved therapy. Worldwide prevalence of HDV infection is 15-20 million. Pegylated interferon-alfa (PegIFN), a Type I IFN, has previously demonstrated a mean HDV RNA decline up to  $-2.5 \log_{10}$  at 48 weeks of treatment (Wedemeyer, N.J.E.M. 2011). PEG IFN-lambda-1a (Lambda), a Type III IFN, has previously demonstrated a good tolerability profile in >3000 HBV and HCV patients, with fewer episodes of cytopenias, flu-like, and psychiatric symptoms compared to Alfa. The goal of this study was to evaluate safety and efficacy of Lambda monotherapy in patients with HDV infection. **Methods:** Randomized, open-label study of Lambda 120 or 180 µg weekly SC injections for 48 weeks in patients with chronic HDV, conducted in Pakistan, Israel, and New Zealand. Dose reductions were permitted. Major inclusion criteria: positive HDV RNA by qPCR (Robogen<sup>®</sup> 2.0, BLO 14 IU/mL), ALT <10xULN, and compensated liver disease. Tenofovir or entecavir were started at baseline (BL). **Results:** This study enrolled 33 patients, randomized to Lambda 180 µg (N=14) and 120 µg (N=19), respectively. BL mean values: HDV RNA 4.1  $\log_{10}$  IU/mL (SD±1.4), ALT 106 IU/L (35-364) and bilirubin 0.5 mg/dL (0.2-1.2). At Week 48, patients in the 180 µg Lambda treated group experienced a  $-2.3 \log_{10}$  mean decline in HDV-RNA, with 7 of 11 (63.6%) experiencing  $\geq 2 \log_{10}$  decline, 5 of 11 (45.5%) patients were HDV-RNA negative at end of treatment. At Week 48, patients in the 120 µg Lambda treated group experienced a  $-1.1 \log_{10}$  mean decline in HDV RNA, with 5 of 13 (38.5%) experiencing  $\geq 2 \log_{10}$  decline, 3 of 13 (23.1%) patients were HDV-RNA negative at end of treatment. The most common adverse events included mild to moderate flu-like symptoms and elevated transaminase levels. Patients previously treated with Alfa noted significantly less side effects on Lambda. Overall, Lambda was well tolerated. Increased incidences of clinical jaundice and bilirubin elevations were observed in the Pakistani cohort, leading to a lower rate of study completion (9 of 15, 60%) compared to patients from Israel and New Zealand (15 of 18, 83%). None of the patients with elevations in bilirubin showed symptoms of decompensation and all responded favorably to dose reduction or dose discontinuation. DILiSym<sup>®</sup> modeling of ALT and bilirubin dynamics indicates a transporter-based mechanism for the observed bilirubin elevations. **Conclusions:** After 48 weeks of treatment, Lambda 180 µg had comparable antiviral activity with better tolerability, compared to historical data for Alfa. Elevated bilirubin levels in a subset of patients are likely due to alteration in bilirubin transport, and not due to meaningful hepatocellular injury. Pharmacogenomic studies are planned to better understand the increased incidence of bilirubin changes in Pakistani patients. Lambda is a promising agent for mono or combination Rx (i.e. lonafambir) development in the treatment of HDV.

2. ABOUT HDV

- Leads to the most severe form of human viral hepatitis
- Always associated with HBV infection
- 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
- 4-6% of HBV infected patients are coinfected with HDV

• PEG IFN Alfa demonstrates modest antiviral activity in HDV-infected patients  
 • Better tolerated interferon needed

3. ABOUT PEGYLATED INTERFERON LAMBDA

- A novel first in class Type III interferon
- Binds to a unique Type III receptor
  - 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) have been dosed with IFN lambda
- Comparable antiviral activity with less severe IFN alfa side effects\*

Limited Extra-hepatic Lambda Receptor Distribution  
 Potential for LESS IFN-associated abnormalities

- Neutropenia
- Thrombocytopenia
- Flu-like Symptoms
- Musculoskeletal Symptoms

4. LIMT HDV STUDY

Lambda Interferon MonoTherapy Study in HDV

**Objectives**

- Evaluate safety, tolerability and efficacy
- Evaluate the proportion of patients with undetectable HDV RNA
  - 12 weeks after the end of treatment
  - 24 weeks after the end of treatment

**Study Sites: 33 Patients Randomized**

- Auckland, New Zealand (N=4)
- Karachi, Pakistan (N=15)
- BeerSheba, Israel (N=11)
- Jerusalem, Israel (N=3)

5. BASELINE CHARACTERISTICS

Median Characteristic Value	Value
N	33
Age (mean range)	38 (20-53)
Male (n (%))	27 (82%)
Race (n (%))	
Asian	13 (39%)
Black	2 (6%)
Pacific Islander	2 (6%)
Other	13 (39%)
AMA score (range)	24.7 (14.0 - 37.1)
HDV RNA log <sub>10</sub> IU/mL (SD)	4.2 ± 1.4
ALT (range)	166 (28-364)
Gamma-GT (range)	125 (20-202)
Albumin (g/dL) (range)	4.4 (3.7-5.2)
Bilirubin (mg/dL) (range)	0.2 (0.1-1.2)
Prothrombin (range)	13.0 (11.2-13.5)

6. RESULTS

HDV-RNA Reduction with Lambda thru Week 48

**Responders\*: 180 mcg Group**  
 9 of 11 Patients (81.8%) are Responders

**Lambda 180 mcg Demonstrates Better Antiviral Activity**  
 Lambda 120 mcg vs 180 mcg

Group	Completed	Dose Reductions	Of Patients Completing Week 48	
			Responders	Non-Responders
120 µg	19	11 (58%)	10 (53%)	9 (47%)
180 µg	14	11 (79%)	7 (50%)	7 (50%)

Higher Incidence of Hyperbilirubinemia\* in Pakistan Cohort

No Signs or Symptoms of Decompensation

- Hyperbilirubinemia in 4/15 (27%) of Pakistani versus 2/18 (11%) of non-Pakistani cohort
- Jaundice observed in 3/15 (20%) of Pakistani patients versus 0/18 (0%) of non-Pakistani patients
- Incidence/severity in non-Pakistani cohort consistent with prior Lambda and Alfa data in HBV\*
- Patients with bilirubin elevations did not experience signs or symptoms of decompensation
  - Bilirubin levels were responsive to dose reduction/interruption
  - Patients exhibited normal hepatic function (Prothrombin time) throughout periods of bilirubin elevation

\*Hyperbilirubinemia = > 2 mg/dL

Responders\*: 180 mcg Group

9 of 11 Patients (81.8%) are Responders

**Adverse Events**  
 Predominantly Grade 1

- Milder and fewer flu-like and psychiatric symptoms with Lambda
- No thrombocytopenia events
- Elevated bilirubin and ALT levels normalized upon dose reduction or treatment discontinuation

All of Special Interest	% Patients Reporting	Lambda 120 µg (N=19)	Lambda 180 µg (N=14)
Flu-like symptoms	27% (52/191)	2/2	3/3
Headache	16% (30/191)	2/2	2/2
Fatigue	16% (30/191)	2/2	2/2
Diarrhea	9% (17/191)	1/1	1/1
Thrombocytopenia	0% (0/191)	0/0	0/0
Neutropenia	9% (17/191)	1/1	3/3
Psychiatric	14% (27/191)	1/1	4/4
Increased ALT	27% (52/191)	2/2	4/4

DILiSym<sup>®</sup> Modeling of ALT/Bilirubin Dynamics

Consistent with Bilirubin Transport Mechanism

- ALT and bilirubin dynamics consistent with bilirubin transporter based mechanism
  - Dynamics are not consistent with hyperbilirubinemia secondary to hepatocyte loss
  - Supported by absence of clinical decompensation
  - Supported by normal hepatic function (normal PT) throughout cases of bilirubin elevation
- Pharmacogenomic assessment of bilirubin transporters in Pakistan cohort is planned to better understand cohort specific increase in incidence and severity of hyperbilirubinemia

7. OBSERVATIONS

- Of the 24 patients who reached Week 48:
  - 120 µg group (N=14)
    - Mean HDV RNA decline = 1.1  $\log_{10}$
    - $\geq 2 \log_{10}$  decline in 5 of 13 (38.5%)
  - 180 µg group (N=10)
    - Mean HDV RNA decline = 2.3  $\log_{10}$
    - $\geq 2 \log_{10}$  decline in 7 of 11 (63.6%)
- Lambda was well tolerated overall
- Increased incidences of clinical jaundice and bilirubin elevations were observed in the Pakistani cohort
  - Led to lower than expected rate of study completion (9 of 15, 60%) for Pakistan site
  - Israel and New Zealand sites had completion rates (15 of 18, 83%) comparable to prior Alfa studies
- None of the patients with elevations in bilirubin showed symptoms of decompensation
  - All responded favorably to dose reduction or dose discontinuation

8. CONCLUSIONS

- Lambda demonstrates comparable anti-HDV activity to historical PEG IFN Alfa data at Week 48
- Lambda was well-tolerated overall
- Most commonly reported AEs: moderate headache, pruritus, fatigue, and myalgia
- ALT flares are due to vigorous antiviral immunological response to treatment, not due to direct hepatotoxicity
- DILiSym<sup>®</sup> modeling indicates a transporter-based mechanism for the observed bilirubin elevations
- Elevated bilirubin levels likely due to alteration in bilirubin transport, not due to hepatocellular injury
- Lambda is a promising agent for mono or combination Rx (i.e. lonafambir) development in the treatment of HDV

# Growing Hepatitis Delta Virus (HDV) Infection Prevalence in the US: Underdiagnosis in Foreign-born Individuals

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Eiger BioPharmaceuticals<sup>1</sup>, Stanford University School of Medicine<sup>2</sup>, Hepatitis B Foundation<sup>3</sup>



## BACKGROUND

Hepatitis Delta Virus (HDV) infection leads to the most aggressive form of human viral hepatitis. It is estimated that 4-6% of the HBV-infected population is co-infected with HDV. In the US the rate of co-infection is believed to be 3-5%, however targeted testing may yield significantly higher rates of HDV positivity. For example, testing HBsAg (+) patients may yield positivity rates between 8-12% (Gish 2012 and Martins 2017).

Worldwide prevalence of HDV infection is between 15-20 million. Global migration in the last decade has shifted HDV-infected population into the western world. US prevalence of HDV infection is estimated to be between 110,000 (Martins 2017) and 135,000 (DeVellis 2016). This may be an underestimate due to underdiagnosis in foreign-born individuals.

The epidemiological study sought to: (1) estimate the number of foreign-born individuals with HDV in the US and (2) identify areas of the US with high HDV prevalence and opportunities to improve screening and diagnosis based upon the composition of foreign-born individuals.

## METHODS

Our analysis combined Symphony Health Solutions (SHS) Integrated Universe a PatientSource<sup>SM</sup> database, US Census Data of foreign-born populations from 109 countries and published HBV and HDV epidemiology studies (Kowdley 2012, Alfaite 2015). SHS is a comprehensive longitudinal patient database with over 4 billion prescription, medical, and hospital claims linked to anonymous patient identifiers, practitioners and payers.

The patient database includes claims' information for over 274 million patients, accounting for over 73% of all prescriptions, over 58% of all electronically processed medical claims and 25% of all hospital claims. The entire dataset is linked to each de-identified patient, with 75% of patients with a linked prescription and diagnosis claim.

This analysis focuses predominantly on those countries with a known HDV prevalence rate among people infected with HBV and whose foreign-born population is tracked by the US Census Bureau to the zip code level.

Limitations to this study include the capture rates from SHS database and the finite number of countries captured in the US census data. Both limitations are likely to underestimate the number of foreign-born people in the US with HDV.

## CONCLUSIONS

- In the US, the number of newly diagnosed HDV patients has grown consistently (2008-2016)
- It is estimated there are at least 55,000 foreign-born individuals with HDV in the US.
- HDV is no longer limited to the East and West coasts of the US.
- HDV testing among chronic HBV patients and foreign-born individuals is recommended.
- Current US HDV prevalence of 110,000 individuals may be an underestimate.

## RESULTS

### 1 > 1.1 MILLION FOREIGN-BORN, HBV-INFECTED PATIENTS IN THE US

- 32 countries account for 80% of the foreign-born population in the US.
- Nearly 50% of those foreign-born people with HBV come from China, Vietnam and the Philippines.
- HDV prevalence rates are known for 31 countries whose foreign-born population is tracked by the US Census Bureau.

Top 20 Countries with Largest HBV-Infected Population in the US

Country	Foreign-Born in US (2016)	HBV Prevalence (%)	HDV Prevalence (%)
China	1,000,000	10.0	10.0
Vietnam	1,000,000	10.0	10.0
Philippines	1,000,000	10.0	10.0
India	1,000,000	10.0	10.0
Indonesia	1,000,000	10.0	10.0
Thailand	1,000,000	10.0	10.0
Malaysia	1,000,000	10.0	10.0
Japan	1,000,000	10.0	10.0
South Korea	1,000,000	10.0	10.0
France	1,000,000	10.0	10.0
Germany	1,000,000	10.0	10.0
Italy	1,000,000	10.0	10.0
Spain	1,000,000	10.0	10.0
United Kingdom	1,000,000	10.0	10.0
Canada	1,000,000	10.0	10.0
Mexico	1,000,000	10.0	10.0
Brazil	1,000,000	10.0	10.0
Argentina	1,000,000	10.0	10.0
Colombia	1,000,000	10.0	10.0
Peru	1,000,000	10.0	10.0
Chile	1,000,000	10.0	10.0
Other	1,000,000	10.0	10.0

### 2 > 50,000 HDV-INFECTED PATIENTS DIAGNOSED BETWEEN 2008-2016

- Based upon ICD-10 codes, there were 53,186 unique patients diagnosed with HDV in the US from 2008-2016. This includes all patients diagnosed with HDV regardless of their birth country.
- The diagnosis of HDV in the US is steadily increasing as HDV testing becomes readily accessible and potential treatments advance through development.

ICD-10 Description

- B17.0 Hepatitis delta without mention of active hepatitis B disease or hepatic coma
- B16.0 Viral hepatitis B with hepatic coma, acute or unspecified, with hepatitis delta
- B16.1 Viral hepatitis B without mention of hepatic coma, acute or unspecified, with hepatitis delta
- B18.0 Chronic viral hepatitis B without mention of hepatic coma with hepatitis delta



### 3 COUNTRIES WITH FOREIGN-BORN IN US WITH HIGHEST PREVALENCE OF HDV

- The US Census Bureau tracks the foreign-born population at the zip code level for most countries with a moderate to high (> 10%) HDV prevalence rate among those infected with HBV.

Country	HDV Prevalence among HBV-Infected Patients (%)
Romania	8%
Spain	6%
Indonesia	6%
Philippines	6%
France	6%
Italy	6%
Malaysia	6%
Japan	6%
Canada	6%
Vietnam	10%
Thailand	10%
Argentina	10%
South Korea	10%
Latin	10%

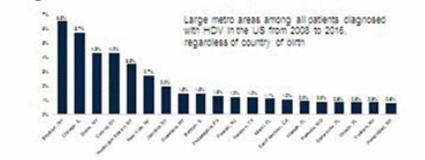
\* There are a select number of countries with a high HDV prevalence rate are not tracked by the US Census Bureau (i.e. Mongolia, Central African Republic). This data is not included in the analysis.

### 4 HDV AMONG FOREIGN-BORN PEOPLE WITH HBV

- There are at least 55,000 foreign-born people infected with HDV in the US.
- Foreign-born people infected with HDV represent approximately 40% of all HDV patients in the US.
- Approximately 50% of all foreign-born HDV patients come from either Romania, Pakistan, Albania, Vietnam or Colombia.

Country	Foreign-Born in US	HBV Prevalence (%)	HDV Prevalence (%)	HDV Prevalence among HBV-Infected (%)	HDV Prevalence in US
Romania	200,000	10.0	10.0	40.0	80,000
Pakistan	150,000	10.0	10.0	40.0	60,000
Albania	100,000	10.0	10.0	40.0	40,000
Vietnam	1,000,000	10.0	10.0	40.0	400,000
Colombia	1,000,000	10.0	10.0	40.0	400,000
Other	1,000,000	10.0	10.0	40.0	400,000

### 5 U.S. CITIES WITH HIGHEST PREVALENCE OF HDV



### 6 TOP US CITIES WHERE HDV IS MOST PREVALENT AND THE ESTIMATED NUMBER OF FOREIGN-BORN PEOPLE WITH HDV

- Top 20 US cities where HDV is most prevalent have been identified.
- It is estimated that 10,284 foreign-born people in the US reside in these top 20 cities where HDV is most prevalent.
- HDV prevalence rates in foreign-born in these cities range from 14-100%.

City	# Foreign-Born in US	Estimated HDV Prevalence (%)	Estimated Number of Foreign-Born with HDV	% Foreign-Born with HDV
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%
Chicago, IL	2,700,000	100%	2,700,000	100%

### 7 UNDERDIAGNOSIS OF HDV IN THE US

- Comparing the number of unique patients diagnosed by city and the estimated number of foreign-born HDV patients in that city, it is possible to identify cities where HDV may be underdiagnosed.

US Cities Where HDV is Likely Underdiagnosed Based Solely on the Composition of Foreign-born Individuals

City	Total Population (2016)	Estimated Number of Foreign-Born with HDV	Estimated Number of Foreign-Born with HDV (Underdiagnosed)
San Francisco, CA	800,000	10,000	10,000
Los Angeles, CA	4,000,000	10,000	10,000
New York, NY	18,000,000	10,000	10,000
Chicago, IL	9,000,000	10,000	10,000
Houston, TX	6,000,000	10,000	10,000
Phoenix, AZ	4,000,000	10,000	10,000
San Antonio, TX	2,000,000	10,000	10,000
San Diego, CA	3,000,000	10,000	10,000
Portland, OR	1,000,000	10,000	10,000
Seattle, WA	1,000,000	10,000	10,000
Denver, CO	1,000,000	10,000	10,000
San Jose, CA	1,000,000	10,000	10,000
San Francisco, CA	800,000	10,000	10,000
Los Angeles, CA	4,000,000	10,000	10,000
New York, NY	18,000,000	10,000	10,000
Chicago, IL	9,000,000	10,000	10,000
Houston, TX	6,000,000	10,000	10,000
Phoenix, AZ	4,000,000	10,000	10,000
San Antonio, TX	2,000,000	10,000	10,000
San Diego, CA	3,000,000	10,000	10,000
Portland, OR	1,000,000	10,000	10,000
Seattle, WA	1,000,000	10,000	10,000
Denver, CO	1,000,000	10,000	10,000
San Jose, CA	1,000,000	10,000	10,000