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): September 22, 2021

FREQUENCY THERAPEUTICS, INC. (Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation)

001-39062 (Commission File Number)

47-2324450 (IRS Employer Identification No.)

75 Hayden Avenue, Suite 300 Lexington, MA 02421 (Address of principal executive offices) (Zip Code)

(781) 315-4600

 $\label{eq:NA} N/A$ (Former Name or Former Address, if Changed Since Last Report)

	eck 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 lowing provisions (see General Instructions A.2 below):						
	ritten communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)						
	Soliciting material pursuant to Rule 14a-12 under the	citing material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)					
	e-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))						
Securi	curities registered pursuant to Section 12(b) of the Act:						
Co	Title of each class	Trading Symbol(s) FREO	Name of each exchange on which registered The Nasdaq Global Select Market				
Common stock, par value \$0.001 per share		rkey	i ne wasuay Giodai 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. \Box

Item 7.01.Regulation FD Disclosure.

On September 22, 2021, Frequency Therapeutics, Inc. (the "Company") posted an updated corporate slide presentation in the "Investors & Media" portion of its website at www.frequencytx.com. A copy of the slide presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report").

The information in Item 7.01 of this Current Report, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "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 incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 8.01.Other Events.

On September 22, 2021, the Company announced that four additional sensorineural hearing loss ("SNHL") subjects from its FX-322-111 open-label study achieved statistically significant hearing improvements when evaluated 8 to 12 months following initial dosing.

Including the five initial responders, there are now a total of nine subjects that participated in the FX-322-111 study (n=32) that have been shown to have statistically significant improvements in word recognition scores, a key measure of speech perception, at time points between 90 days and one year.

These new results suggest that the hearing of individuals administered with a single dose of FX-322 may improve over extended periods. The longer-term measures of their treated ear demonstrated word recognition score improvements when compared to pre-treatment baseline levels and no significant changes were detected in their untreated ears. Of the five subjects that had a statistically significant response at day-90, the four that returned for evaluation had scores that remained above their baseline word recognition measures, though were below the threshold for statistical significance. The Company plans to assess individuals treated in its other studies to evaluate if those subjects may have experienced these longer-term benefits.

FX-322 is the Company's lead product candidate for the treatment of acquired SNHL, which is the primary cause of more than 90 percent of all cases of hearing loss. FX-322 is designed to regenerate auditory sensory hair cells located in the cochlea within the inner ear and to potentially restore hearing in individuals with SNHL.

The FX-322-111 study is an open-label, multi-center, single-dose trial designed to evaluate the impact of FX-322 injection conditions on tolerability, as well as key measures of hearing benefit. In the study, subjects with mild to severe SNHL (n=33) were injected in one ear with FX-322, with the untreated ear serving as the control. Hearing function was tested in 32 subjects (one subject did not finish the study) over the course of 90 days following dosing. Twenty-five subjects were subsequently evaluated at 8-12 months following FX-322 dosing, with four subjects that had shown improvement trends in word recognition scores at day-90 reaching statistically significant scores when tested at the later time points.

Subjects in the study had an array of hearing loss etiologies, including sudden SNHL, noise-induced SNHL and idiopathic SNHL. Additionally, the subjects ranged in severity from mild to severe. The single dose had a favorable safety profile and both injection conditions were well tolerated. Based on the overall learnings from the multiple FX-322 learning studies, the Company plans to initiate a new FX-322 Phase 2 trial in the fourth quarter of this year to evaluate the impact of single-dose FX-322 administration in a refined population of individuals with SNHL.

Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the initiation, timing and design of the new Phase 2 trial of FX-322, the interpretation and implications of the results of the FX-322-111 study as well as the results from the follow-up to the FX-322-111 study, the plan to assess individuals in earlier trials for longer-term benefits, and the treatment potential of FX-322.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause 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, but not limited to, the following: the impact of COVID-19 on the Company's ongoing and planned clinical trials, research and development and manufacturing activities; the Company's business and financial markets; the Company has incurred and will continue to incur significant losses and is not and may never be profitable; the Company's need for additional funding to complete development and commercialization of any product candidate; the Company's dependence on the development of FX-322; the unproven approach of the Company's PCA platform; the lengthy, expensive and uncertain process of clinical drug development and regulatory approval; limited experience successfully obtaining marketing approval for and commercializing product candidates; the results of earlier clinical trials not being indicative of the results from later clinical trials; differences between preliminary or interim data and final data; adverse events or undesirable side effects; disruptions at the FDA and other regulatory agencies; failure to identify additional product candidates; new or changed legislation; failure to maintain Fast Track designation for FX-322 and such designation failing to result in faster development or regulatory review or approval; costly and damaging litigation, including related to product liability or intellectual property or brought by stockholders; dependence on Astellas Pharma Inc. for the development and commercializion of FX-322 outside of the United States; misconduct by employees or independent contractors; reliance on third parties, including to conduct clinical trials and manufacture product cand

These and other important factors discussed under the caption "Risk factors" in the Company's Form 10-Q filed with the Securities and Exchange Commission ("SEC") on August 12, 2021 and its other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relates to Item 7.01, and shall be deemed to be furnished, and not filed:

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.

FREQUENCY THERAPEUTICS, INC.

Date: September 22, 2021

By: \[\begin{align*} \langle /s \ \text{David L. Lucchino} \]
\[\text{Name: David L. Lucchino} \]
\[\text{Title: President and Chief Executive Officer} \]





Forward-Looking Statements and

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the interpretation and implications of the results of the Phase 2a study as well as the FX-322-112 and the FX-322-111 studies, the timing and results of top-line data from the Phase 1b study in severe SNHL, the initiation, timing and design of the new Phase 2 trial of FX-322, including the ability of study design to address study bias, the design and timing of future studies of and clinical development path for FX-322, the results and implications of the Phase 1/2 durability of response data, the ability of our technology platform to provide patient benefit, the impact of COVID-19 on the Company's on-going and planned clinical trials and business, future milestone and royalty payments under the license and collaboration agreement with Astellas Pharma Inc. ("Astellas"), the sufficiency of the Company's cash, cash equivalents and short-term investments, estimates of the size of the hearing loss population and population at risk for hearing loss, estimates of the commercial opportunity of FX-322 and the impact on existing treatment paradigms, the timing and progress of the remyelination program, and the potential application of the PCA platform to other diseases.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause 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, but not limited to, the following: the impact of COVID-19 on the Company's ongoing and planned clinical trials, research and development and manufacturing activities, the relocation of the Company's offices and laboratory facilities, the Company's business and financial markets; Frequency Therapeutics (the "Company") has incurred and will continue to incur significant losses and is not and may never be profitable; need for additional funding to complete development and commercialization of any product candidate; the Company's dependence on the development of FX-322; the unproven approach of the PCA platform; the lengthy, expensive and uncertain process of clinical drug development and regulatory approval; limited experience successfully obtaining marketing approval for and commercializing product candidates; the results of earlier clinical trials not being indicative of the results from later clinical trials; differences between preliminary or interim data and final data; adverse events or undesirable side effects; disruptions at the FDA and other regulatory agencies; failure to identify additional product candidates; new or changed legislation; failure

Frequency Today: Guided by a Clear Signal

Leading the field of hearing restoration

First ever known clinical studies demonstrating hearing improvements

Defining the Target, Expanding the Pipeline

Learnings from exploratory studies support new Phase 2 trial and help define path forward

Working to expand our pipeline for hearing therapeutics and for other degenerative diseases



Today's Hearing Loss Market Has No Restorative Tre



Only 20% market penetration for hearing aids



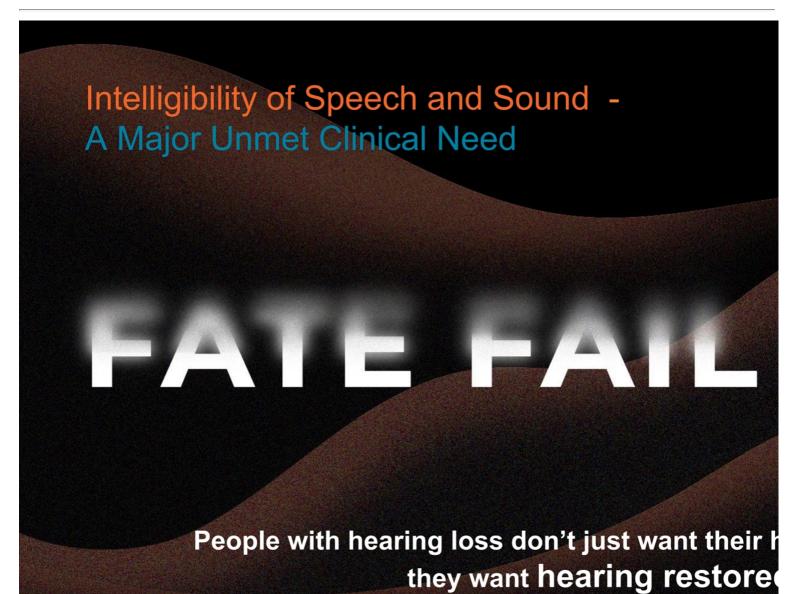
US hearing aid market annual sales

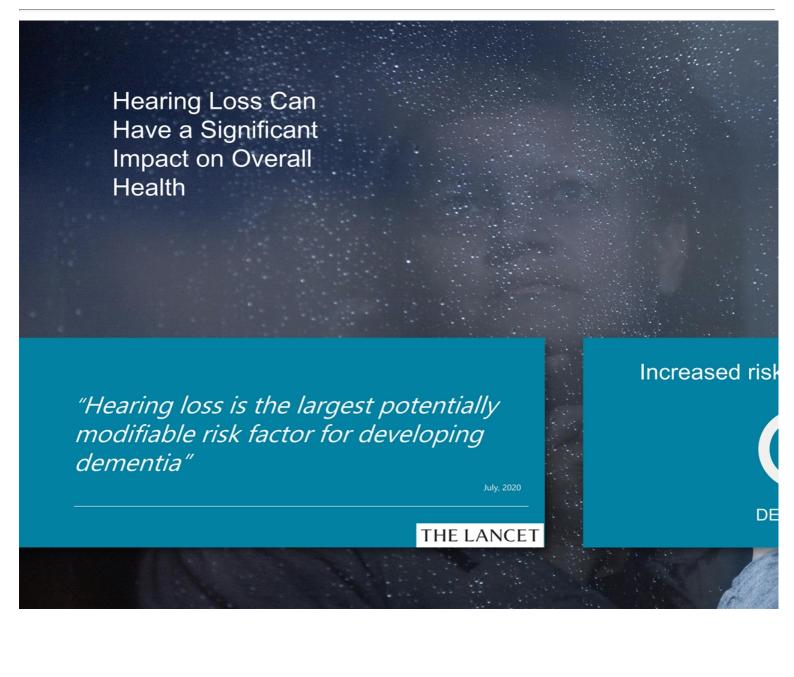
~\$10 Billion



~41 Million
Individuals
with SNHL in
U.S.

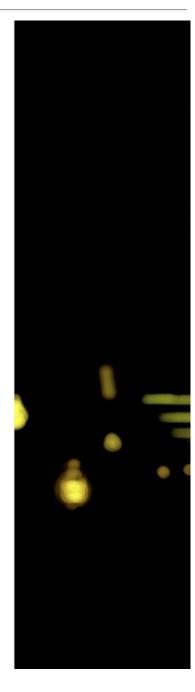
*Source: World Health Organization





Frequency Therapeutics: A Vision Built on Regeneration

Since 2014, Frequency has focused on developing therapeutics by activating a person's innate regenerative potential, within the body, to repair tissue and restore human function.



The Problem: Missing Sensory Hair Cells in the Cochlea

"Analysis of hair cells, auditory nerve fibers and strial tissues ... shows that the degree of hearing loss is well predicted from the amount of hair cell loss."

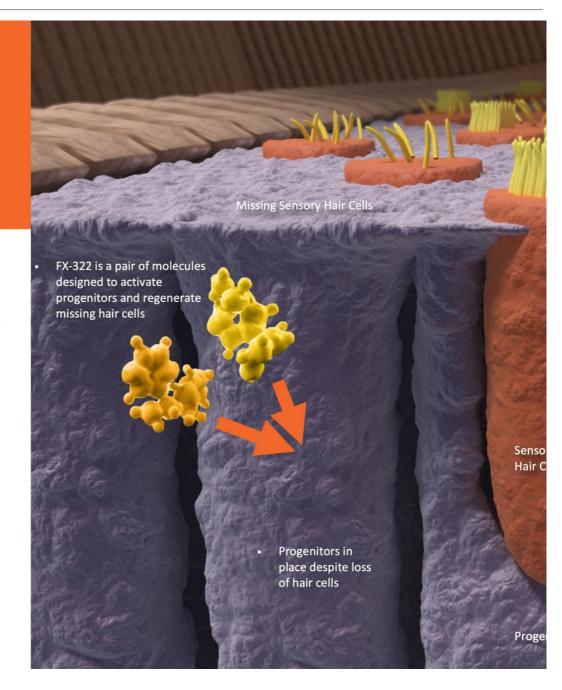
- Journal of Neuroscience

July 2020



Solution: A Therapy to Address the Underlying Pathology

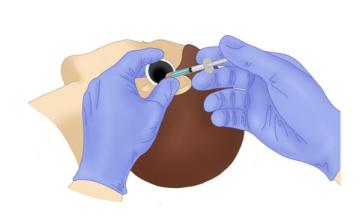
Synergy between pathways aims to activate progenitor cells and regenerate sensory cells in the cochlea

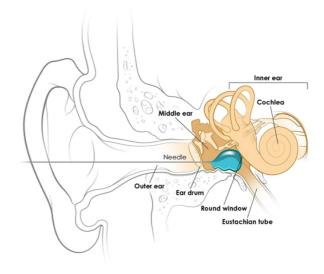


FX-322: Directly Targeting the Regeneration of Sensory Hair Cells in the Cochlea

FX-322 is administered via a standard intratympanic injection, a routine procedure performed by ENTs

The injection of the cochlesispeed





Not to scale- for illustrative purposes only.

Increasing Focus on Hearing Clarity

Audibility (Loudness) measured with pure tone test



Intelligibility (Clarity)
measured with word recognition and
words-in-noise tests



Word Recognition Test

- List of 50 monosyllabic words
- Single words played in quiet

Words-in-Noise Test

- Background noise from multiple voices
- Played at different signal-to-noise ratios

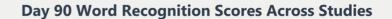
Two Independent Studies (FX-322-201, FX-322-111 Hearing Improvements with Single Dose

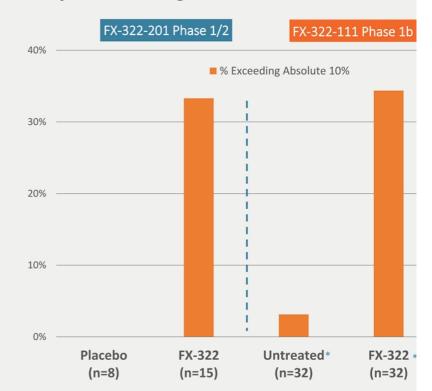
Phase 1/2 Study FX-322-201 Overview

- Placebo-controlled, multi-center, randomized study
- Mild to moderately severe subjects, age 18-65 (n=23)
- NIHL/SSNHL

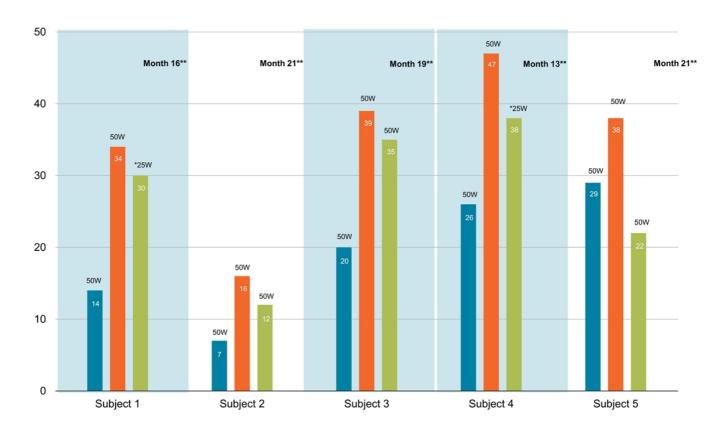
Study Results

- 33% of subjects achieved 10% or greater absolute improvement in word recognition in treated ear
- Statistically significant and clinically meaningful improvements in WR
- No meaningful changes in placebo group
- Favorable safety profile





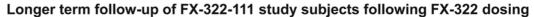
FX-322 Phase 1/2 Durability Data: Patients Show Sustained Improvements 13-21 Months After Initial Dosing



- *25W = 25 Word test performed outside an official study site at 13-18 months after dosing; results scaled to 50 words
- 50W = 50 Word test performed under a formal protocol at original study site at 18-21 months after dosing

**Since FX-322 dosing

New FX-322-111 Phase 1b Data Show that Additional Study Improvements at Later Time Points



25 of 33 study subjects were evaluated at 8-12 months following FX-322 dosing

Potential for FX-322 to result in accumulating hearing benefits over time

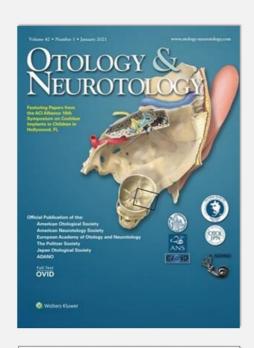
 4 subjects that had shown improvement trends in word recognition scores at day 90, statistically significant scores when tested at the later time points

To date, 9 of 32 evaluated study subjects have shown statistically significant improven word recognition scores in treated ears between 90 days and 1 year

No change observed in their untreated ears

Company will use insights to inform time points for evaluation in future studies and lo term strategy for retreatment

FX-322 Clinical Data Published in Leading Journal



DOI: 10.1097/MAO.0000000000003120

FX-322 Phase 1/2 and drug delivery s

- Improved Speech Intelligibility in Subjects wi Hearing Loss Following Intratympanic Dosing 1b Study (W.J. McLean, et al., et al.,
- · Pre-eminent, peer-reviewed journal in the fie

FX-322 Clinical Profile Informed by Broad Range of Learnin

Phase 1/2 (FX-322-201)	Phase 1b (FX-322-111)	Phase 1b (FX-322-112)	(F
Subjects with mild-to-moderately severe SNHL	Subjects with mild-to-severe SNHL	Subjects with presbycusis (agerelated hearing loss) mild-to-mod. severe	Subjects wit severe SNH
Subjects with Noise-Induced or Sudden SNHL	Subjects with Noise-Induced or Sudden SNHL	NO SUBJECTS with Noise- Induced or Sudden SNHL	Subjects wit Sudden SN
Age 18-65; <i>N</i> =23	Age 18-65; <i>N</i> =33	Age 66-85; <i>N=30</i>	Age 18-65;
Single administration	Single administration	Single administration	Four admini regimen
•Double-blind, placebo controlled, multi-center, randomized study	Open-label, multi-center, randomized study FX-322 injected in one ear – contra lateral ear acted as control	Placebo controlled Multi-center, randomized	Double-bling multi-center
•Clinically meaningful and statistically significant improvements in word recognition scores in patients with measurable word recognition deficits	•Clinically meaningful and statistically significant improvements in word recognition scores In patients with measurable word recognition deficits	No significant treatment effect observed with FX-322 compared to placebo No response in placebo groups or in untreated ears	Unexpected (WR) scored suggests because of relified terms and the suggests because the s
Favorable safety and tolerability profile	Favorable safety and tolerability profile	Favorable safety and tolerability profile	Favorable s profile

© Frequency Therapeutics, Inc.

[Detail from subjects across all single-dose studies will provide key insights into po

Next Steps for Continued FX-322 Clinical Developmer

Clinical data demonstrate potential of FX-322 as a restorative treatment for SNHL

- Two FX-322 single administration studies have demonstrated treatment benefit
- Favorable safety profile

Important learnings informing continued FX-322 development

- Understanding specific populations where FX-322 demonstrates benefit
- Lead-in baseline assessments and other controls may mitigate study design bias
- Build off totality of study subject data

Remyelination Program for Multiple Sclerosis

Repair of neurological damage is the major unmet need in MS

- Currently approved immunomodulators do not restore myelin
- Remyelination of damaged neurons has potential to reverse neurological damage
- Target population for remyelination represents 50% of MS patients

Using PCA approach to address restoration in MS patients

- Pre-clinical data has demonstrated potential to remyelinate with proprietary small molecule combinations
- Research efforts underway to confirm optimal combination of molecules for clinical program
- · Strong IP portfolio

Frequency: Developing a Platform Approach that Rethe Complexity of Regenerative Medicine



Harnessing
Innate Biology
Progenitors
already
located within
target tissue



No Change to Genome Activating native programs, reducing safety concerns

Summary and Financial Profile



Two Single Dose FX-322 Studies Show Hearing Improvements

Statistical significance in key measures of hearing clarity



Defining FX-322 Path and Advance

Continued clinic developme



\$175.5 Million in Cash and Cash Equivalents*

Runway into 2023



Ex-US Part Strong Poten and Ro



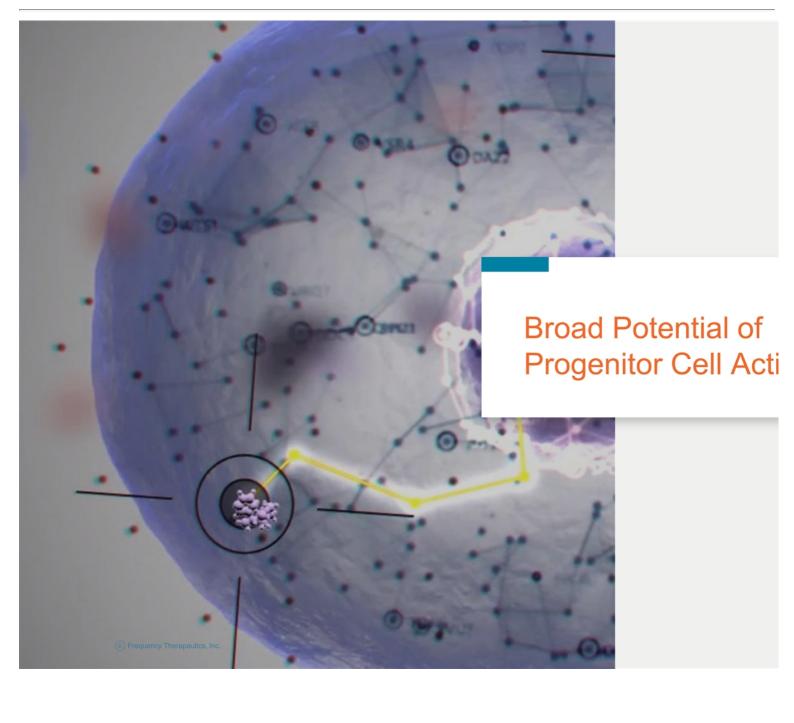
*As of March. 31, 2021. Excludes restricted cash

EXAMPLE 1R&D Event for Inverteguency Therapeuti

Tuesday, November 9th 8:00am - 10:00am ET Details available at investors.frequencytx.cor







Origin of Frequency Therapeutics



Decoding Intestinal Regeneration

Langer and Karp publish small molecules activate intestinal progenitors



Niche-independent high-purity cultures of Lgr5+ intestinal stem cells and their progeny



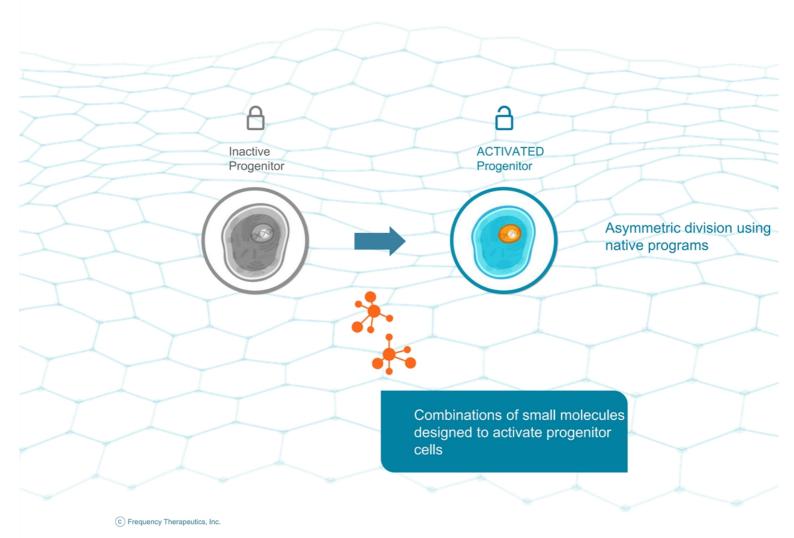
Enabling Cochlear Regeneration

Same cues reactivate normally inactive progenitors in the cochlea

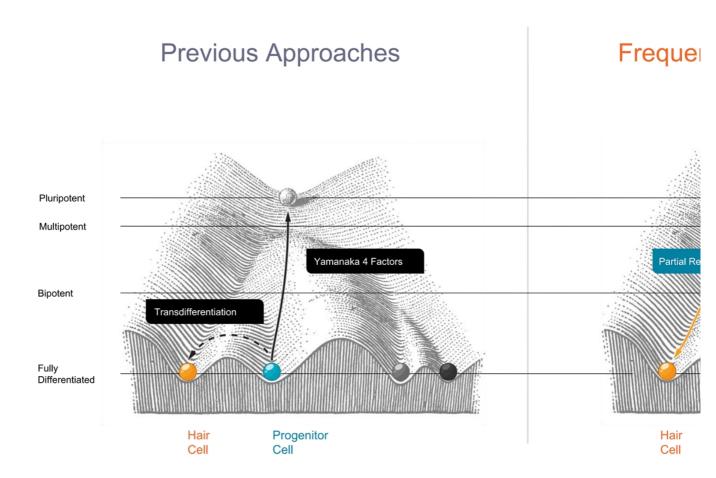


Clonal Expansion of Lgr5-Positive Cells from Mammalian Cochlea and High-Purity Generation of Sensory Hair Cells

Frequency Progenitor Cell Activation (PCA) Approac



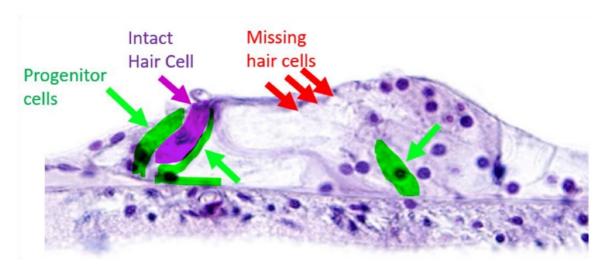
Uniqueness of Our PCA approach



[©] Frequency Therapeutics, Inc.

Our Approach: Activation of Progenitors to Replace Hair Cell Loss

Despite Hair Cell Loss, Progenitor Cells Remain



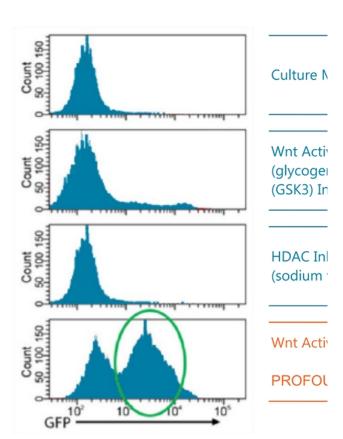
Human Cochlea Cross-section

47 Year Old Male with Occupational Noise Deafness

Profound Synergy Between Pathways to Regenerate

Cochlear Progenitor Proliferation (Lgr5-GFP)

HDAC = Histone deacetylase NCE = new chemical entity In vitro mouse model testing



Strong FX-322 Pre-Clinical Validation

Test	Outcome
In vitro	
Adult human inner ear tissue	 Created new hair cell
In vivo	
Adult deafened mice	 Restored hair cells ar across all frequencies
Therapeutic drug levels	 Achieved active level cochlea in multiple sp

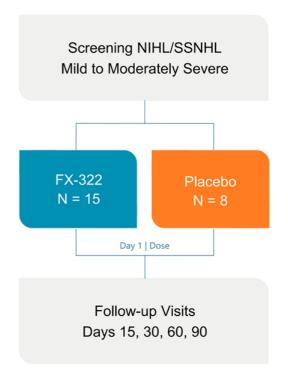
[©] Frequency Therapeutics, Inc.



FX-322: Robust Clinical Phase 1/2 Design

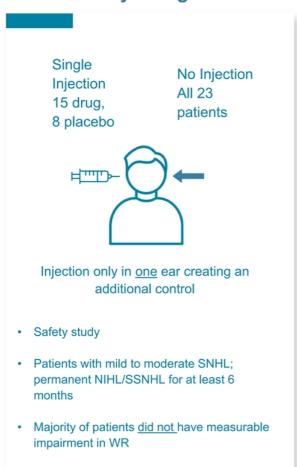
Study Overview

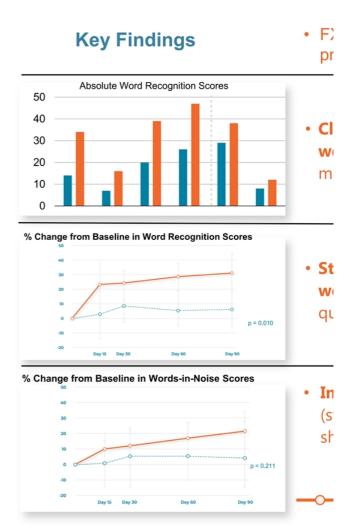
- Assess safety in patients with sensorineural hearing loss
- · Stable patients
- Evaluated hearing by word testing and pure tones



Recap: Completed FX-322 Phase 1/2 Safety Study

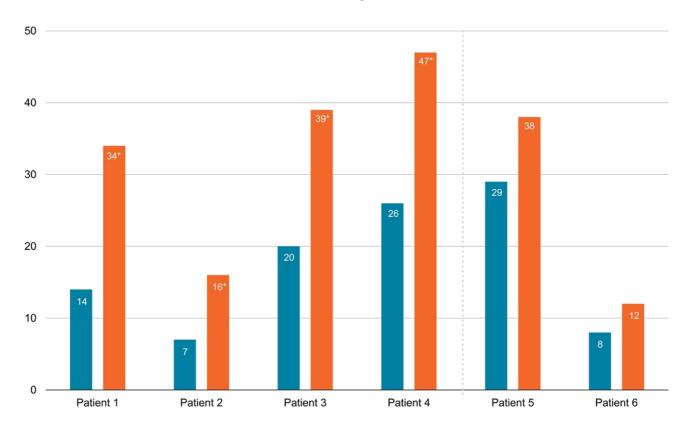
Study Design





First Drug Candidate to Show Clinically Meaningful Improvements in Word Recognition

Absolute Word Recognition Scores



Phase 1/2 Study Results: Sustained Improvements i Sound Clarity

Statistically Significant Improvement in Sound Clarity (Words-in-Quiet)



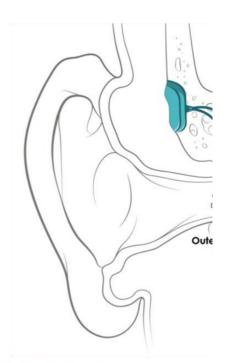
[©] Frequency Therapeutics, Inc.

Clinical Data Confirms FX-322 Delivery to Cochlea

Exploratory study to determine direct measurement of cochlear drug levels in patients undergoing cochlear implant surgery following FX-322 injection

Key Findings:

- Measurement of cochlear fluid confirmed successful drug delivery to cochlea in all samples analyzed
- Drug levels predicted to result in therapeutic activity



Taken together with the clinical study results, we believe this is the first known clinical evidence of a pharmacokinetic / pharmacodynamic effect of a potential hearing restoration therapeutic

End of Phase 2a Study Conclusions*

There was an unexpected increase in WR scores in the placebo group, which did not or previous FX-322 trials and exceeded well-established published standards. Potentially suggesting bias due to trial design

As a result of unreliable baseline WR scores in the placebo group due to potential trial bias, the Company was unable to evaluate hearing improvements in WR scores for FX-dosing regimens versus placebo.

Four weekly injections of FX-322 did not demonstrate improvements in any other hea measures versus placebo

FX-322 continues to have a favorable safety and tolerability profile.

Although there was a higher rate of AEs noted in this 4x dosing trial, there were no treatment-associated serious adverse events observed and no patients withdrew from study due to treatment-associated AEs.

Pipeline

Sensorineural Hearing Loss (SNHL)

FX-322 Phase 2a – 202 Study

Study of noise induced and sudden SNHL patients with mild to moderately severe acquired SNHL, ages 18-65

FX-322 Phase 1b – 111 Study

Open-label safety study focused on administration conditions for FX-322. Subjects had mild to severe SNHL, ages 18-65

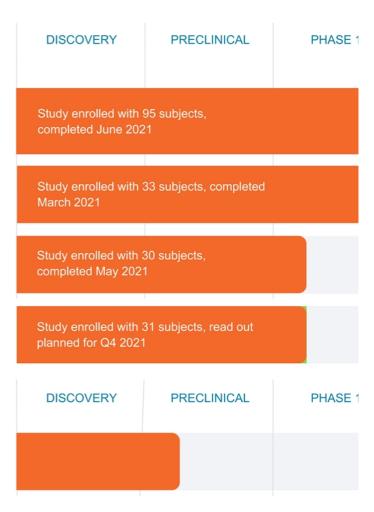
FX-322 Phase 1b - 112 Study

Study of (presbycusis (age-related hearing loss patients) ages 66 - 85

FX-322 Phase 1b – 113 Study

Study of patients with severe SNHL, ages 18-65

Remyelination in Multiple Sclerosis*



^{*}We established an internal research program using PCA to drive remyelination as a potential therapy for MS and have identified compoun promising preliminary preclinical results in an *in vivo* model of remyelination.

Astellas Collaboration: Ex-US Development and Commercialization of FX-322

- Development and commercialization collaboration for FX-322, including lifecycle improvements
- Astellas has ex-US rights; Frequency retains US rights to FX-322
- Payments of up to \$625mm which included \$80mm upfront
 - Development milestone payments to Frequency of \$65.0 million and \$25.0 million upon the first dosing of a patient in a Phase 2b clinical trial for SNHL in Europe and Asia, respectively
 - \$100.0 million and \$40.0 million upon the first dosing of a patient in a Phase 3 clinical trial for SNHL in Europe and Asia, respectively
- Development & commercialization:
 Astellas responsible for execution and costs of ex-US clinical development and commercialization



Proven Leadership Team

David Lucchino

President, CEO & Co-Founder

Former CEO of Entrega Bio (PureTech). Co-founder/CEO of Semprus BioSciences (acquired), Polaris Partners. MIT Sloan Fellow.

Chris Loose, Ph.D.

Chief Scientific Officer & Co-Founder

Co-founder/CTO of Semprus BioSciences through FDA/CE clearance and acquisition. Princeton, MIT, Hertz Fellow and Yale Faculty.

Dana Hilt, M.D.

Chief Medical Officer

Neurologist and neuroscientist with two decades in biopharma and CNS drug development. Amgen, Lysosomal, Forum Pharma.

Carl Lebel, Ph.D.

Chief Development Officer

Chief Scientific Officer of Otonomy (2009 to 2016). Executive Director, Amgen. Scientific fellow of the American Academy of Otolaryngology.

Wendy Arnold

Chief People Officer

HR leader with extensive life science experience including senior leadership roles at Kaleido Biosciences, Moderna, Celgene Avilomics Research, and Inotek Pharmaceuticals

Quentin McCubbin, Ph.D.

Chief Manufacturing Officer

Led pharmaceutical sciences and process chemistry at Takeda/Millennium and headed technical operations Cerevel Therapeutics.

Scientific Advisory Board

Clinical Advisory B



Jeff Karp, Ph.D. Associate Professor at Brigham and Women's Hospital, Harvard Medical School



SC.D.

David H. Koch Institute

Professor at the

Massachusetts Institute

of Technology

Robert Langer,



Ph.D.
Professor of Stem Cell
Medicine,
Wellcome Trust-MRC
Cambridge
Stem Cell Institute

Robin Franklin,



Sheng Ding,

Ph.D.
Senior Investigator,
Gladstone
Institute of
Cardiovascular Disease



Dan Lee, M.D. Director, Pediatric Otology and Neurotology, Mass Eye and Ear



Ph.
Assc
Pedi
Direc
Impl
Vanc



Morrison, Ph.D.

Director of the
Children's Medical
Center Research
Institute,
UT Southwestern

Sean J.



Mukherjee, M.D., D.Phil. Assistant Professor of Medicine, Columbia University

Medical Center

Siddhartha



Amy Wagers,

Ph.D.
Forst Family Professor of
Stem Cell and
Regenerative Biology,
Harvard University



Ph.D.
Chief of the Division of Communication
Sciences, Medical
College of Wisconsin

Chris Runge,



Me

Jo

