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): December 9, 2021

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

Delaware	001-39062	47-2324450
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

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

(781) 315-4600
(Registrant's telephone number, include area code)

N/A
(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 (see General Instructions A.2 below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**FREQ**	**The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)**

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

Emerging growth company ☒

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

Item 7.01. Regulation FD Disclosure.

On December 9, 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 December 9, 2021, the Company announced the results from its FX-322-113 study, a placebo-controlled trial evaluating the administration of FX-322 in subjects with severe sensorineural hearing loss (SNHL). In the study, FX-322 was associated with a hearing signal as shown by improvements by four subjects in a sentence-in-noise test.

FX-322-113 is a double-blind, placebo-controlled Phase 1b study designed to assess the local and systemic safety of a single dose of FX-322, and to evaluate hearing responses in a cohort of individuals with severe SNHL (pure tone average deficit between 71-90 decibel (dB) hearing level), a patient population that may have considerable damage to their inner ears and where cochlear implants may be the only potential intervention to improve hearing. Subjects were randomized 4:1 and received either FX-322 or placebo in one ear. Safety, otologic and audiologic assessments were conducted at days 30 and 90 following administration of FX-322 or placebo.

To gain a more comprehensive understanding of the potential impact of FX-322 in this population, the Company evaluated hearing function using multiple tests of speech perception in both quiet and noisy backgrounds, including the Bamford-Kowal-Bench Sentence-in-Noise exam (BKB-SIN). BKB-SIN is a validated test designed for severe SNHL populations (including cochlear implant patients), measuring the change in signal-to-noise ratios (SNR) required for a subject to correctly repeat words in a sentence.

In the FX-322-113 study, BKB-SIN test improvements were observed in four subjects, all of whom exceeded the 95 percent critical difference of 3.1dB SNR, with two subjects showing a 6dB response. A single placebo patient had a 3.6dB change. In the study, subjects did not show substantial changes in speech perception measures in quiet, the safety profile in the study was favorable and there were no treatment-related serious adverse events reported.

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 interpretation and implication of the results and learnings of FX-322-113.

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 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 PCA platform; the lengthy, expensive and uncertain process of clinical drug development and regulatory approval; the Company's 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; ability to seek and receive Breakthrough Therapy designation for FX-322; the Company's ability to enroll and retain patients in clinical trials; 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 commercialization 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 candidates; compliance with changing laws and regulations, including healthcare and environmental, health, data privacy and safety laws and regulations; failure to obtain, maintain and enforce protection of patents and other intellectual property rights covering product candidates; security breaches or failure to protect private personal information; attracting and retaining key personnel; and the Company's ability to manage growth.

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 November 15, 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 exhibits relate to Items 7.01, and shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Frequency Therapeutics, Inc. Corporate Slide Presentation as of December 9, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FREQUENCY THERAPEUTICS, INC.

Date: December 9, 2021

By: /s/ David L. Lucchino
Name: David L. Lucchino
Title: President and Chief Executive Officer

Exhibit 99.1

Pioneering a New Category in Regenerative Medicine

Frequency Therapeutics Corporate Presentation

December 2021

FREQUENCY THERAPEUTICS

Forward-Looking Statements and Other Disclaimers

FREQUENCY THERAPEUTICS

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 timing and design of the new Phase 2b trial of FX-322, including the type of SNHL that the enrolled patients will have and the ability of design features to reduce bias, the interpretation and implications of the results and learnings of other FX-322 clinical studies, the acceptance by the FDA of particular endpoints in the Company's trials, the treatment potential of FX-322, FX-345, and the novel approach for remyelination in multiple sclerosis, the timing and progress of the FX-345 and remyelination programs, 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 ability of our technology platform to provide patient benefit, 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 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, intellectual property or brought by stockholders; dependence on Astellas Pharma Inc. for the development and commercialization 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 candidates; compliance with laws and regulations, including healthcare and environmental, health, and safety laws and regulations; failure to obtain, maintain and enforce protection of patents and other intellectual property; security breaches or failure to protect private personal information; attracting and retaining key personnel; and ability to manage growth.

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 November 15, 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 presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. 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 presentation.

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.

Power of the Progenitor Cell Activation (PCA) Platform

FREQUENCY THERAPEUTICS

No Change to Genome

Activating native programs, reducing safety concerns

Harnessing Innate Biology

Progenitors already located within the target tissue

Ease of Manufacturing

Use of small molecules: no need to remove or grow cells *ex vivo*

A Series of Firsts in Hearing Restoration

FREQUENCY THERAPEUTICS

First PK/PD shown for a hearing therapeutic candidate

First clinical studies to show hearing improvements

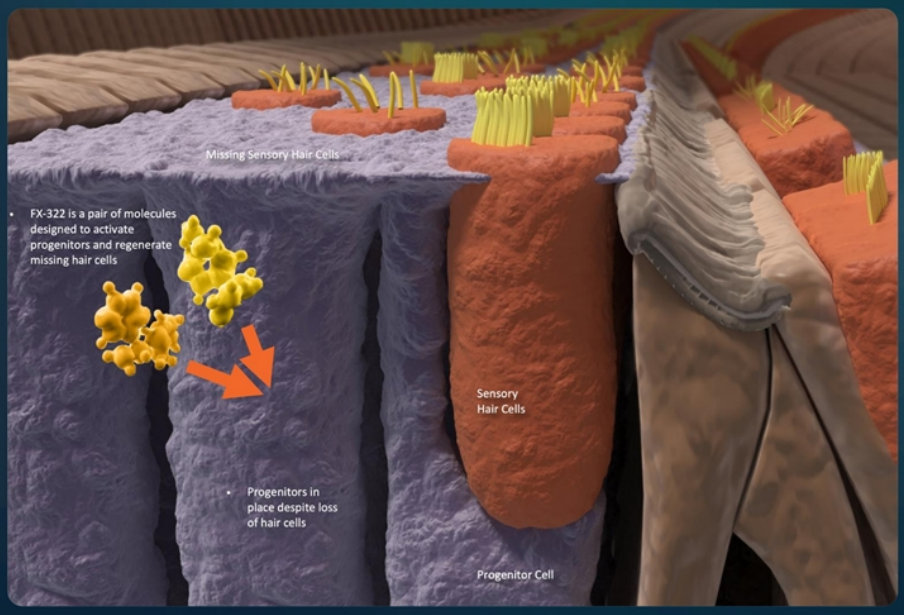
First speech perception improvements measured

First to show sustained improvements and continued improvements over time

FX-322:
A Small Molecule Candidate to Address the Underlying Pathology

FREQUENCY THERAPEUTICS

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

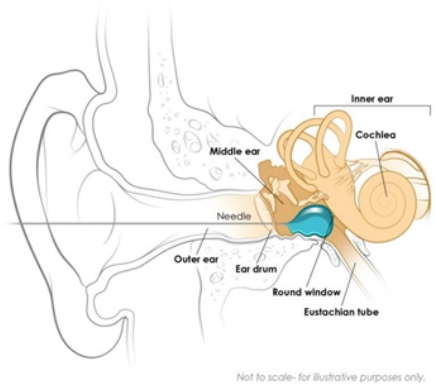


FX-322:

Directly Targeting the Regeneration of Sensory Hair Cells in the Cochlea

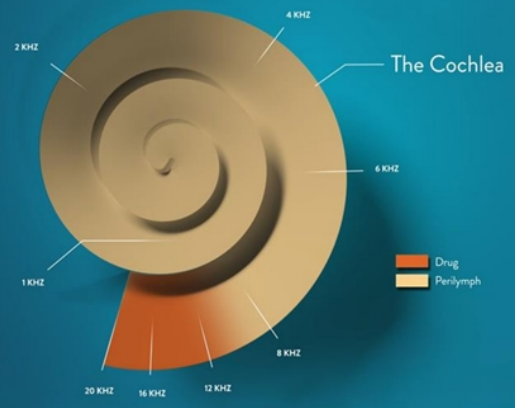
FREQUENCY THERAPEUTICS

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



Not to scale- for illustrative purposes only.

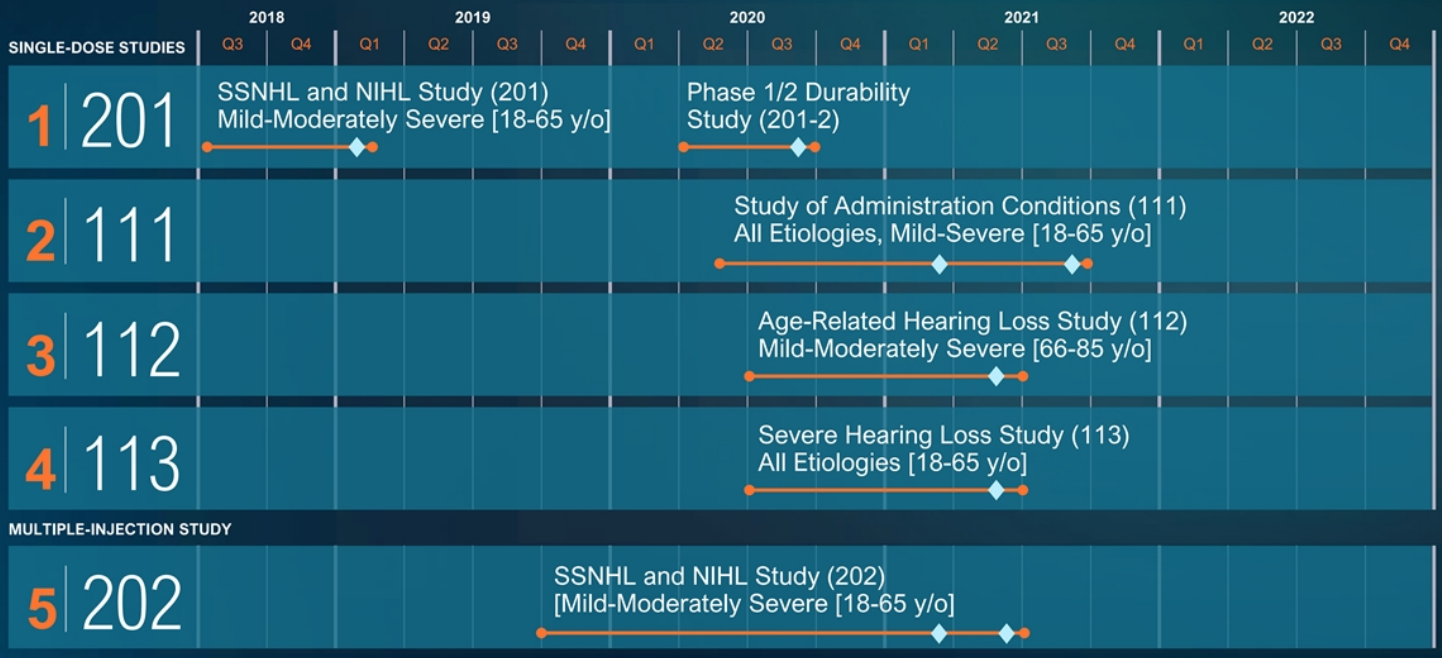
The injection concentrates FX-322 in the cochlear region critical for speech intelligibility



Five FX-322 Completed Studies: 193 Treated Subjects

Favorable Safety Profile with No Treatment-Related SAEs

FREQUENCY THERAPEUTICS

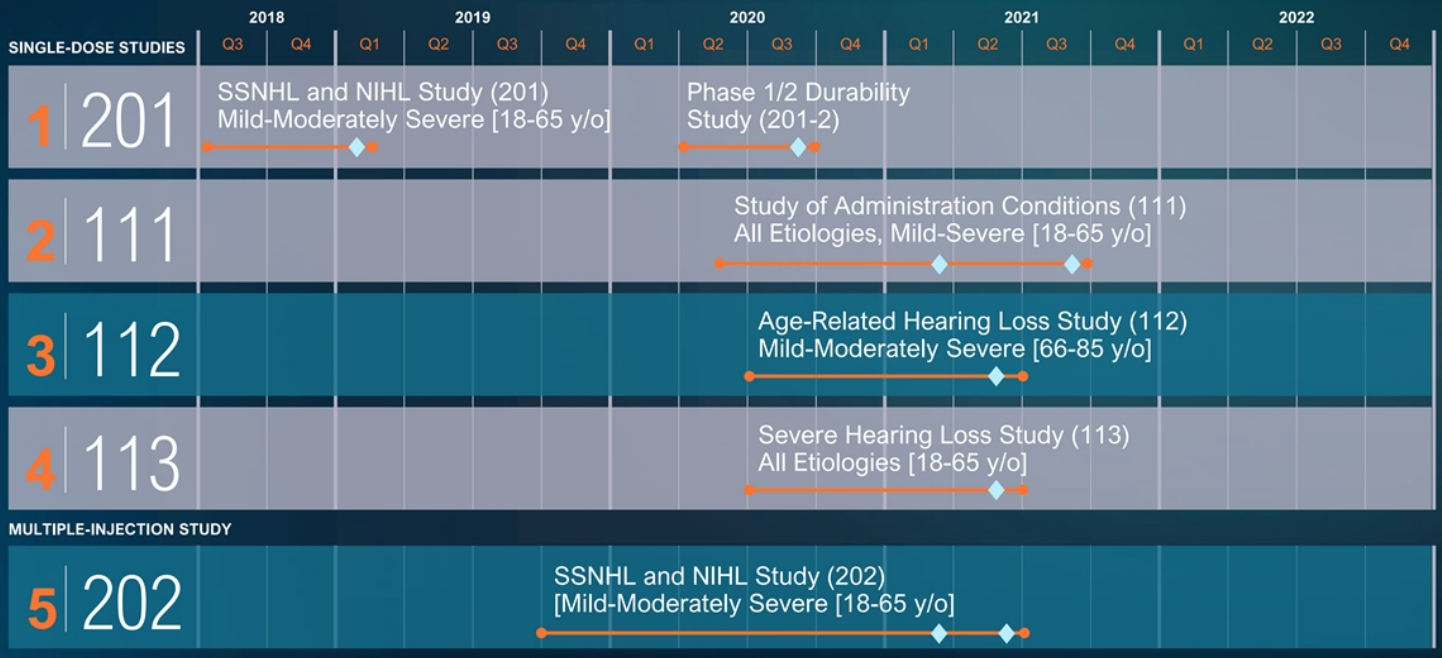


◆ = Data Readout

FX-322-201, FX-322-111, FX-322-113

Single-Dose Safety Studies with Hearing Improvement Signal

FREQUENCY THERAPEUTICS



◆ = Data Readout

Data from Controlled Studies (FX-322-201, FX-322-111)

Improvement Shown in Speech Perception in Quiet with Single Dose

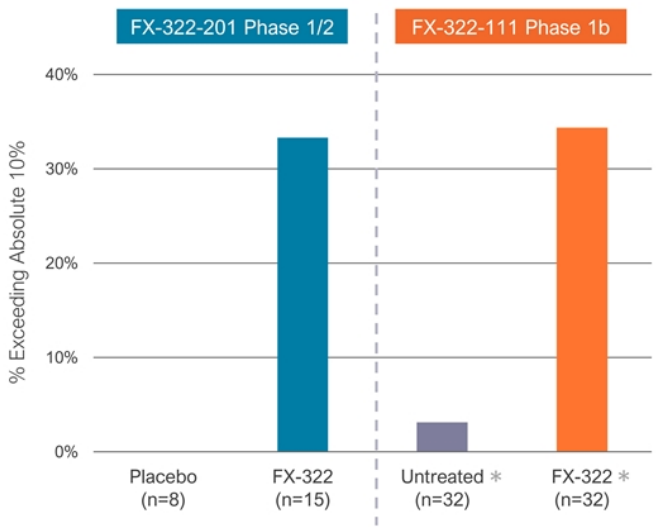
FREQUENCY THERAPEUTICS

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



Phase 1b Study FX-322-111 Overview

- Compared different FX-322 administration conditions
- Open-label, multi-center, randomized study
- Mild to severe subjects, age 18-65 (n=33)

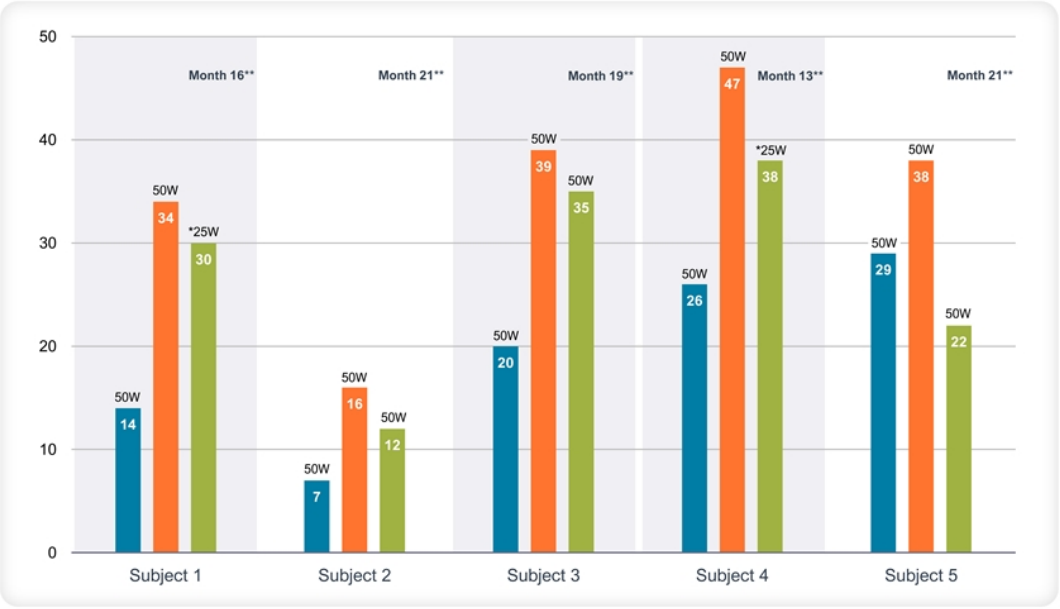
Study Results

- 34% of subjects achieved 10% or greater absolute improvement in word recognition (WR) in treated ear
- Statistically significant *and* clinically meaningful improvements in WR
- Favorable safety profile

**Total of 33 patients enrolled in study, 32 subjects completed 90-day clinical assessment period*

FX-322 Phase 1/2 Durability Data:

Patients Show Sustained Hearing 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

Key Findings

Preliminary evidence indicating a durable benefit of hearing clarity

Baseline - Correct words out of 50

Day 90 - Correct words out of 50

1-2 Years - Correct words out of 50

Three patients who had durable improvements in intelligibility also had pure tone audiometry improvements of 10 – 15 dB at the highest frequency tested (8k Hz)

Subjects in FX-322-111 Study Show Additional Hearing Improvements at Later Time Points

FREQUENCY THERAPEUTICS

Conducted longer-term, follow-up of FX-322-111 study subjects

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

Results show some FX-322 dosed subjects accumulated hearing benefits over time

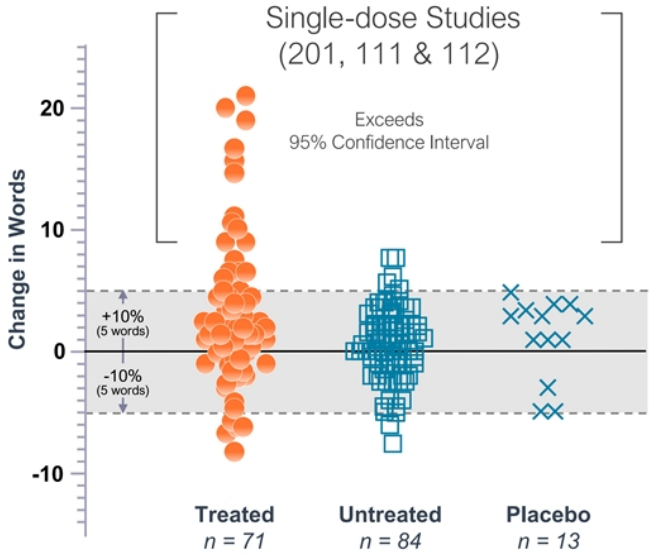
- 4 subjects that had shown improvement trends in word recognition scores at day 90, achieved statistically significant scores when tested at the later time points

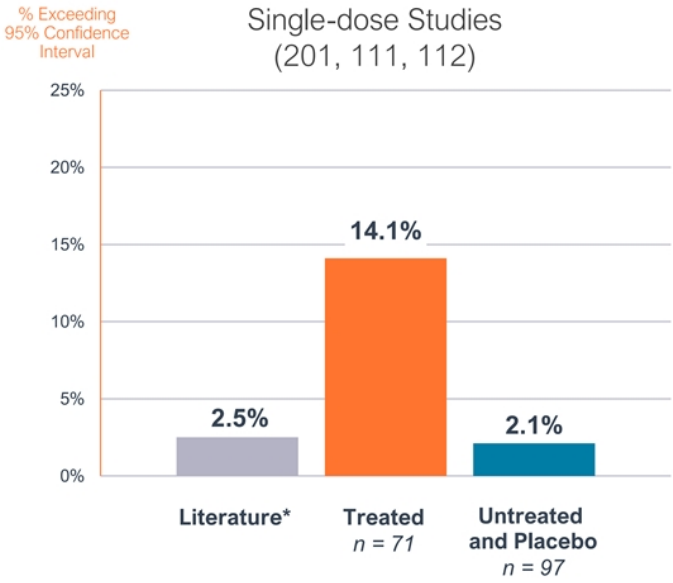
To date, 9 of 32 evaluated study subjects have shown statistically significant improvements in speech perception scores in treated ears between 90 days and 1 year

- No change observed in untreated ears

Pooled FX-322 Data Shows Patterns of Response

Single-dose Studies (201, 111, 112) Exceed 95% Confidence Interval





95% confidence intervals established by Thornton & Raffin (1978) and modified by Carney & Schlauch (2007)

FX-322-113: Hearing Signal and Speech Perception Improvements Observed in Subjects with Severe SNHL

FREQUENCY THERAPEUTICS

Double-blind, placebo-controlled study of 31 individuals randomized 4:1

- Pure tone average deficit between 71-90 decibel hearing level (dBHL)
- Potential cochlear implant candidates

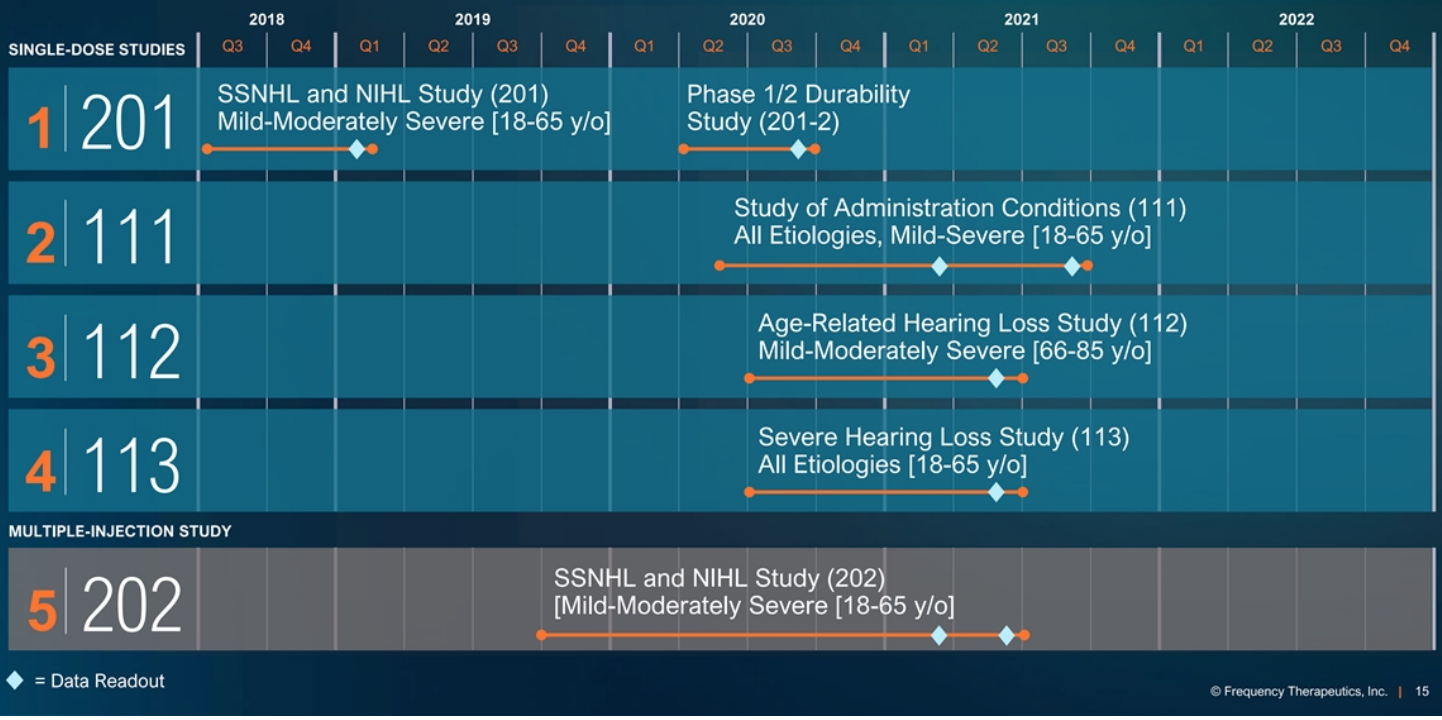
Improvements in Bamford-Kowal-Bench Sentence-in-Noise exam (BKB-SIN) observed in treated ears

- BKB-SIN measures signal-to-noise ratios required for subjects to correctly repeat words in sentences
- Four FX-322 treated subjects show improvement, two with a 6 db response
- A single placebo subject showed a 3.6 db change
- Improvements consistent with cochlear implantation
- No improvements observed in words-in-quiet

Favorable safety profile

- No treatment-related SAEs

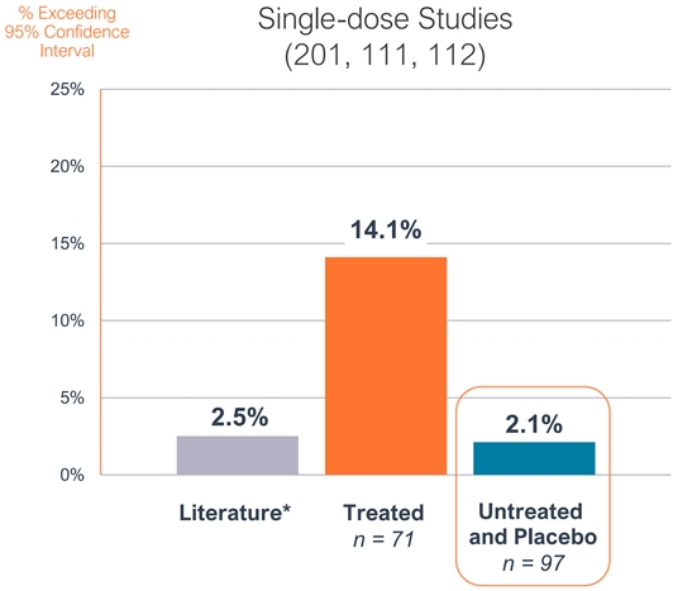
FX-322-202: Multiple Injection Study Impacted by Inconsistent Baseline Measures

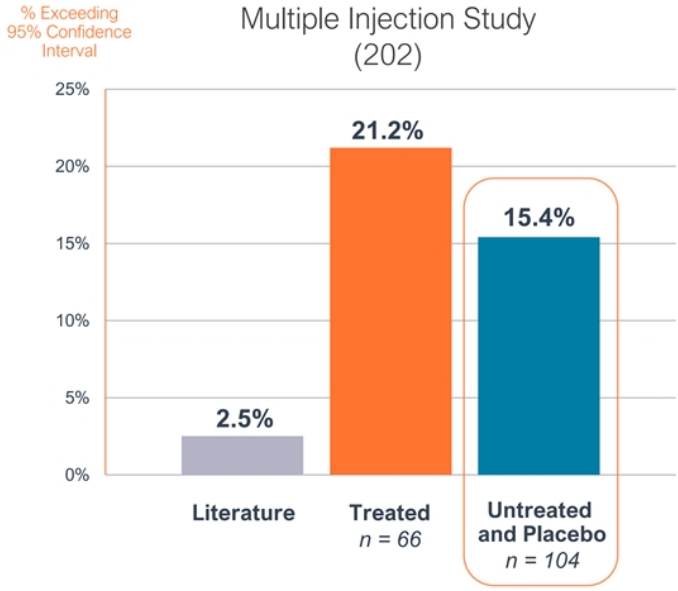


◆ = Data Readout

Comparing Pooled Data to Multiple-Injection Study FX-322-202

Placebo-Treated and Untreated Ears are Outside 95% Confidence Interval





95% confidence intervals established by Thornton & Raffin (1978) and modified by Carney & Schlauch (2007)

Clinical Study Data Informs New FX-322 Phase 2b Study

New Clinical Study FX-322-208 Designed to Advance Drug Candidate to Pivotal Trials

FREQUENCY THERAPEUTICS

Built upon insights from trials with hearing restoration signal

Etiology, severity, baseline speech perception

Sufficient sample size to demonstrate efficacy

Approach based on pooled data

Primary endpoint of speech perception

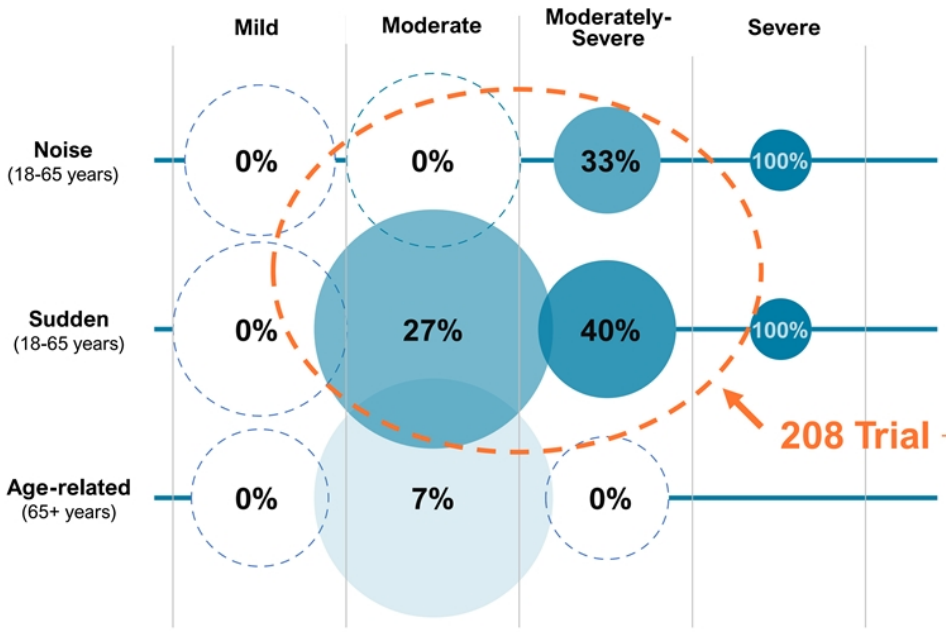
Reduce potential for bias

Multiple baseline measures

Multiple speech perception tests

Pooled Single-Dose Studies (201, 111, 112)

Data Suggest Patterns Between Etiology/Severity and Response



71 Treated
with single-dose
of FX-322

The size of each circle represents the number of people tested per group

The color of the circle represents the percentage of responders

208 Trial: Target Population

7-10 Million
U.S. patients

FX-322: Extended Population

15+ Million
U.S. patients

Multiple Design Features Have Been Added to Mitigate Bias

And Demonstrate Greater Separation Between Signal and Placebo

- **Lead-in phase with multiple baseline measures**
- **Sites and patients masked to qualifying test results**
- **All sessions recorded and monitored**
- **Ability to disqualify subjects based on symptom stability**

New FX-322 Placebo-Controlled Phase 2b Study Commenced

First patient dosed in FX-322-208 Study in October 2021

124 Subjects

Subjects will have diagnosed noise induced or sudden sensorineural hearing loss

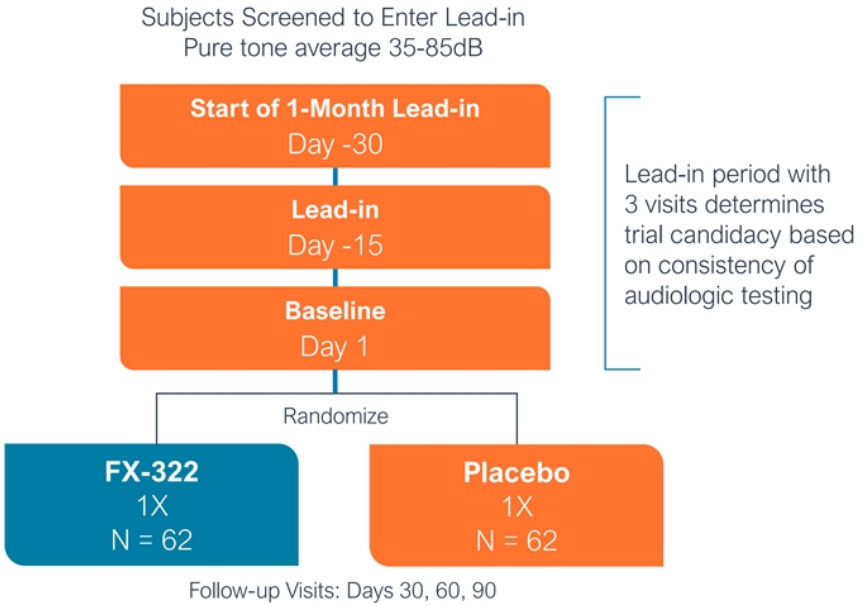
Ages 18 – 65

124 subjects assumes 10% attrition

Study powered at 80%

Effect size 20% over placebo

Significance level is 0.05



FDA Type C Meeting Held to Gain Alignment

ALIGNMENT

Primary Endpoint

Gained alignment with FDA on speech perception as the primary endpoint

208 Study Design

FDA reviewed and commented on 208 study, comments were incorporated into study protocol

Patient Reported Outcomes (PRO)

FDA feedback provided on novel PRO development called **RADIAL**; special meeting granted for further discussion

Today's Hearing Loss Market Has No Restorative Treatments

FREQUENCY THERAPEUTICS

Market penetration for hearing aids

US hearing aid market annual sales

Individuals with SNHL in U.S.

Lost annually due to untreated hearing loss globally*

*Source: World Health Organization

Hearing Loss Can Have a Significant Impact on Overall Health

FREQUENCY THERAPEUTICS

THE LANCET
July, 2020

"*Hearing loss is the largest potentially modifiable risk factor for developing dementia*"

JAMA
November, 2018

Increased risks with untreated hearing loss

Dementia

Depression

JAMA Nov 8, 2018, Deal J, et al. Incident Hearing Loss and Comorbidity. A Longitudinal Administrative Claims Study.

Pipeline Expansion

New Regenerative Program

FREQUENCY THERAPEUTICS

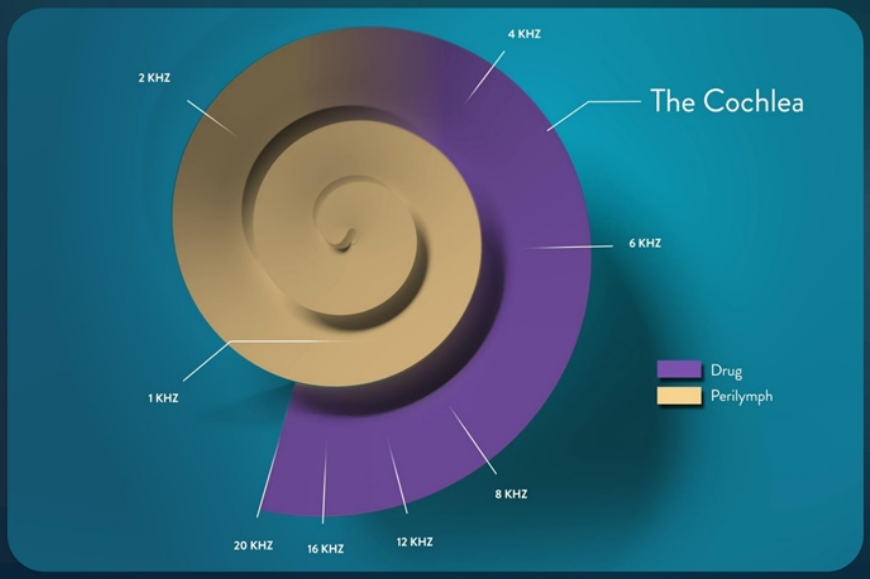
What if we were able to get drug deeper into the cochlea?

FX-345

Working to Achieve Broad Exposure Through the Cochlea

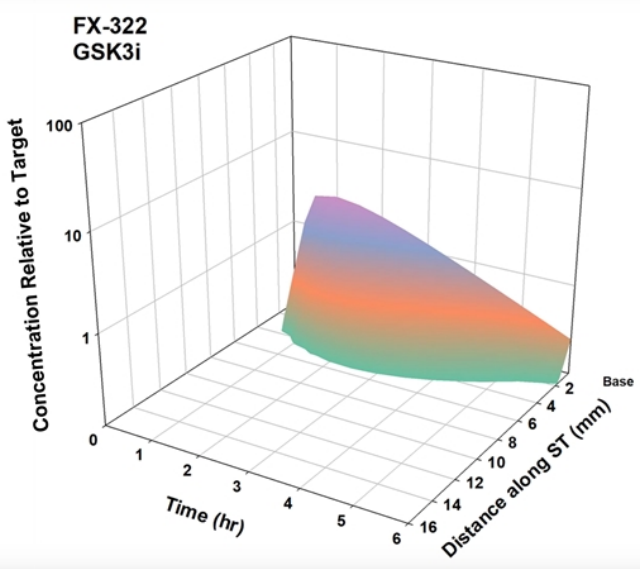
FREQUENCY THERAPEUTICS

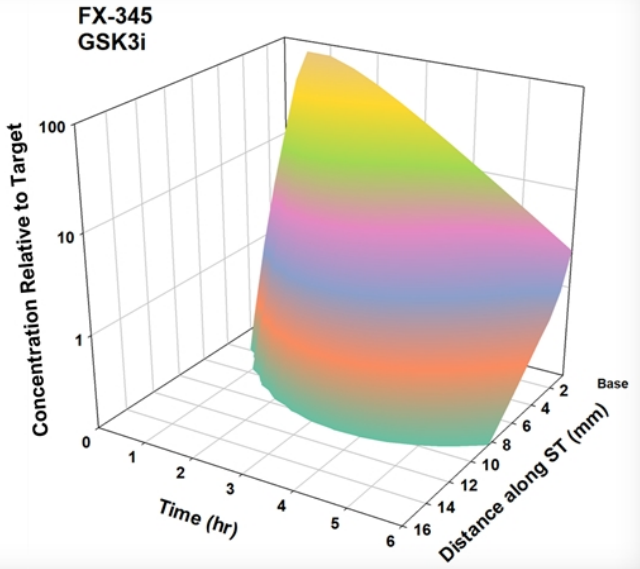
- Second clinical program focused on regrowth of sensory cells
- Enables coverage of large portion of cochlea
- Potential to address additional SNHL patient types
- Formulation enabling evaluation of a range of dose levels
- Developing in addition to FX-322. Clinical data will drive commercial positioning



FX-345 – A New Development Candidate

Creating Effective Drug Levels Through Large Portion of Cochlea





FX-345 Path to Clinic

FREQUENCY THERAPEUTICS

IND planned for H1:2022 for a Phase 1b study in patients with SNHL

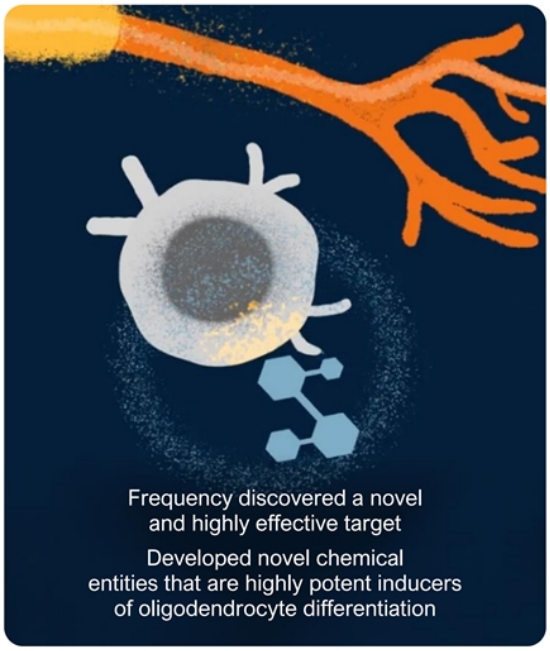
Enables us to clinically evaluate increased cochlear coverage across range of doses in multiple patient populations

New Regenerative Program

FREQUENCY THERAPEUTICS

What if we could extend our approach to other degenerative diseases?

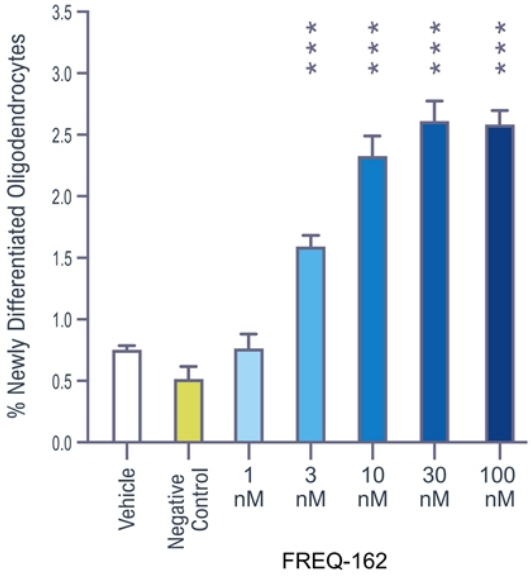
Novel Frequency Small Molecule Inhibitors Drive Oligodendrocyte Differentiation



Frequency discovered a novel and highly effective target

Developed novel chemical entities that are highly potent inducers of oligodendrocyte differentiation

Lead Optimization generated FREQ-162

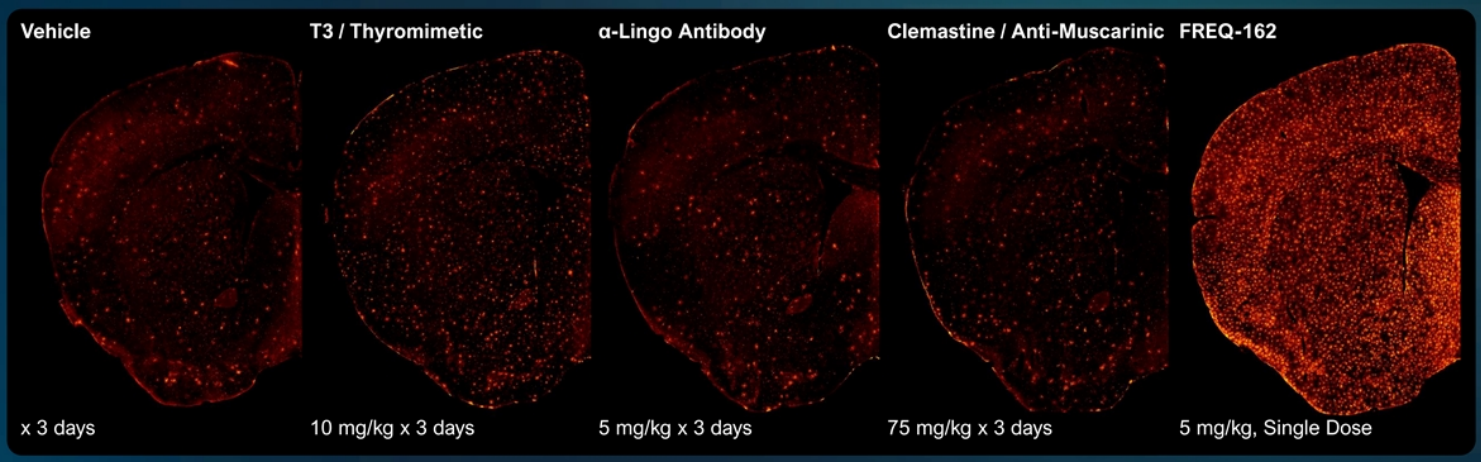


- Highly potent
- Highly efficacious
- Orally bioavailable
- Brain penetrant
- Novel chemical entity
- Patent application filed

FREQ-162 Outperforms Literature Compounds *In Vivo*

FREQUENCY THERAPEUTICS

Adult mice received 3 doses of comparator compounds or a single dose of FREQ-162
Brains were stained for a marker of newly generated oligodendrocytes
Single dose FREQ-162 induces more OPCs to differentiate than comparator compounds

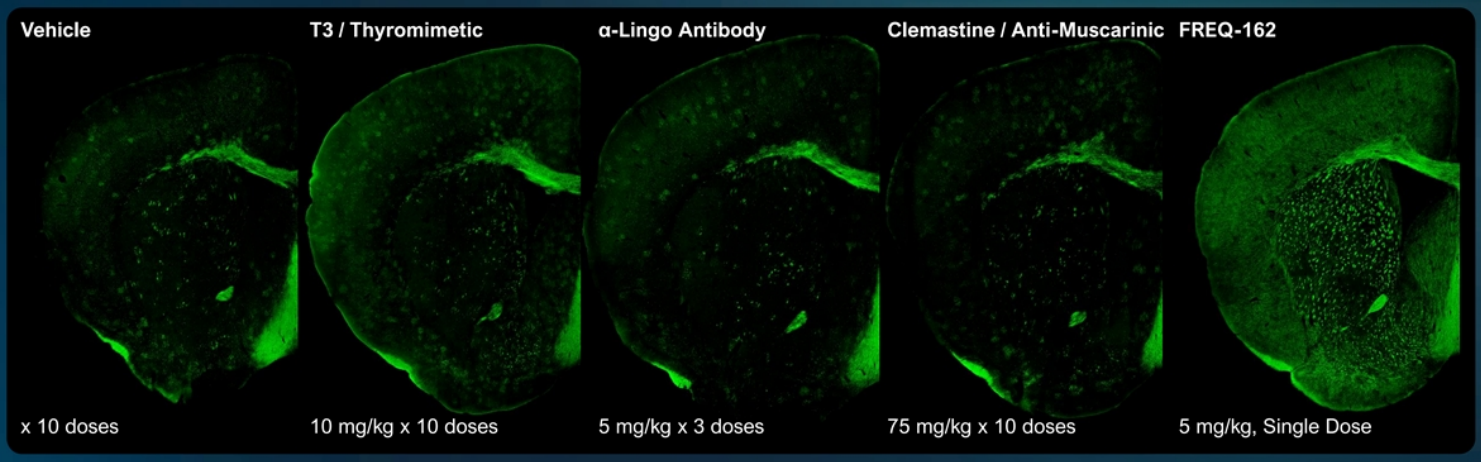


	Thyroid Hormone: Thyromimetic Class	α-Lingo antibody: Blocking antibody	Clemastine: Anti-Muscarinic Class	FREQ-162 induces formation of newly differentiated oligodendrocytes in both white and gray matter

FREQ-162 Outperforms Published Compounds *In Vivo*

FREQUENCY THERAPEUTICS

Adult mice received up to 10 daily doses of comparators or a single dose of FREQ-162
Brains were stained for Myelin Basic Protein (green)
Single dose FREQ-162 induces more remyelination than comparator compounds



Thyroid Hormone:
Thyromimetic Class

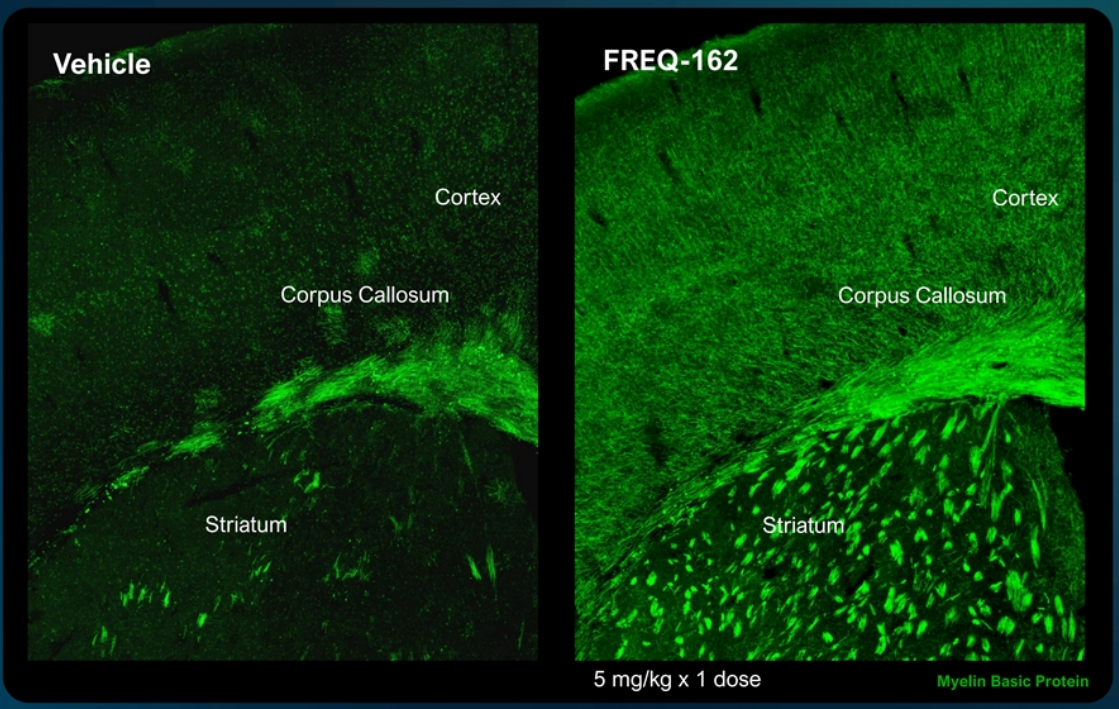
α-Lingo antibody:
Lingo inhibitor

Clemastine:
Anti-Muscarinic Class

FREQ-162 induces formation of new myelin in white and gray matter

Frequency NCEs Outperform Competitors: High Magnification

FREQUENCY THERAPEUTICS



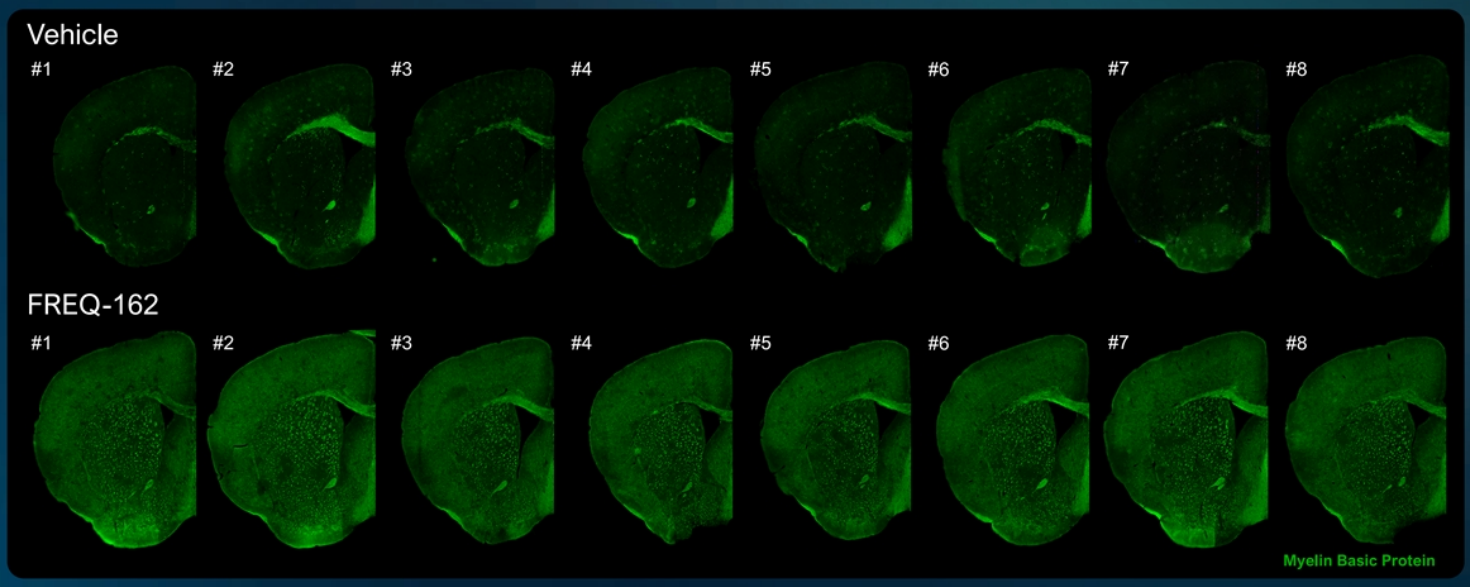
High Magnification view reveals that FREQ-162 yields myelination

- in both white and gray matter
- In the appropriate orientation and location

FREQ-162: Highly Reproducible Increases in Myelination

FREQUENCY THERAPEUTICS

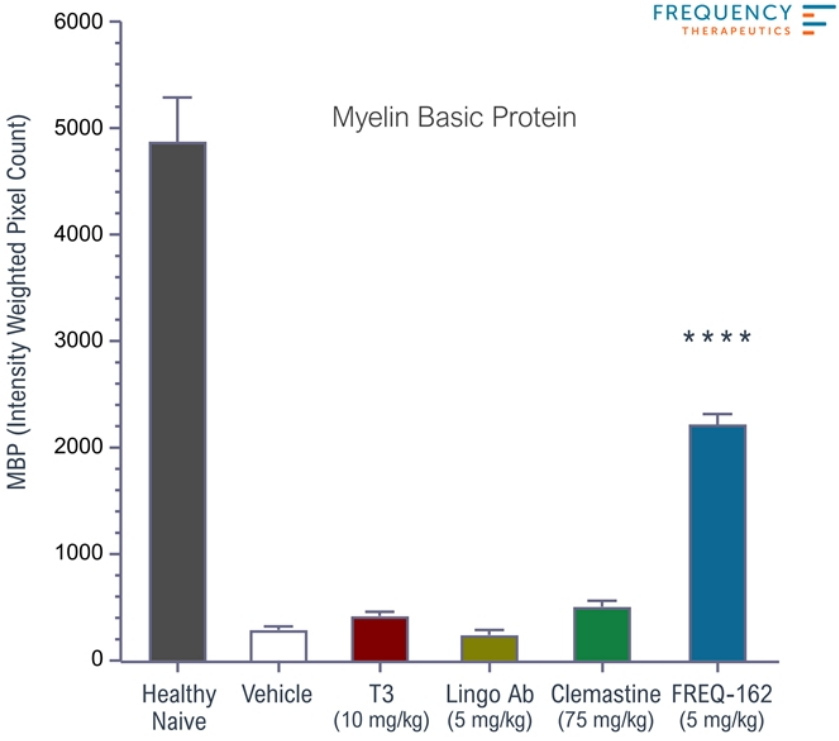
All 8 out of 8 mice treated with FREQ-162 showed robust increases in myelination in both white and gray matter tracts



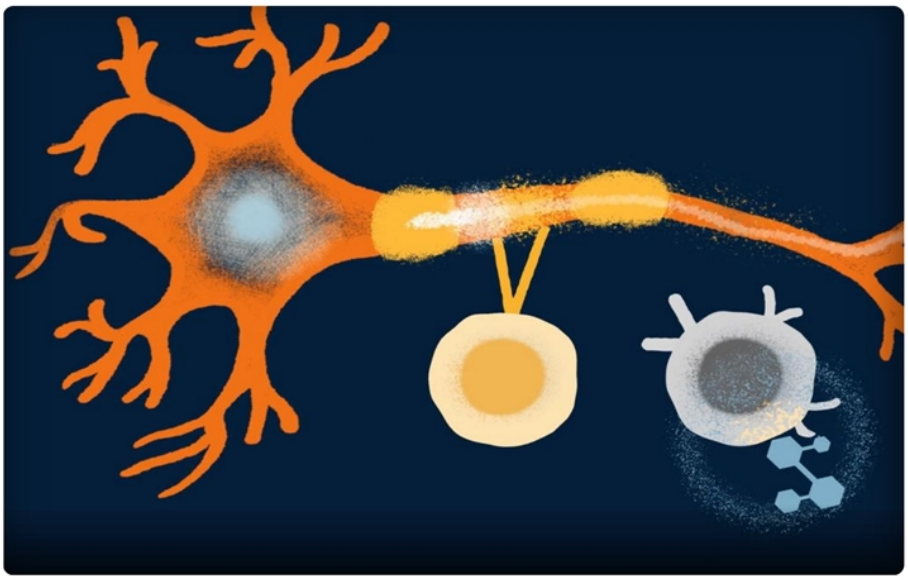
Freq-162 Induces Robust Increases in Myelination

- Forebrain myelin basic protein levels quantitated
- A single dose of a Frequency compound induces robust remyelination

Compound	Dose (mg/kg)	# of doses	Fold change	P=
α-Lingo antibody	5	3	0.9 x	0.99
Clemastine	75	10	1.7 x	0.70
Thyroid Hormone (T3)	10	10	1.4 x	0.95
FREQ-162	5	1	7.7 x	<0.0001



Remyelination: Path Forward



- Discovered novel target
- Generated multiple compounds
- Induced high levels of oligodendrocyte differentiation and remyelination *in vivo*
- Initiating IND enabling studies

Our Path Forward

FREQUENCY THERAPEUTICS

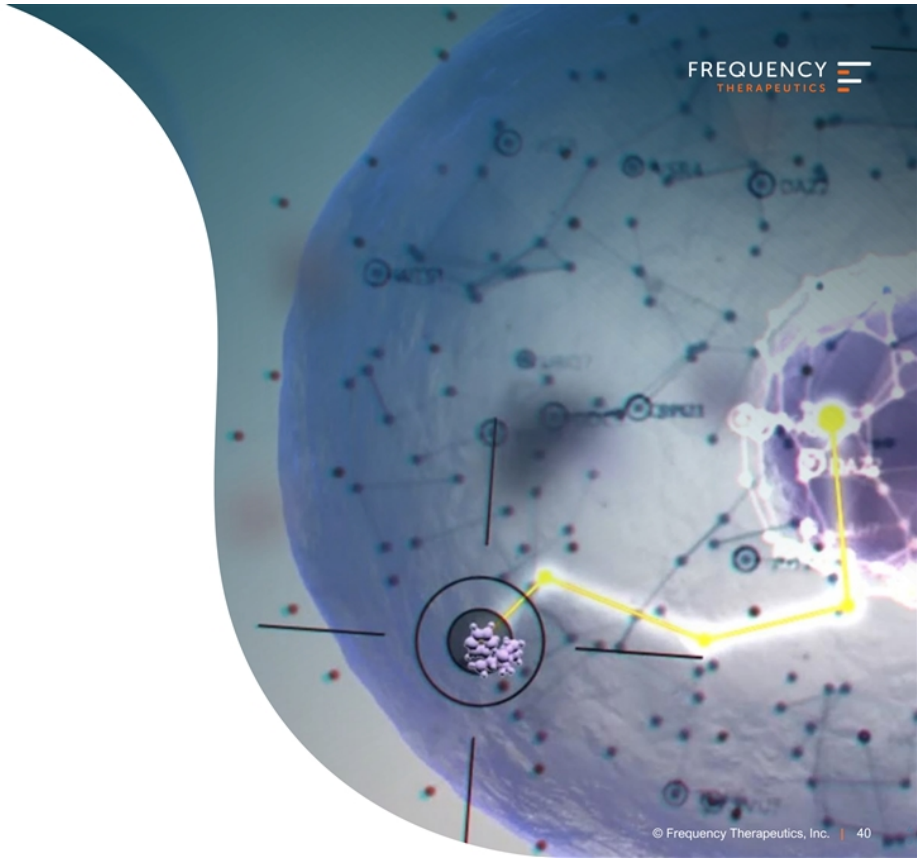
- **We believe FX-322 restores hearing.**
- **We know characteristics of FX-322 responders.**
- **Learnings from previous trials informed new trial design with strong controls and FDA aligned clinical endpoints.**
- **We have a compelling new hearing program that will allow us to explore the impact of going deeper into the cochlea.**
- **We also have an exciting remyelination program in multiple sclerosis with a novel target and a strong response *in vivo*.**
- **We are a well capitalized company with resources to deliver innovation for patients and value for investors.**
  - $160.5m in cash and cash equivalents*, runway into 2023
  - Ex-US partnership with Astellas, significant milestones and royalties

*Number reflects unaudited Cash, Cash Equivalents, and Marketable Securities as of 9/30/21, and does not include Restricted Cash

Appendix

FREQUENCY THERAPEUTICS

Broad Potential of Progenitor Cell Activation Approach



Origin of Frequency Therapeutics

Tissue-Specific, Pre-programmed Stem Cells

FREQUENCY THERAPEUTICS

Decoding Intestinal Regeneration

Langer and Karp publish small molecules activate intestinal progenitors

nature methods

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

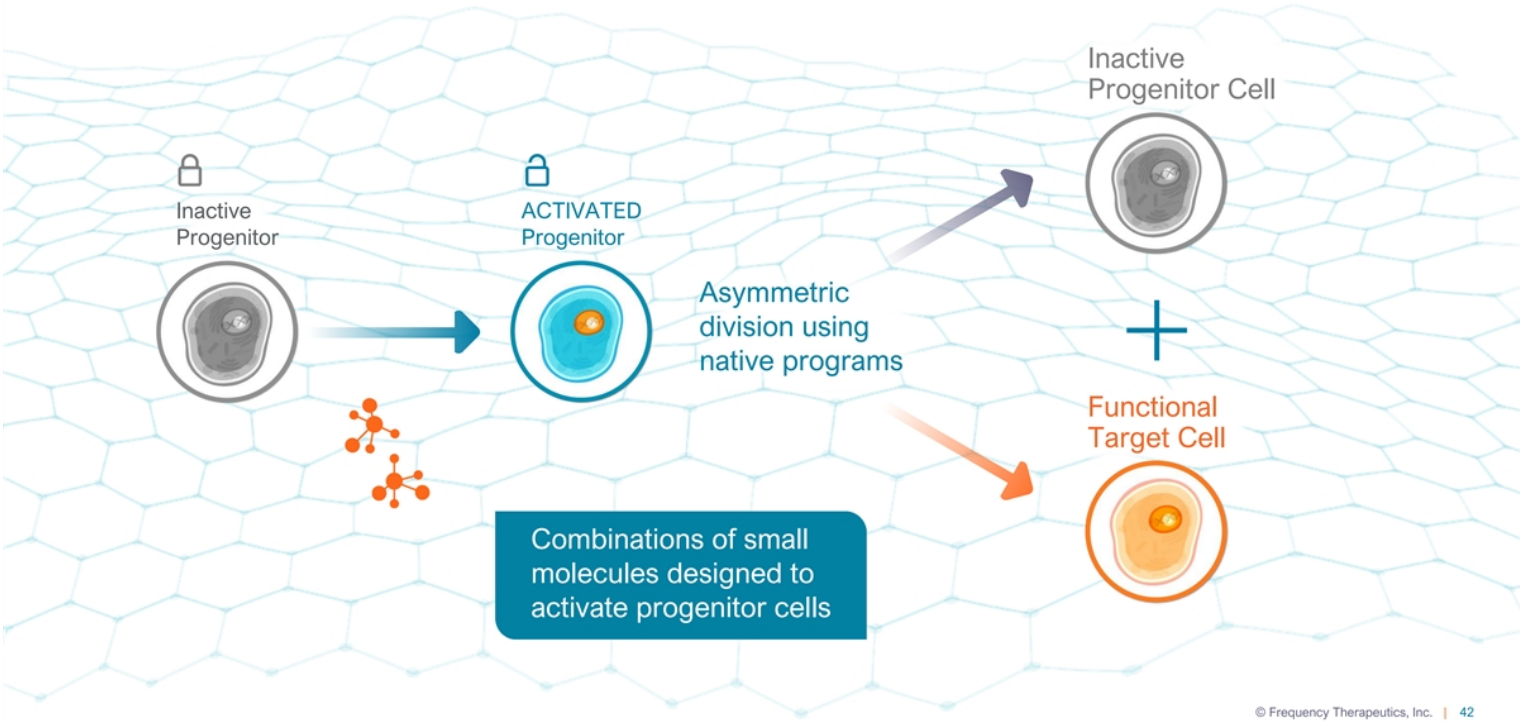
Cell Reports

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

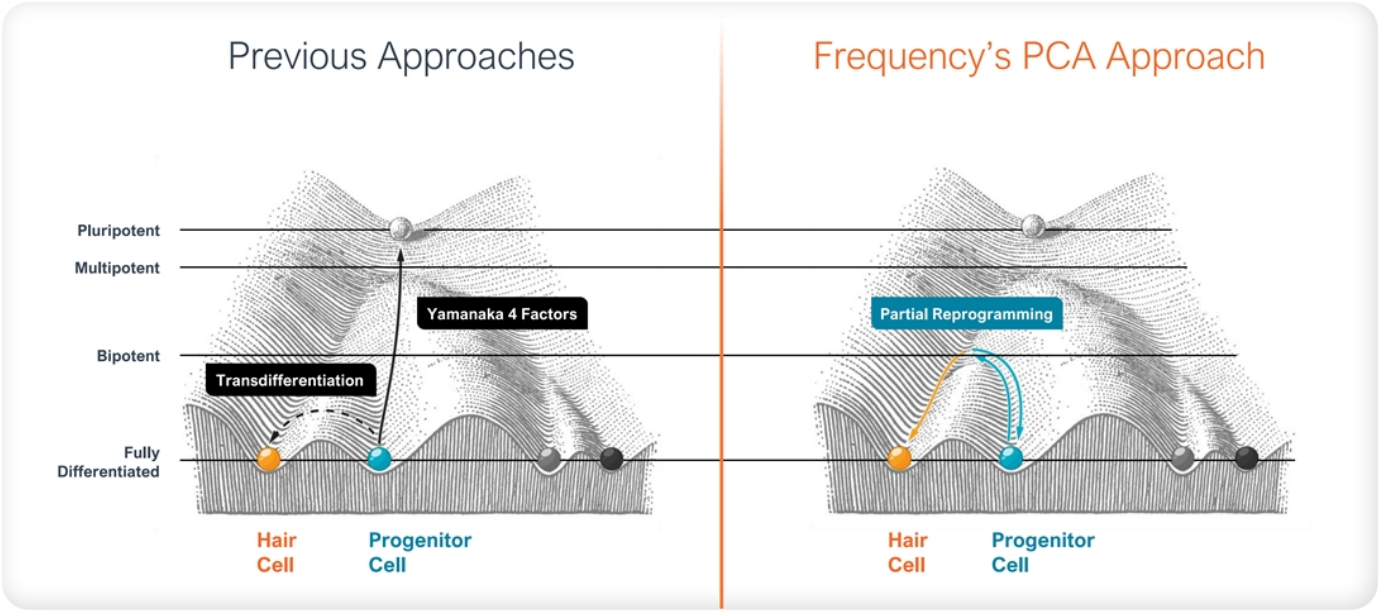
Frequency Therapeutics

Small molecule therapeutics show clinical proof of concept

Frequency Progenitor Cell Activation (PCA) Approach



Uniqueness of Our PCA approach

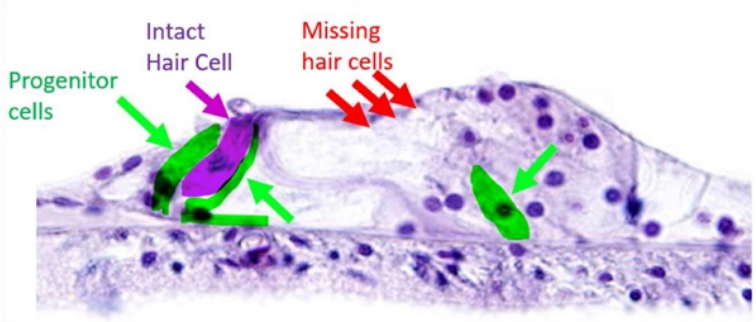


Our Approach:

Activation of Progenitors to Replace Hair Cell Loss

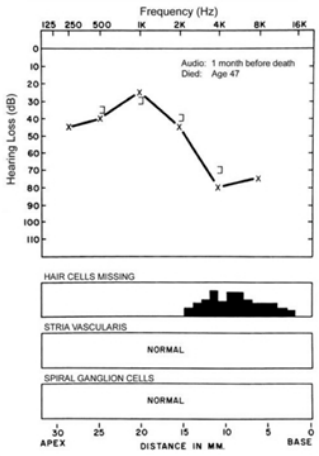
FREQUENCY THERAPEUTICS

Despite Hair Cell Loss, Progenitor Cells Remain



Human Cochlea Cross-section

Audiogram

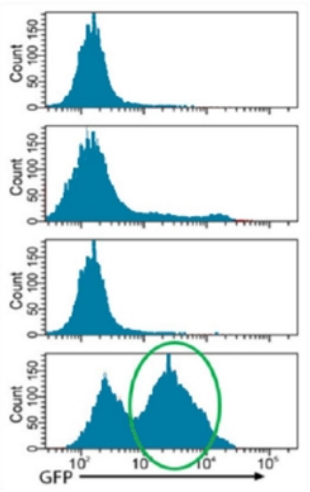


47 Year Old Male with Occupational Noise Deafness

Profound Synergy Between Pathways to Regenerate Cells

FREQUENCY THERAPEUTICS

Cochlear Progenitor Proliferation (Lgr5+ – GFP)



Culture Media

Wnt Activation
(glycogen synthase kinase-3 (GSK3) Inhibitor; NCE)

HDAC Inhibition
(sodium valproate)

Wnt Activation + HDAC inhibition

PROFOUND SYNERGY

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

FX-322 Agents Induce Protein Expression Consistent with Fully Functional Sensory Hair Cells

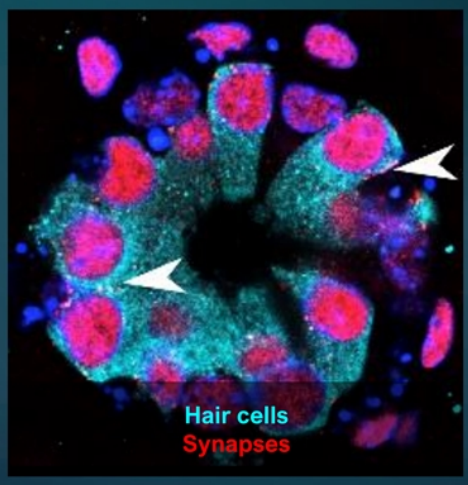
FREQUENCY THERAPEUTICS

Sensing Sound

Generating intricate hair bundles

Creating Signal

Producing functional ion channels



Transmitting Signal

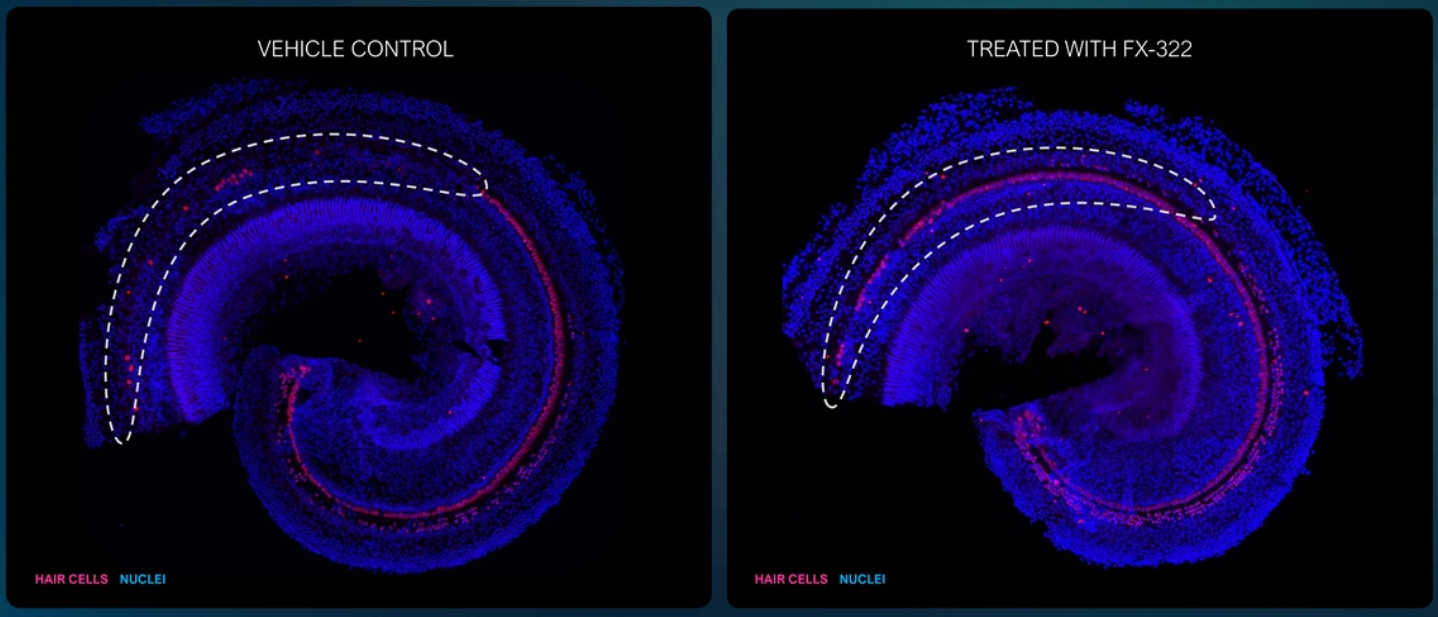
Synaptic proteins to communicate with nerve are present

McLean et al., 2017, Cell Reports 18, 1917–1929 February 21
http://dx.doi.org/10.1016/j.celrep.2017.01.066

Images Showing Cellular Regeneration

In Vivo Hearing Loss Model

FREQUENCY THERAPEUTICS



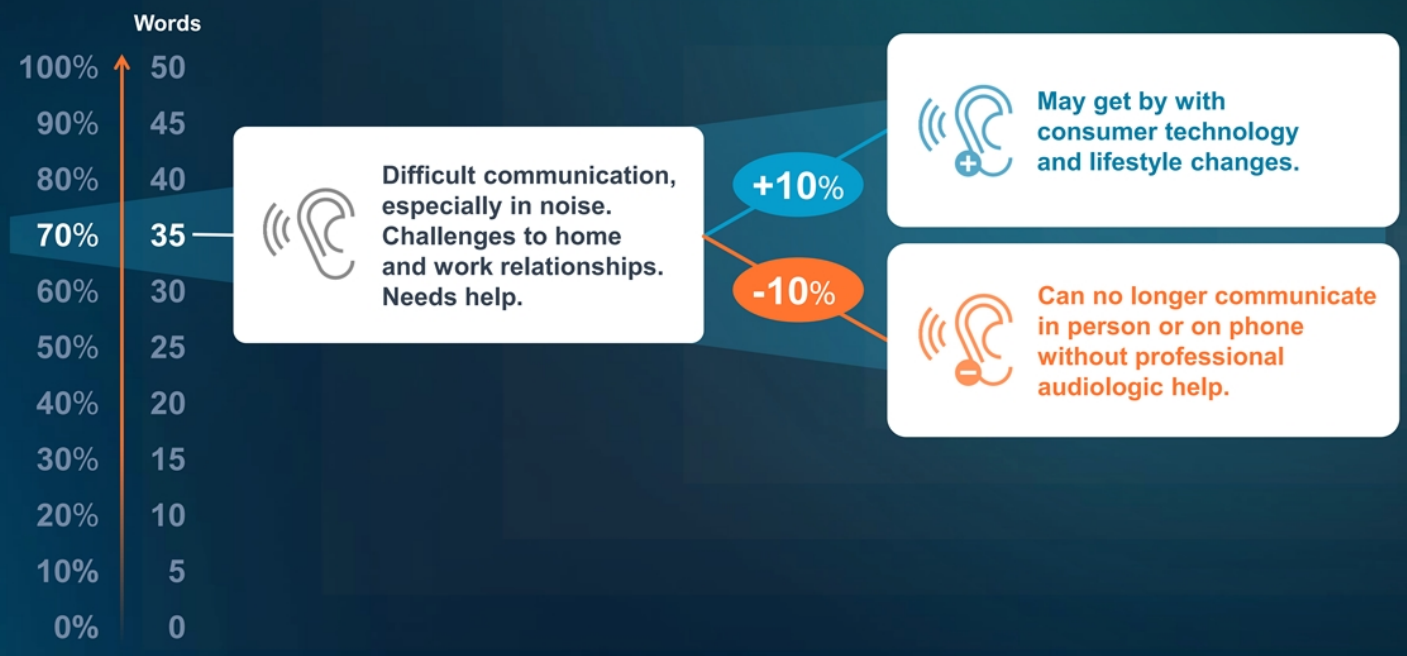
Representative of n=7; Numbers correspond to frequencies; 30 days after treating

Strong FX-322 Pre-Clinical Validation

Test		Outcome
In vitro		
Adult human inner ear tissue	→	Created new hair cells
In vivo		
Adult deafened mice	→	Restored hair cells and hearing across all frequencies
Therapeutic drug levels	→	Achieved active levels in the cochlea in multiple species

Clinically Meaningful:
10% Means Needing Audiologic Help

FREQUENCY THERAPEUTICS



Clinically Meaningful:
10% Means Functional Deafness or Need for Implant

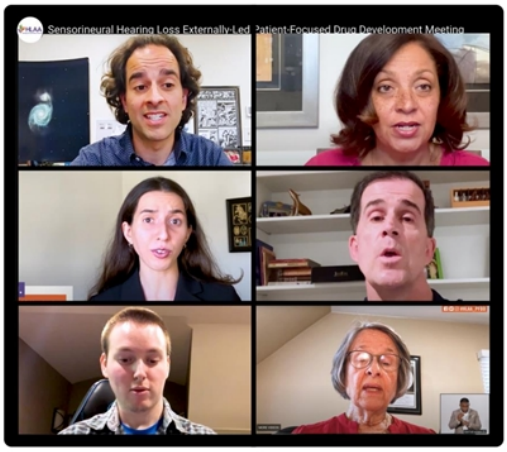
FREQUENCY THERAPEUTICS

Externally-Led (HLAA) Patient Focused Drug Development Program on Sensorineural Hearing Loss

FREQUENCY THERAPEUTICS

Top two needs for new drug or device

Top two hearing loss concerns



Credit: Hearing Loss Association of America (HLAA)

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

astellas

Strategic commitment to invest in ENT as a therapeutic area

Research focus in regenerative medicine

Global footprint in major markets and distributorship model in Africa/ME and LATAM

Proven Leadership Team

FREQUENCY THERAPEUTICS

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.

Peter Pfreundschuh
Chief Financial Officer

CFO of numerous public life sciences companies including UroGen and Sucampo, as well as business development and finance leadership positions at Astra Zeneca and J&J.

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.

Sue Stewart, J.D., LLM
Chief Regulatory Officer

CRO at numerous biopharma companies including Kaleido Biosciences, Candel Therapeutics, and regulatory leadership roles at Tokai Pharma, Transmolar and Genzyme Corp.

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.

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David Friedland, M.D., Ph.D.

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Pioneering a New Category
in Regenerative Medicine
Frequency Therapeutics Corporate Presentation
December 2021
FREQUENCY
THERAPEUTICS