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): November 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 2.02. Results of Operations and Financial Condition.

On November 9, 2021, Frequency Therapeutics, Inc. (the "Company") announced that its unaudited cash, cash equivalents and marketable securities totaled $160.5 million as of September 30, 2021, which does not include Restricted Cash.

Item 7.01. Regulation FD Disclosure.

On November 9, 2021, the Company posted an updated corporate slide presentation and a slide presentation from its R&D Event to be held today, Tuesday, November 9, 2021 at 8:00 a.m. Eastern Time (R&D Event) in the "Investors & Media" portion of its website at www.frequencytx.com. Copies of the slide presentations are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K (the "Current Report").

The information in this Item 7.01 of this Current Report, including Exhibits 99.1 and 99.2, 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, or the Exchange Act, except as expressly provided by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibits 99.1 and 99.2.

Item 8.01. Other Events.

On November 9, 2021, the Company announced the following highlights to be disclosed during its R&D Event:

FX-322

- Clinical data review from four completed FX-322 clinical studies, including 169 subjects with a range of hearing loss severities and sensorineural hearing loss (SNHL) etiologies (sudden, noise-induced, age-related).
- Analysis of statistically significant and clinically meaningful patient responses following a single FX-322 administration, establishing the range of severity and etiologies that will be explored in the upcoming FX-322-208 study.
- Review of design of ongoing FX-322-208 study, including use of multiple lead-in hearing measures implemented to reduce study bias and baseline variability.
- Alignment with the U.S. Food and Drug Administration around speech perception measures as a primary efficacy endpoint and the importance of speech perception as the key unmet need for individuals with SNHL.

FX-345

- Introduction of new SNHL investigational therapeutic program, including a more potent GSK3 inhibitor designed to achieve broader exposure of the cochlea.
- Preclinical pharmacokinetic measures and human modeling data have indicated that therapeutically active FX-345 drug levels could be reached in areas of the cochlea corresponding to a wider range of hearing frequencies.
- Potential to benefit an expanded SNHL patient population.
- Investigational New Drug application submission anticipated in Q2 2022.

Remyelination in Multiple Sclerosis

- Identified novel therapeutic target that drives oligodendrocyte progenitor cell differentiation and myelination.
- FREQ-162, preclinical stage lead compound, showed substantial remyelination in preclinical studies.
- FREQ-162 being advanced in preclinical safety studies toward the initiation of clinical development.

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 design of the new Phase 2 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 topics to be discussed during the R&D event, the ability of our technology platform to provide patient benefit, the ability to continue to develop our Progenitor Cell Activation (PCA) platform and identify additional product candidates, 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 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 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 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 November 9, 2021
99.2	Frequency Therapeutics, Inc. R&D Event Slide Presentation
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: November 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

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 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 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*

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A Series of Firsts in Hearing Restoration

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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

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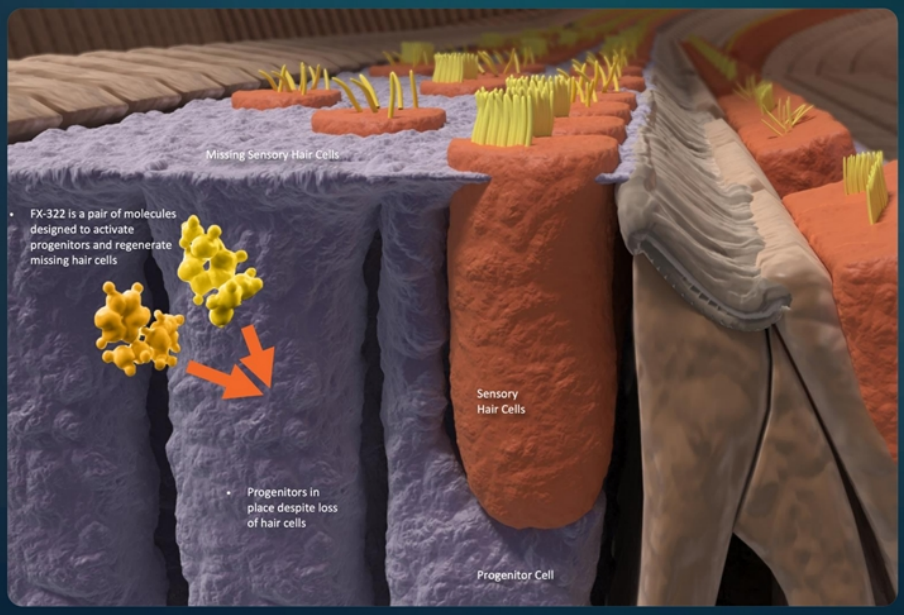
FX-322:
A Small Molecule Candidate to Address the Underlying Pathology

FREQUENCY THERAPEUTICS

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



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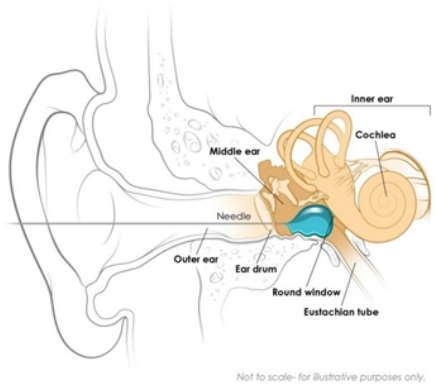
FX-322:

Directly Targeting the Regeneration of Sensory Hair Cells in the Cochlea

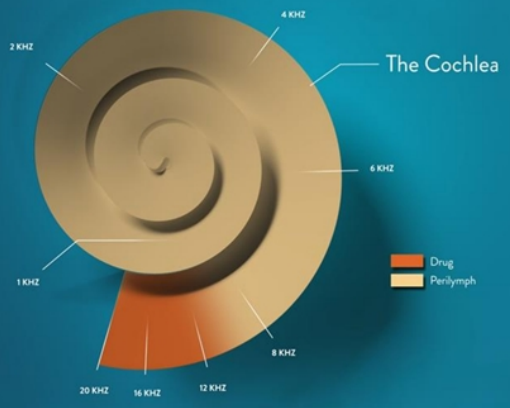
FREQUENCY THERAPEUTICS

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



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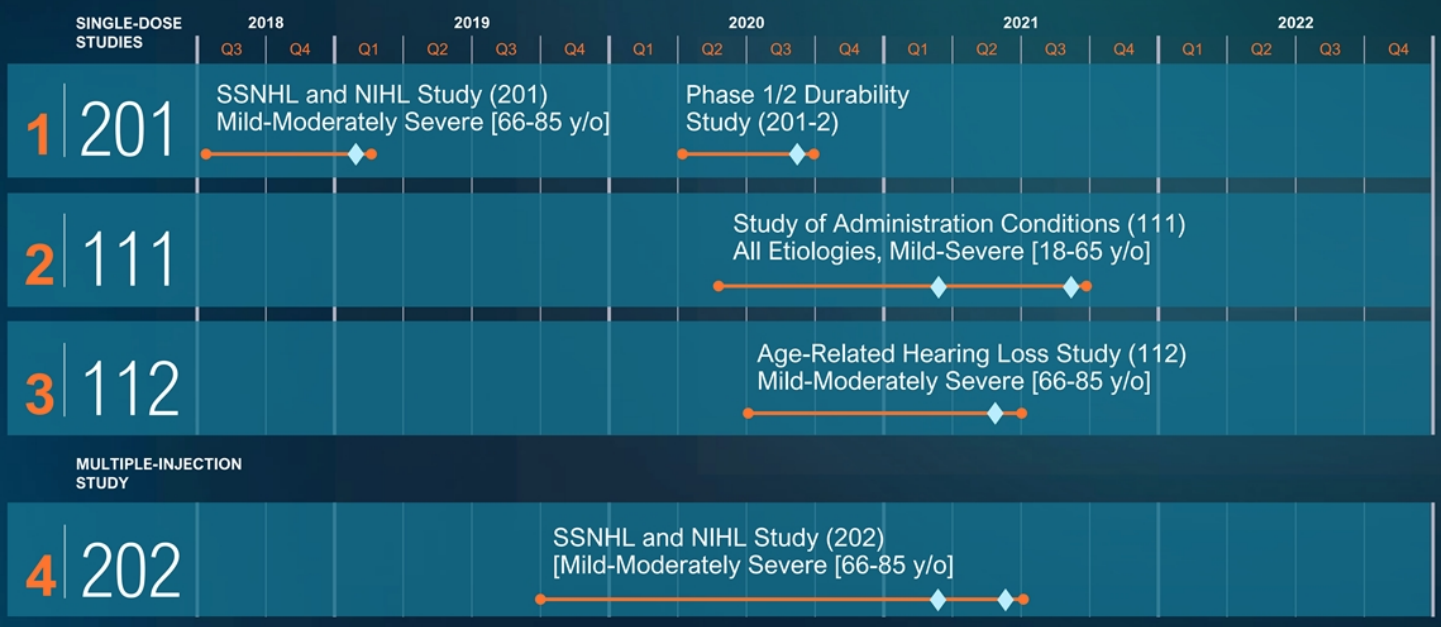
Four FX-322 Completed Studies: 169 Subjects

Favorable Safety Profile with No Treatment-Related SAEs

FREQUENCY THERAPEUTICS



◆ = Data Readout

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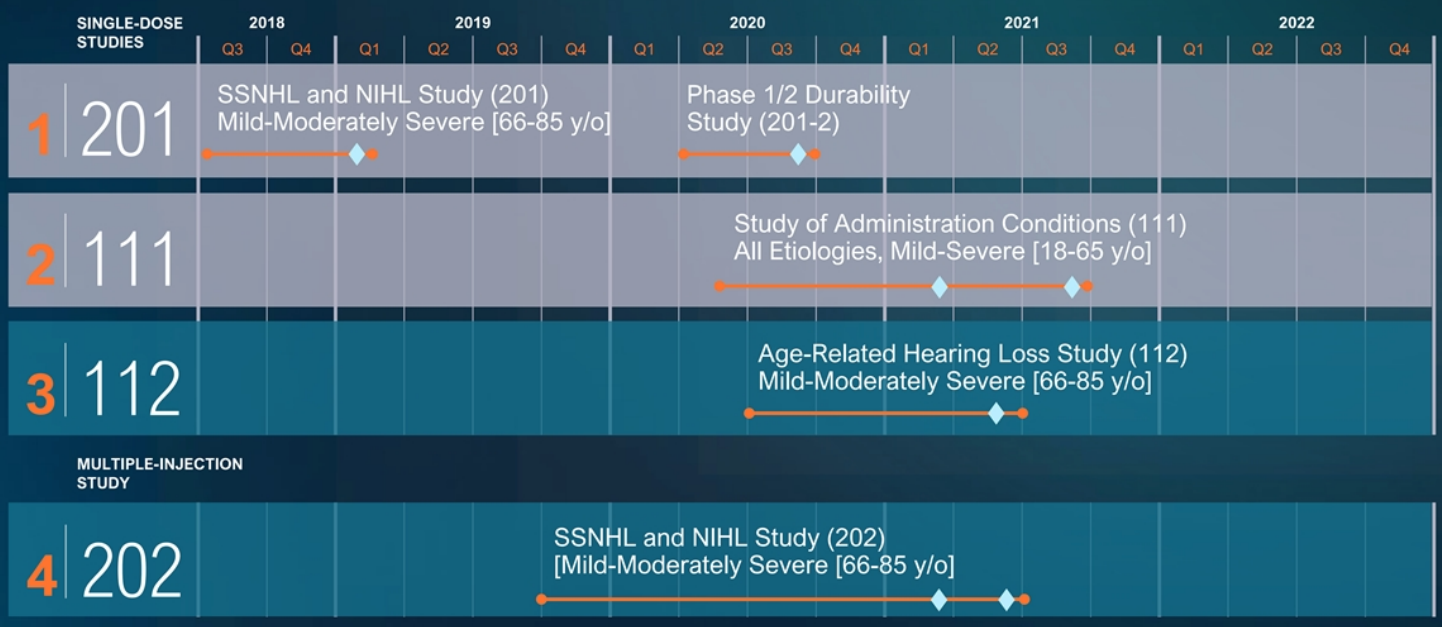
FX-322-201 and FX-322-111

Single-Dose Safety Studies with Hearing Improvement Signal



◆ = Data Readout

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

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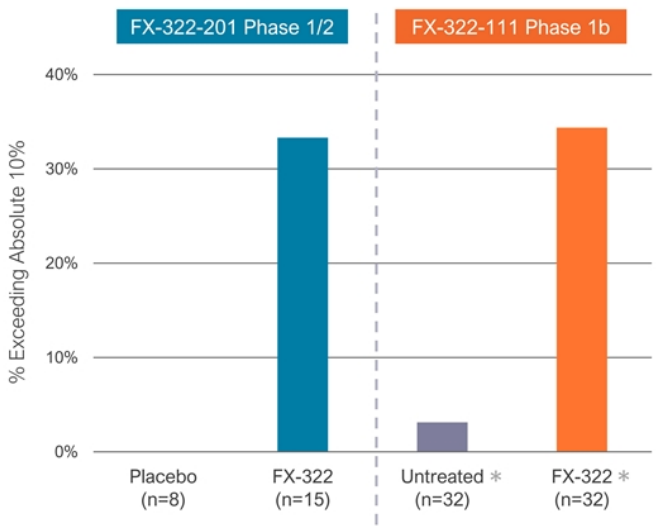
Phase 1/2 Study FX-322-201 Overview

- 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*

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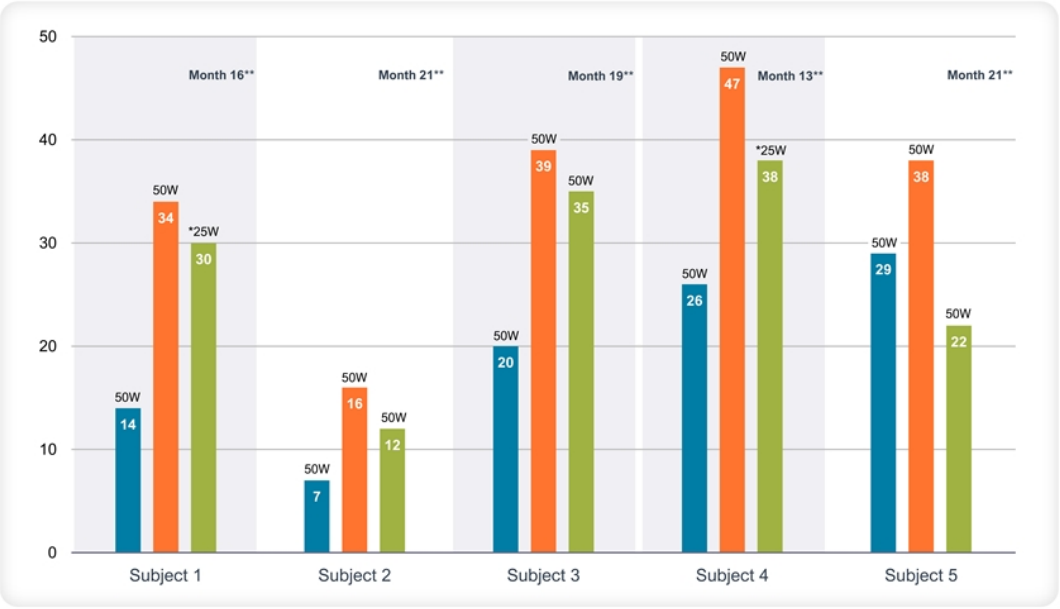
FX-322 Phase 1/2 Durability Data:

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)

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Follow up of FX-322-111 Subjects Show Additional Hearing Improvements at Later Time Points

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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

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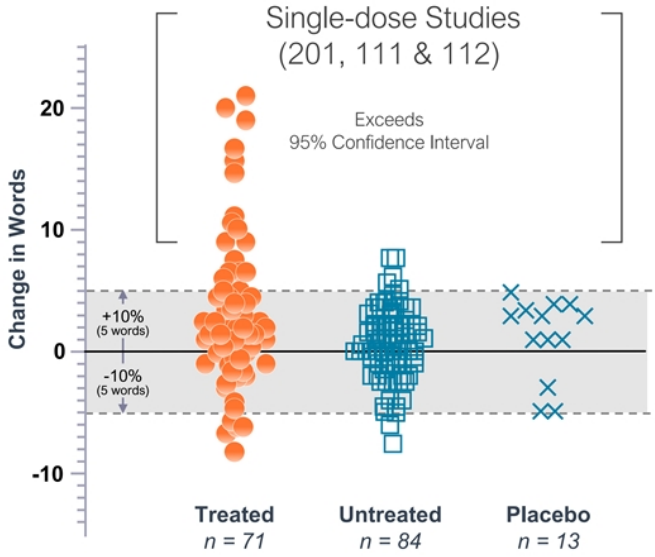
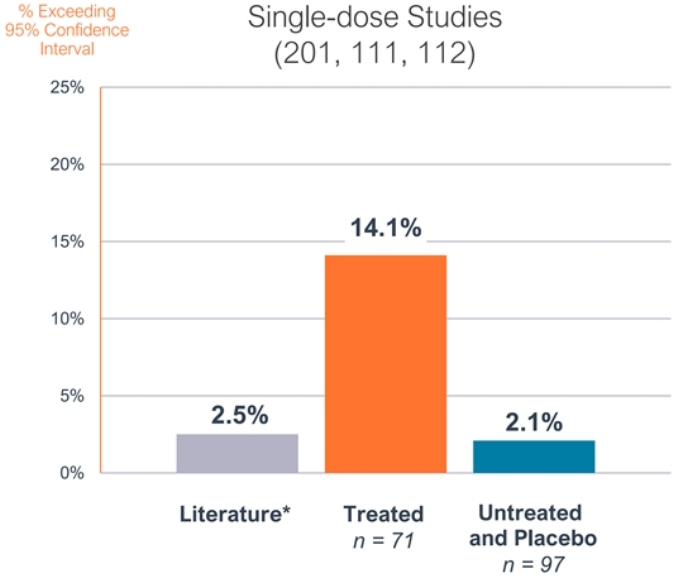
Pooled FX-322 Data Shows Patterns of Response

Single-dose Studies (201, 111, 112) Exceeding 95% Confidence Interval, Suggesting Inconsistent Baseline Value Measures





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

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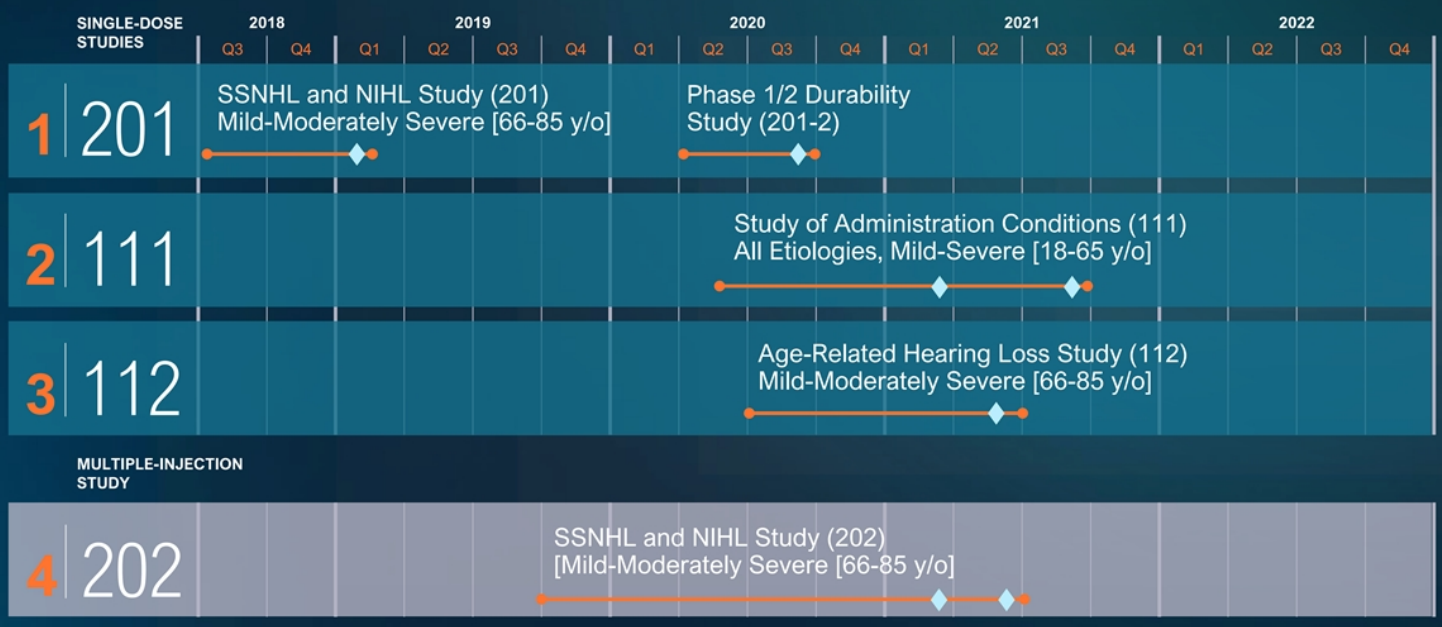
FX-322-202

Multiple Injection Study to Assess Safety of Increased FX-322 Exposure

FREQUENCY THERAPEUTICS



◆ = Data Readout

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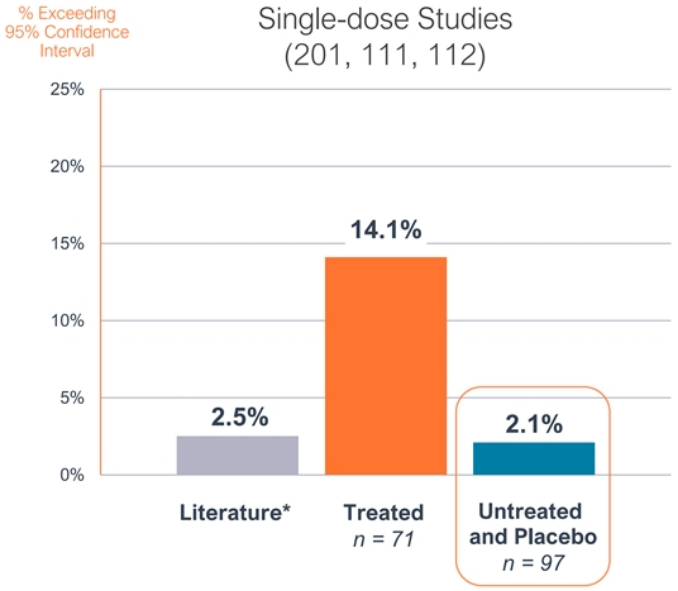
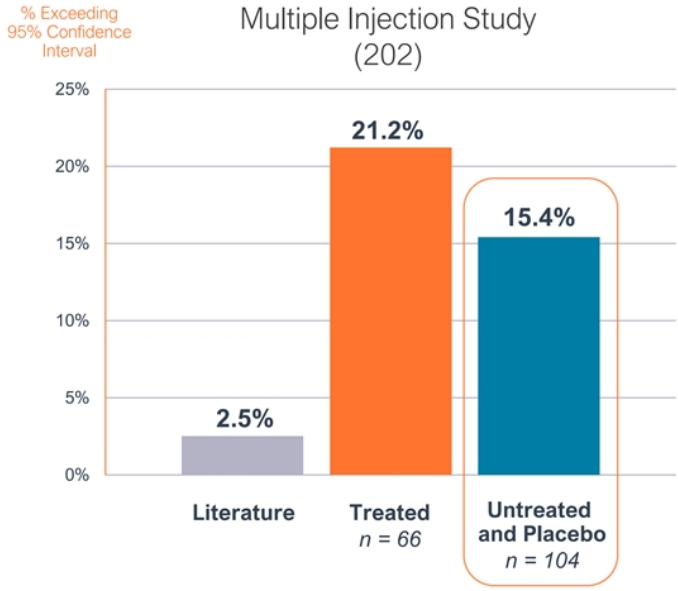
Comparing Pooled Data to Multiple-Injection Study FX-322-202

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





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

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

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

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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

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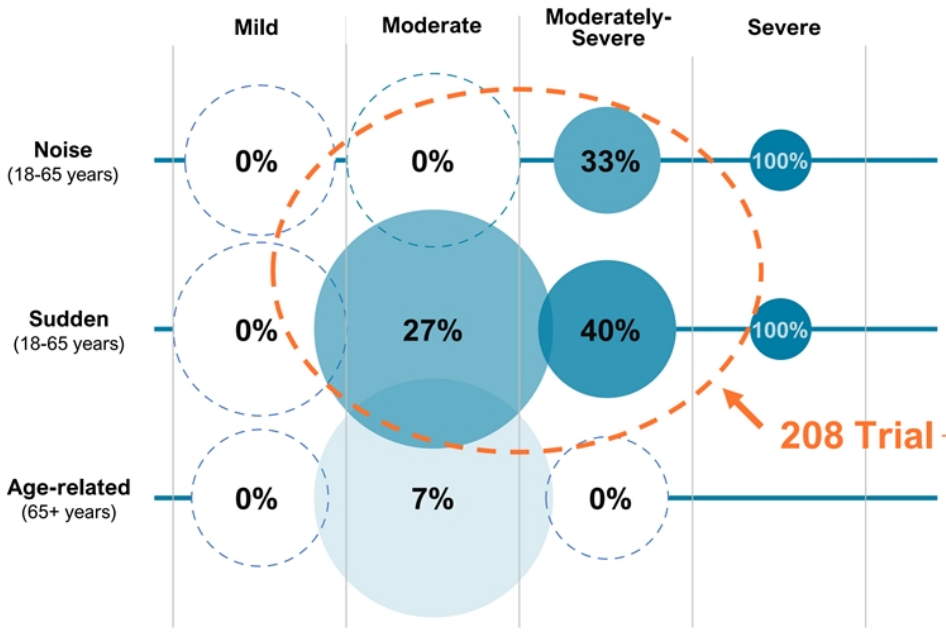
Pooled Single-Dose Studies (201, 111, 112)

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

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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**

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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

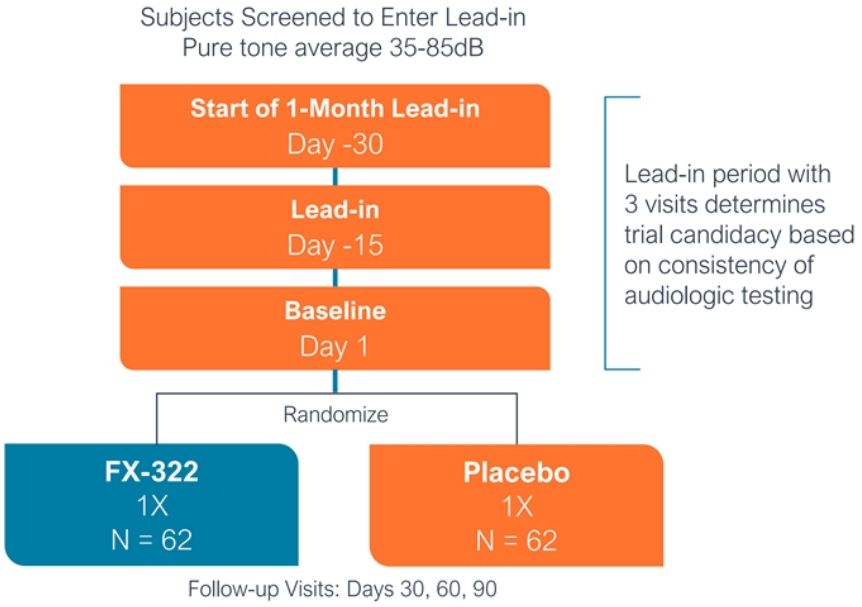
Ages 18 – 65

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

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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

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

Pipeline Expansion

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Two New Regenerative Programs

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

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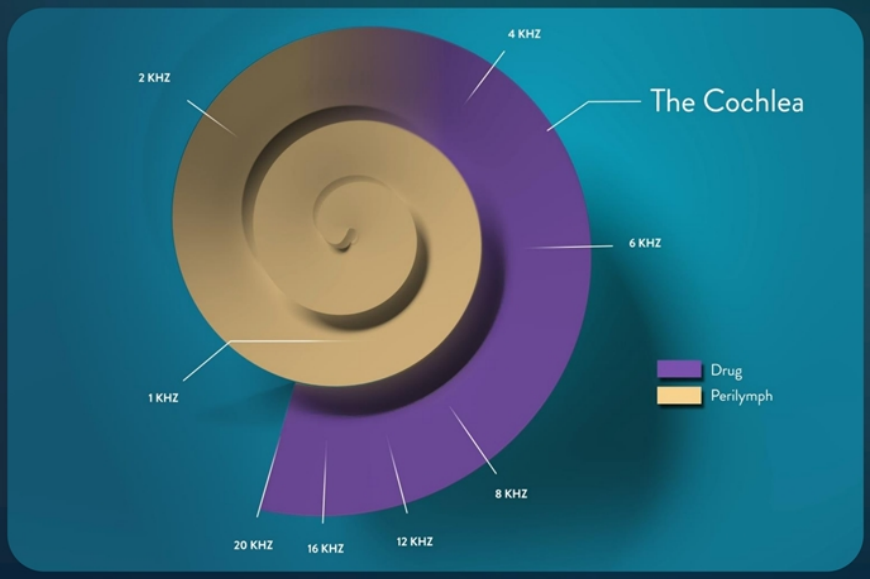
FX-345

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, and clinical data will drive commercial positioning



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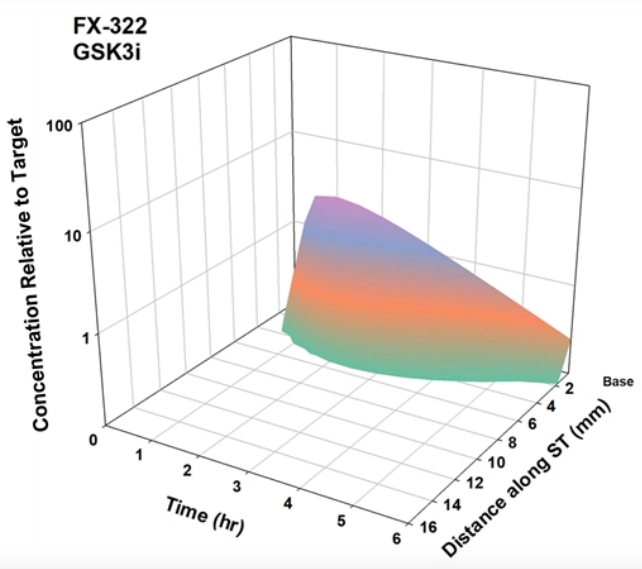
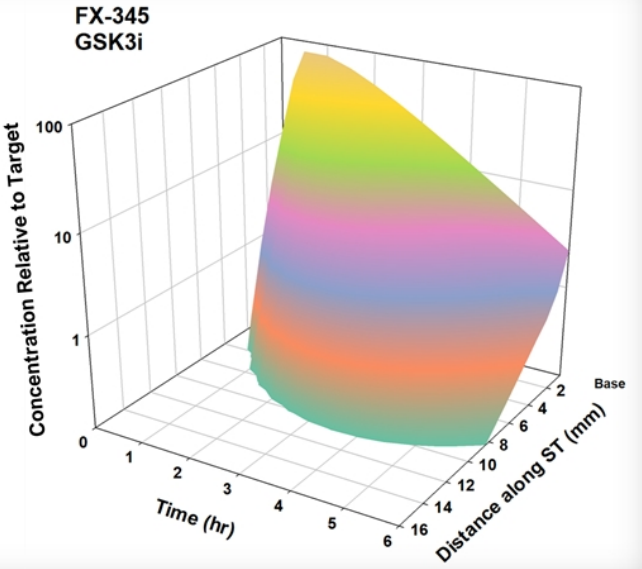
FX-345 – A New Development Candidate

Creating Effective Drug Levels Through Large Portion of Cochlea

FREQUENCY THERAPEUTICS





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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

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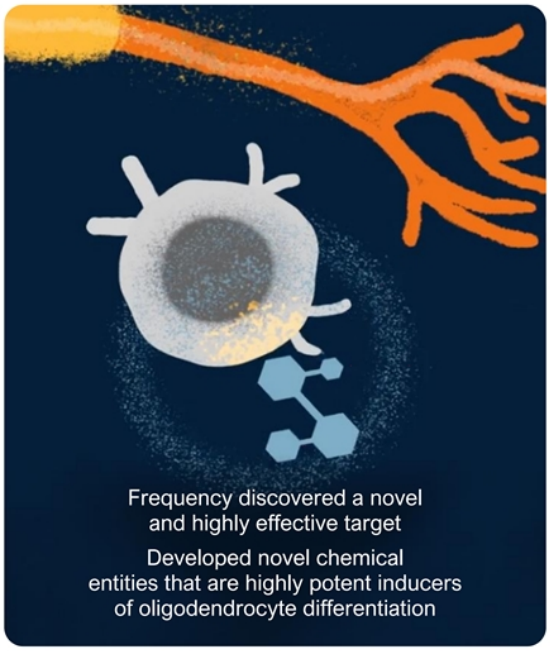
Two New Regenerative Programs

FREQUENCY THERAPEUTICS

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

© Frequency Therapeutics, Inc.

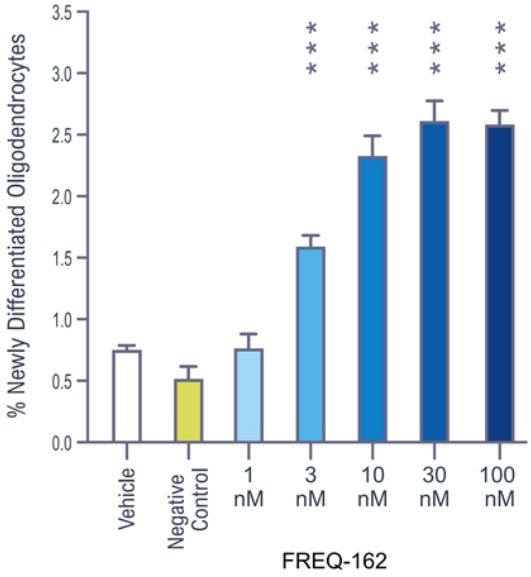
Novel Frequency Small Molecule Inhibitors Drive Oligodendrocyte Differentiation



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



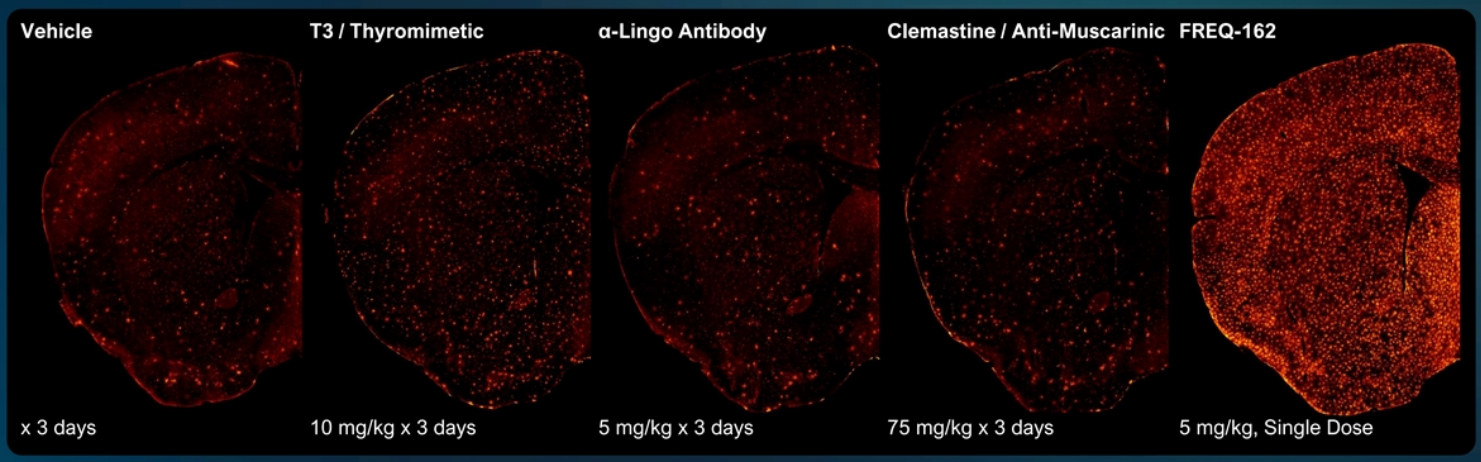
- Highly potent
- Highly efficacious
- Orally bioavailable
- Brain penetrant
- Novel chemical entity
- Patent application filed

© Frequency Therapeutics, Inc.

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

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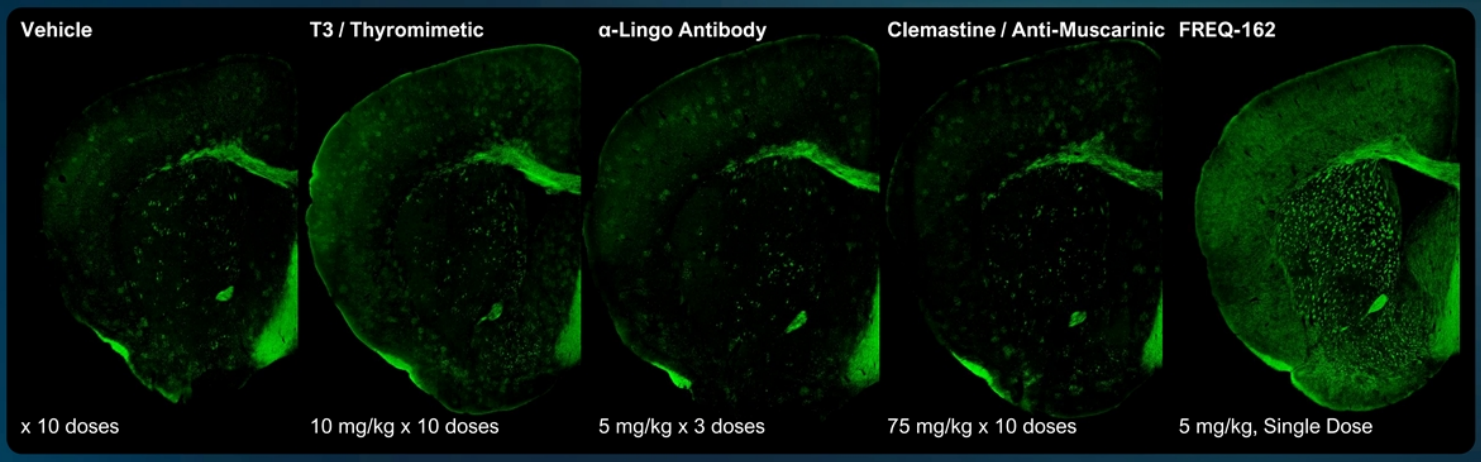
FREQ-162 Outperforms Published Compounds *In Vivo*

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



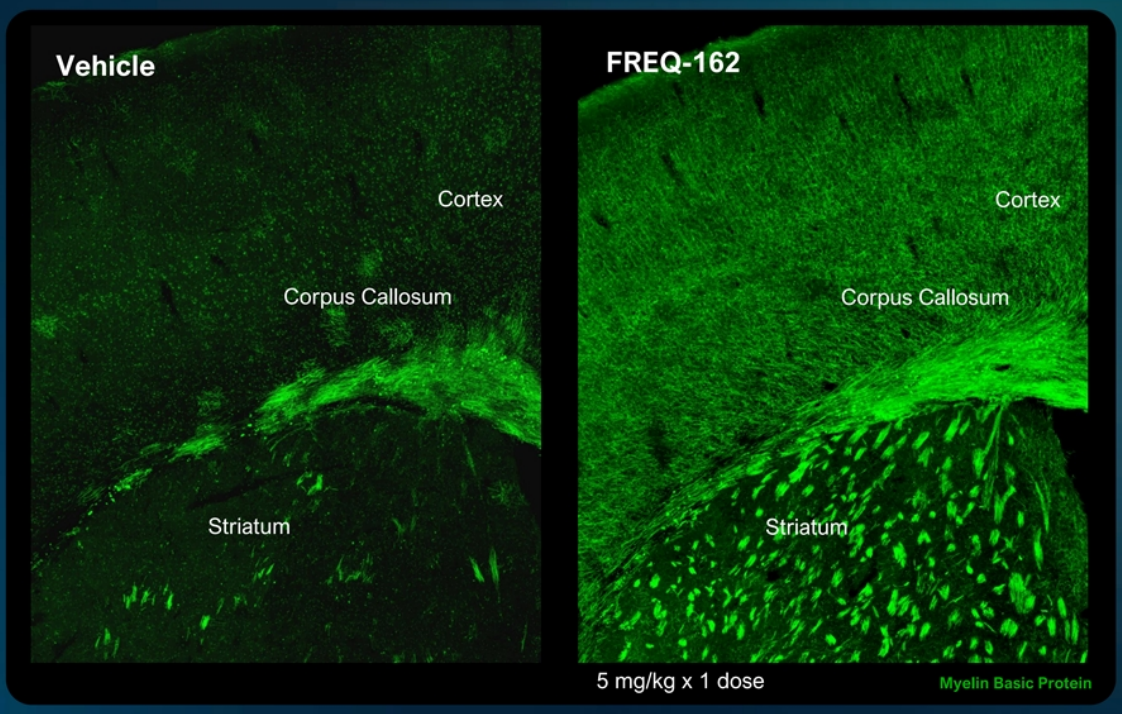
Thyroid Hormone:
Thyromimetic Class

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



High Magnification view reveals that FREQ-162 yields myelination

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

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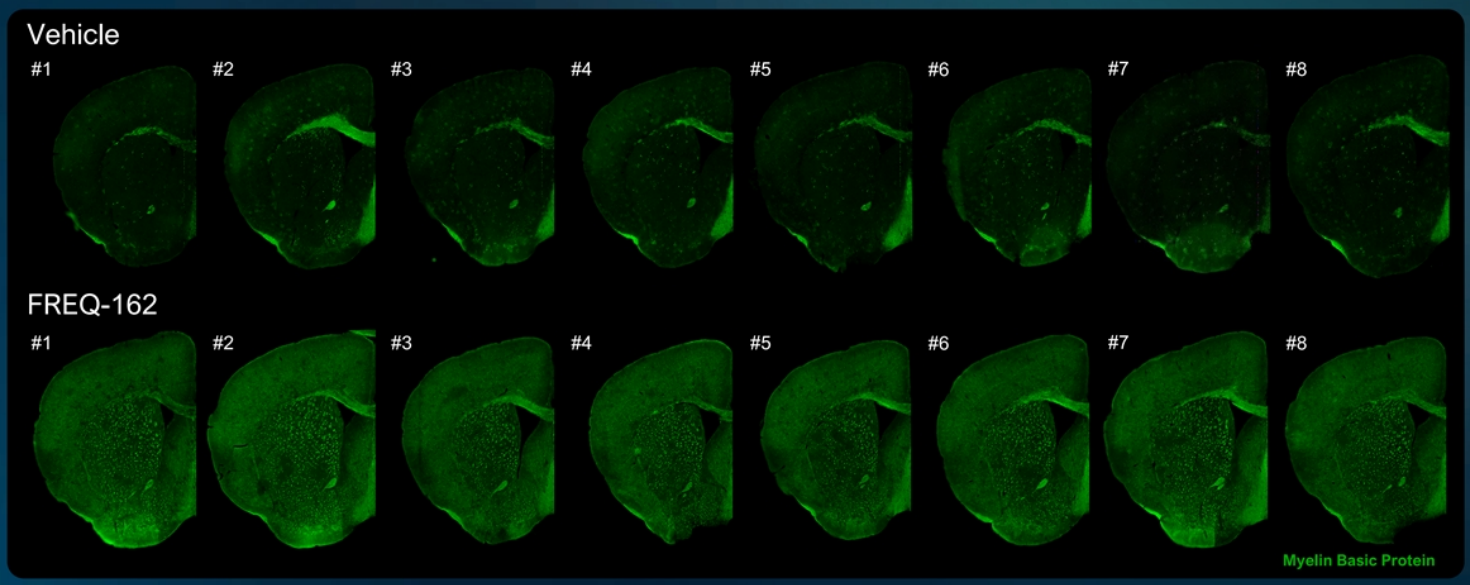
FREQ-162: Highly Reproducible Increases in Myelination

FREQUENCY THERAPEUTICS

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

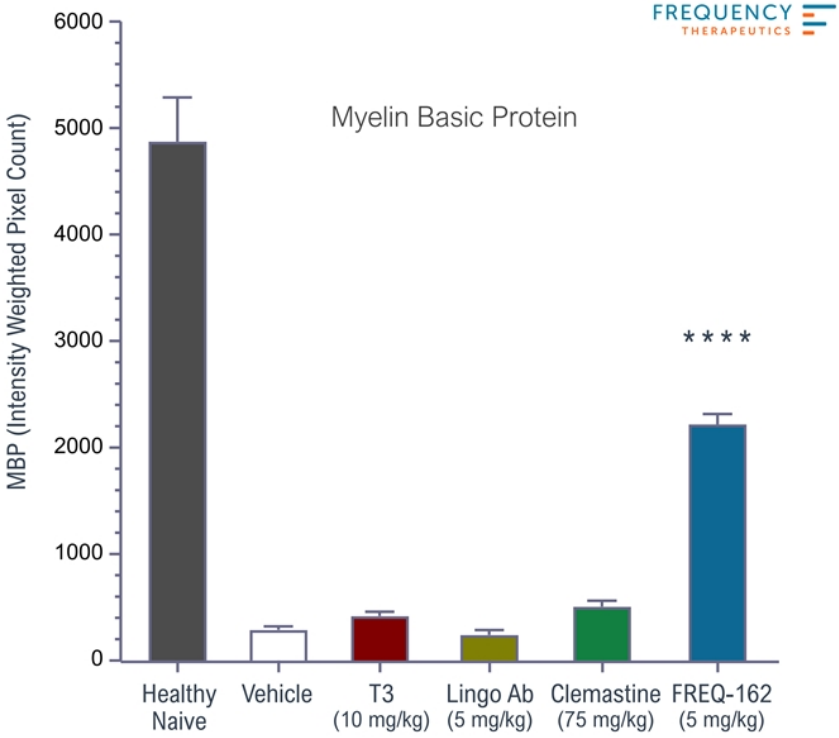


© Frequency Therapeutics, Inc.

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



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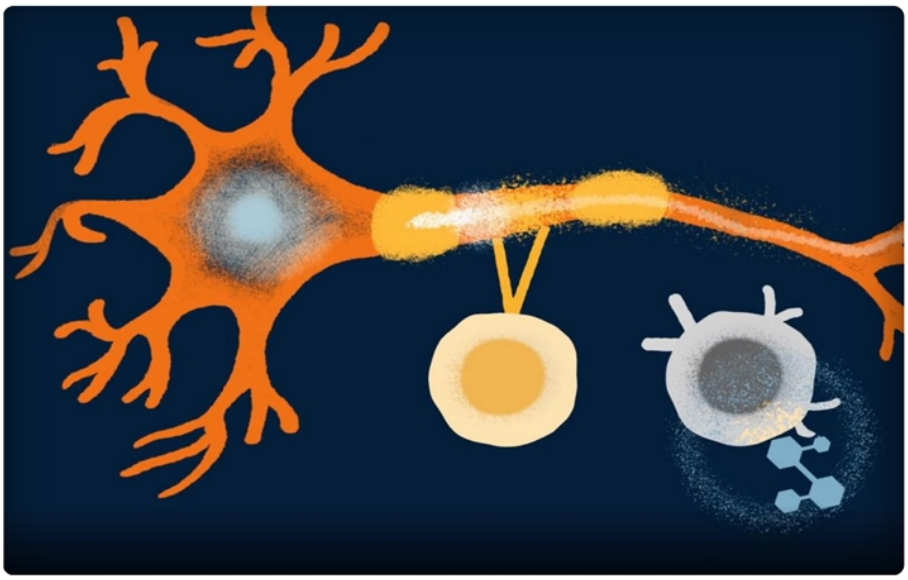
Remyelination: Path Forward



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

© Frequency Therapeutics, Inc.

Our Path Forward

- **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 approved 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

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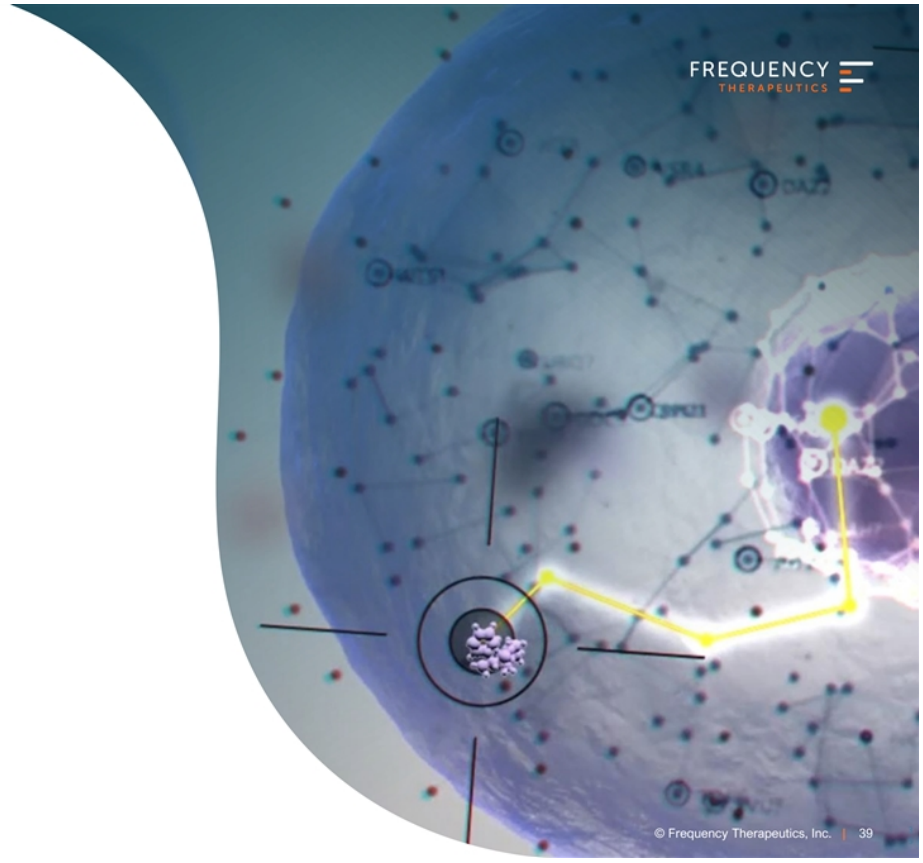
Appendix

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

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 Therapeutics

Small molecule therapeutics show clinical proof of concept

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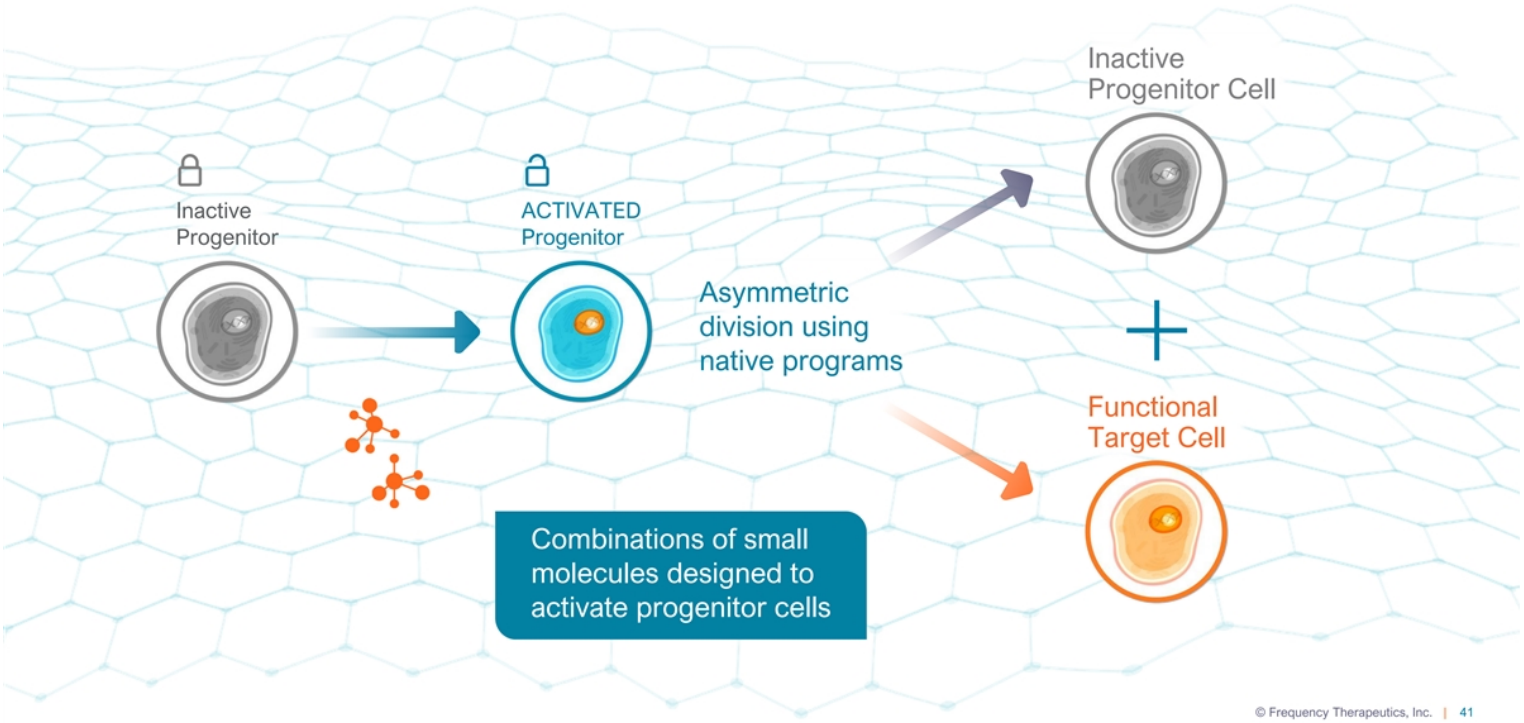
Frequency Progenitor Cell Activation (PCA) Approach



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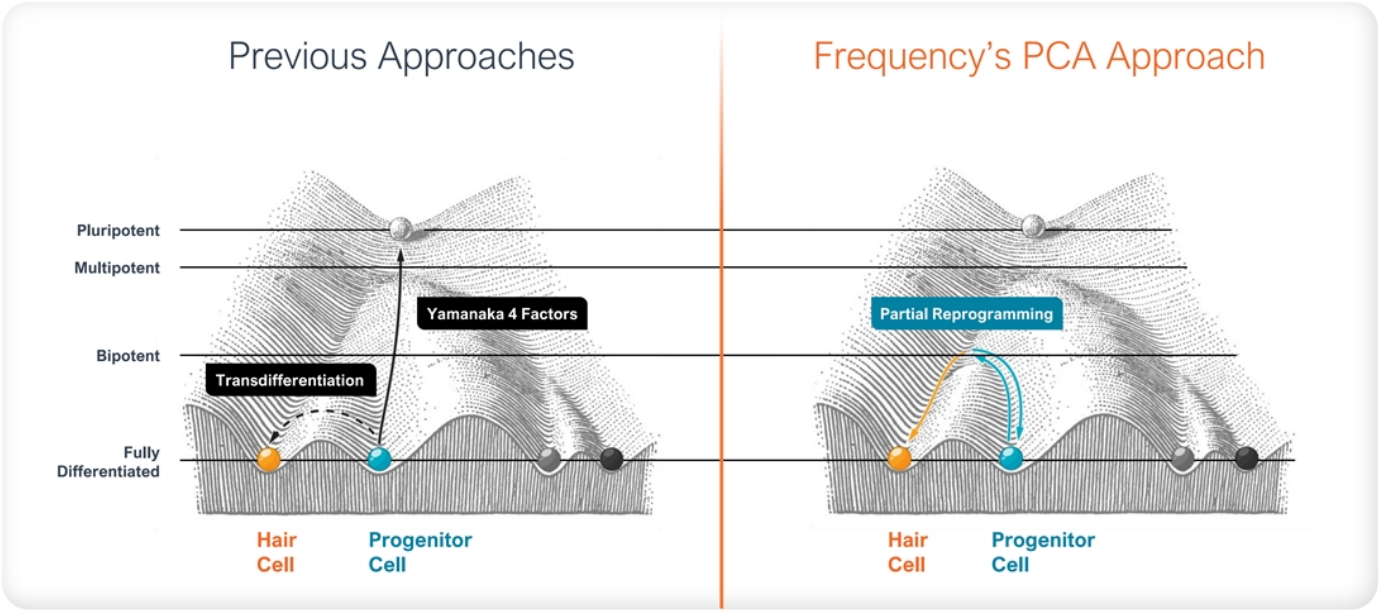
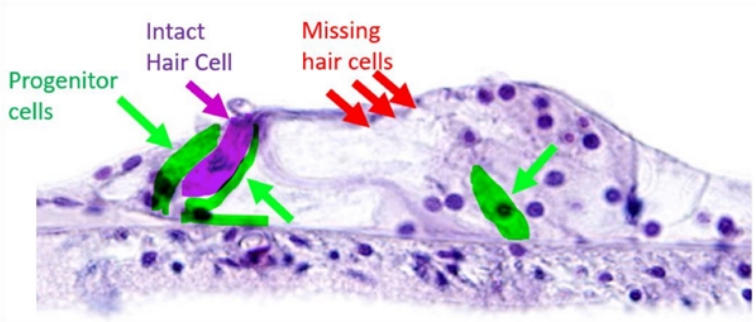
Uniqueness of Our PCA approach



Our Approach:
Activation of Progenitors to Replace Hair Cell Loss

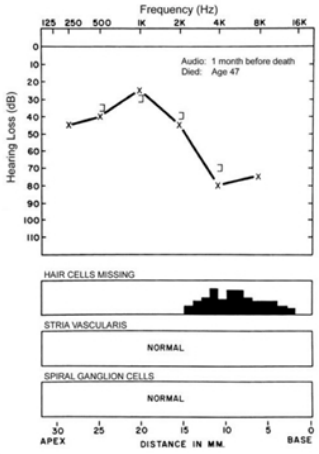
FREQUENCY THERAPEUTICS

Despite Hair Cell Loss, Progenitor Cells Remain



Human Cochlea Cross-section

Audiogram



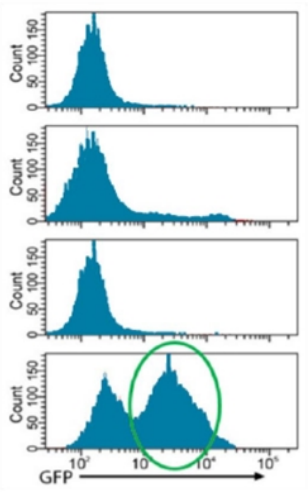
47 Year Old Male with Occupational Noise Deafness

Can we re-draw charts

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

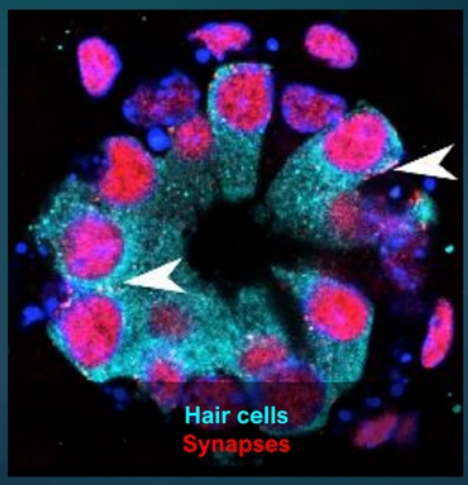
FREQUENCY THERAPEUTICS

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

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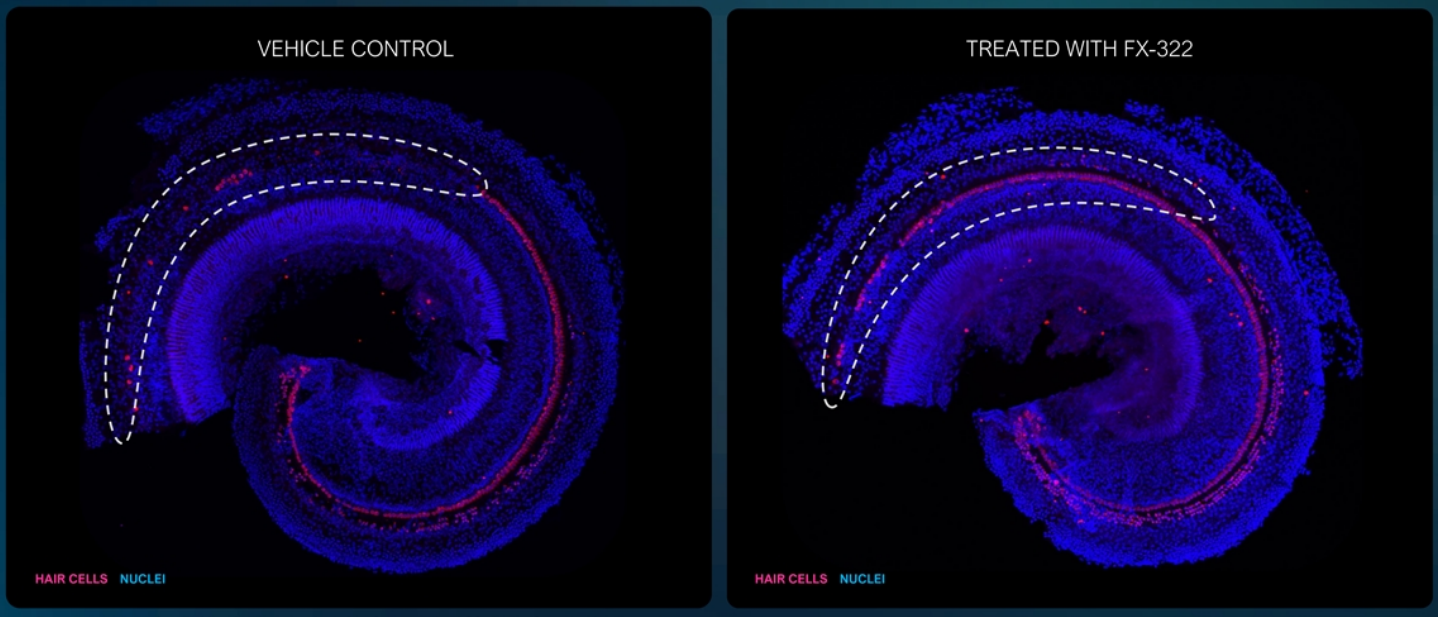
Images Showing Cellular Regeneration

In Vivo Hearing Loss Model

FREQUENCY THERAPEUTICS



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

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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

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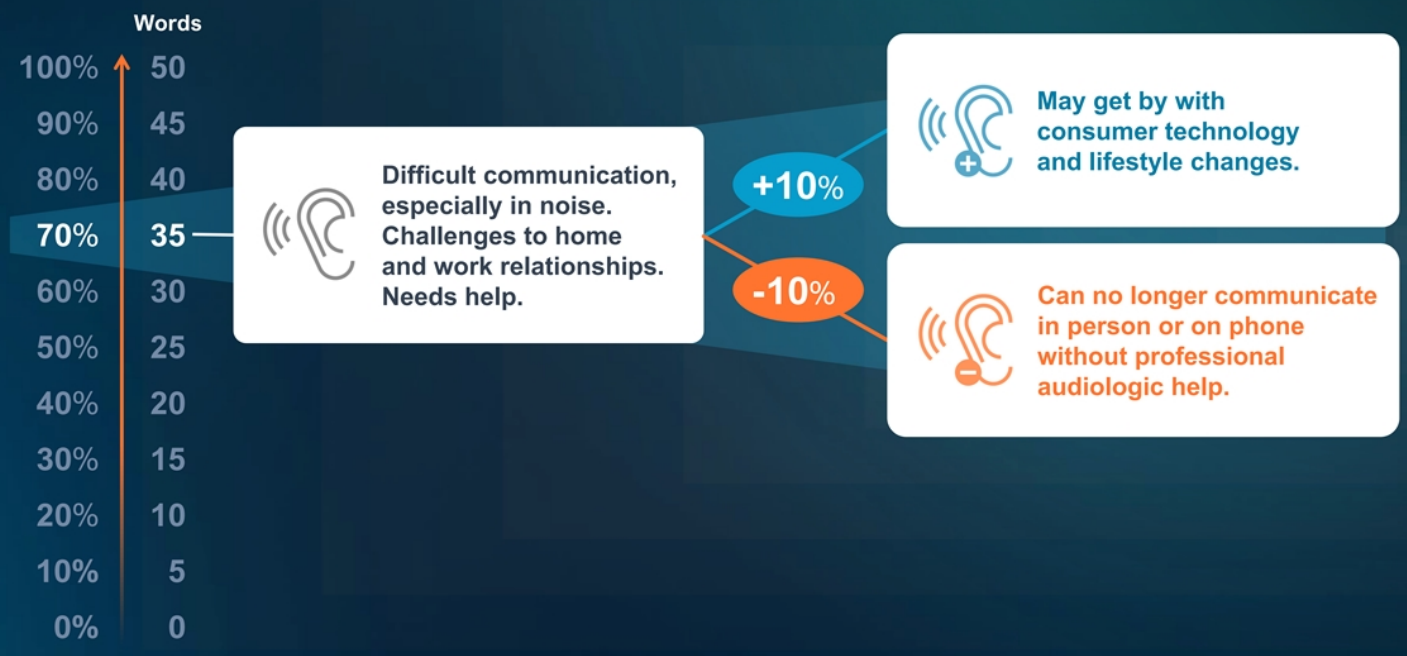
Clinically Meaningful:
10% Means Needing Audiologic Help

FREQUENCY THERAPEUTICS



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

FREQUENCY THERAPEUTICS

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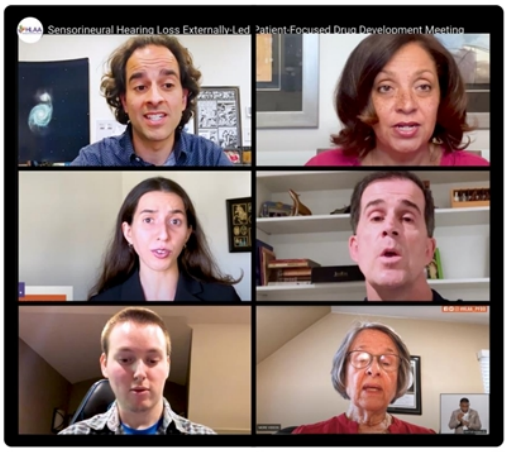
Externally-Led (HLAA) Patient Focused Drug Development Program on Sensorineural Hearing Loss

Top two needs for new drug or device

Top two hearing loss concerns



Credit: Hearing Loss Association of America (HLAA)

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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

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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.

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.

FREQUENCY THERAPEUTICS

Scientific Advisory Board

Jeff Karp, Ph.D.

Associate Professor at Brigham and Women's Hospital, Harvard Medical School

Robert Langer, SC.D.

David H. Koch Institute Professor at the Massachusetts Institute of Technology

Robin Franklin, Ph.D.

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

Sheng Ding, Ph.D.

Senior Investigator, Gladstone Institute of Cardiovascular Disease

Sean J. Morrison, Ph.D.

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

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Assistant Professor of Medicine, Columbia University Medical Center

Amy Wagers, Ph.D.

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

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Associate Director of Pediatric Audiology, Director of Cochlear Implant Program, Vanderbilt University

Steve Rauch, M.D.

Director, Vestibular Division, Medical Director, Mass. Eye and Ear Balance and Vestibular Center

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Chief of the Division of Communication Sciences, Medical College of Wisconsin

Joni Doherty, MD, Ph.D.

Assistant Professor of Clinical Otolaryngology-Head and Neck Surgery, Keck School of Medicine of USC.

Julie Arenberg, MS, Ph.D.

Associate Director of Clinical Audiology for Research and Education, Mass Eye and Ear

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

Vice-Chair of the Department of Otolaryngology and Communications Sciences, Medical College of Wisconsin


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

Exhibit 99.2

Pioneering a New Category in Regenerative Medicine

Frequency Therapeutics Virtual R&D Event

November 9, 2021

FREQUENCY THERAPEUTICS

Strategic Overview

David L. Lucchino
Chief Executive Officer

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 ability of our technology platform to provide patient benefit, the ability to continue to develop our Progenitor Cell Activation (PCA) platform and identify additional product candidates, the potential application of the PCA platform to other diseases, and the sufficiency of the Company's capital resources.

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 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 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 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 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.

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Overview
FREQUENCY THERAPEUTICS
Pioneering a New Category of Regenerative Medicine
Developing the First Therapeutic for Acquired Sensorineural Hearing Loss
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Two New Regenerative Programs

FREQUENCY THERAPEUTICS

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

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

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Agenda

FREQUENCY THERAPEUTICS


David L. Lucchino
President and CEO

Dr. Robert Langer, PhD
Scientific co-founder of Frequency
David H. Koch MIT Institute Professor

Pioneering a new category in regenerative medicine


Carl LeBel, PhD
Chief Development Officer

Kevin Franck, PhD
SVP, Strategic Marketing and New Product Planning

Advancing the first hearing restoration drug candidate

- Pooled FX-322 data show clear improvement in speech perception
- Well-designed and powered FX-322 Phase 2b study
- Clear understanding of hearing loss types that may benefit
- FDA alignment on primary endpoints


Sumit Dhar, PhD
Hugh Knowles Professor of Hearing Science, Northwestern University

Steven D. Targum, MD
Scientific Director, Signant Health

KOL perspectives

- Why FX-322 data align with how the inner ear is expected to respond
- Strength of new FX-322 study design


Chris Loose, PhD
Chief Scientific Officer

Sanjay Magavi, PhD
VP, Myelination Research

Expanding regenerative pipeline with two new programs

- FX-345 in hearing restoration
- FREQ-162 for remyelination in MS

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Execution and Pipeline Expansion

FREQUENCY THERAPEUTICS

Team and resources to advance these programs to the millions in need of new treatment options.

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Pioneering a New Category in Regenerative Medicine

Dr. Robert Langer

Frequency Therapeutics Co-founder and
MIT Institute Professor

Key Learnings from FX-322 Hearing Restoration Program

Carl LeBel, PhD
Chief Development Officer

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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

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

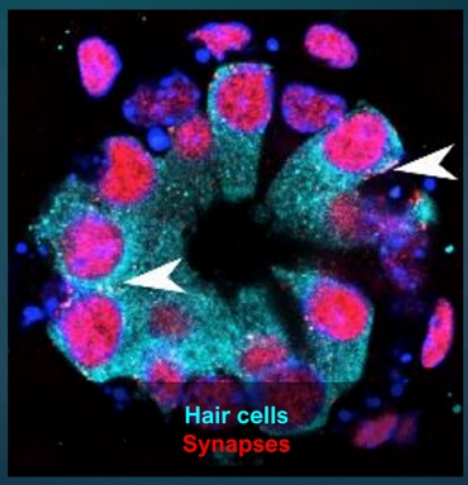
FREQUENCY THERAPEUTICS

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

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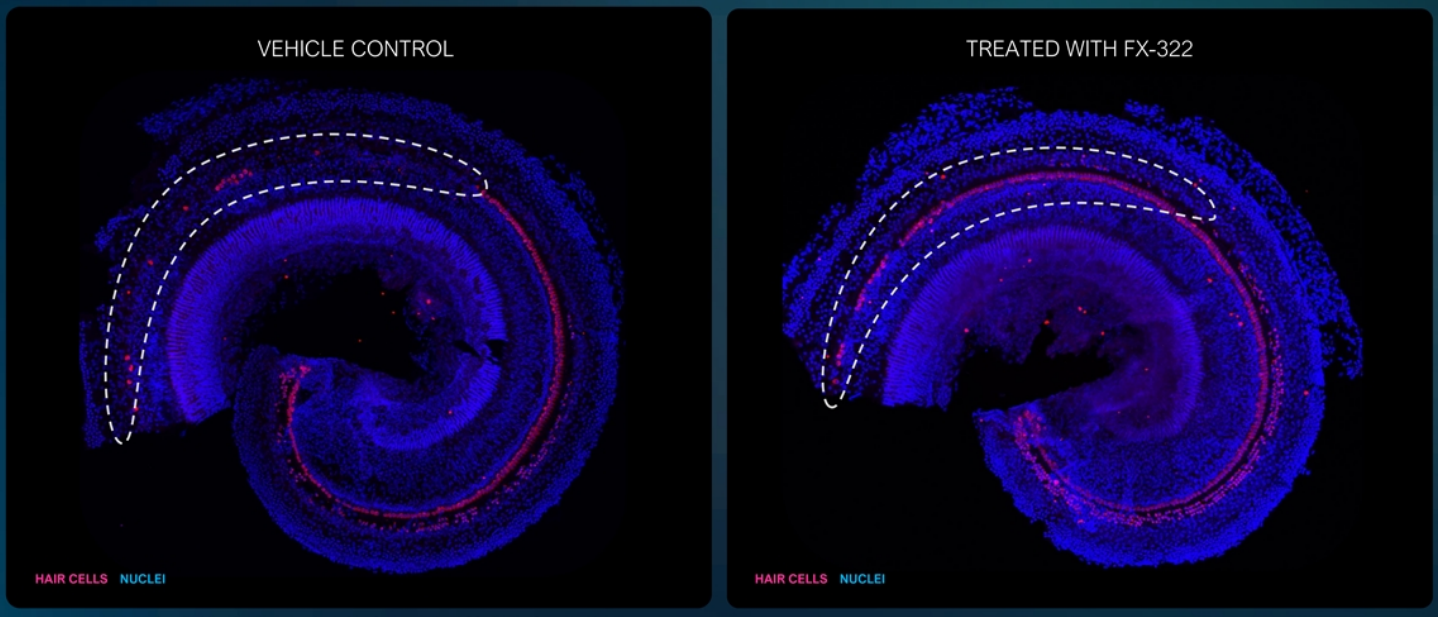
Images Showing Cellular Regeneration

In Vivo Hearing Loss Model

FREQUENCY THERAPEUTICS



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

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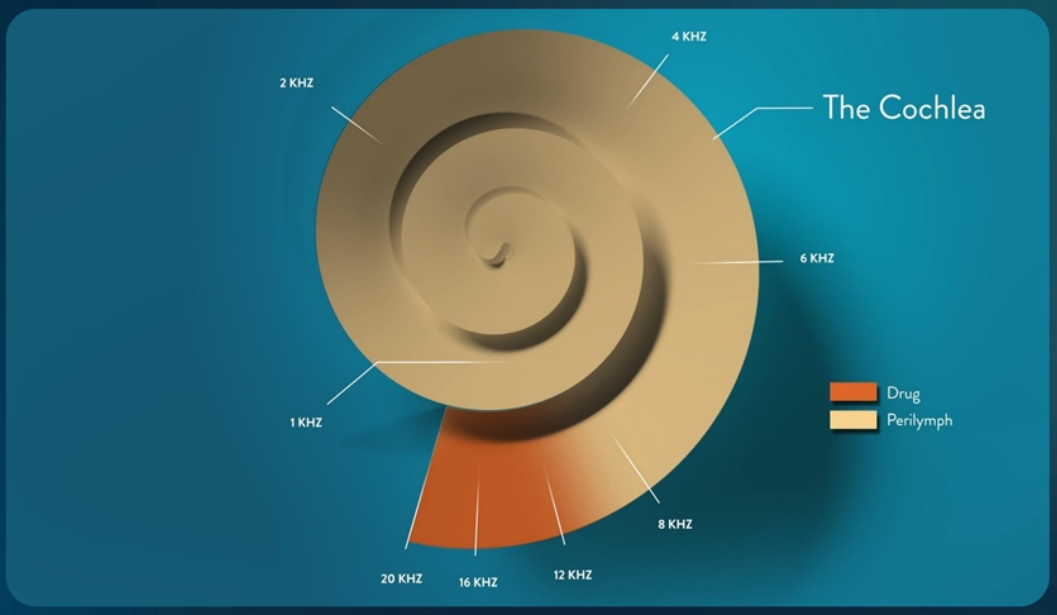
First to Prove FX-322 Delivery to the Human Cochlea

FREQUENCY THERAPEUTICS



FX-322

Clinical signal achieved with drug localized in the high frequency region

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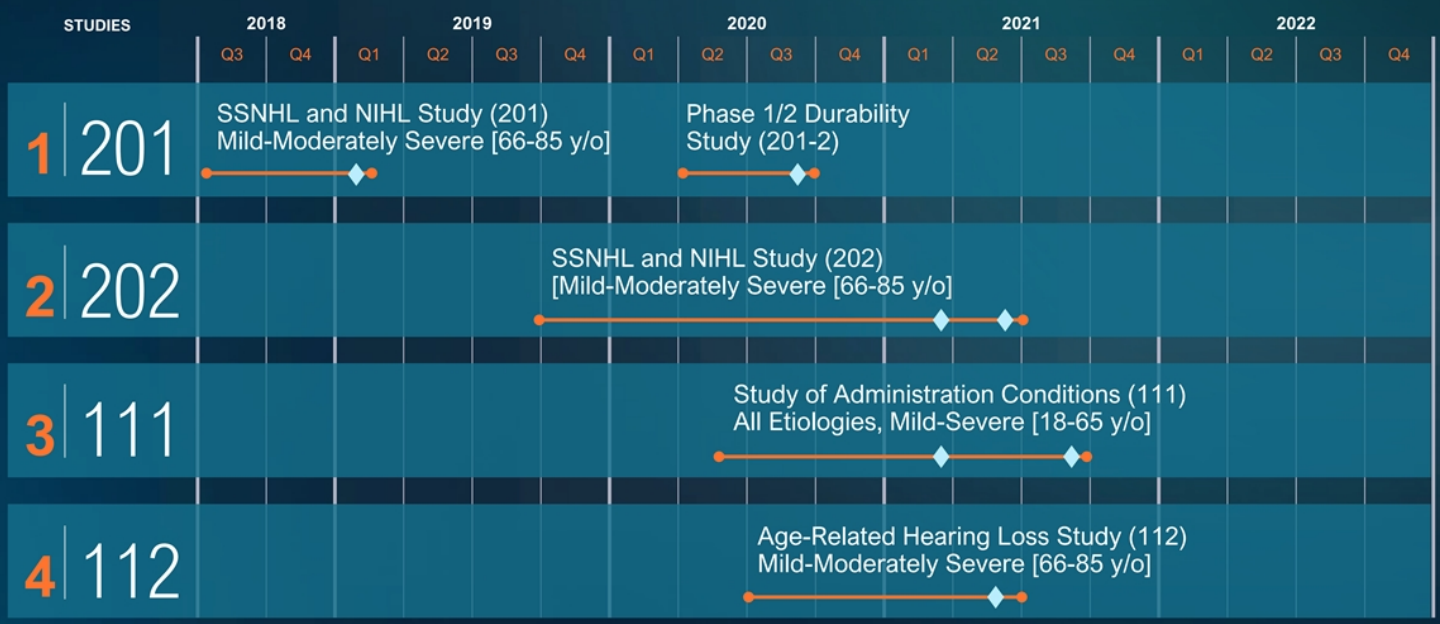
Four FX-322 Completed Studies: 169 Subjects

Favorable Safety Profile with No Treatment-Related SAEs

FREQUENCY THERAPEUTICS



◆ = Data Readout

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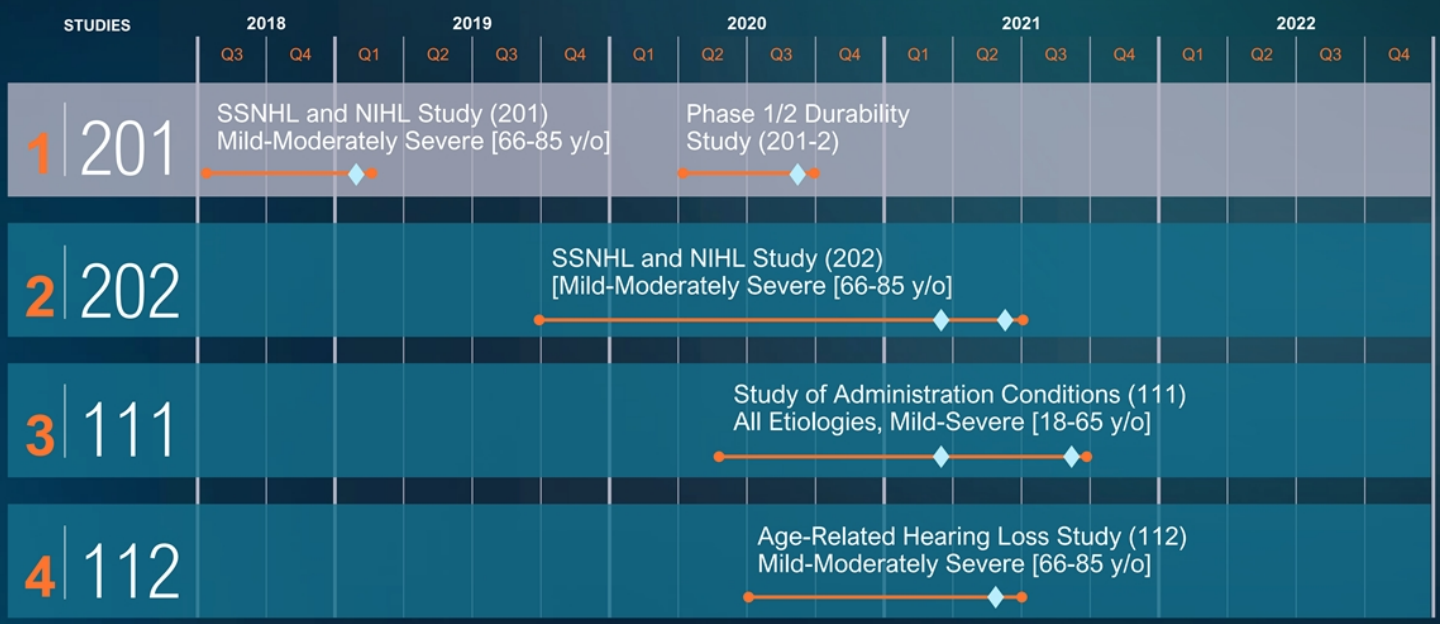
FX-322-201

Single-Dose Safety Study With First Hearing Improvement Signal



◆ = Data Readout

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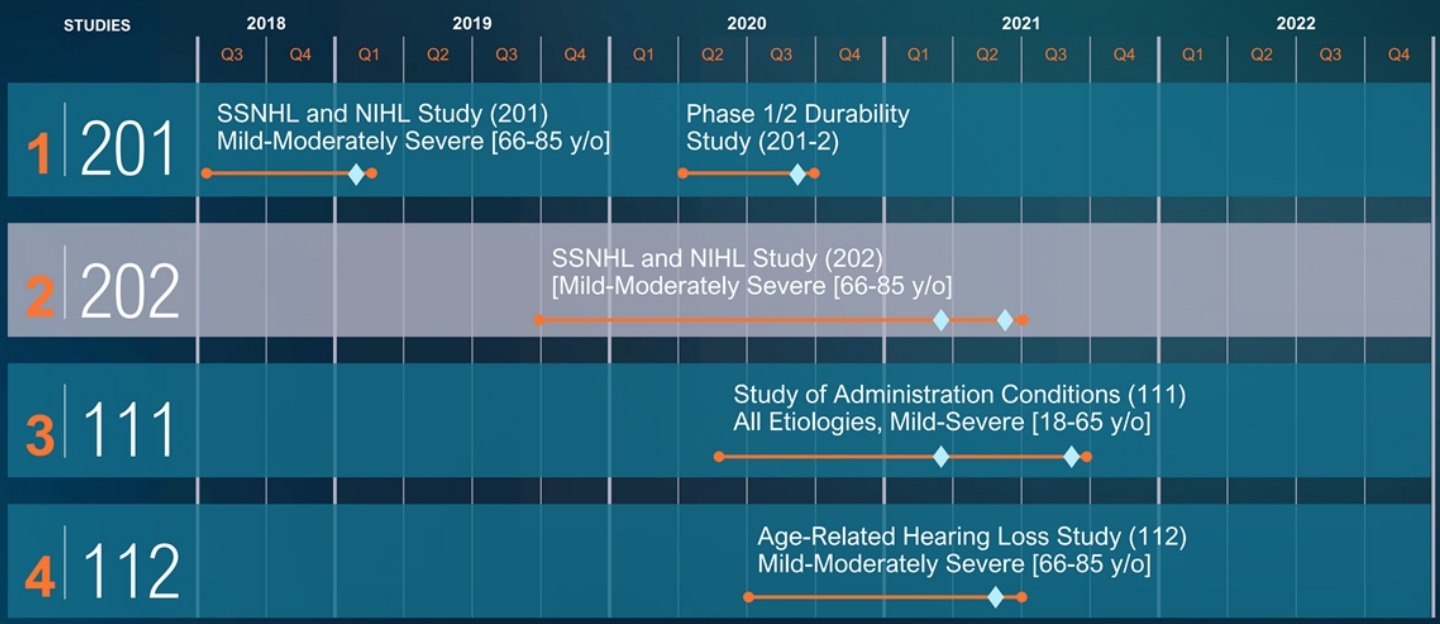
FX-322-202

Multiple Injection Study to Assess Safety of Increased FX-322 Exposure



◆ = Data Readout

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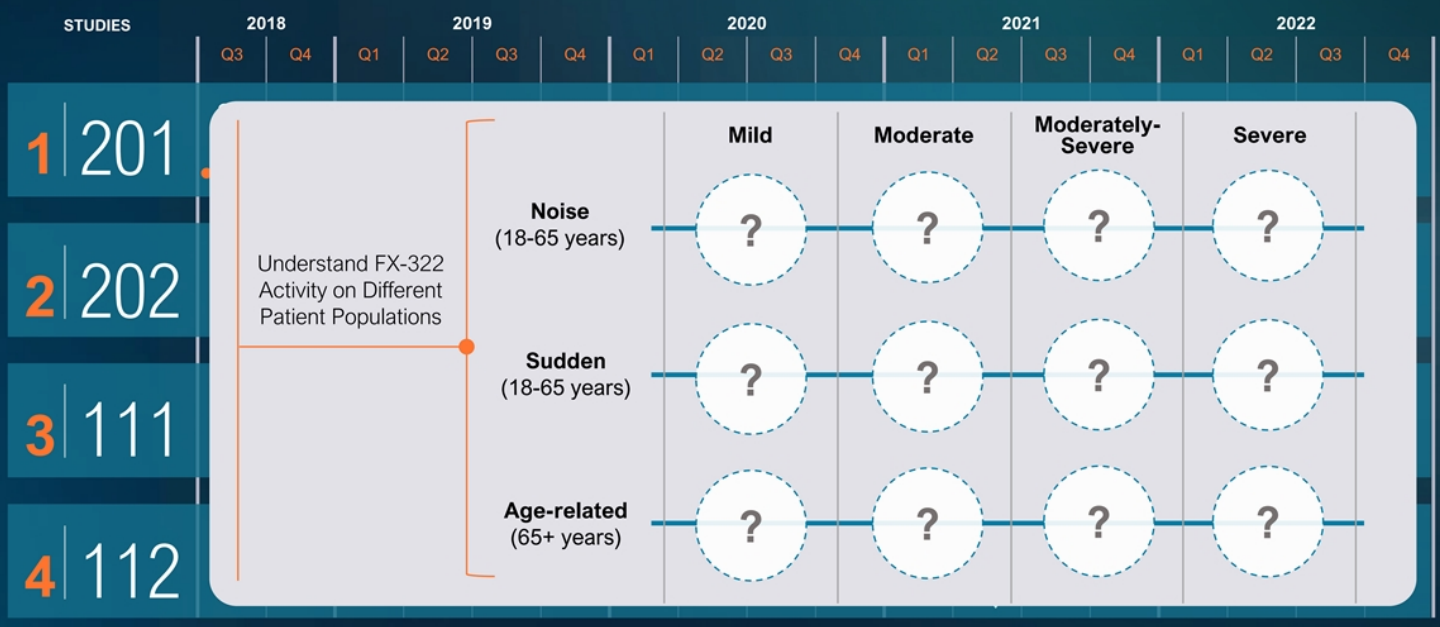
FX-322 Clinical Strategy

Evaluate Etiologies and Severities to Understand FX-322 Activity



◆ = Data Readout

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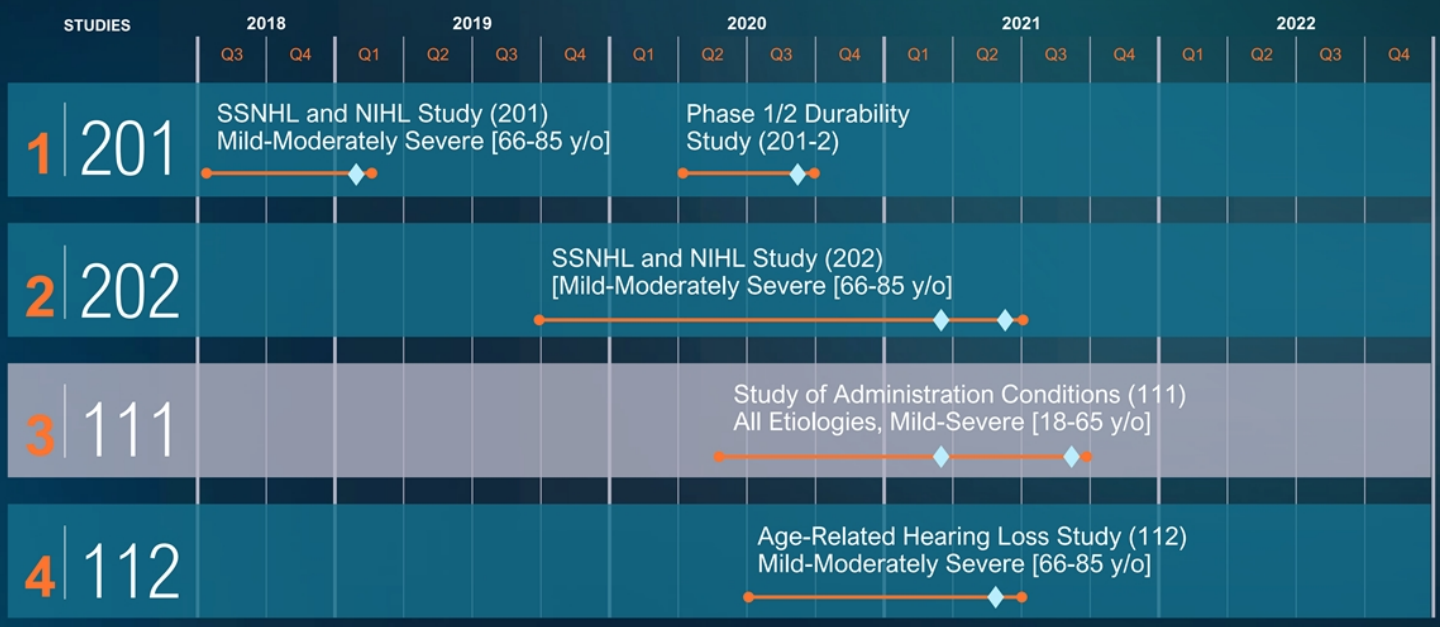
FX-322-111

Second Single-Dose Safety Study with Hearing Improvement Signal



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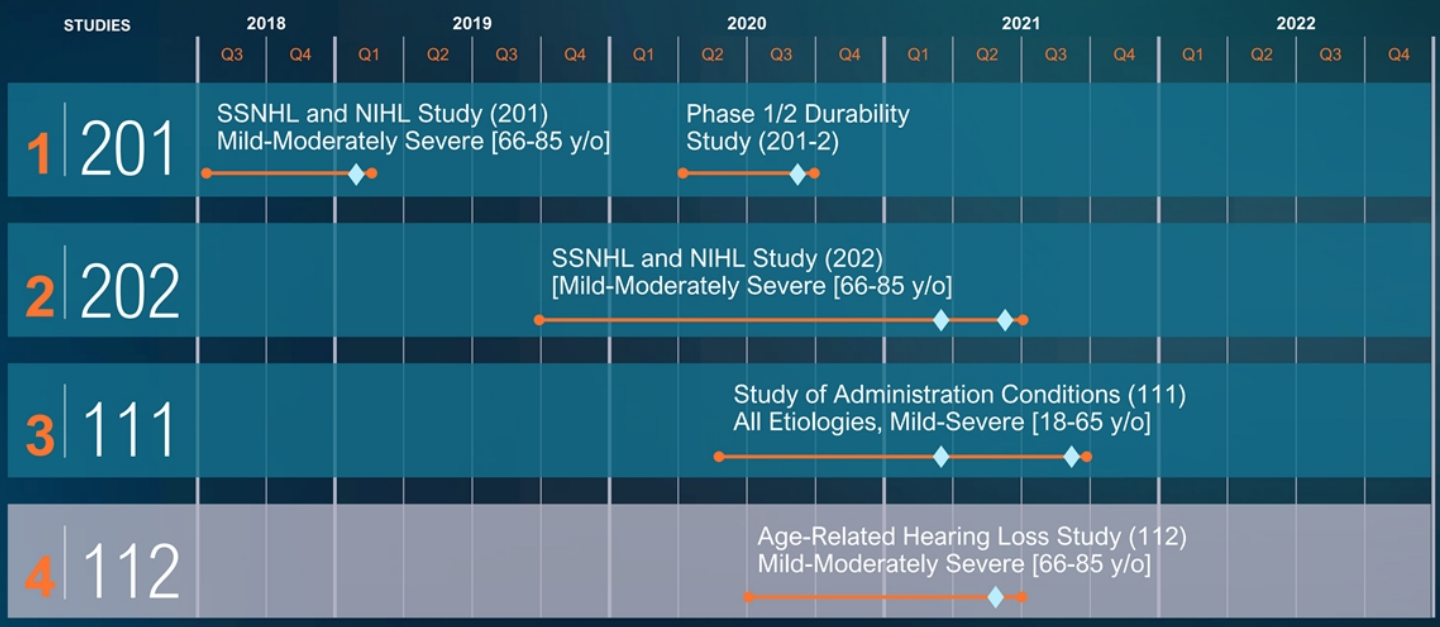
FX-322-112

Single-Dose Safety Study in Older Patients without NIHL or SSNHL



◆ = Data Readout

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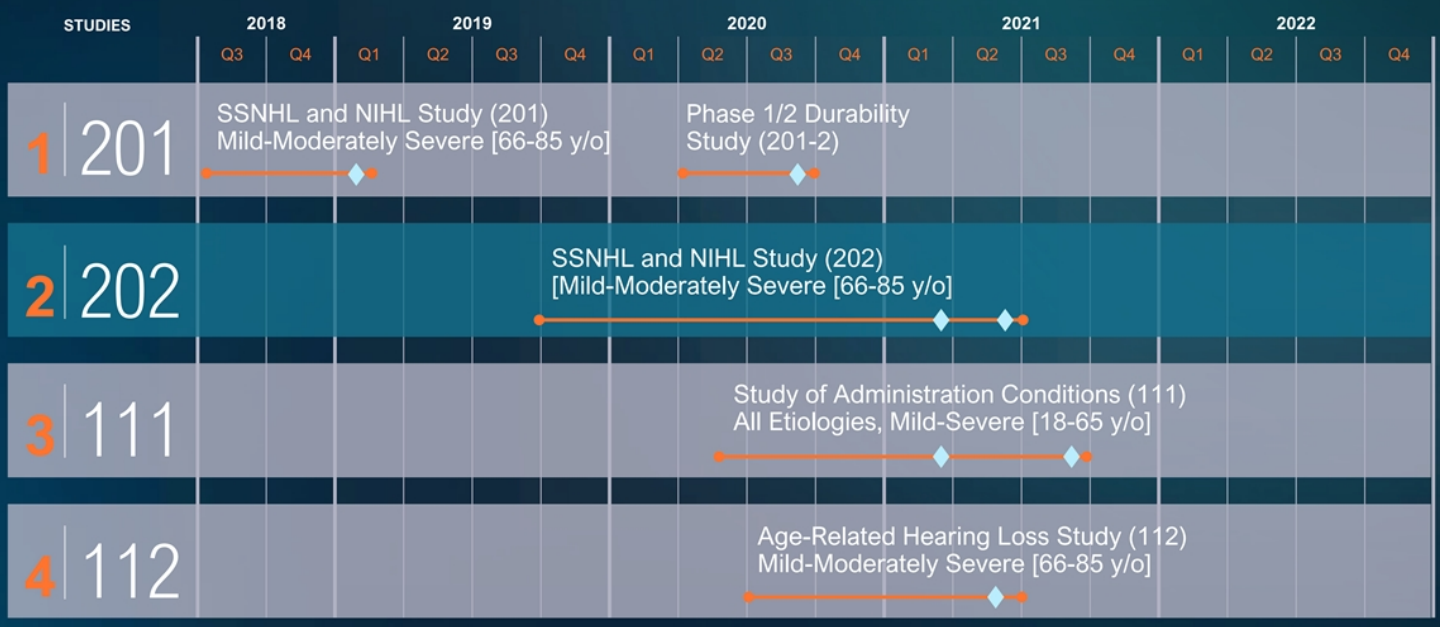
Pooling Data From Three Single-Dose FX-322 Trials

Evaluate Characteristics of Responders



◆ = Data Readout

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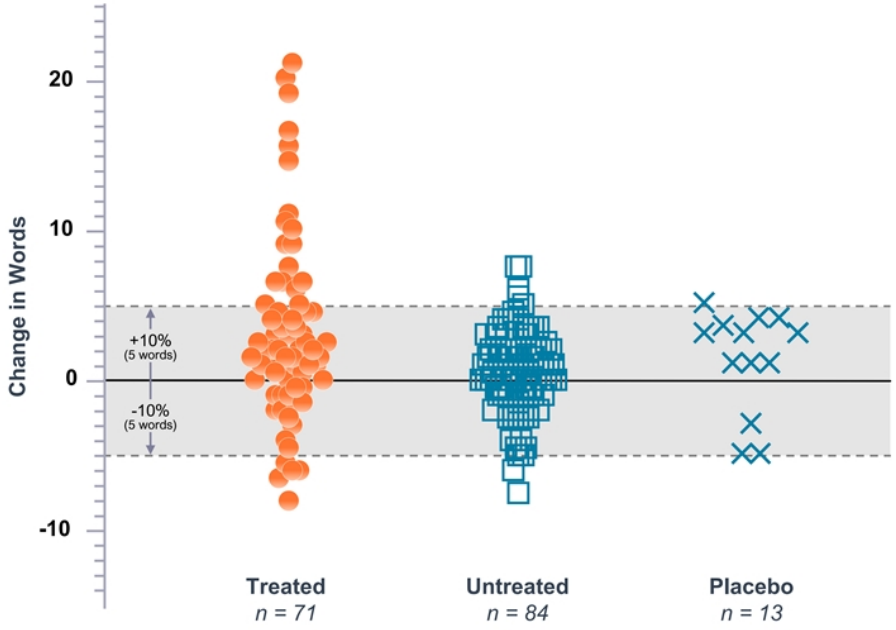
Pooled FX-322 Data Shows Patterns of Response

Single-dose Studies (201, 111, 112) Using a Responder Definition



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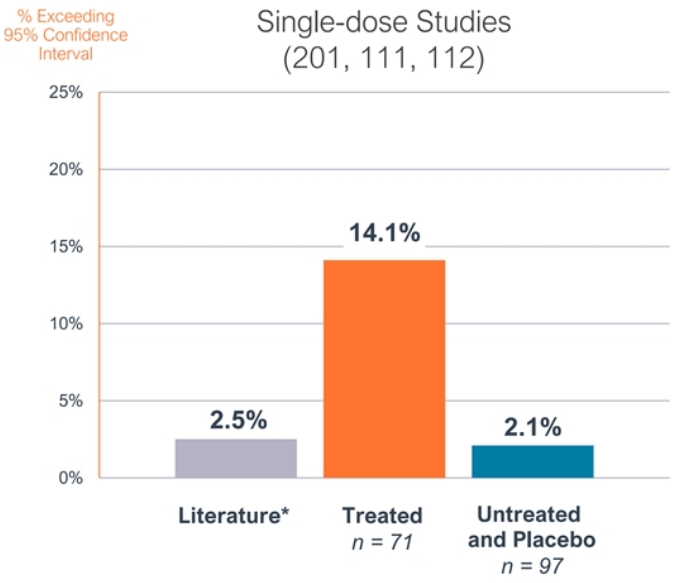
Pooled FX-322 Data Shows Patterns of Response

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



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

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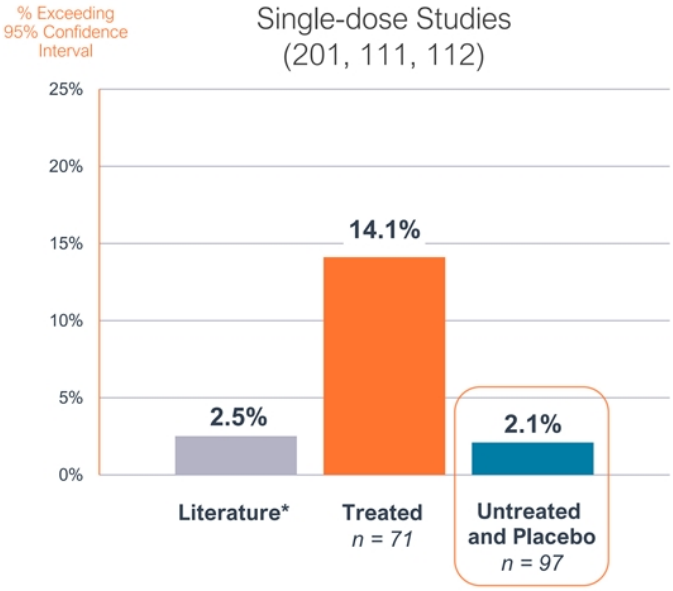
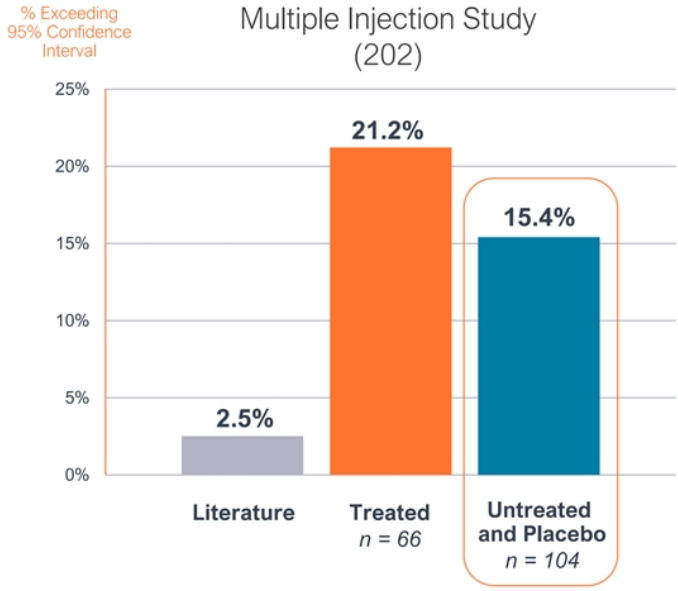
Comparing Pooled Data to Multiple-Injection Study FX-322-202

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





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

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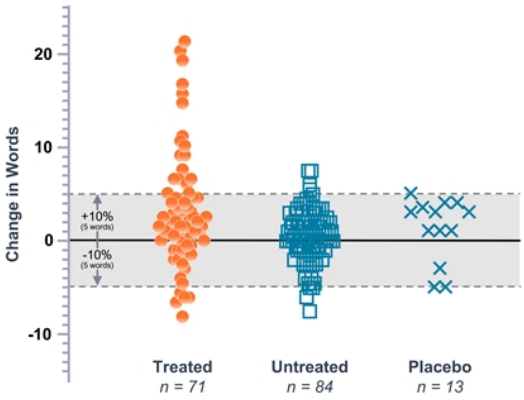
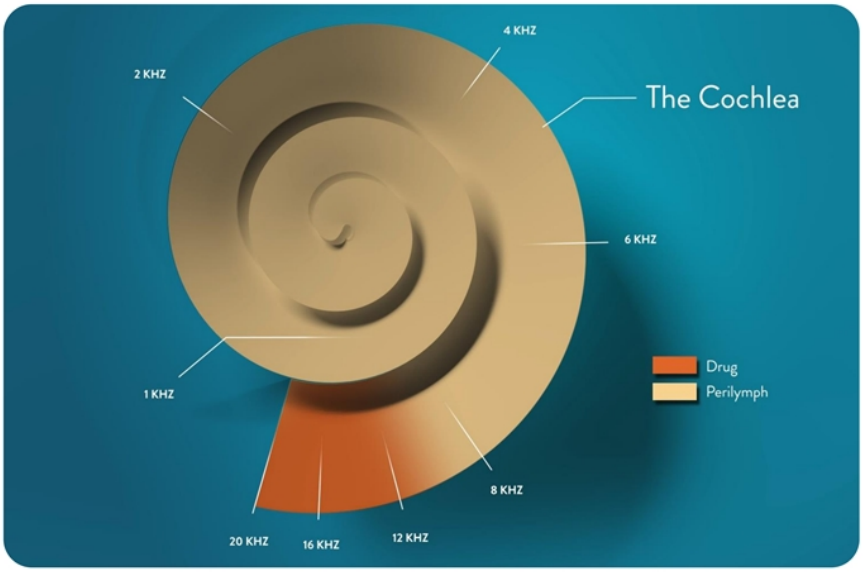
Clear Speech Perception Improvements from FX-322 in High Frequency Range of Cochlea

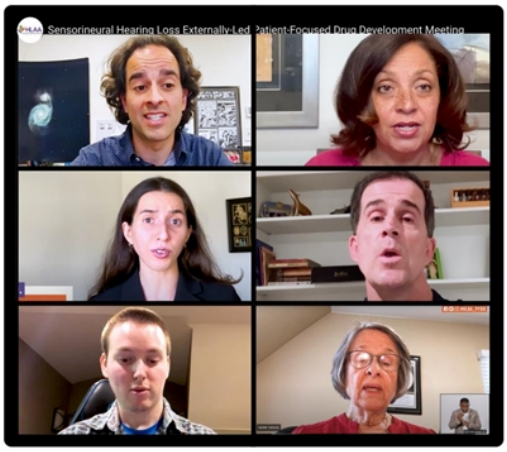




Externally-Led (HLAA) Patient Focused Drug Development Program on Sensorineural Hearing Loss

Top two needs for new drug or device

Top two hearing loss concerns



Credit: Hearing Loss Association of America (HLAA)

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

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Summary

FREQUENCY THERAPEUTICS

- Developed a novel, locally delivered, drug-drug combination that regenerates cochlear function preclinically
- First hearing restoration signal observed in humans
- Second independent trial shows hearing restoration signal
- Favorable safety profile
- Alignment with FDA on primary endpoint for 208 and future FX-322 studies

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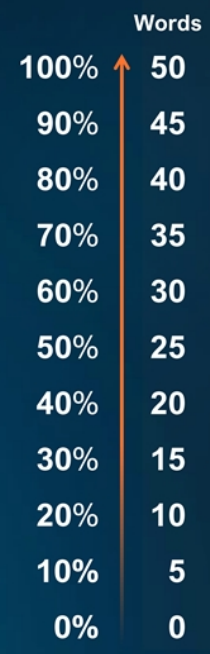
FX-322 Clinical Data and Real-World Impact of Speech Perception Improvements

Kevin Franck, PhD

SVP, Strategic Marketing and New Product Planning

Clinically Meaningful:



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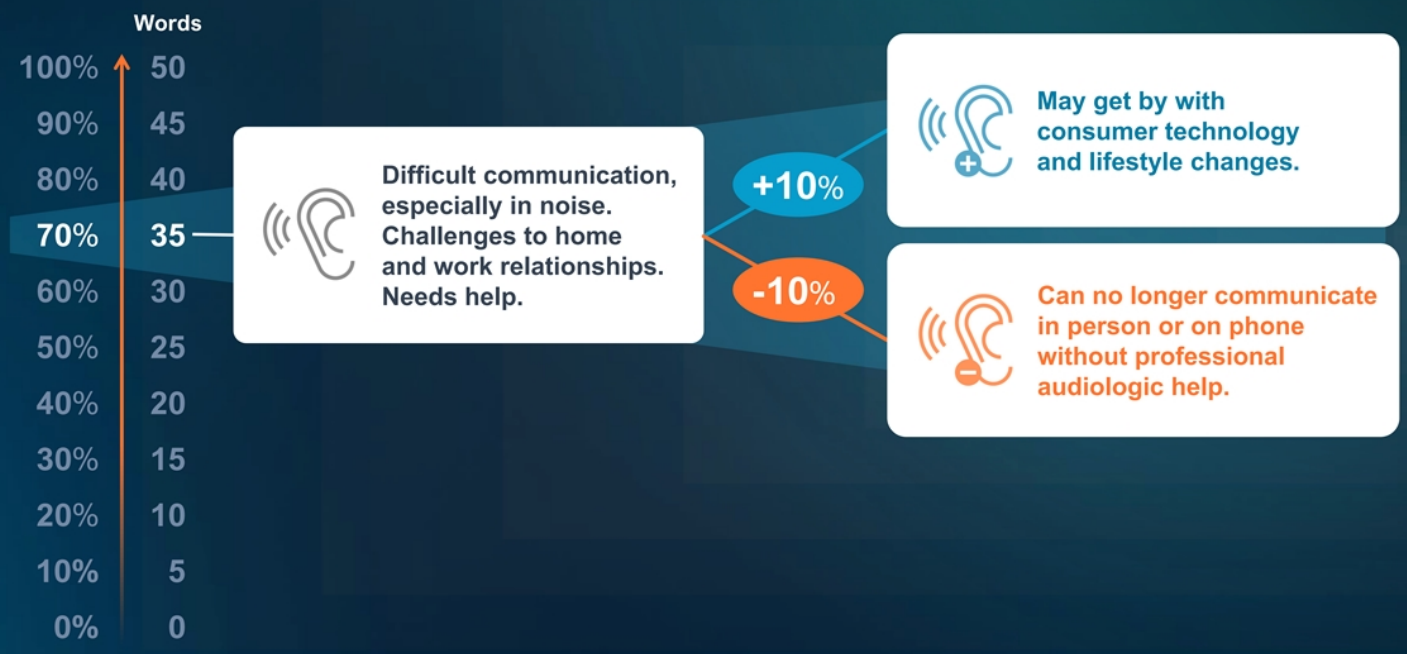
Clinically Meaningful:
10% Means Needing Audiologic Help

FREQUENCY THERAPEUTICS



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

FREQUENCY THERAPEUTICS

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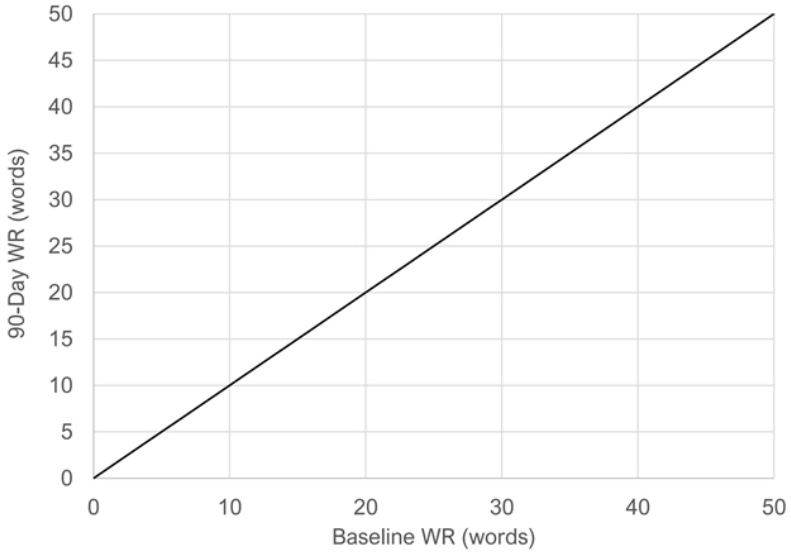
10% Absolute Change is Clinically Meaningful

Speech Perception

10% absolute change is considered clinically meaningful



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

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10% Absolute Change is Clinically Meaningful

Speech Perception

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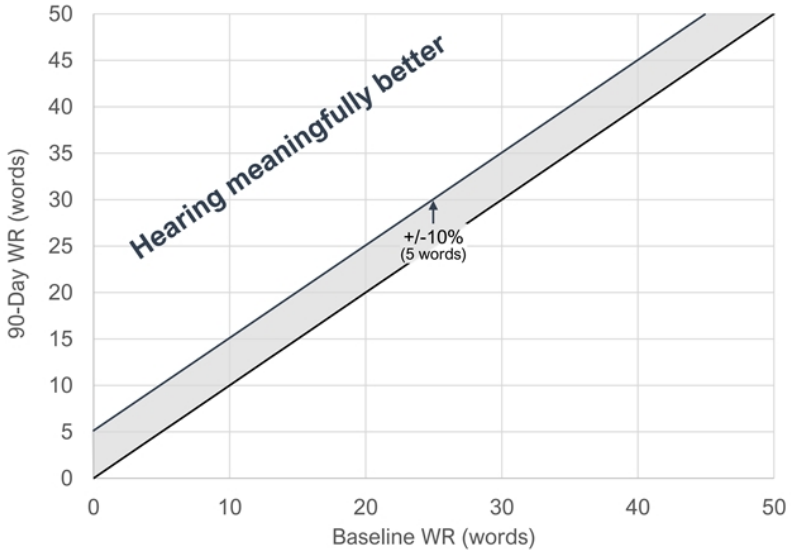

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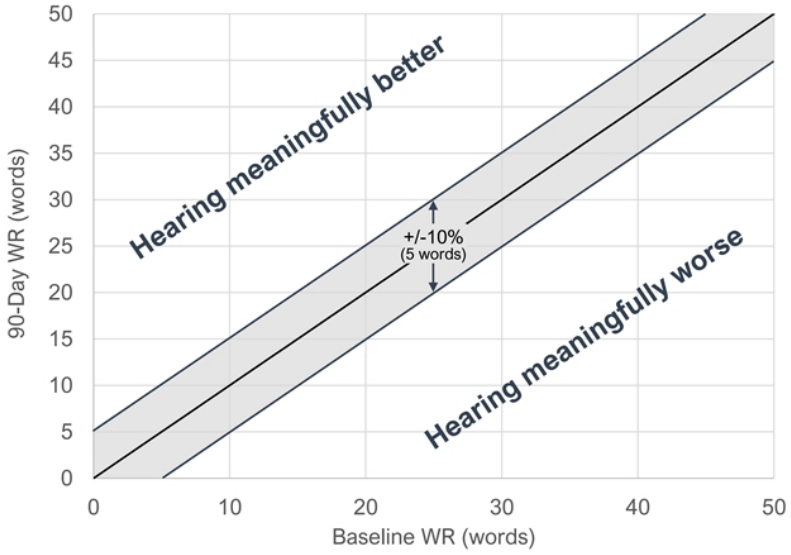

95% confidence intervals established by Thornton & Raffin (1978) and modified by Carney & Schlauch (2007)

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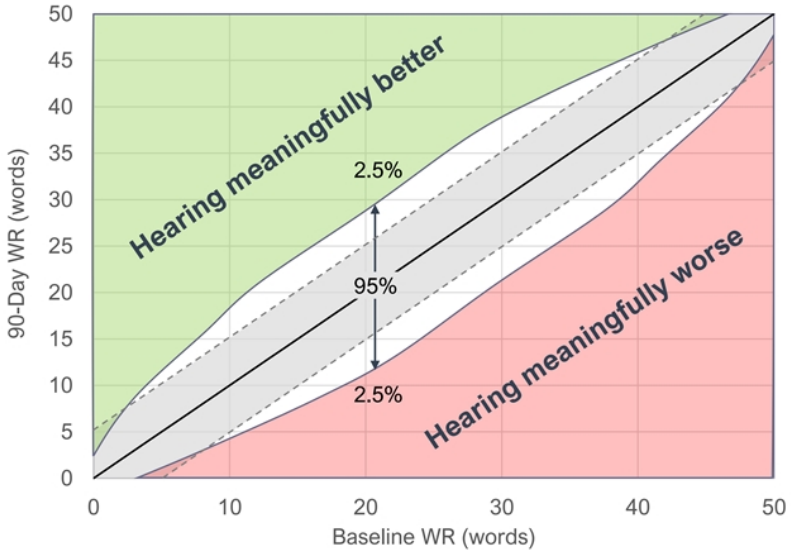
Statistical Significance Sets a Higher Bar

FREQUENCY THERAPEUTICS

Speech Perception

10% absolute change is considered clinically meaningful

A 95% confidence interval can show patients with statistical improvement from their starting point



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

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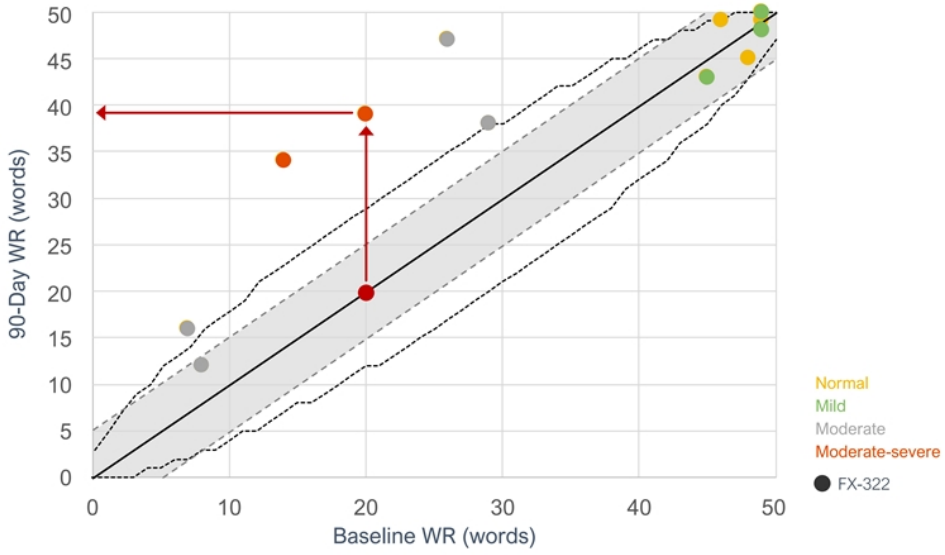
Study 201

Responders Shown within 95% Confidence Interval

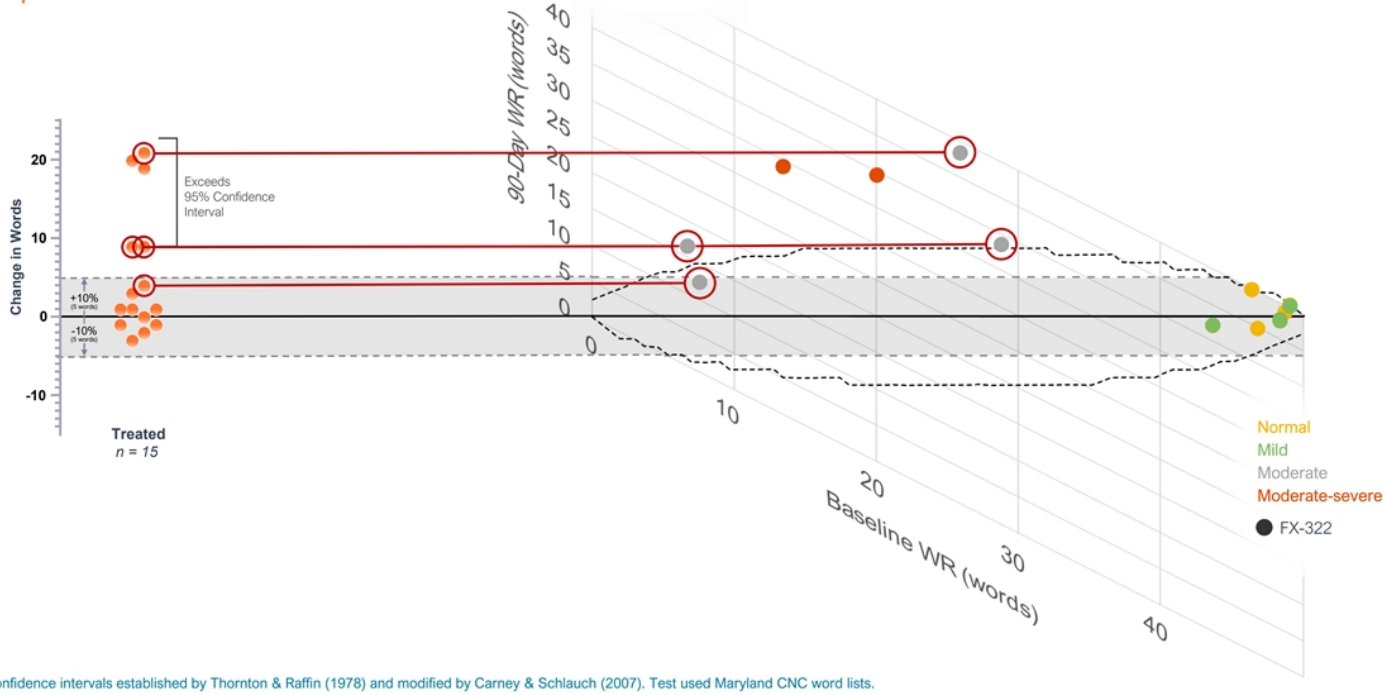


95% confidence intervals established by Thornton & Raffin (1978) and modified by Carney & Schlauch (2007). Test used Maryland CNC word lists.
McLean et al O&N 2021

© Frequency Therapeutics, Inc.

Study 201

Responders Shown within 95% Confidence Interval



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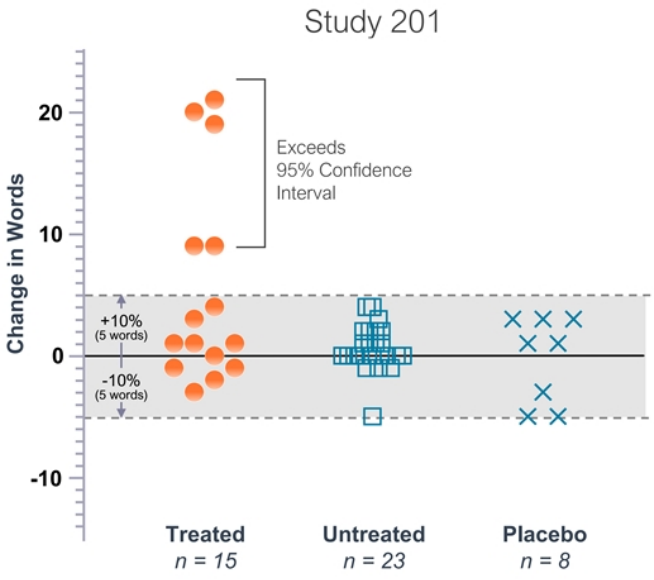

Study 201

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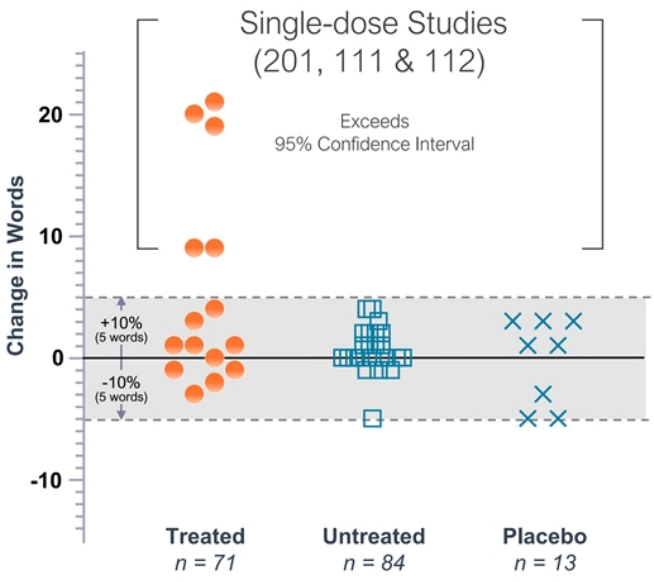

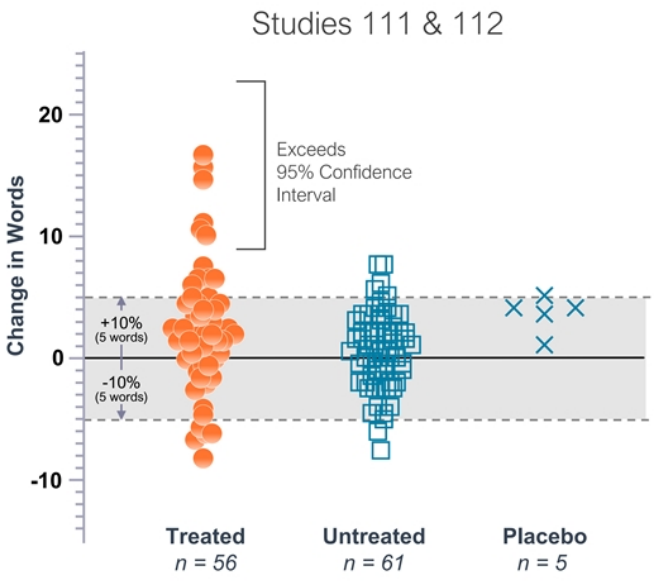

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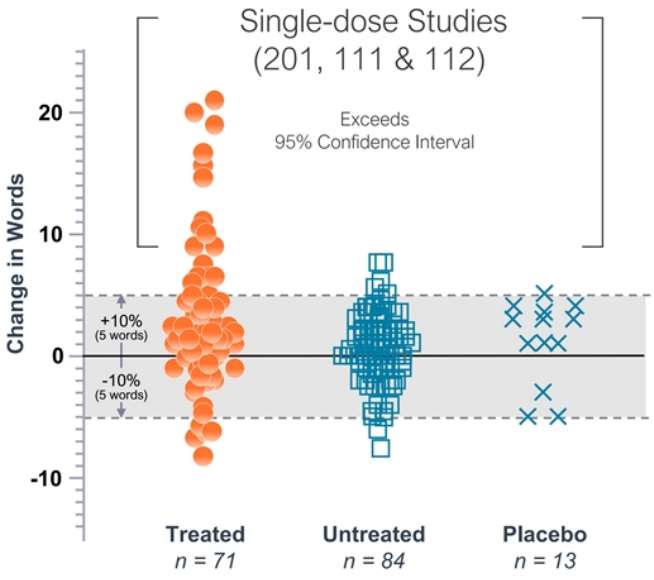
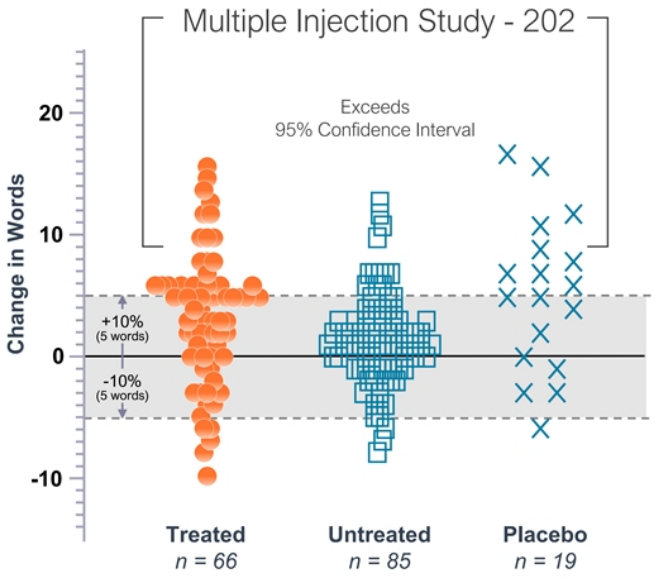
Pooled Single-Dose Studies (201, 111, 112)

Highlights 202 Anomalies





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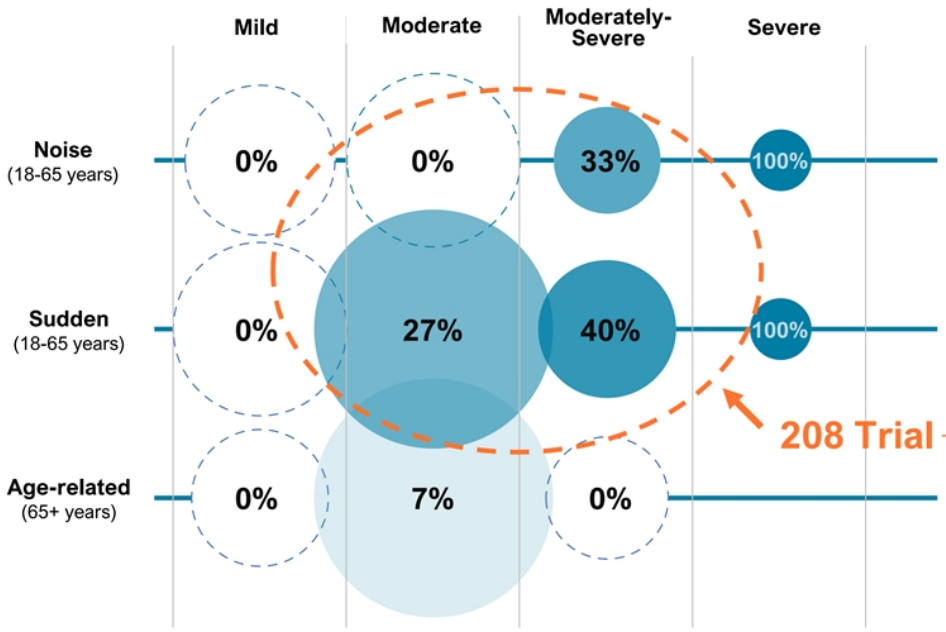
Pooled Single-Dose Studies (201, 111, 112)

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

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Cochlear Pathology and the Impact of High Frequencies on Speech Perception

Sumit Dhar, PhD

Hugh Knowles Professor of Hearing Science and
Associate Provost for Faculty at Northwestern University

Disclosures

Honorarium from Frequency TX to review all clinical data from past studies and assess planned clinical trial. Participated on external panel of KOL's on auditory science.

Primary employment at Northwestern University.

Parts of my salary are paid by the NIH and PCORI.

I receive royalty and consulting fees from Plural Publishing.

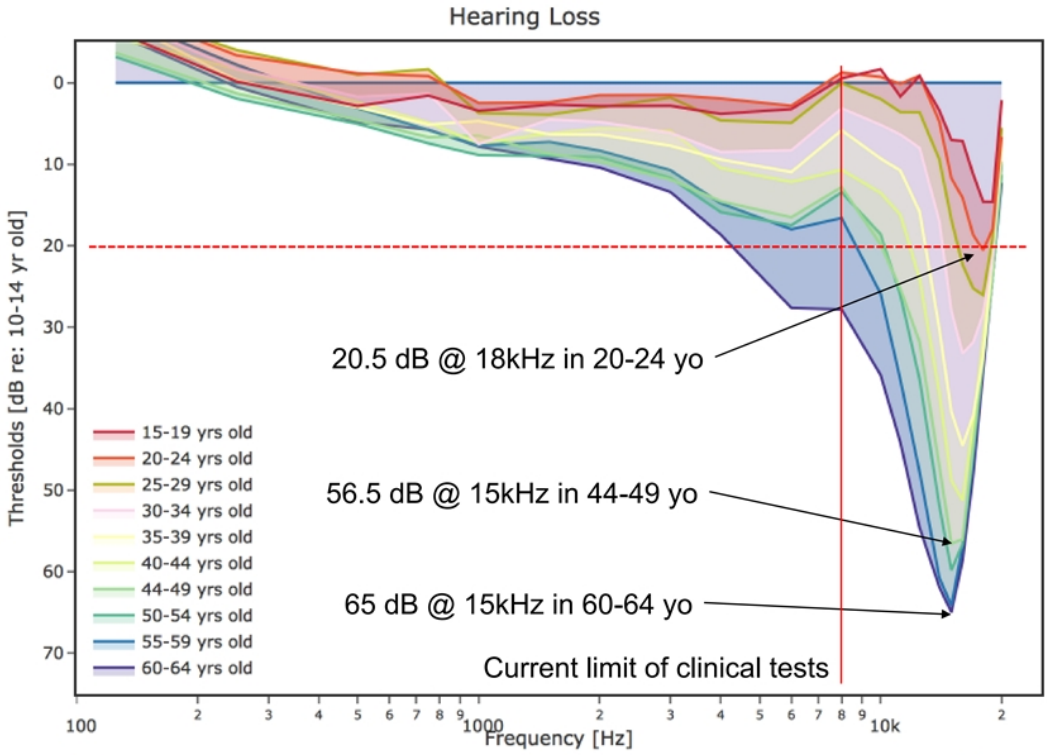
I receive licensing fees from Etymotic Research.

I serve on the Board of Directors of the American Auditory Society.

I serve on the Board of Directors of LeAP (Language Empowers All People).

Why Treat the High-Frequency Region of the Cochlea?

Common Forms of Hearing Loss is Dominant in the Highest Frequencies



N=976; Lee et al., 2012; Hunter et al., 2020

How Does High Frequency Cochlear Function Influence Speech Perception?

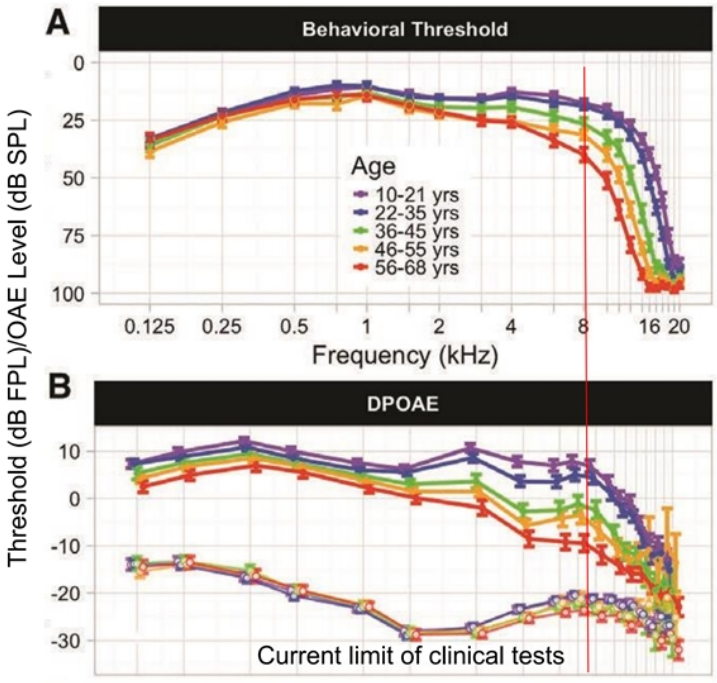
Speech Perception Influenced by Cochlear Function in High-Frequency Regions

N = 921

DPOAE levels between 12.5 – 16 kHz drive speech perception in noise scores (p = 0.047, R^2 = 0.017) more than audibility.

Speech perception is the complaint that leads patients to seek treatment.

Speech perception is the the long-standing gold standard in determining functional outcomes of *any* treatment for hearing loss.



Stiepan et al., 2020

Should We Expect Heterogeneity in Treatment Outcomes?

Response Variability Predicted by Cochlear Heterogeneity

Heterogeneity of response magnitude and response timeline is the reality of all hearing loss treatments

- Decades of data from cochlear implants and hearing aids definitively demonstrate heterogeneity in response
- Likely driven by varying damage and rates of plasticity in the auditory system.

Impact of Heterogeniety on Clinical Study Planning

Etiology and duration of pathology is heterogenous across individuals.

Frequency TX's approach of exploring various etiologies and pathologies in early studies was the necessary approach to identify target responder populations.

The design and controls put in place for the next study represent the best path forward.

Takeaways

Treating the HF region of the cochlea is critical.

Function of the HF region can influence speech perception.

Heterogeneity of response is a reality of all treatments for hearing loss.

Clinical Development Path for Hearing Restoration Program

Carl LeBel, PhD
Chief Development Officer

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

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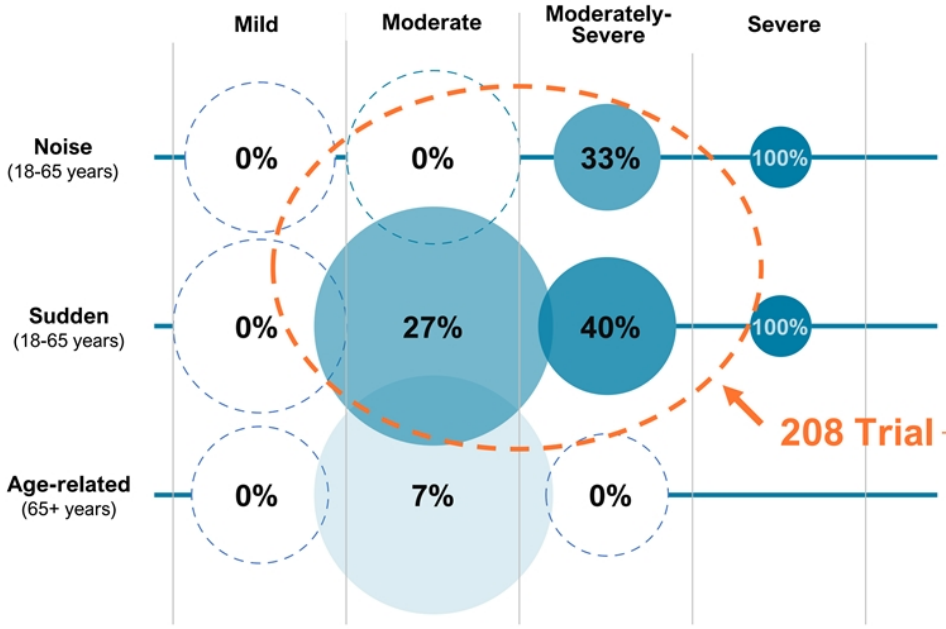
Pooled Single-Dose Studies (201, 111, 112)

Data Suggest Patterns Between Etiology/Severity and Response



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208 Trial: Target Population

7-10 Million
U.S. patients

FX-322: Extended Population

15+ Million
U.S. patients

© Frequency Therapeutics, Inc.

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

Data Show Clear Subset of Patients Responding to FX-322

FREQUENCY THERAPEUTICS

- **Observed consistent response in two major etiologies**
  - Noise-induced Hearing Loss
  - Sudden Sensorineural Hearing Loss
- **Observed consistent response in specific range of SNHL severity**
  - Moderate to lower end of severe

Study powered at 80%

Effect size 20% over placebo

Significance level is 0.05

Sample size is 124 subjects (assumes 10% attrition)

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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**

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

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

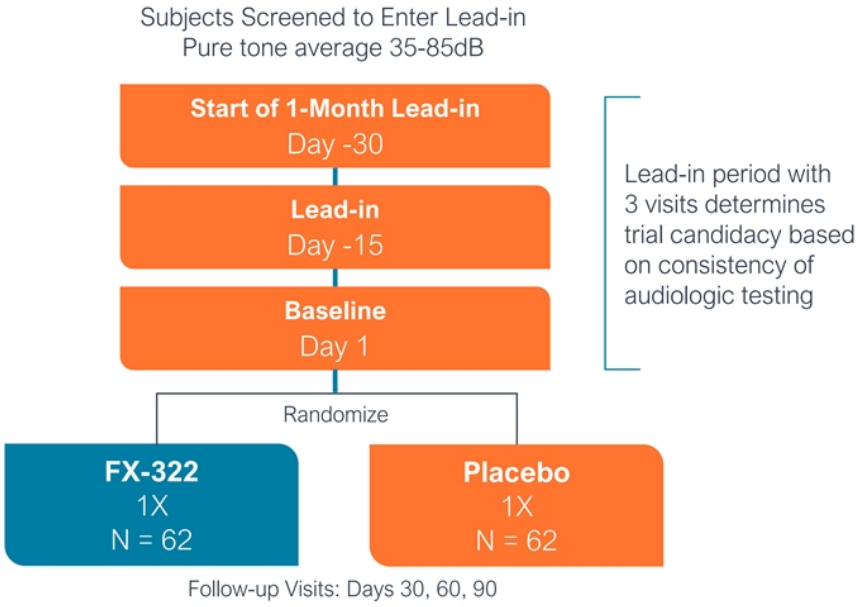
124 Subjects

Subjects will have diagnosed noise induced or sudden sensorineural hearing loss

Rigorous bias management controls in place

Ages 18 – 65

Primary endpoint:
Speech perception
(in agreement with FDA)



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Confidence in Path Forward for FX-322

FREQUENCY THERAPEUTICS

- FX-322 shows hearing signal in speech perception; aligns with FDA endpoint
- FREQ has unparalleled dataset providing extensive insight into responder profiles
- Learnings from trials have provided critical insight into mitigating bias through multiple trial design components
- Phase 2b study optimized to confirm that FX-322 can restore hearing in targeted study population

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Addressing Placebo Response in Clinical Trials: Best Practices

Steven D. Targum MD

Clinical Consultant

Scientific Director, Signant Health

Steven D. Targum MD
Disclosures

Scientific Director, Signant Health

Clinical consultant/Scientific Advisory Board activities (past 3 years):

- Acadia Pharmaceuticals Inc., Alkermes Inc., AZ Therapies, BioXcel Therapeutics Inc., Denovo Biopharma, EMA Wellness, Epiodyne, Frequency Therapeutics, Functional Neuromodulation LLC, Johnson and Johnson PRD, Karuna Pharmaceuticals, Methylation Sciences Inc., Merck Inc., Navitor Pharmaceuticals, Neurim Pharmaceuticals, Neurocrine, Pax Neuroscience, Resilience Therapeutics, Sunovion Inc., Takeda Pharmaceuticals, XR Health, Yale University school of medicine.

The Inherent Challenge of Clinical Trials: Reliability

- **Challenges** to study reliability include:
  - **Misplaced enrollment incentives**
  - **Expectation bias**
  - **Pre-randomization symptom fluctuation**
  - **Lack of ratings precision** and **consistency**

The Frequency Experience in FX-322-202
Can Inform the Next Study

- **Post-hoc review of the FX-322-202 trial found:**
  - **Inflation of hearing deficits at screen**
    - Subjects under-reported the number of words they could understand from the word recognition test in order to achieve study eligibility.
  - **Open communication about eligibility criteria**
    - Some clinical trial site staff shared with subjects the reasons that they were excluded from the trial.
    - Frequency vocally communicated the requisite hearing deficits necessary to enter the trial *and* the intended primary endpoint.
  - **Social media**
    - Some subjects shared their information on social media platforms that are routinely used by subjects with hearing loss.

Experience Informs the Next Study: FX-322-208

Best Practices to Optimize Trial Outcome and Mitigate the Placebo Response

- A protocol that **blinds** the key eligibility metric criteria from both staff and subjects (***masking***) and employs **multiple hearing assessment measures**
  - Blinding mitigates the risk of intentional inflation of hearing loss deficits
  - Multiple measures distract subjects from the “true” eligibility criteria
  - Blinding mitigates the risk of site staff sharing specifics about the study
- Employ a protocol addendum for the masked criteria
  - FX-322-208 Unmasked Addendum is ***not seen by the trial site***
- **Add an interim visit** to assess symptom stability
- Add **rater training** and **site-independent monitoring** as quality assurance layers to assure ratings precision

Regenerative Medicine: The Path Forward

David L. Lucchino
Chief Executive Officer


FREQUENCY
THERAPEUTICS
Delivering FX-322
as the First Therapeutic
to Restore Hearing
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Regenerative Medicine: Expanding and Extending Our Pipeline

Two New Regenerative Programs

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Two New Regenerative Programs

- Restoring hearing across more and different types of patients
- New remyelination program aimed at repairing the underlying cause of MS

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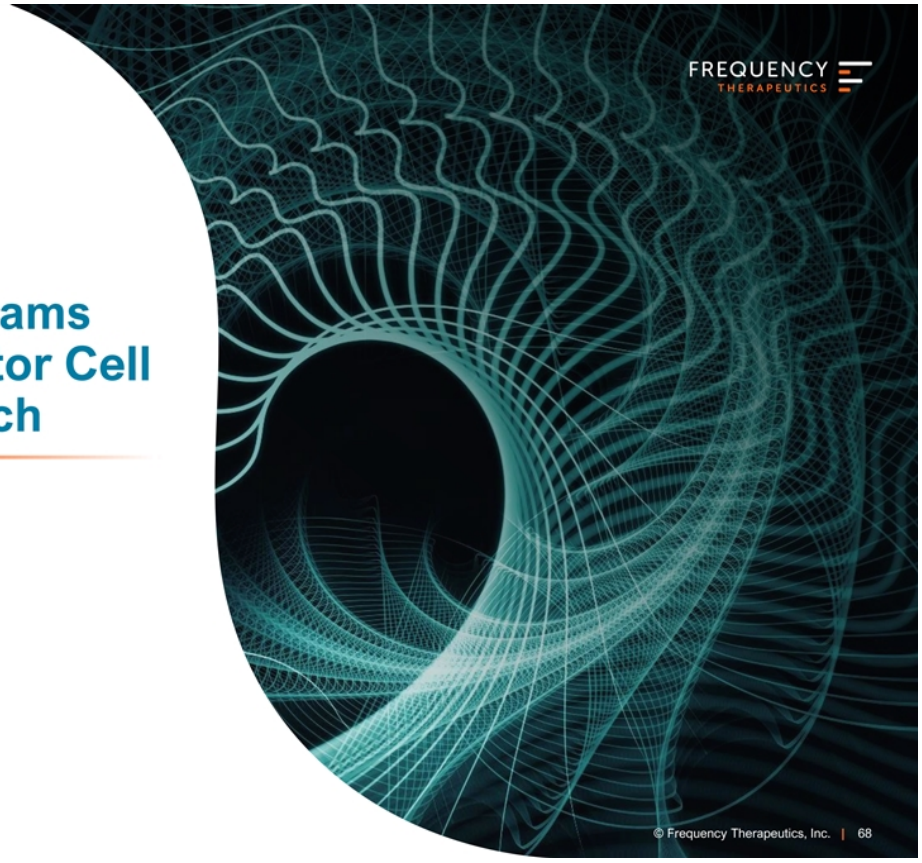

New Regenerative Programs from Continued Progenitor Cell Activation (PCA) Research

Chris Loose, PhD
Chief Scientific Officer

Power of the 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*

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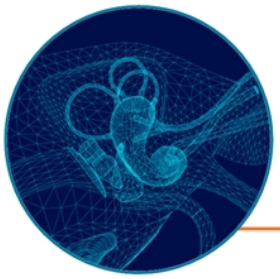
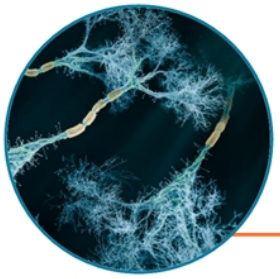
Two New Regenerative Programs



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



How do we extend this approach to other degenerative diseases?

FREQUENCY THERAPEUTICS

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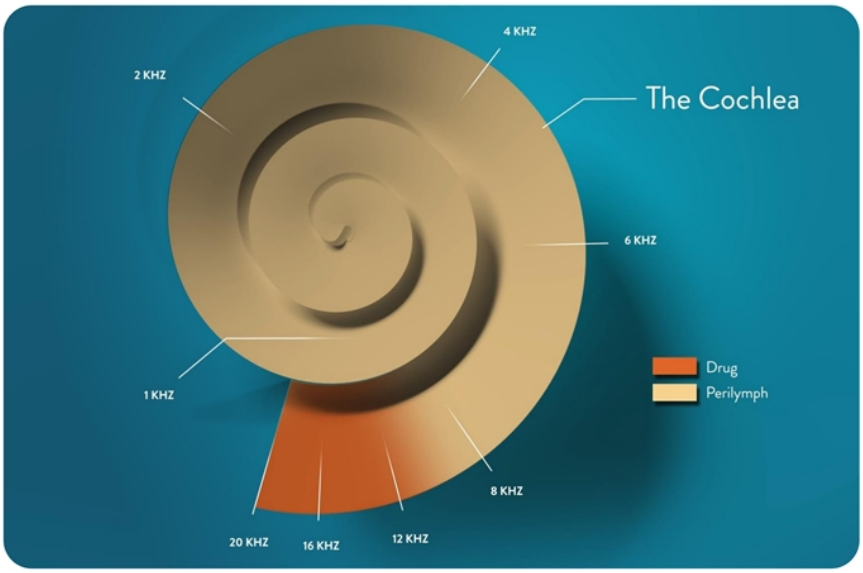
FX-322

High Frequency Exposure in the Cochlea

FREQUENCY THERAPEUTICS

Demonstrated hearing signal when FX-322 reaches the highest frequency region of the cochlea

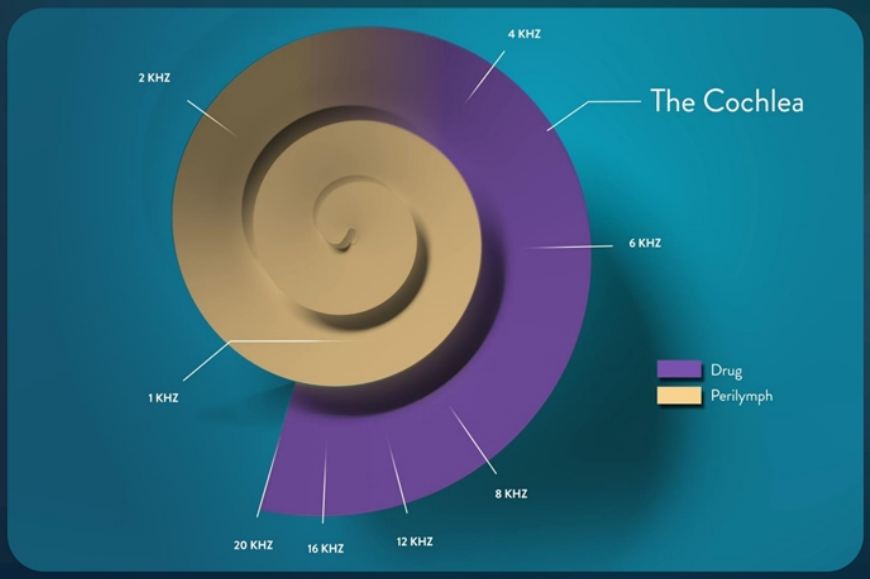


FX-345

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, and clinical data will drive commercial positioning



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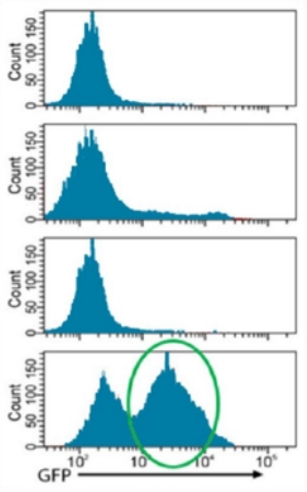
Profound Synergy Between Pathways to Regenerate Cells

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

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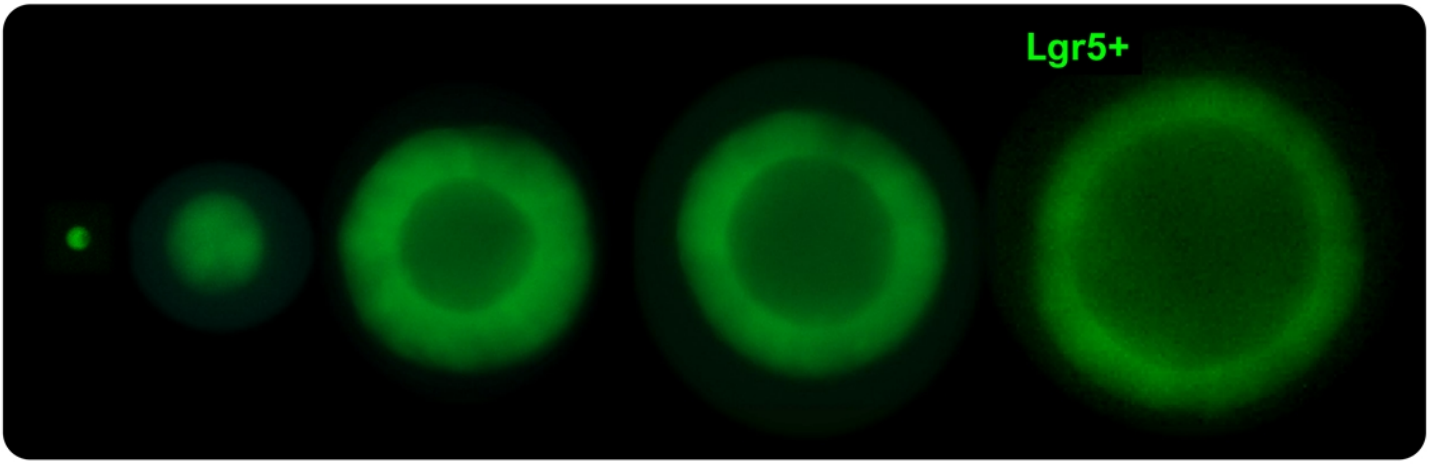
Pioneering Advanced Tools Unique in Hearing Restoration

Activating and Proliferating Lgr5+ Progenitor Cells



Clusters of Lgr5+ Progenitor Cells proliferating as organoids

More potent compound found

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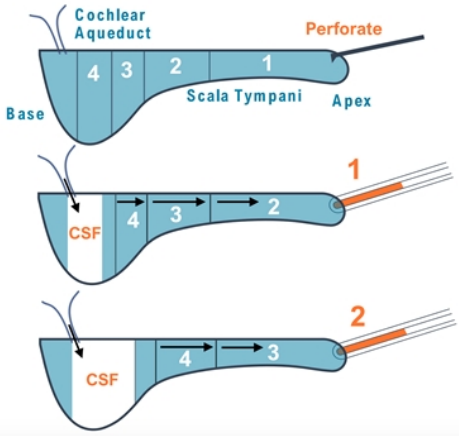
Pioneering Advanced Tools Unique in Hearing Restoration

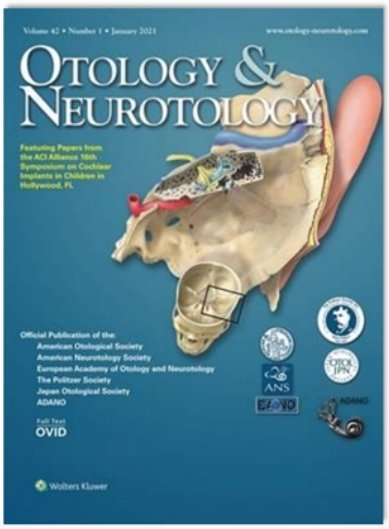
Cochlear Drug Sampling and Modeling

FREQUENCY THERAPEUTICS

Perilymph Sampling

FX-322 was dosed in animals and humans, and perilymph was sampled





Laryngoscope. 2007 Jul; 117(7): 1191–1198.
doi: 10.1097/MLG.0b013e318058a06b (S.K. Plontke, et. al.)

Improved Speech Intelligibility in Subjects with Stable Sensorineural Hearing Loss Following Intratympanic Dosing of FX-322 in a Phase 1b Study (W.J. McLean, et. al. 2021)

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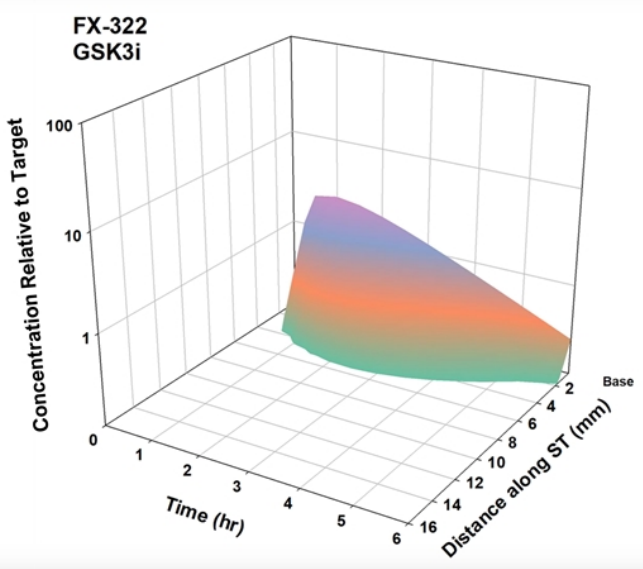
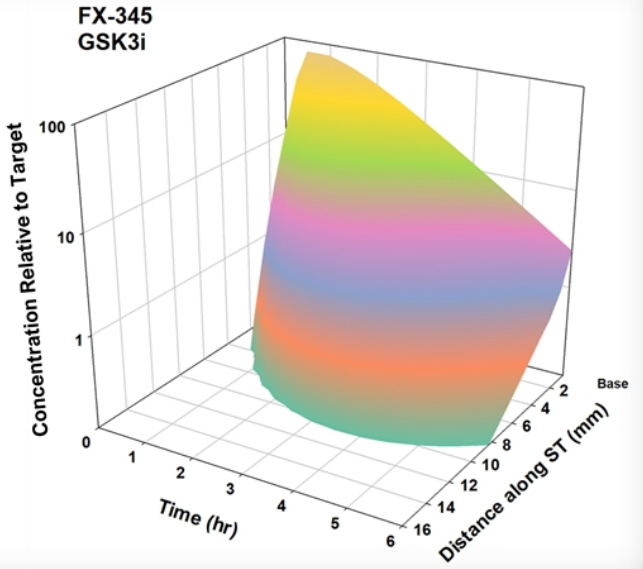
FX-345 – A New Development Candidate

Creating Effective Drug Levels Through Large Portion of Cochlea

FREQUENCY THERAPEUTICS





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FX-345 Path to Clinic

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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

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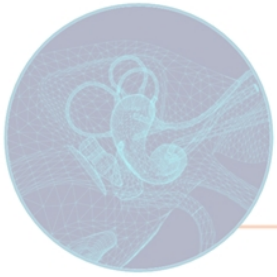
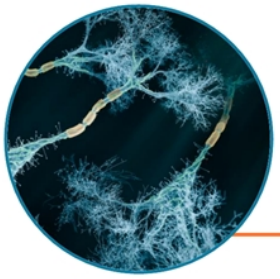
Two New Regenerative Programs



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



How do we extend this approach to other degenerative diseases?

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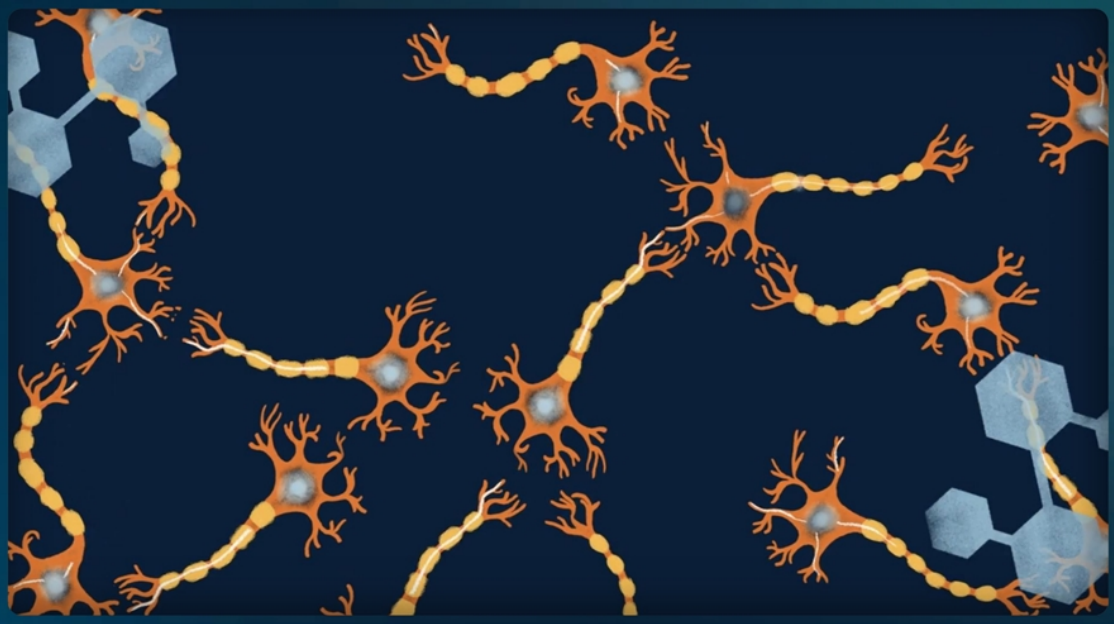
Progenitor Cell Activation: Remyelination

FREQUENCY THERAPEUTICS



Identified Novel Target

Developed Multiple NCEs

Established *in vivo* efficacy

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Remyelination for Multiple Sclerosis: Discovery of a Novel Target with Exceptional *in vivo* Activity

Sanjay Magavi, PhD
VP, Myelination Research

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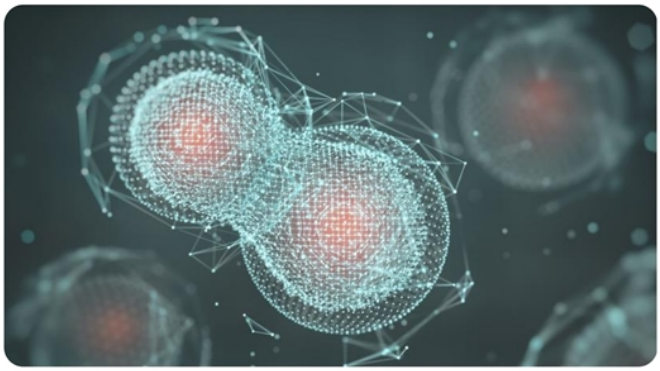
Frequency Discovered a Novel Remyelination Target

FREQUENCY THERAPEUTICS

Progenitor Cell Activation



Bioinformatics

Target 1
Target 2
Target 3
Target 4
Target 5

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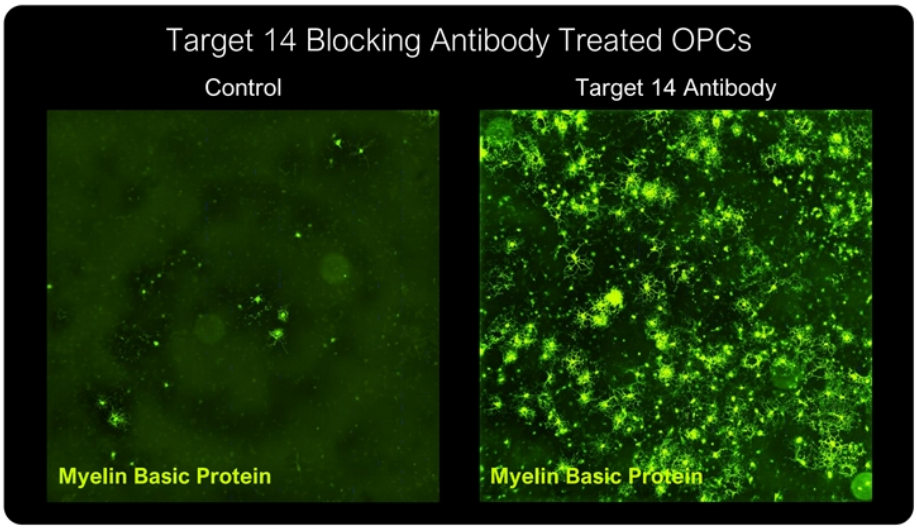
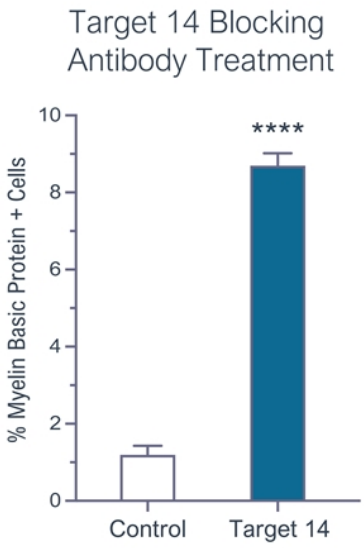
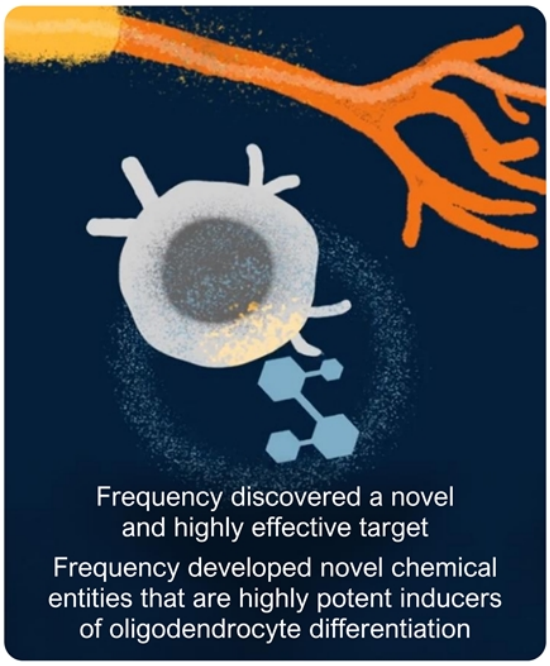
Frequency Discovered a Novel Remyelination Target





Target 14 blocking antibodies increase myelin basic protein expressing cells in vitro. Discovery of target allowed rapid screening for novel small molecule drugs.

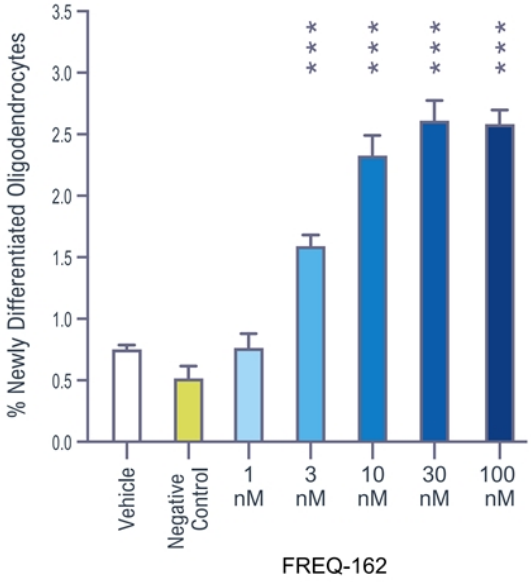
Small Molecule Target 14 Inhibitors Drive Oligodendrocyte Differentiation



Frequency discovered a novel and highly effective target

Frequency 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

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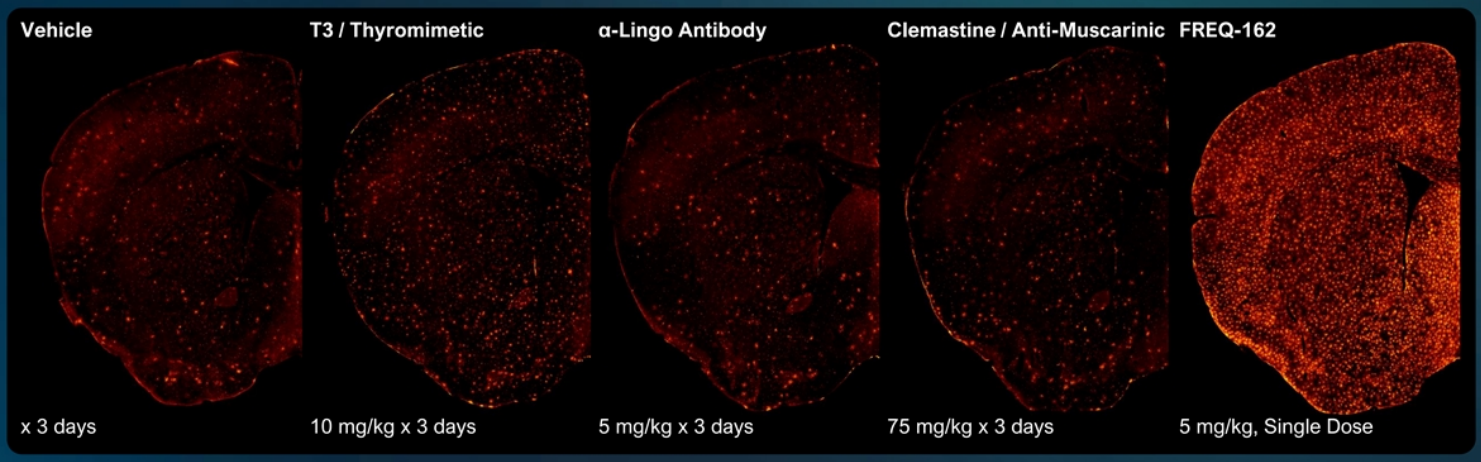
FREQ-162 Outperforms Literature Compounds *In Vivo*

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



x 3 days	10 mg/kg x 3 days	5 mg/kg x 3 days	75 mg/kg x 3 days	5 mg/kg, Single Dose
	Thyroid Hormone: Thyromimetic Class	α-Lingo antibody: Blocking antibody	Clemastine: Anti-Muscarinic Class	FREQ-162 induced formation of newly differentiated oligodendrocytes in both white and gray matter

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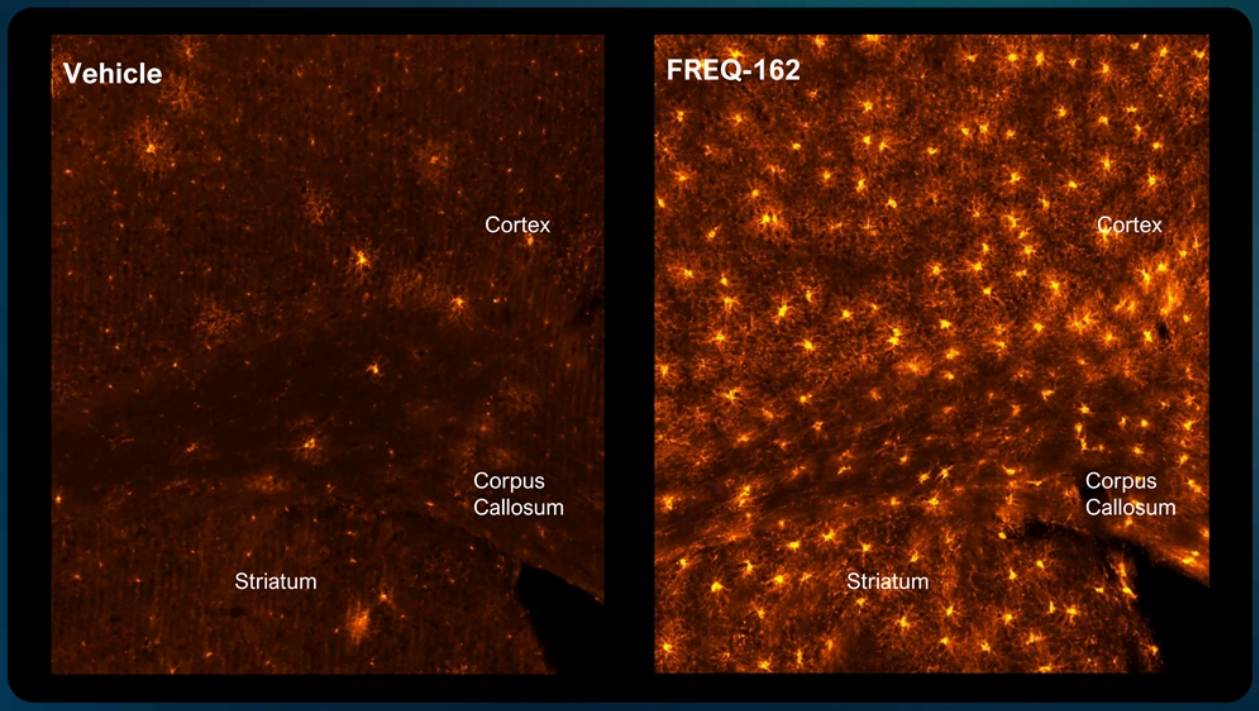
Frequency NCEs Outperform Competitors: High Magnification



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FREQ-162 Drives More Oligodendrocyte Differentiation than Competitor Mechanisms

Adult mice received

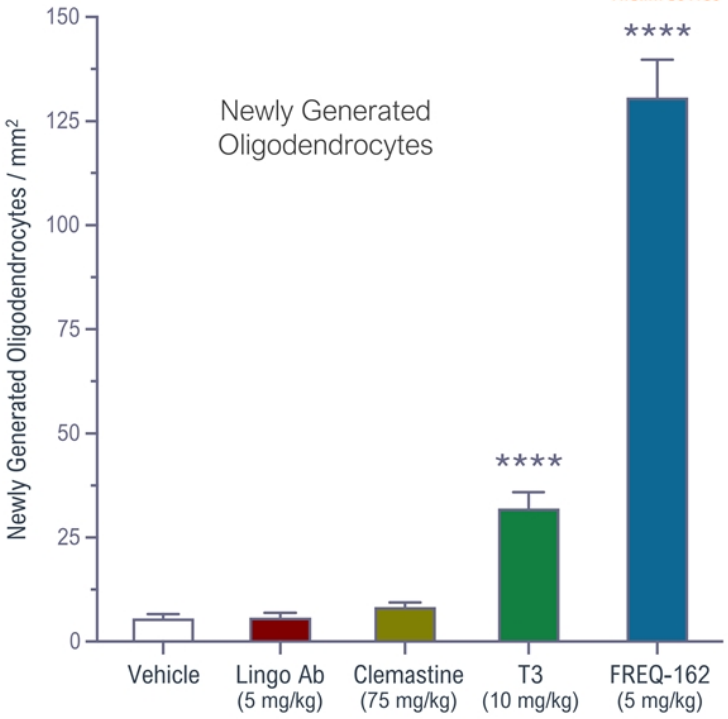
- Three Daily doses of anti-Lingo antibody, Clemastine, or Thyroid Hormone (T3)
- A single dose of FREQ-162

Newly Generated Oligodendrocytes were quantitated via automated AI image analysis

A single dose of a Frequency Compound induces more oligodendrocyte differentiation than multiple doses of comparators

Compound	Dose (mg/kg)	# of doses	Fold change	P=
α-Lingo antibody	5	3	1.1 x	0.99
Clemastine	75	3	1.5 x	0.60
Thyroid hormone (T3)	10	3	5.7 x	<0.0001
FREQ-162	5	1	23.2 x	<0.0001

(One Way ANOVA, n ≥ 7)



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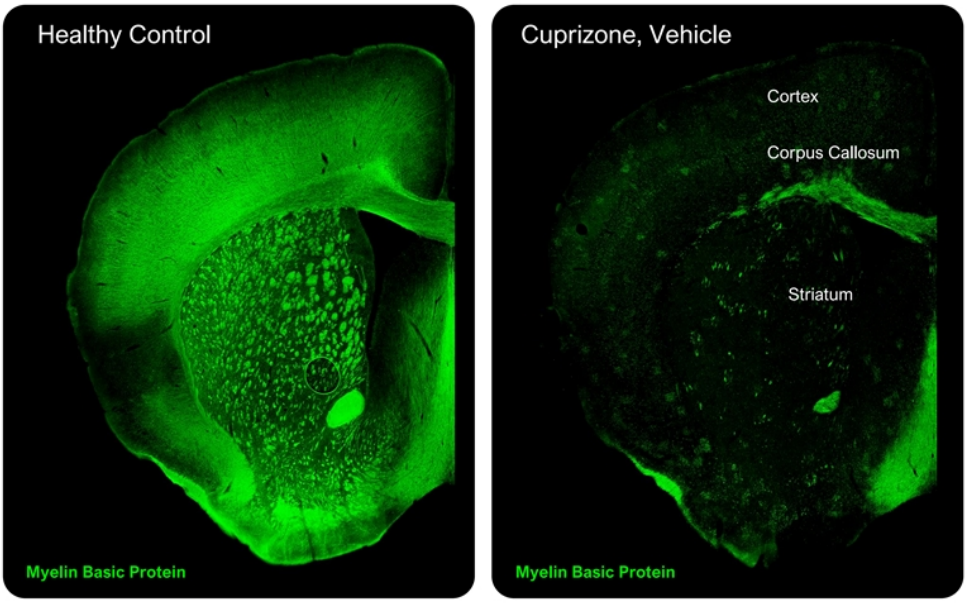
The Cuprizone Model of Chronic Demyelination



Adult mice were demyelinated via 17 months of cuprizone administration

- Elderly mice with long term demyelination

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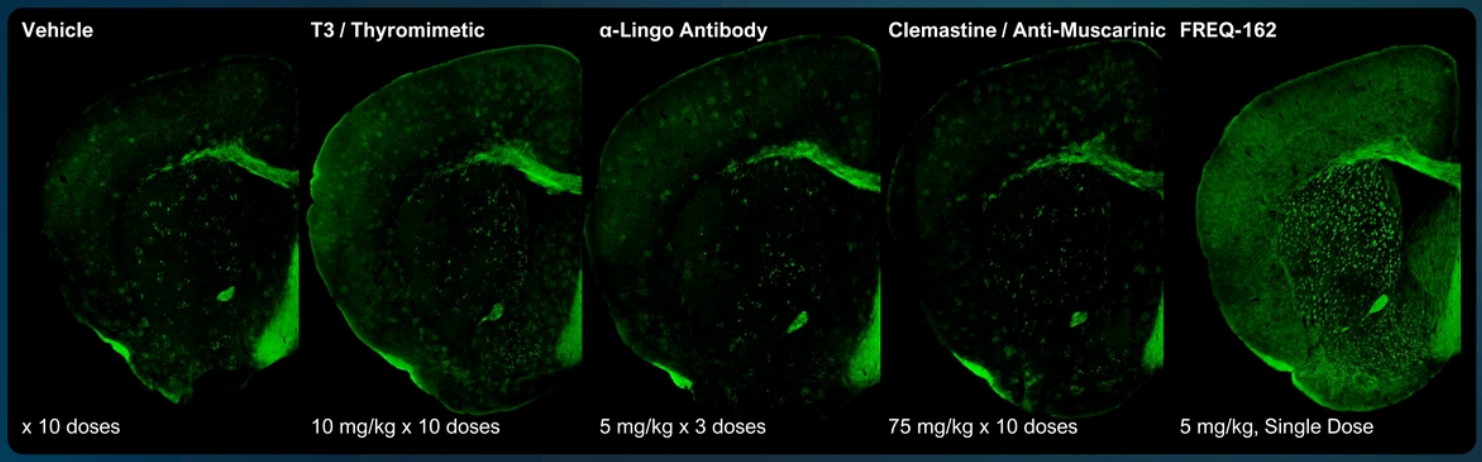
FREQ-162 Outperforms Published Compounds In Vivo

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)



	Thyroid Hormone: Thyromimetic Class	α-Lingo antibody: Lingo inhibitor	Clemastine: Anti-Muscarinic Class	FREQ-162 induced formation of new myelin in white and gray matter

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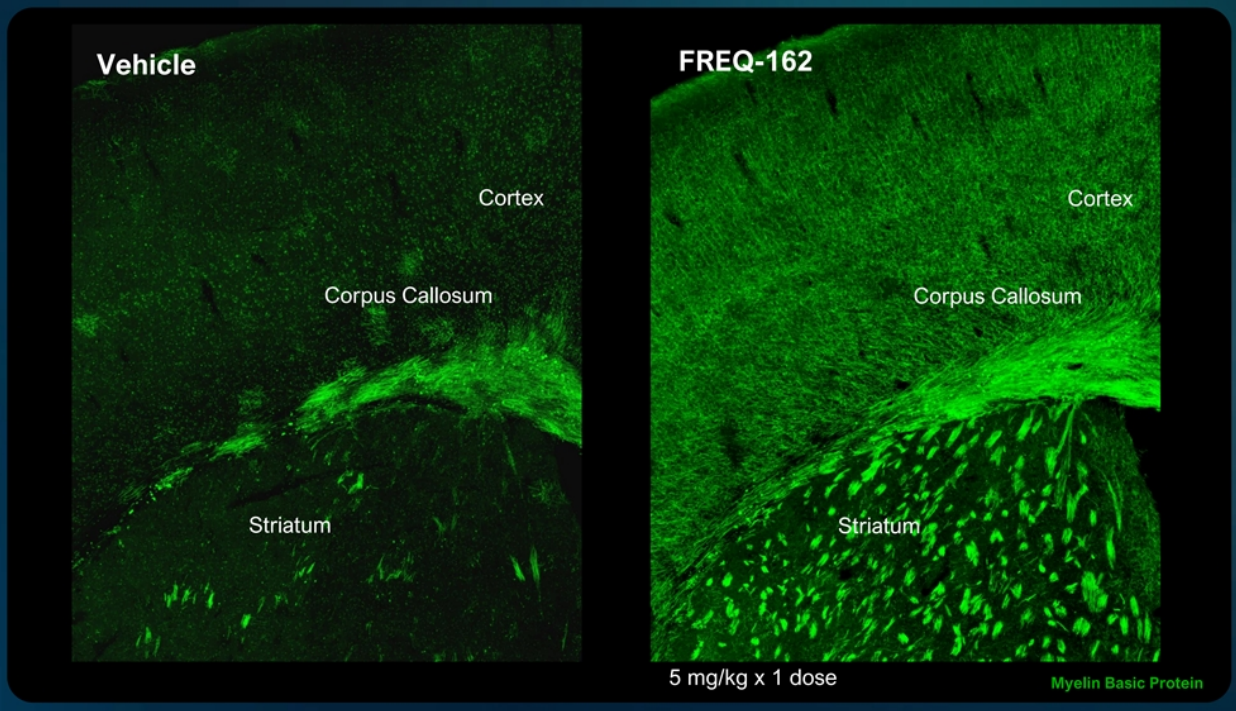
Frequency NCEs Outperform Competitors: High Magnification

FREQUENCY THERAPEUTICS



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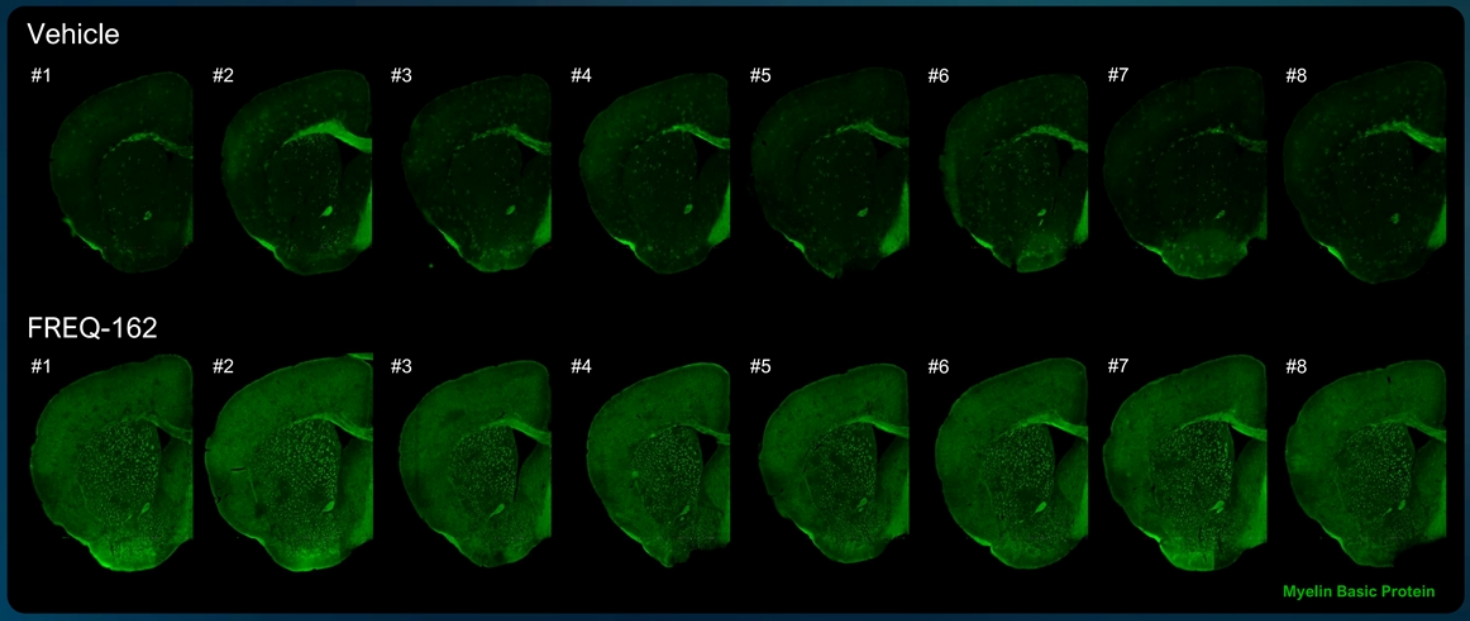
FREQ-162 Robustly Induces Remyelination

FREQUENCY THERAPEUTICS

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



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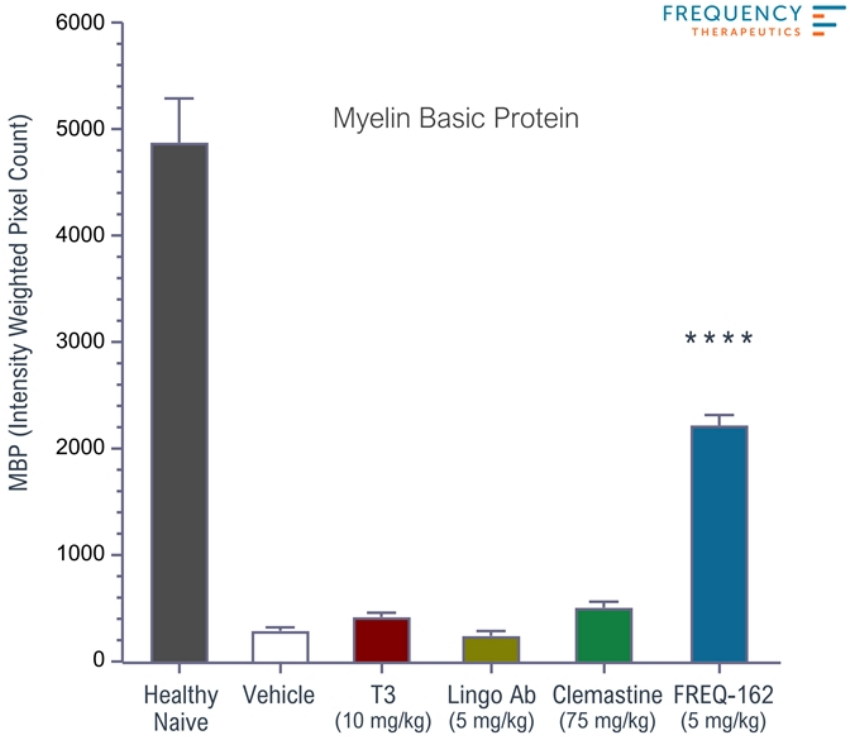
Freq-162 Induces Robust Increases in Myelination

- 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



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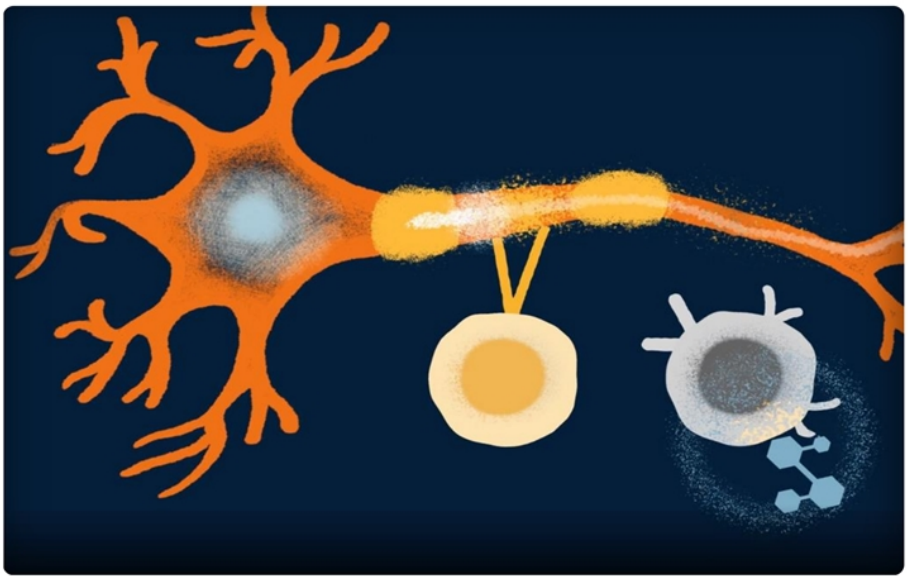
Remyelination: Path Forward



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

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Our Path Forward

David L. Lucchino
Chief Executive Officer

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 approved 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.

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Pioneering a New Category
in Regenerative Medicine
Frequency Therapeutics Virtual R&D Event
November 9, 2021
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THERAPEUTICS