

**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): January 13, 2022

FREQUENCY THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39062
(Commission
File Number)

47-2324450
(IRS Employer
Identification No.)

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

(781) 315-4600
(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 January 13, 2022, 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 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:

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Frequency Therapeutics, Inc. Corporate Slide Presentation as of January 13, 2022 |
| 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: January 13, 2022

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

Pioneering a New Category in Regenerative Medicine

Frequency Therapeutics Corporate Presentation

January 2022

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 Frequency Therapeutics' (the "Company") 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 size of the population with multiple sclerosis, 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 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; 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.

2022/2023 Milestones and Catalysts

FX-322-208

Projected Enrollment
Completion
Q3:22

Projected Readout
Q4:22 or Q1:23

FX-345

Phase 1b Start
H2:22

Phase 1b
Readout
H1:23

Remyelination in M.S.

Candidate
Selection
2022

MS Clinical
Trial Start
2023

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.



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

First PK/PD shown for a hearing therapeutic candidate

First clinical studies to show hearing improvements

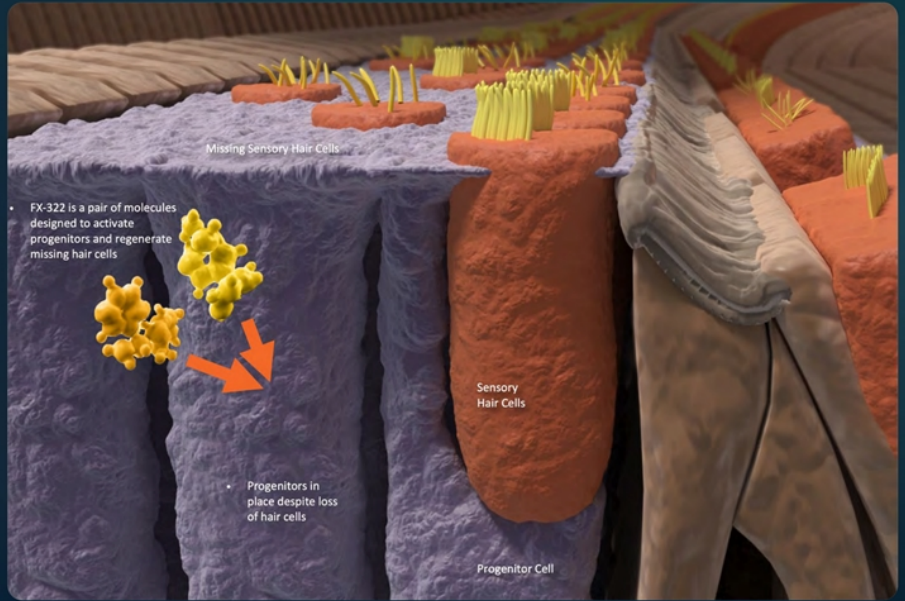
First speech perception improvements measured

First to show sustained improvements and continued improvements over time

FX-322:

A Small Molecule Candidate to Address the Underlying Pathology

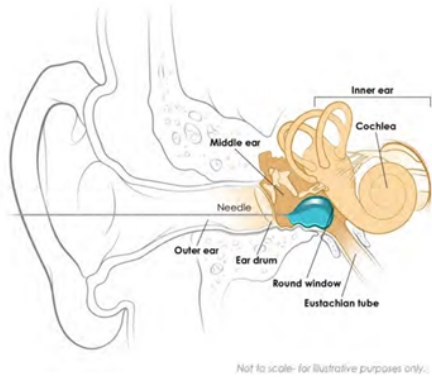
Synergy between pathways aims to activate progenitor cells and regenerate sensory cells in the cochlea



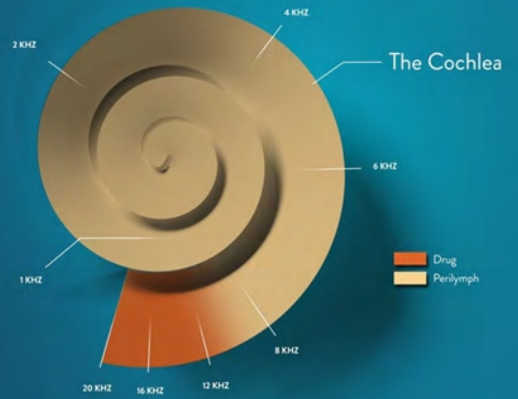
FX-322:

Directly Targeting the Regeneration of Sensory Hair Cells in the Cochlea

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

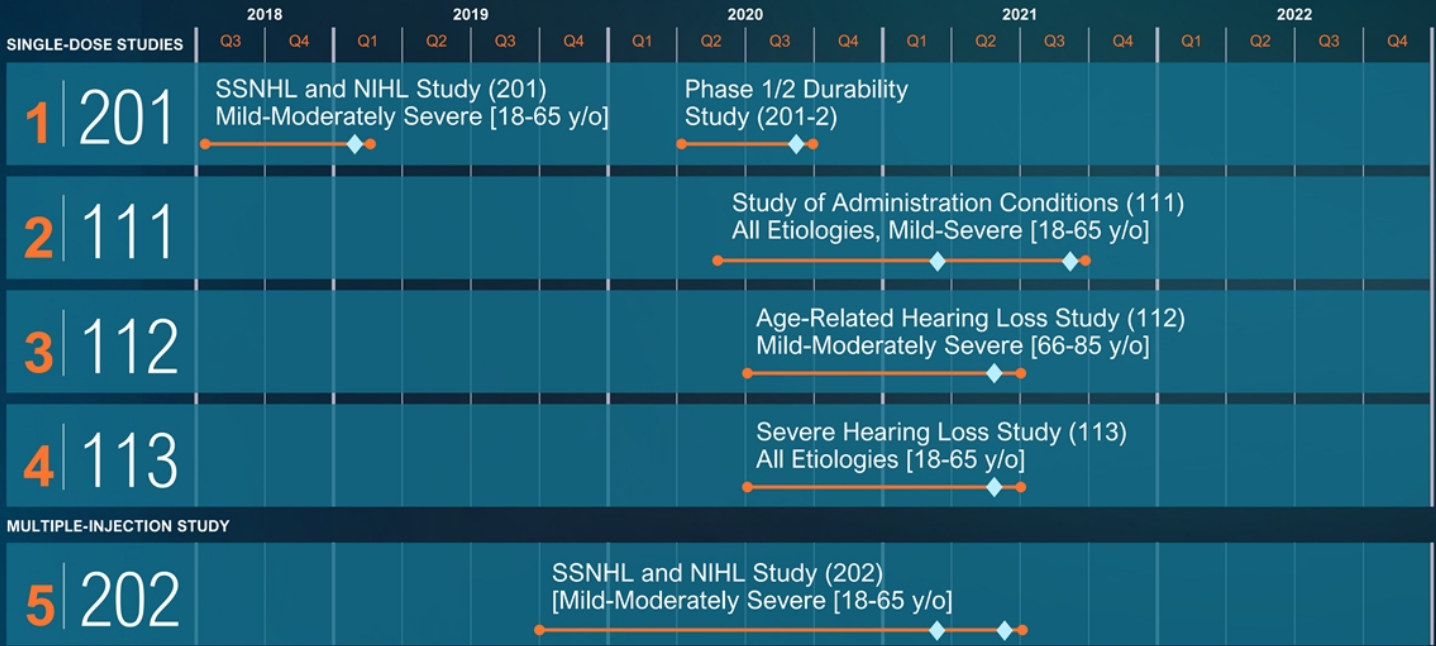


The injection concentrates FX-322 in the cochlear region critical for speech intelligibility



Five FX-322 Completed Studies: 193 Treated Subjects

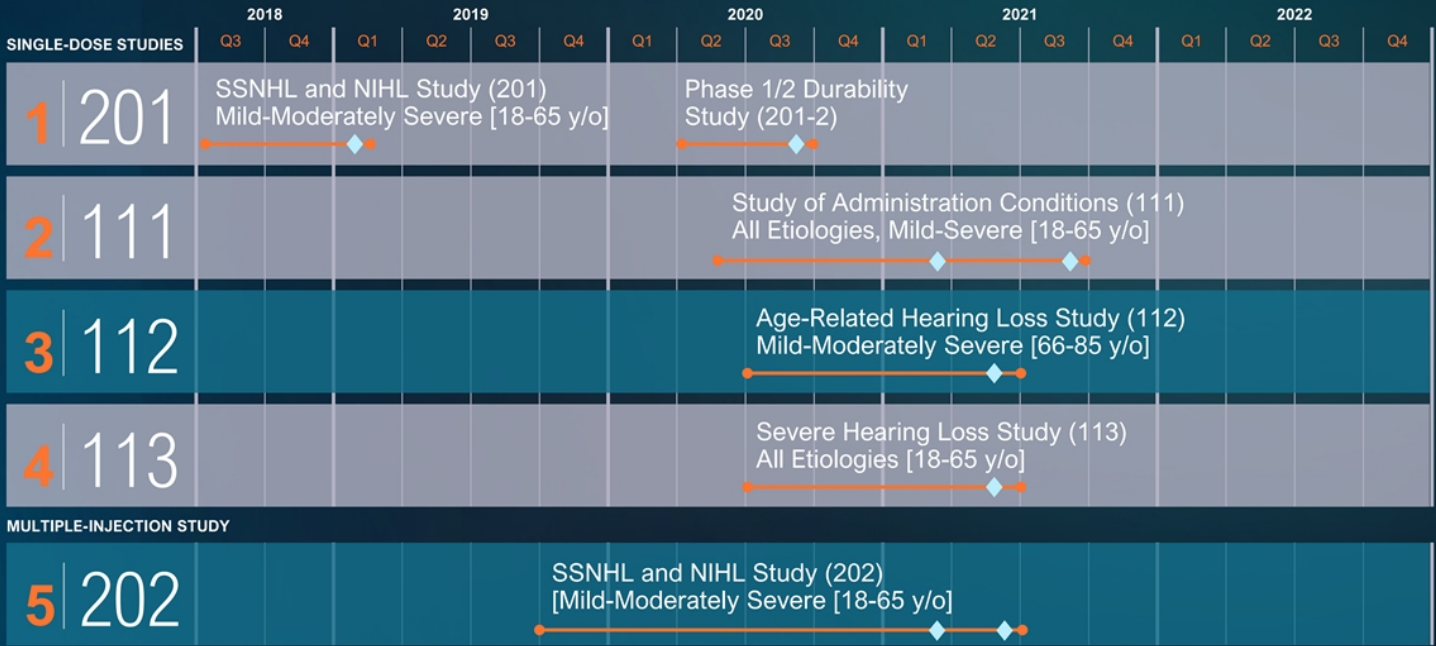
Favorable Safety Profile with No Treatment-Related SAEs



◆ = Data Readout

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

Single-Dose Safety Studies with Hearing Improvement Signal



◆ = Data Readout

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

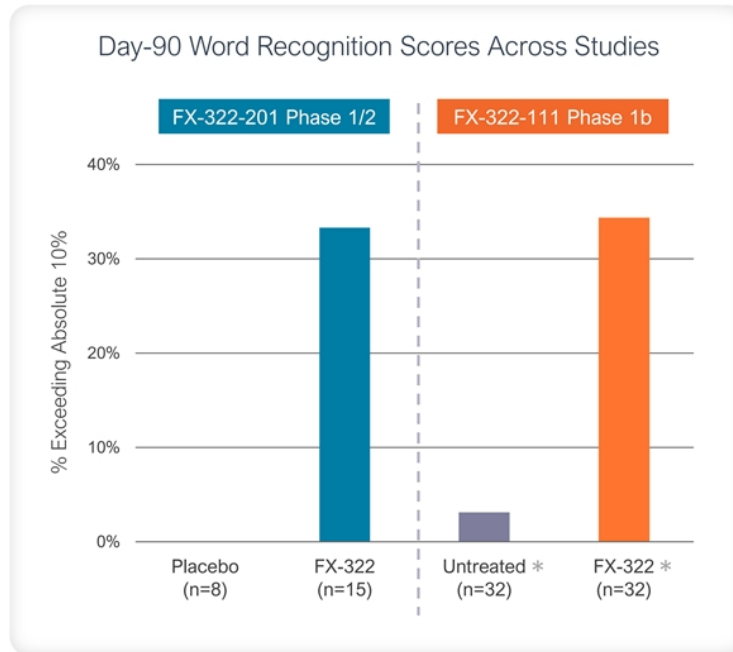
Improvement Shown in Speech Perception in Quiet with Single Dose

Phase 1/2 Study FX-322-201 Overview

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

Study Results

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



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



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)

* 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

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

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

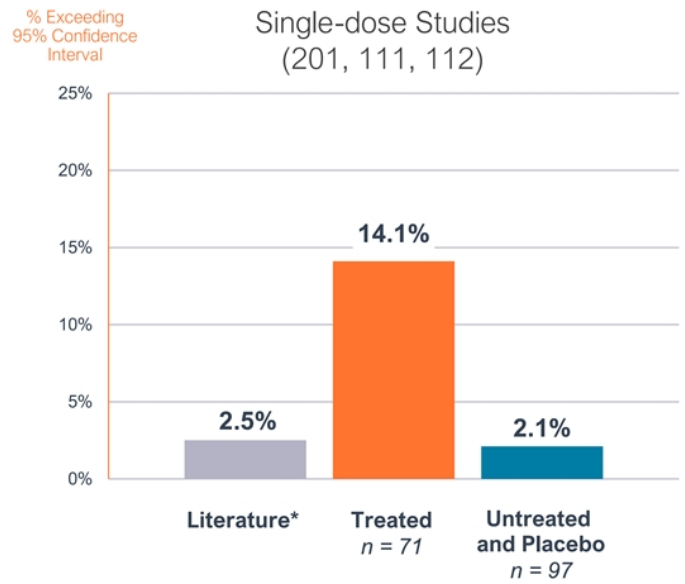
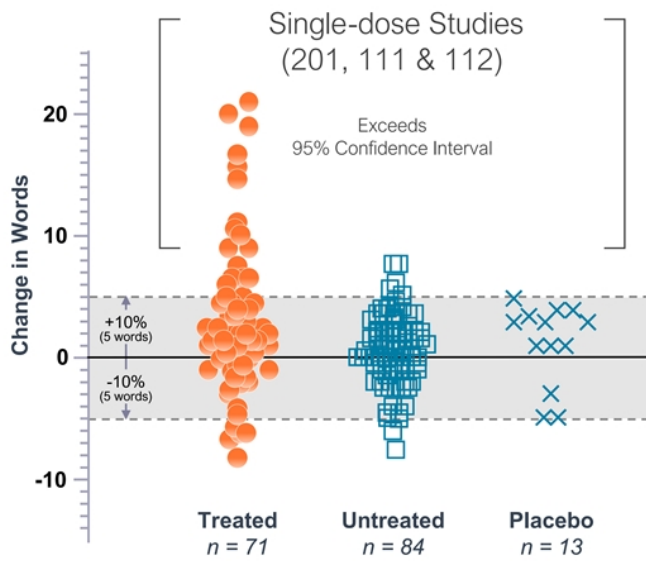
- 4 subjects that had shown improvement trends in word recognition scores at day 90, achieved statistically significant scores when tested at the later time points

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

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

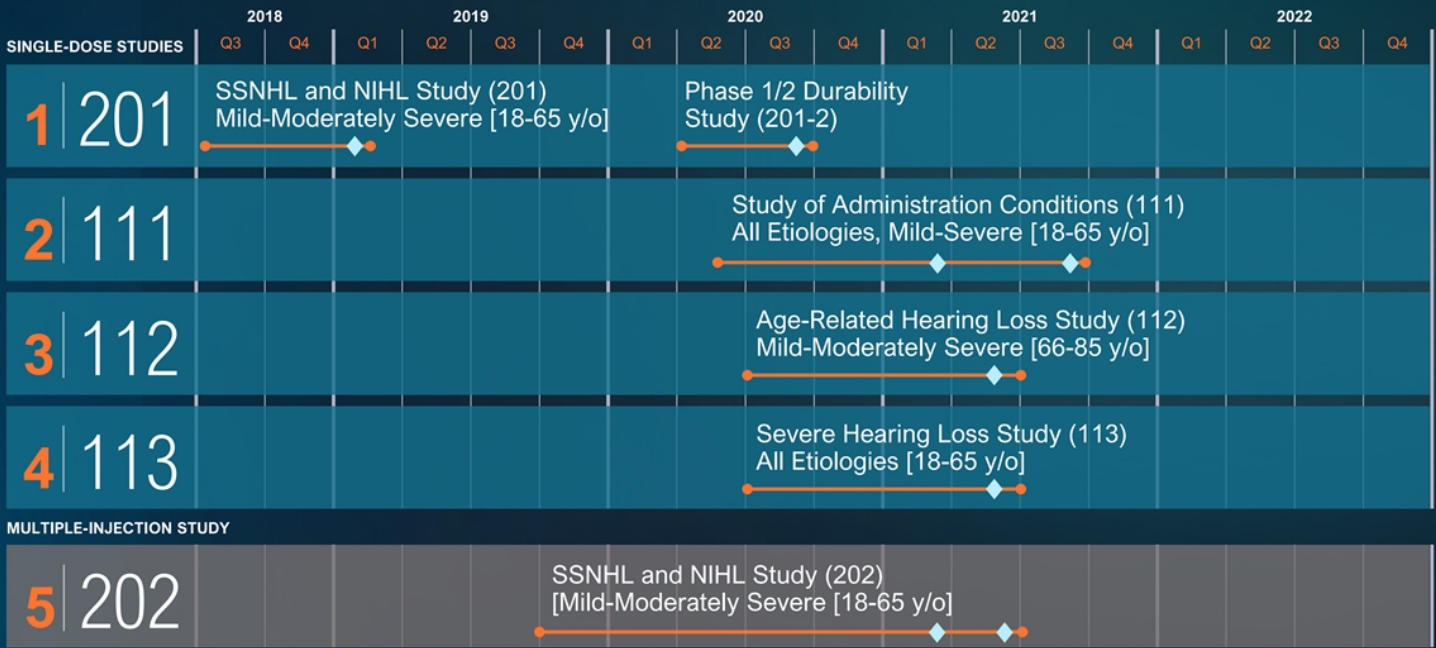
Improvements in Bamford-Kowal-Bench Sentence-in-Noise exam (BKB-SIN) observed in treated ears

- 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
- 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



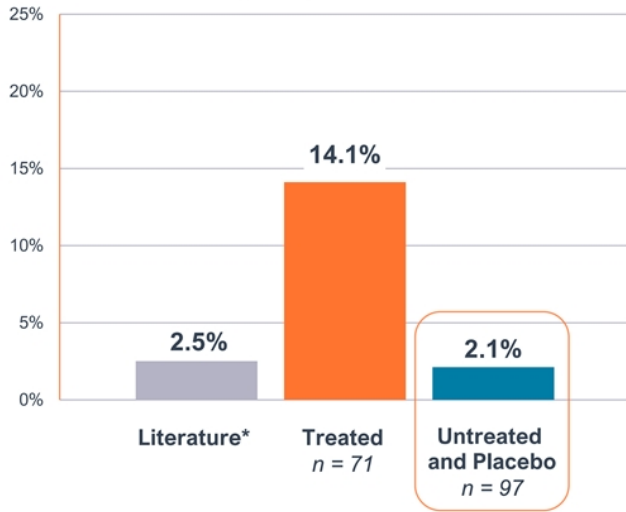
◆ = Data Readout

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

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

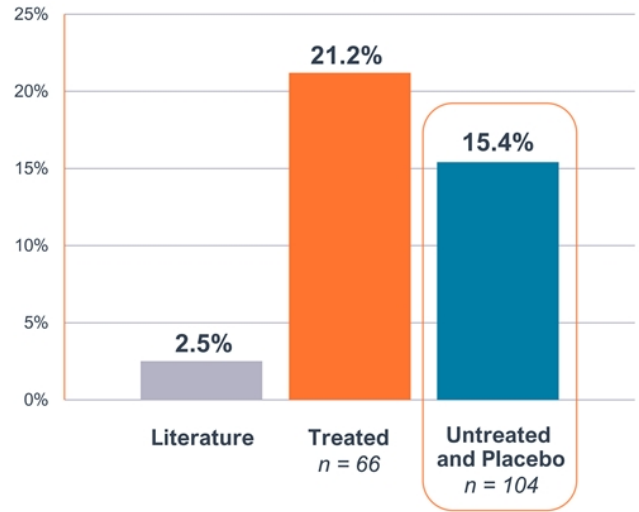
% Exceeding 95% Confidence Interval

Single-dose Studies (201, 111, 112)



% Exceeding 95% Confidence Interval

Multiple Injection Study (202)



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

Built upon insights from trials with hearing restoration signal

Etiology, severity,
baseline speech
perception

Sufficient sample size to demonstrate efficacy

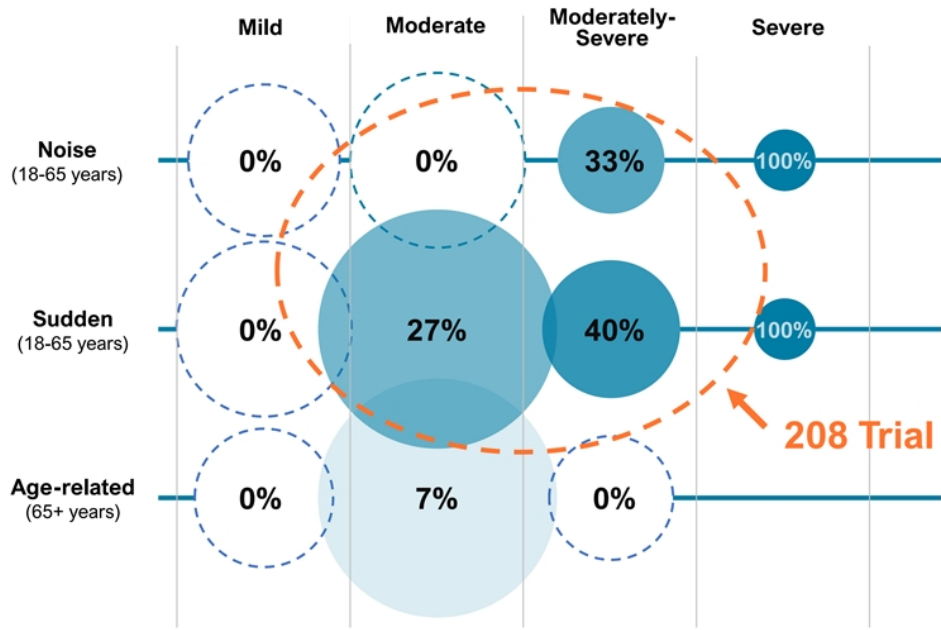
Approach based
on pooled data
Primary endpoint of
speech perception

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

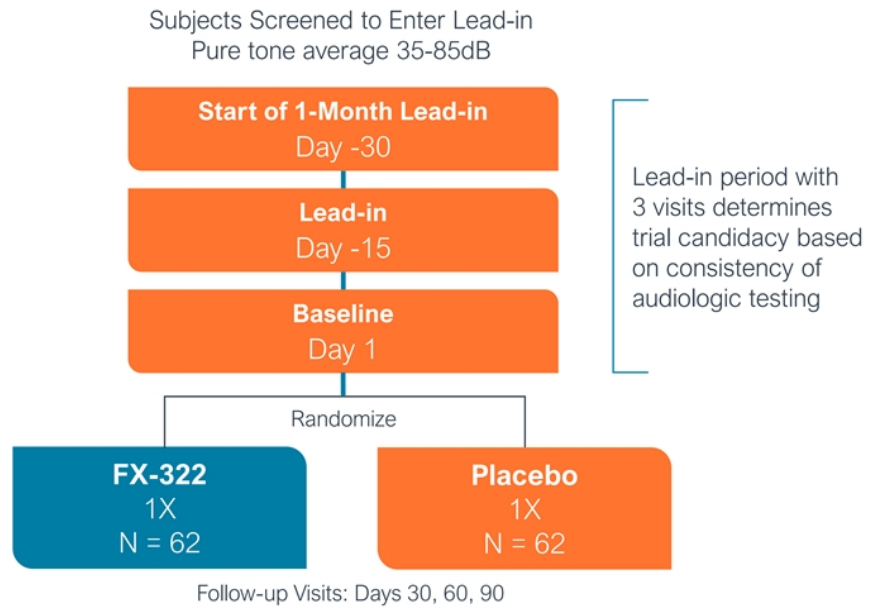
First patient dosed in FX-322-208 Study in October 2021

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



FDA

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



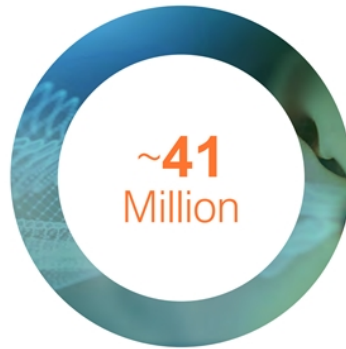
Today's Hearing Loss Market Has No Restorative Treatments



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

THE LANCET
July, 2020

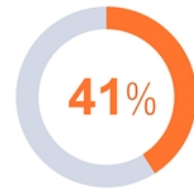
“Hearing loss is the largest potentially modifiable risk factor for developing dementia”

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

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



FX-345

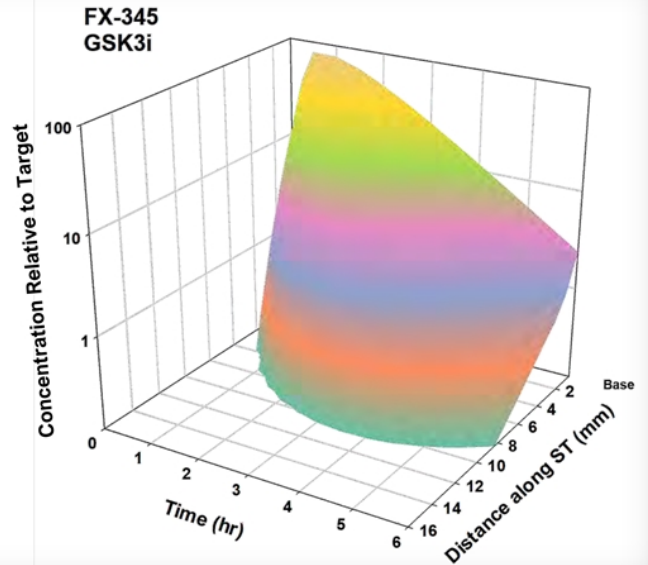
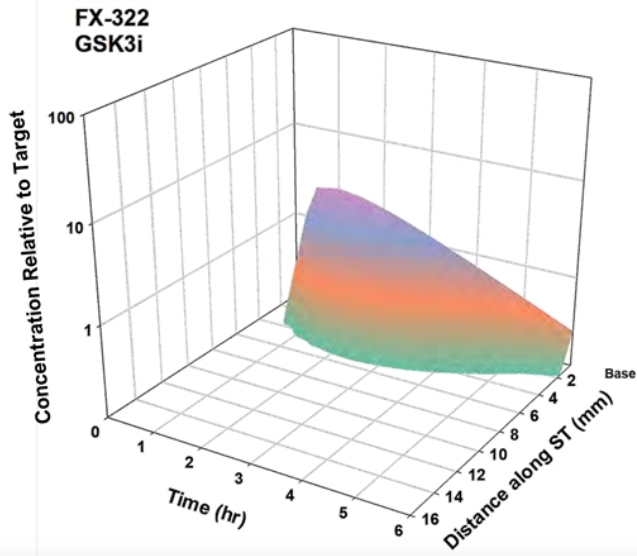
Working to Achieve Broad Exposure Through the Cochlea

- 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



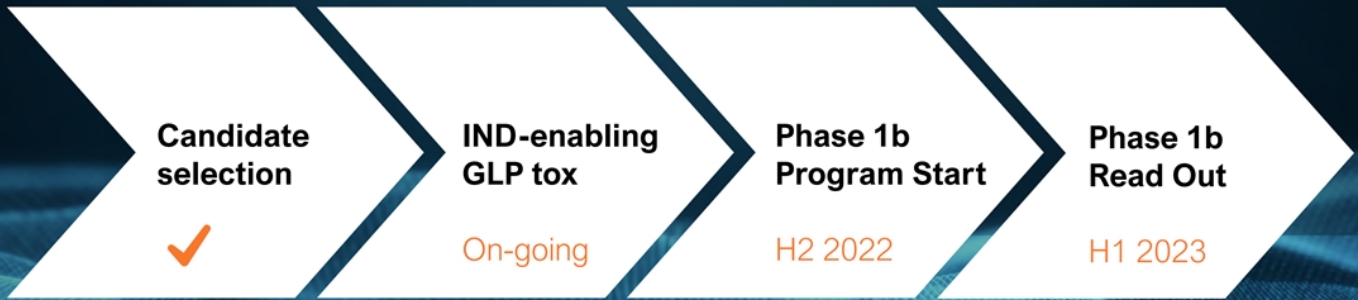
FX-345 – A New Development Candidate

Creating Effective Drug Levels Through Large Portion of Cochlea



FX-345 Path to Clinic

Program start planned for H2:2022 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

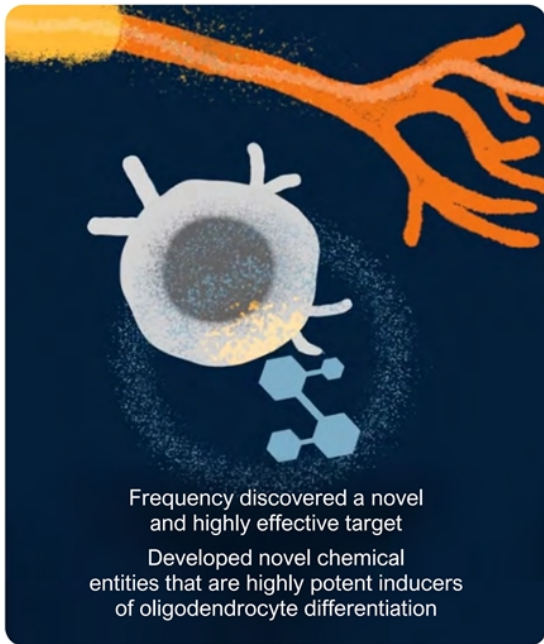


New Regenerative Program

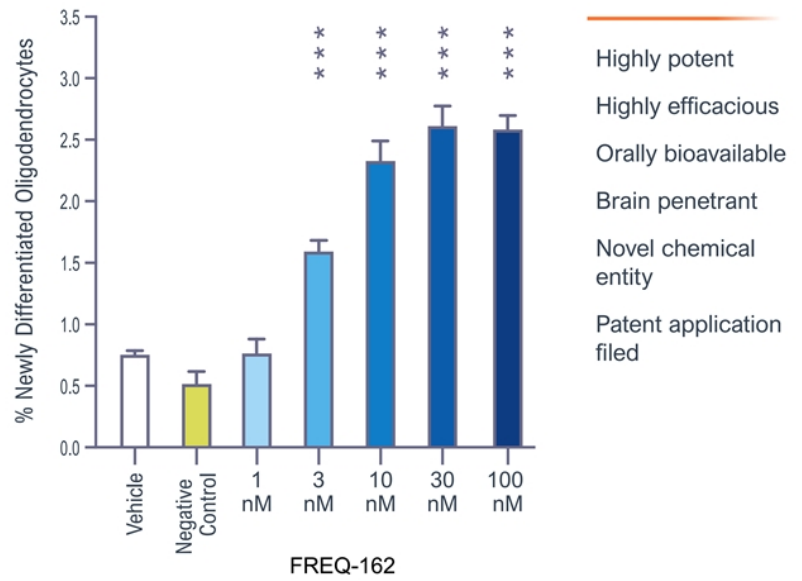


What if we could extend
our approach to other
degenerative diseases?

Novel Frequency Small Molecule Inhibitors Drive Oligodendrocyte Differentiation



Lead Optimization generated FREQ-162

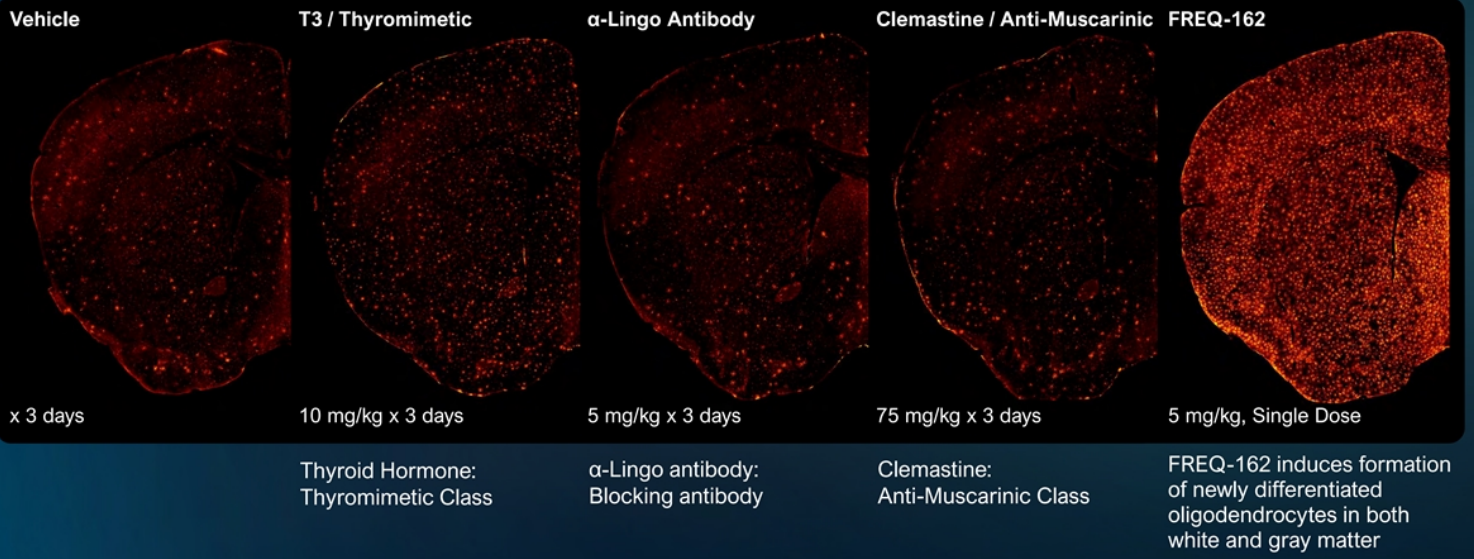


FREQ-162 Outperforms Literature Compounds *In Vivo*

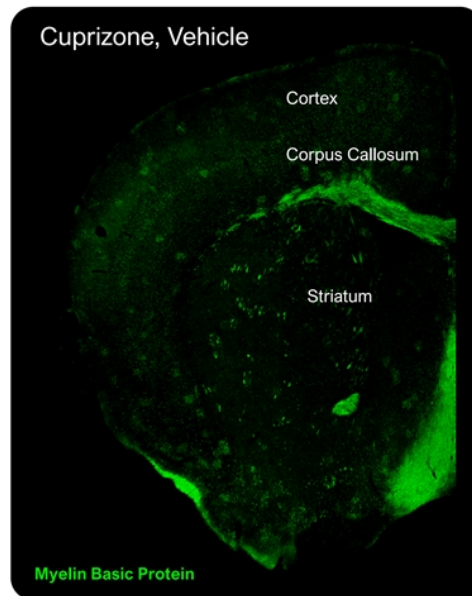
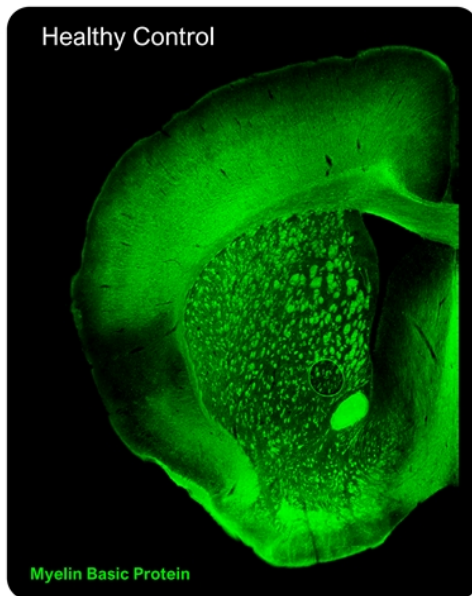
Adult mice received 3 doses of comparator compounds or a single dose of FREQ-162

Brains were stained for a marker of newly generated oligodendrocytes

Single dose FREQ-162 induces more OPCs to differentiate than comparator compounds



The Cuprizone Model of Chronic Demyelination



Adult mice were demyelinated via 17 months of cuprizone administration

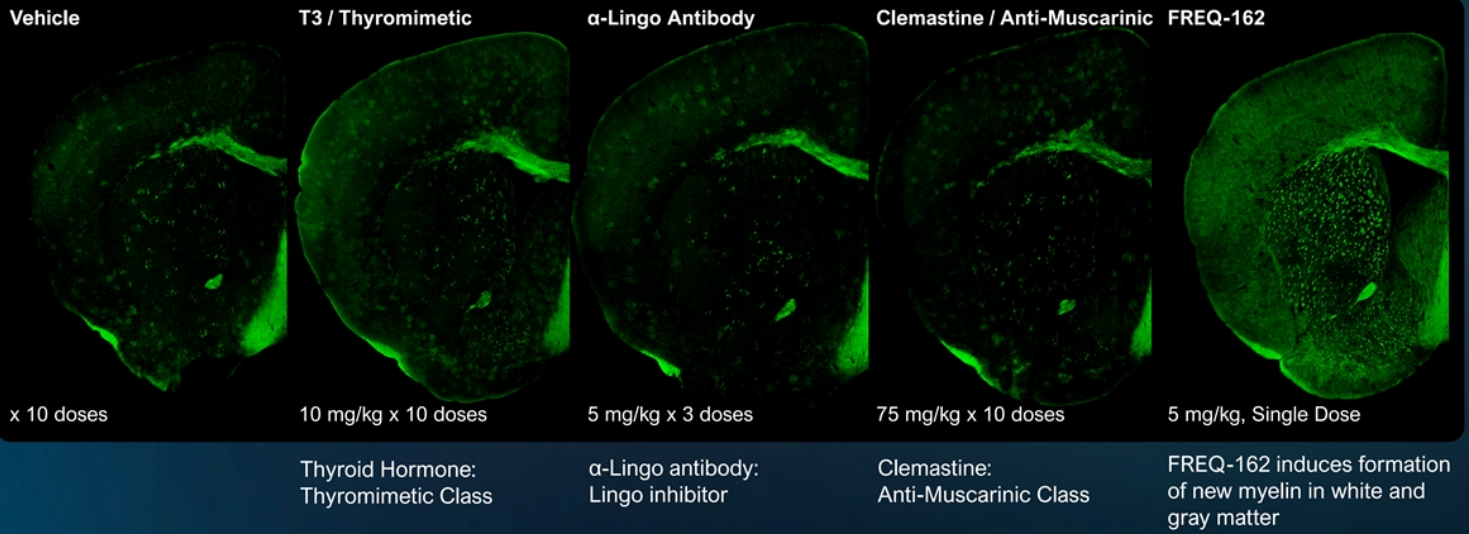
- Elderly mice with long term demyelination

FREQ-162 Outperforms Published Compounds *In Vivo*

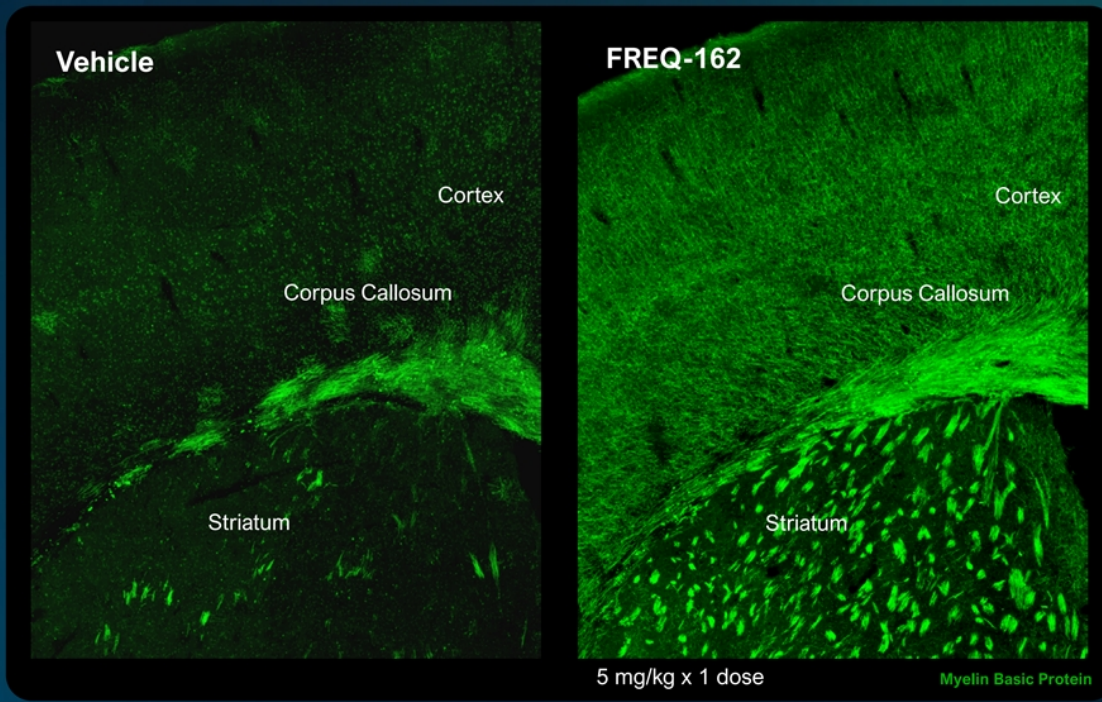
Adult mice received up to 10 daily doses of comparators or a single dose of FREQ-162

Brains were stained for Myelin Basic Protein (green)

Single dose FREQ-162 induces more remyelination than comparator compounds



Animals demyelinated for 17 months via cuprizone treatment

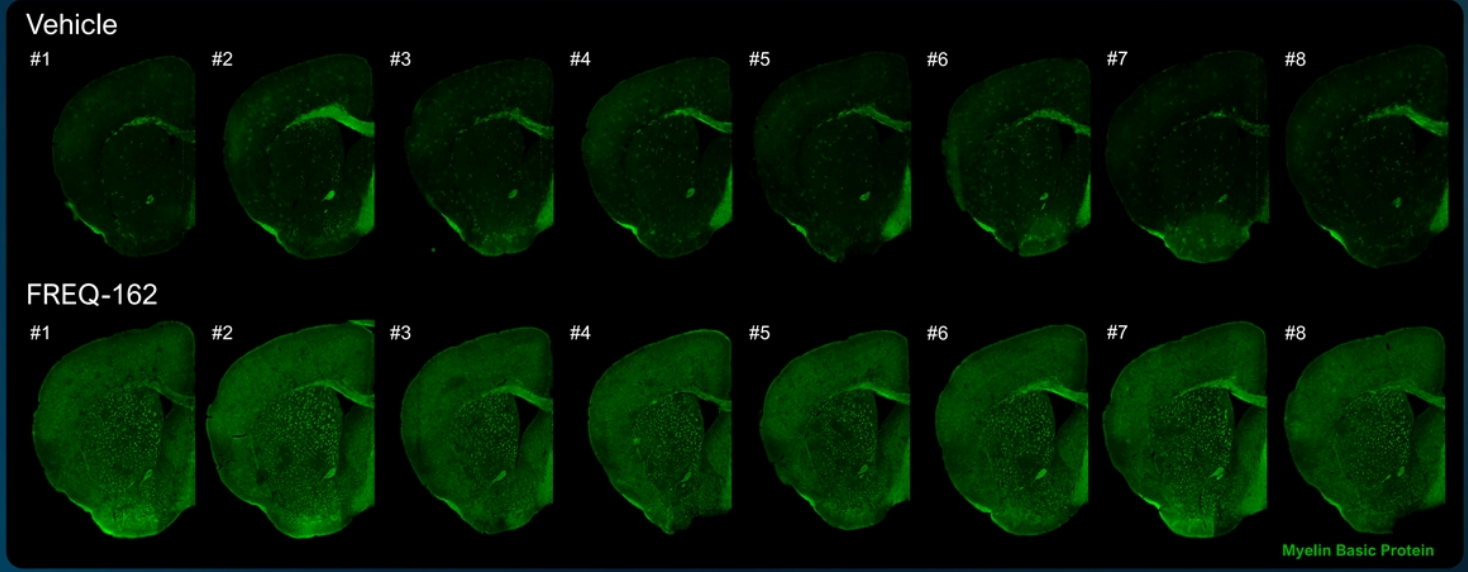


High Magnification view reveals that FREQ-162 yields myelination

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

FREQ-162: Highly Reproducible Increases in Myelination

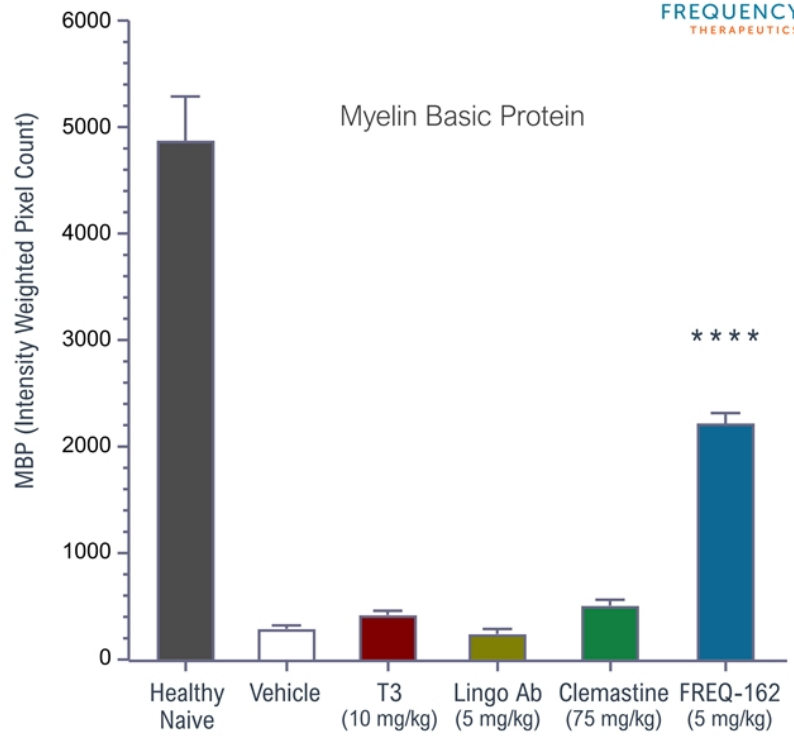
All 8 out of 8 mice treated with FREQ-162 showed robust increases in myelination in both white and gray matter tracts

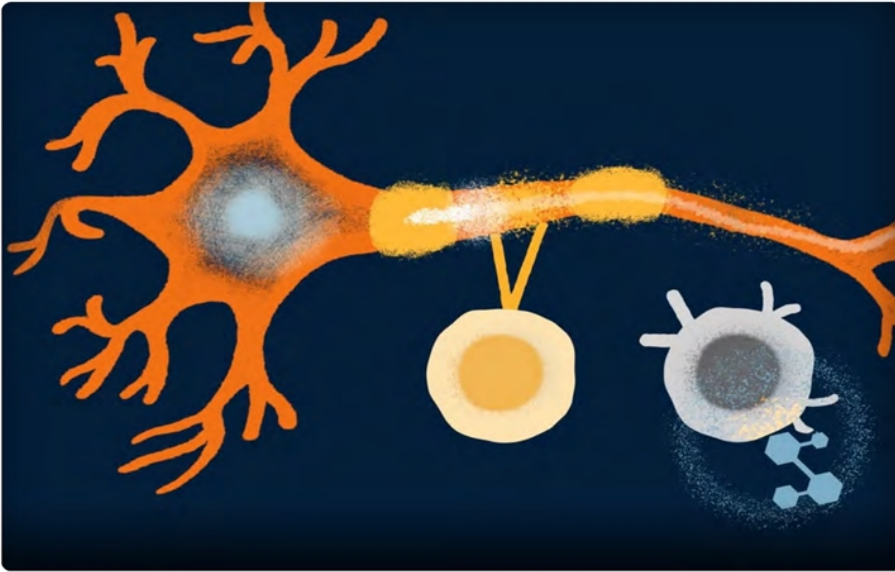


Freq-162 Induces Robust Increases in Myelination

- 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 |





Discovered novel target

Generated multiple compounds

Induced high levels of oligodendrocyte differentiation and remyelination *in vivo*

Initiating IND enabling studies

Our Path Forward

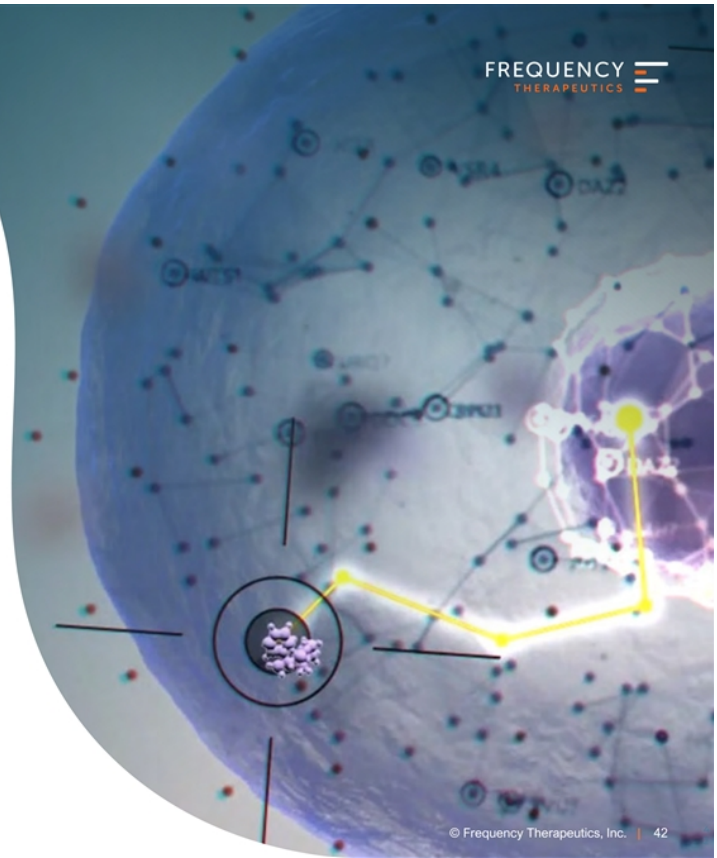
- ✓ We believe FX-322 restores hearing.
- ✓ We know characteristics of FX-322 responders.
- ✓ Learnings from previous trials informed new trial design with strong controls and FDA aligned clinical endpoints.
- ✓ We have a compelling new hearing program that will allow us to explore the impact of going 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

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



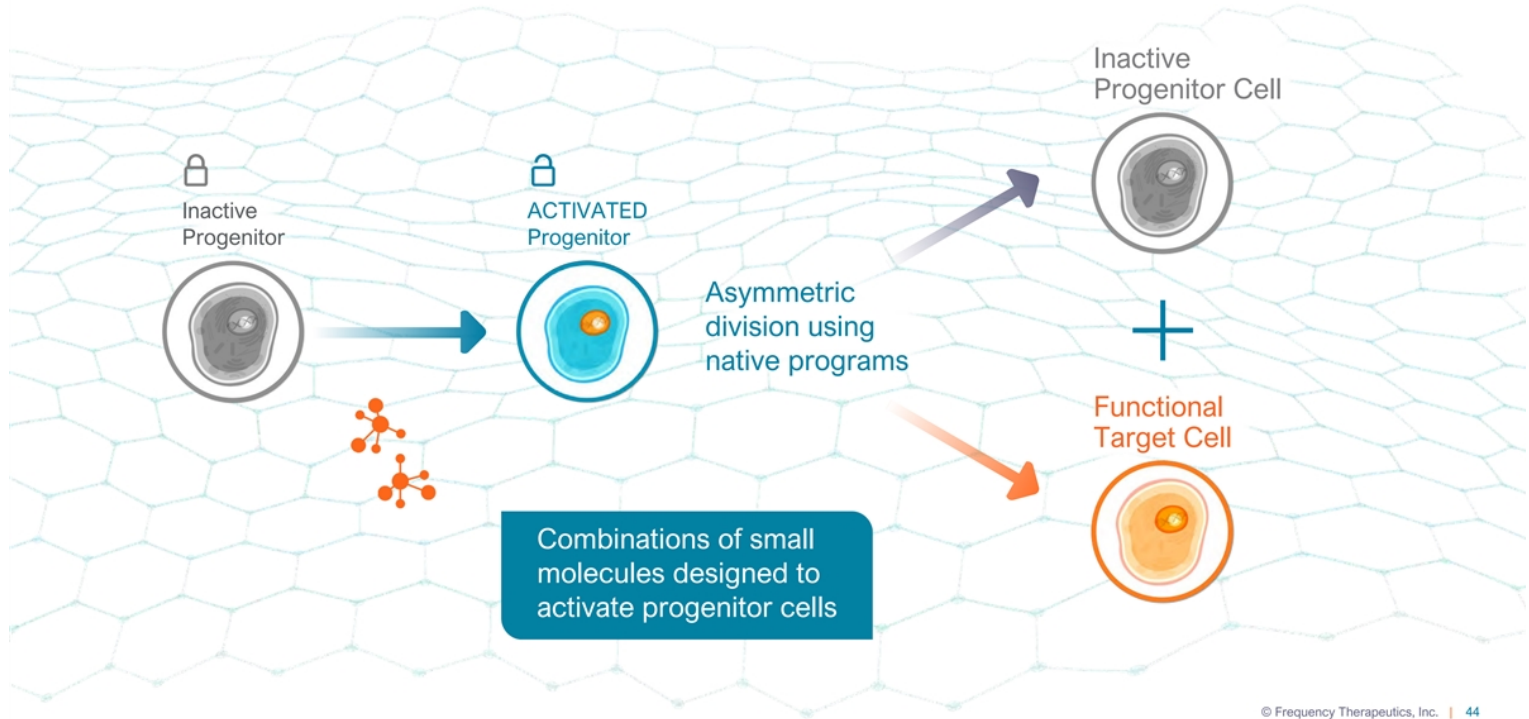
Clonal Expansion of Lgr5-Positive Cells
from Mammalian Cochlea and High-
Purity Generation of Sensory Hair Cells

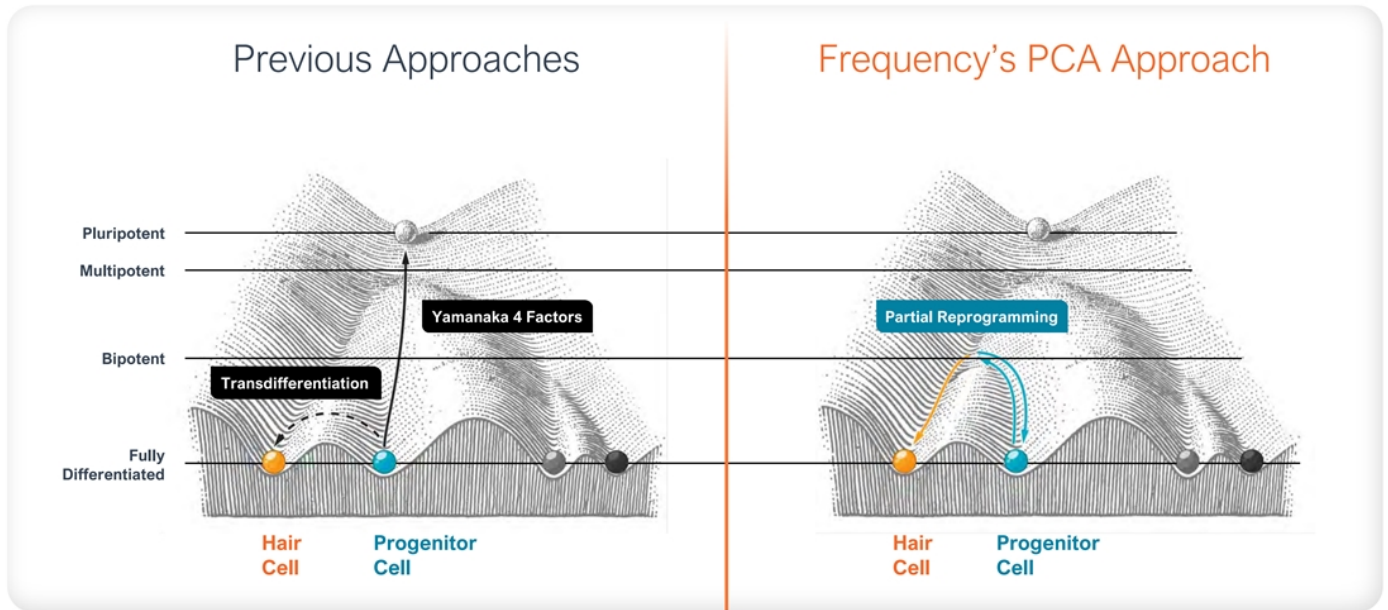
Frequency Therapeutics

Small molecule
therapeutics show
clinical proof
of concept



Frequency Progenitor Cell Activation (PCA) Approach

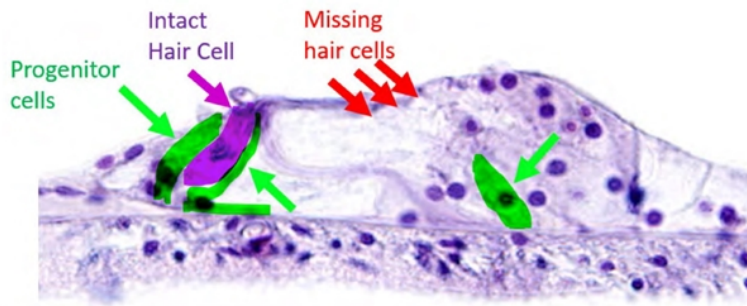




Our Approach:

Activation of Progenitors to Replace Hair Cell Loss

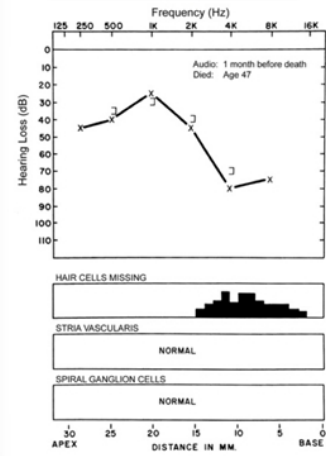
Despite Hair Cell Loss, Progenitor Cells Remain



Human Cochlea Cross-section

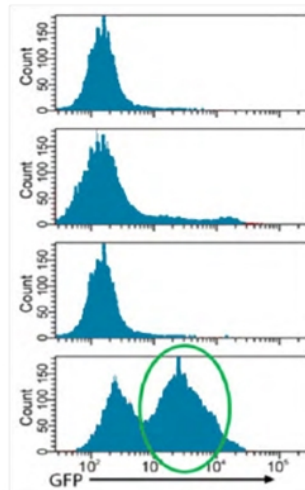
47 Year Old Male with Occupational Noise Deafness

Audiogram



Cochlear Progenitor Proliferation (Lgr5+ – GFP)

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



Culture Media

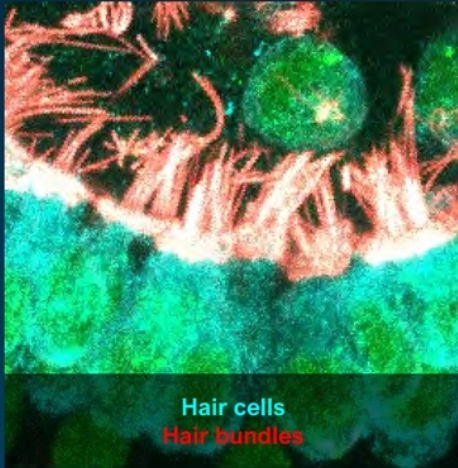
Wnt Activation
(glycogen synthase kinase-3
(GSK3) Inhibitor; NCE)

HDAC Inhibition
(sodium valproate)

Wnt Activation + HDAC inhibition

PROFOUND SYNERGY

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



Hair cells
Hair bundles

Sensing Sound
Generating intricate
hair bundles



Hair cells
Transducing cell dye

Creating Signal
Producing functional
ion channels

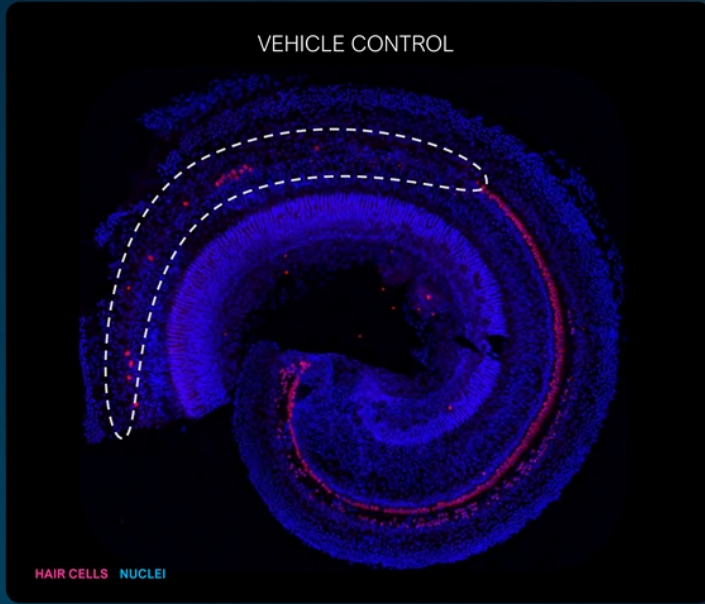


Hair cells
Synapses

Transmitting Signal
Synaptic proteins to communicate
with nerve are present

Images Showing Cellular Regeneration

In Vivo Hearing Loss Model



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

| 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



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

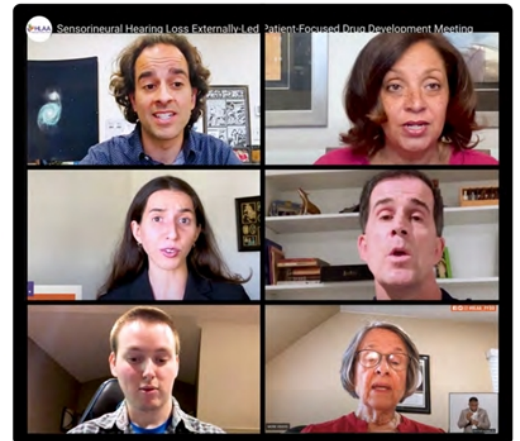


Externally-Led (HLAA) Patient Focused Drug Development Program on Sensorineural Hearing Loss

Top two needs for new drug or device



Top two hearing loss concerns



Astellas Collaboration:

Ex-US Development and Commercialization of FX-322

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



Proven Leadership Team



David Lucchino
President, CEO
& Co-Founder

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



Chris Loose, Ph.D.
Chief Scientific Officer
& Co-Founder

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



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.

Scientific Advisory Board



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Ph.D.**

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



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SC.D.**

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Ph.D.**

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Clinical Advisory Board



Pioneering a New Category in Regenerative Medicine

Frequency Therapeutics Corporate Presentation

January 2022

FREQUENCY
THERAPEUTICS 