

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): December 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:

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

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

Emerging growth company

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

Item 7.01. Regulation FD Disclosure.

On December 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. In the updated corporate slide presentation, the Company indicates that it expects to disclose the results of its FX-322-208 trial in the second half of the first quarter of 2023. 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 December 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: December 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
December 2022

FREQUENCY 
THERAPEUTICS

Forward-Looking Statements and Other Disclaimers

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 design of Frequency Therapeutics' (the "Company") 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 timing of the Company's trials, including the Phase 2b trial of FX-322 and Phase 1b trial of FX-345, the timing of the Investigational New Drug application for remyelination in multiple sclerosis ("MS") program, the interpretation and implications of the results and learnings of previous FX-322 clinical studies, the acceptance by the FDA of particular endpoints in the Company's trials, the acceptance by the FDA of the Phase 2b trial of FX-322 as a pivotal trial, the treatment potential of FX-322, FX-345, and the novel approach for remyelination in MS, 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 MS, estimates of the commercial opportunity of FX-322, FX-345, and the novel approach to remyelination, the impact on existing treatment paradigms, the potential for payor reimbursements for treatment, the ability of our technology platform to provide patient benefit, and the potential application of the progenitor cell activation ("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 8, 2022 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.

Vision

A new approach to regenerative medicine

- Using small molecules to activate the body's innate regenerative potential
- Applicable to many other degenerative diseases with large patient populations

Opportunity

The first drug candidate shown to improve hearing

- Potential to transform treatment for millions
- Key clinical readout in Q1 2023

Capitalized to Achieve Major Milestones

FX-322

Lead Hearing Program

Phase 2b 208
study readout

Second half of Q1 2023

Lead hearing restoration study in sudden sensorineural and noise-induced hearing loss

FX-345

Second Hearing Program

Phase 1b
readout

H2 2023

New hearing restoration candidate explores impact of broader cochlear drug distribution

Development Candidate

MS Remyelination Program

IND Submission

H2 2023

Small-molecule therapeutic to activate oligodendrocyte precursor cells to restore myelin

Transforming the Standard of Care for Hearing Loss

FX-322 for Hearing Restoration

SIGNIFICANT UNMET NEED

There are no solutions to address the underlying biological cause of hearing loss

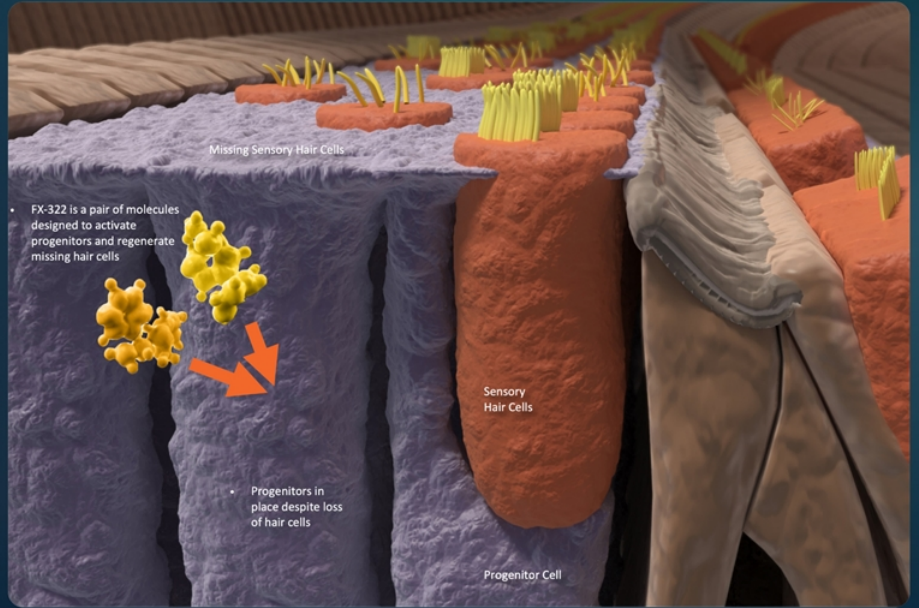
POTENTIAL PARADIGM- CHANGING THERAPY

Enhancing speech perception — the greatest need for millions of individuals with hearing loss

FX-322:

A Small Molecule Candidate to Address the Underlying Pathology

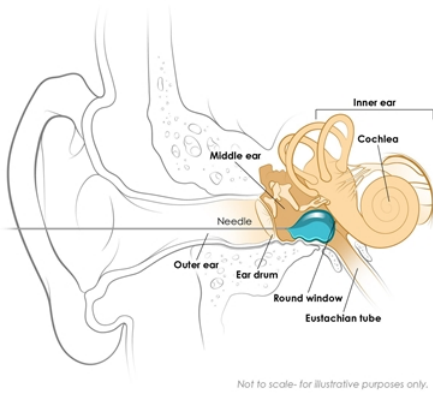
Combination of pathways aims to activate progenitor cells and regenerate sensory cells in the cochlea



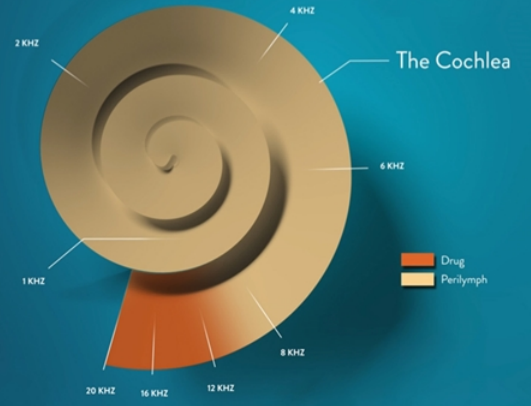
FX-322:

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

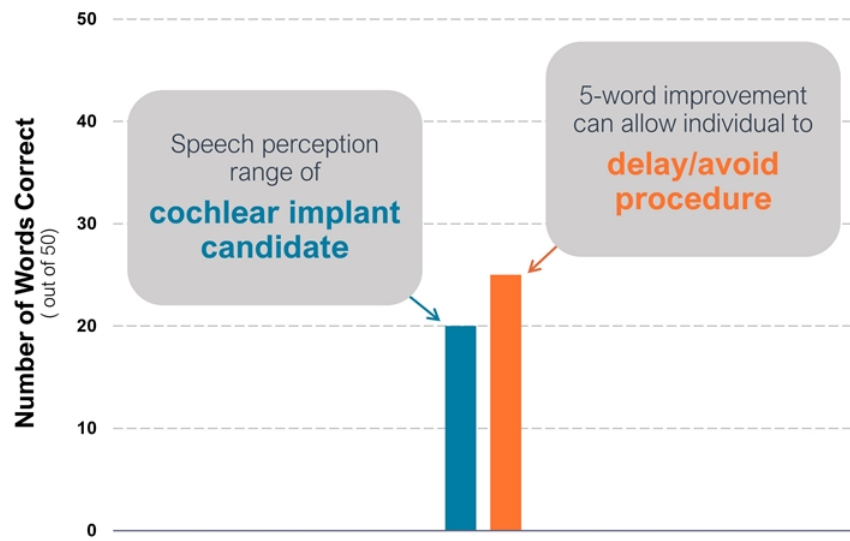


The injection concentrates FX-322 in the cochlear region critical for speech intelligibility



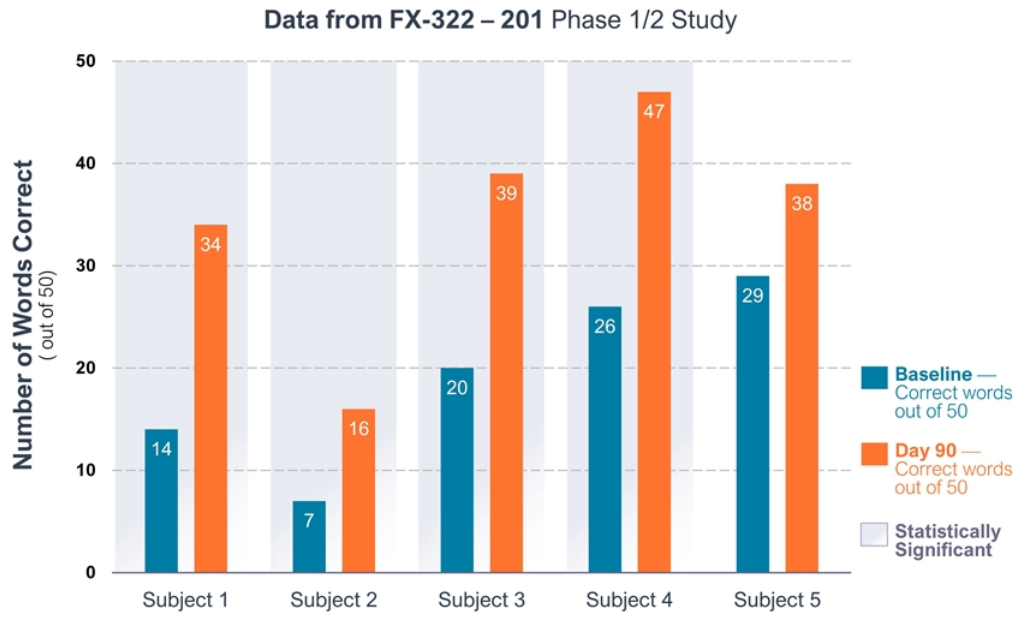
Clinical Impact of a 5-word Improvement for Hearing Loss Patient

- 5-word increase out of 50 (10% absolute) is clinically meaningful
- Impacts treatment recommendation
- Individuals with stable hearing loss *do not spontaneously improve*



Speech Perception Improvements with FX - 322

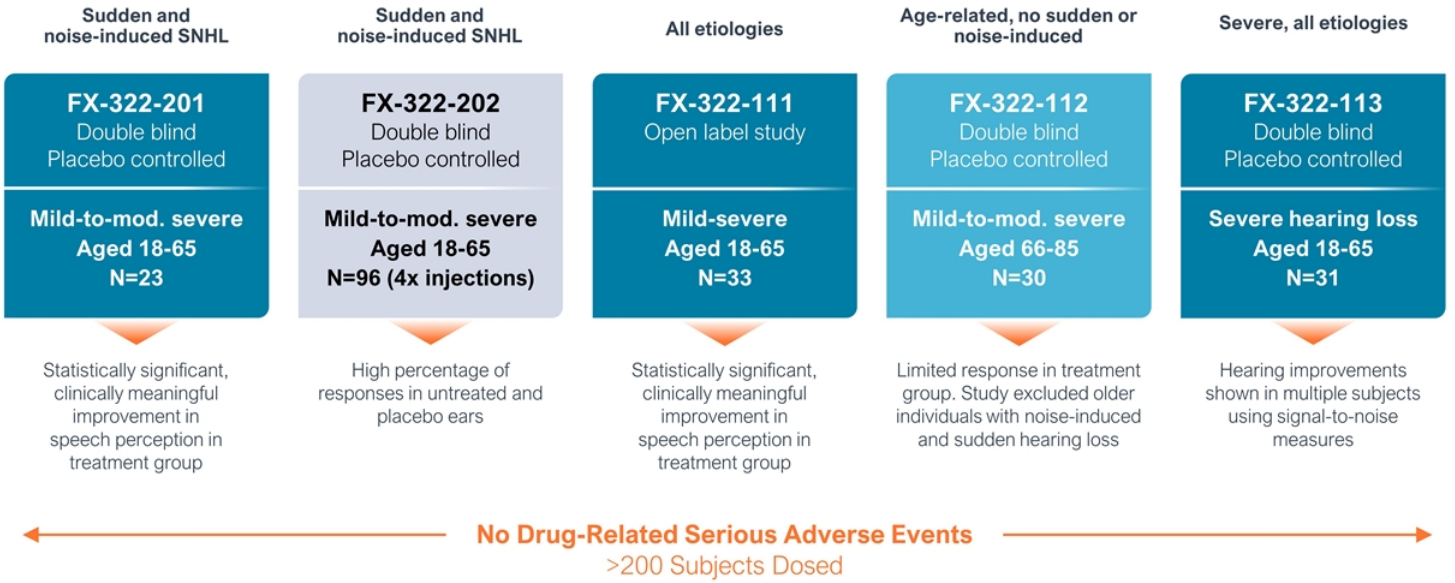
- More than 30% of subjects had a greater than 5-word improvement in speech perception scores
- Some subjects more than doubled their scores
- Some maintained improvements one to two years later



Published in *Otology and Neurology*, February 2021 *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.)

Outcomes from Five FX-322 Studies

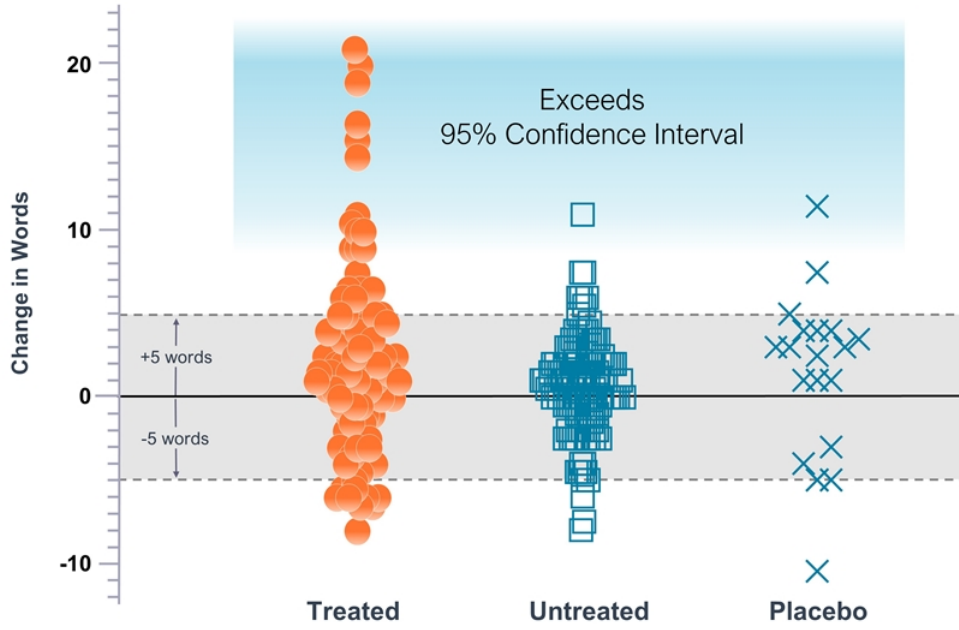
Building a Clinical Path for a Hearing Therapeutic



Hearing signal No change between placebo and treated groups Inconsistent baselines undermined data

Pooled FX-322 Data Across Studies Shows Pattern of Response

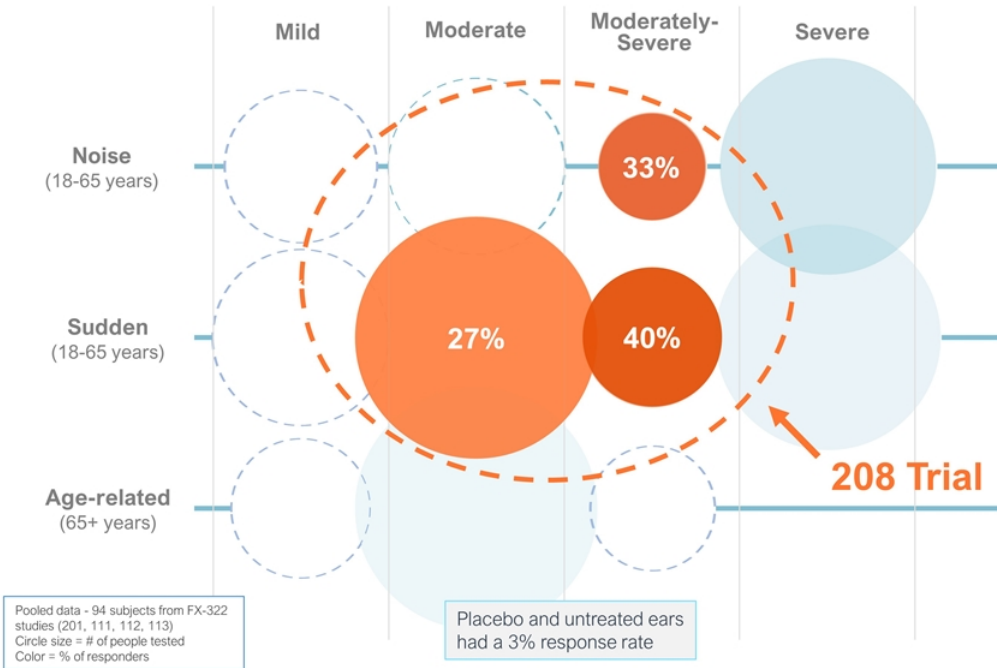
Studies 201, 111, 112 & 113



95% confidence intervals established by Thornton & Raffin (1978) and modified by Carney & Schlauch (2007).
Word improvement to reach 95% confidence interval depends on starting performance.

Pooled Data from Single Dose Trials

Understanding Which Patients are Most Responsive to FX-322

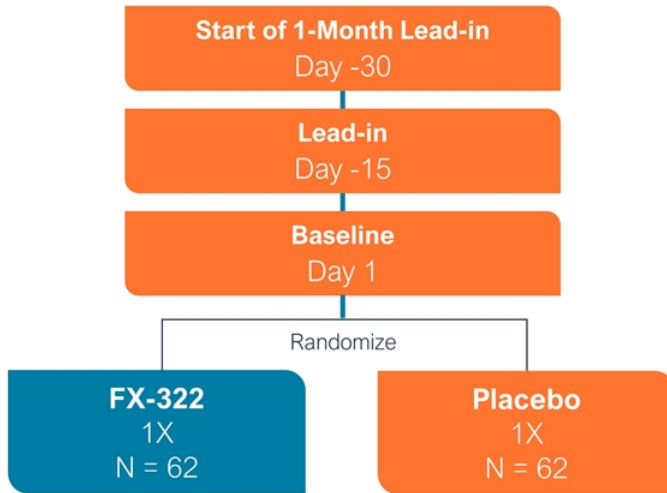


208 study:
Target population
7-10 million
people in the U.S.

FX-322-208 Phase 2B Study

Powered to show statistically significant improvement in speech perception

124 Subjects, SSNHL and NIHL, Ages 18-65
3 screenings to enter lead-in
Pure tone average 35-85 dBHL



Follow-up Visits: Days 30, 60, 90

Rigorous Study Design

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

208 Study Enrollment

Recruitment driven by high interest and strict protocols

~11,000 total trial applicants



- 417 patients attended an initial study visit
- Screen failure rate of 65% due to strict protocols
- 142 patients randomized

208 Enrollment

Subjects reflect etiologies and severities of responders from pooled data and meet the study's speech perception deficit criteria

	Mod	Mod/Sev	Sev	Total
Idiopathic Sudden SNHL (SSNHL)	12%	42%	15%	69%
Noise-induced SNHL (NIHL)	6%	19%	6%	31%
Total	18%	61%	21%	100%

Current patient retention rate is better than 99%

Clearly Defined Criteria for FX-322-208 Study Success

Pre-specified, FDA-aligned clinical endpoints

Powered to detect efficacy over placebo

Study powered to show greater responder rate in FX-322 treated patients than placebo ($p < 0.05$)*

*80% power assuming 20% effect size in 112 patients

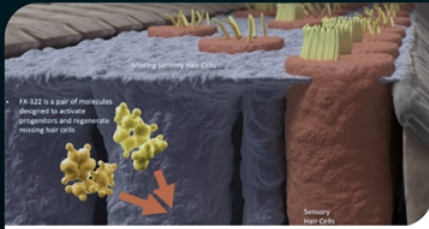
Pre-Specified Responder Definition

Responders have statistically significant and clinically meaningful improvements (Exceed 95% confidence interval on speech perception test*)

*Speech perception test used as a primary endpoint is pre-specified but not publicly disclosed to keep clinicians and patients blinded

Clear Commercial Path

First Potential Therapy for Millions of People with Hearing Loss



Small molecule approach

- Not gene or cell therapy
- Favorable safety profile
- Ease of manufacturing and drug delivery



Established ENT physician channel

- Medicine would enable ENTs to offer intervention to patients with SNHL
- Standard trans-tympanic injection



Path to reimbursement

- Existing reimbursement (and CPT code) for trans-tympanic injection
- ENTs are currently reimbursed for many hearing interventions

Hearing Loss Can Have a Significant Impact on Overall Health

THE LANCET
July, 2020

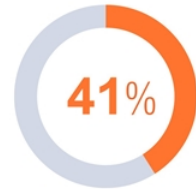
“Hearing loss is the largest potentially modifiable risk factor for developing dementia”

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.

Current device solutions aren't enough

There's a clear demand for cochlear regeneration as a solution

Hearing Aids



Cochlear Implants



- ▶ **Only 20%* of people who need hearing aids actually use them**
- ▶ **Current devices don't address the underlying biological problem**
- ▶ **Speech clarity is the critical unmet need as identified by patients**

*<https://www.nidcd.nih.gov/health/statistics/use-hearing-aids-adults-hearing-loss>

Opportunities Enabled by a Positive FX-322-208 Study Outcome

Regulatory

Defined path to registrational studies

- Potential for FX-322-208 to be considered a pivotal study
- One additional study for approval

Potential for Breakthrough Therapy designation

FX-322 Partner Milestones



\$625m for ex-US development
and commercialization

AST Development milestone payments to Frequency

- \$90 million for Phase 2b start in Europe and Asia
- \$140 million for Phase 3 start in Europe and Asia



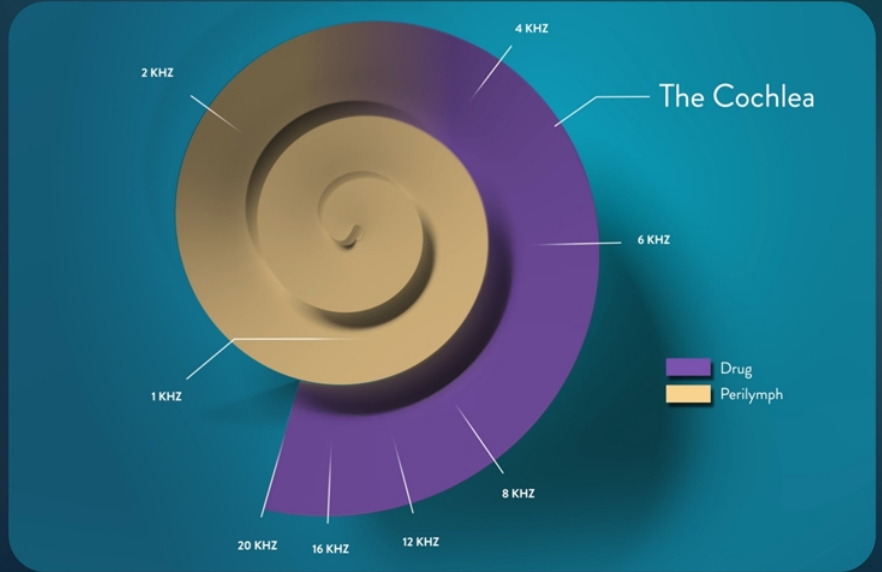
Pipeline Expansion



FX-345

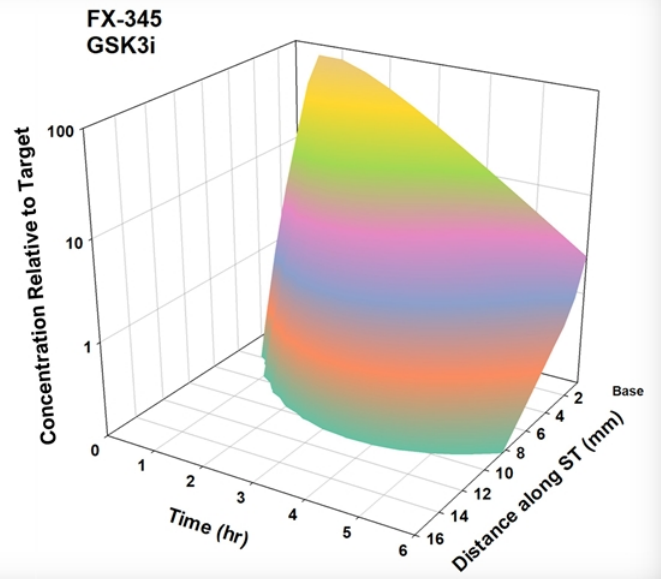
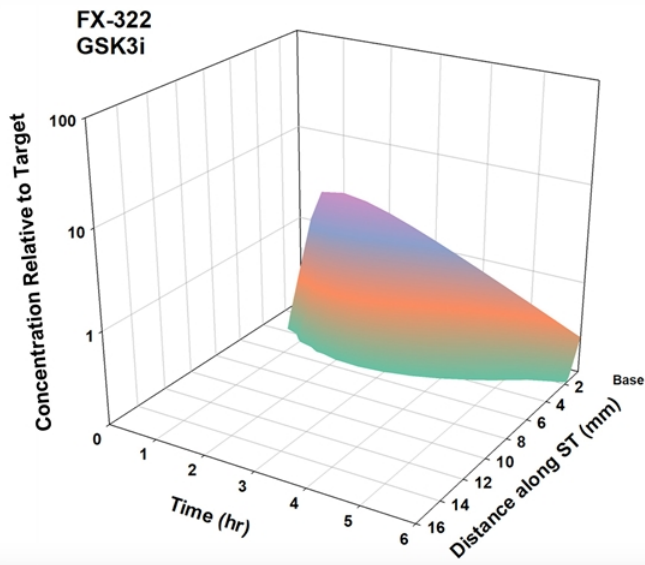
Working to Achieve Broad Exposure Through the Cochlea

- Second hearing restoration program
- Enables coverage of a large portion of the cochlea
- Potential to address additional SNHL patient types
- Formulation may enable evaluation of a range of dose levels
- Developing in addition to FX-322. Clinical data will drive commercial positioning

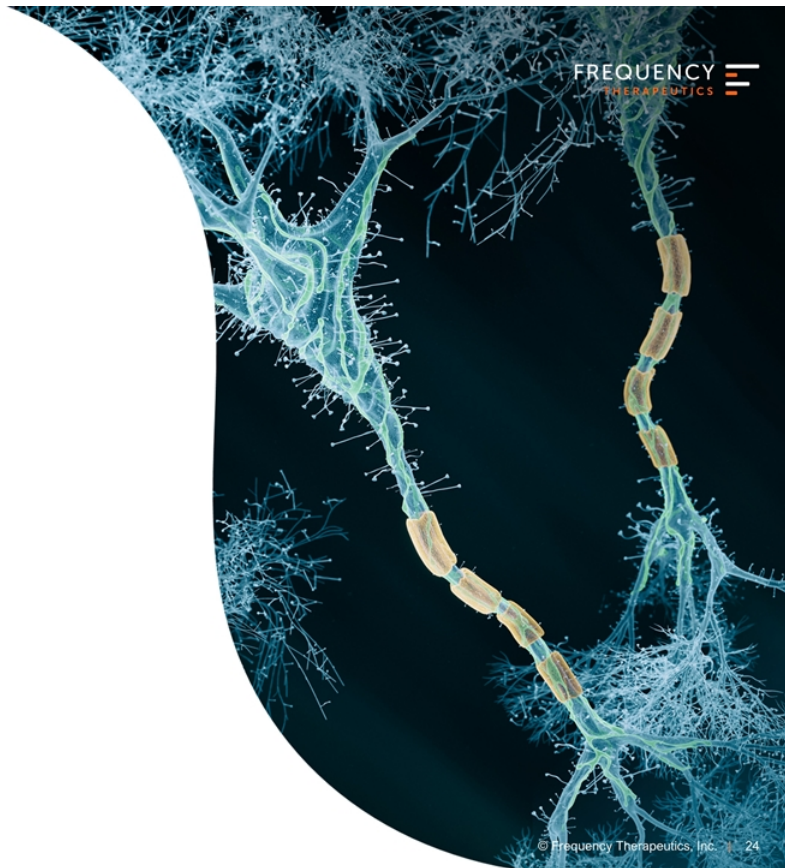


FX-345

Creating Effective Drug Levels Through Large Portion of Cochlea



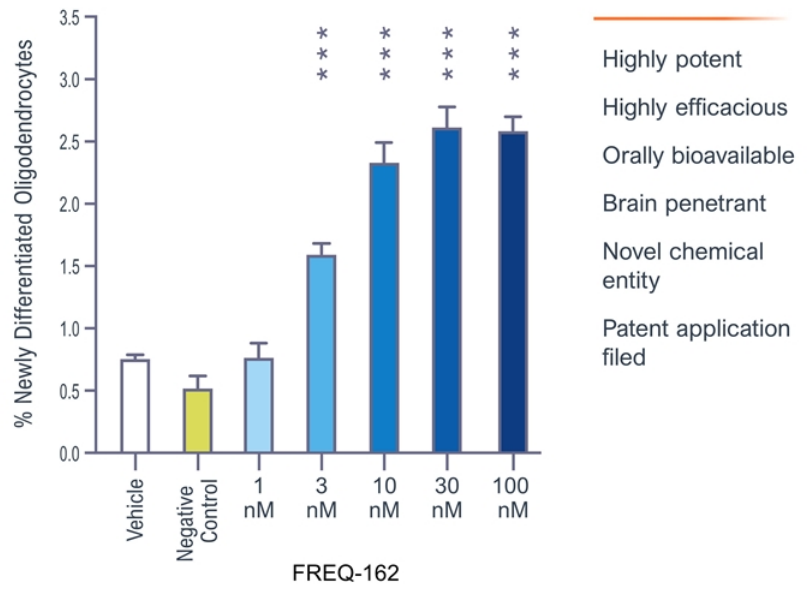
**What if we could
extend our approach
to other degenerative
diseases?**



Novel Frequency Small Molecule Inhibitors Drive Oligodendrocyte Differentiation

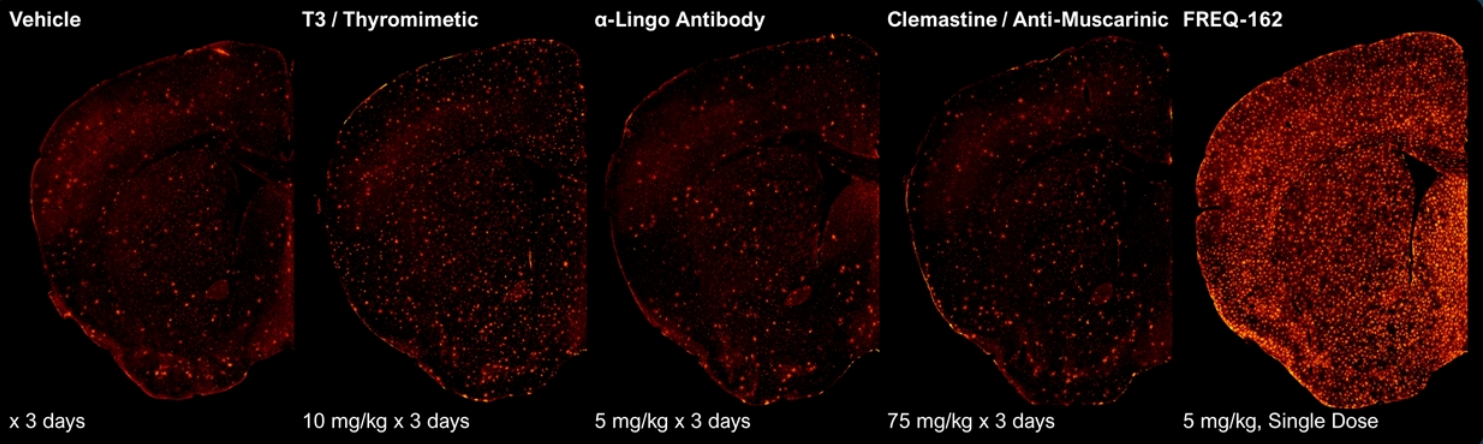


Lead Optimization generated FREQ-162



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



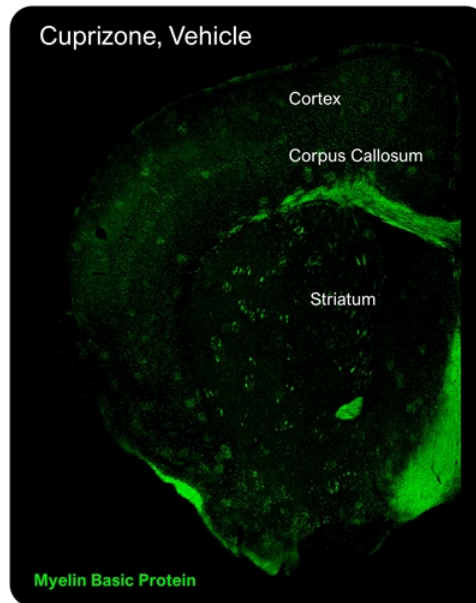
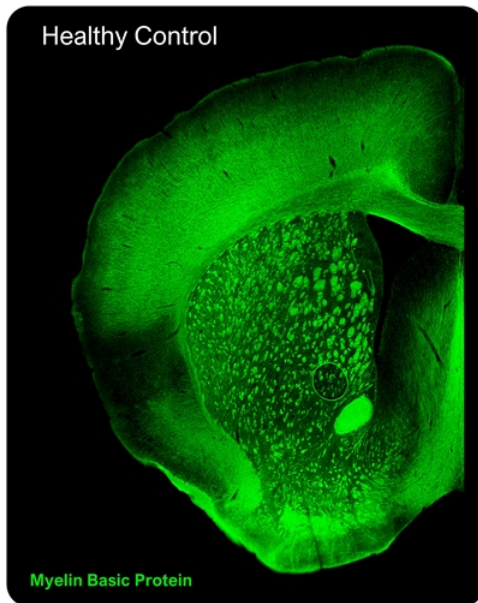
Thyroid Hormone:
Thyromimetic Class

α-Lingo antibody:
Blocking antibody

Clemastine:
Anti-Muscarinic Class

FREQ-162 induces formation
of newly differentiated
oligodendrocytes in both
white and gray matter

The Cuprizone Model of Chronic Demyelination



Adult mice were demyelinated via 17 months of cuprizone administration

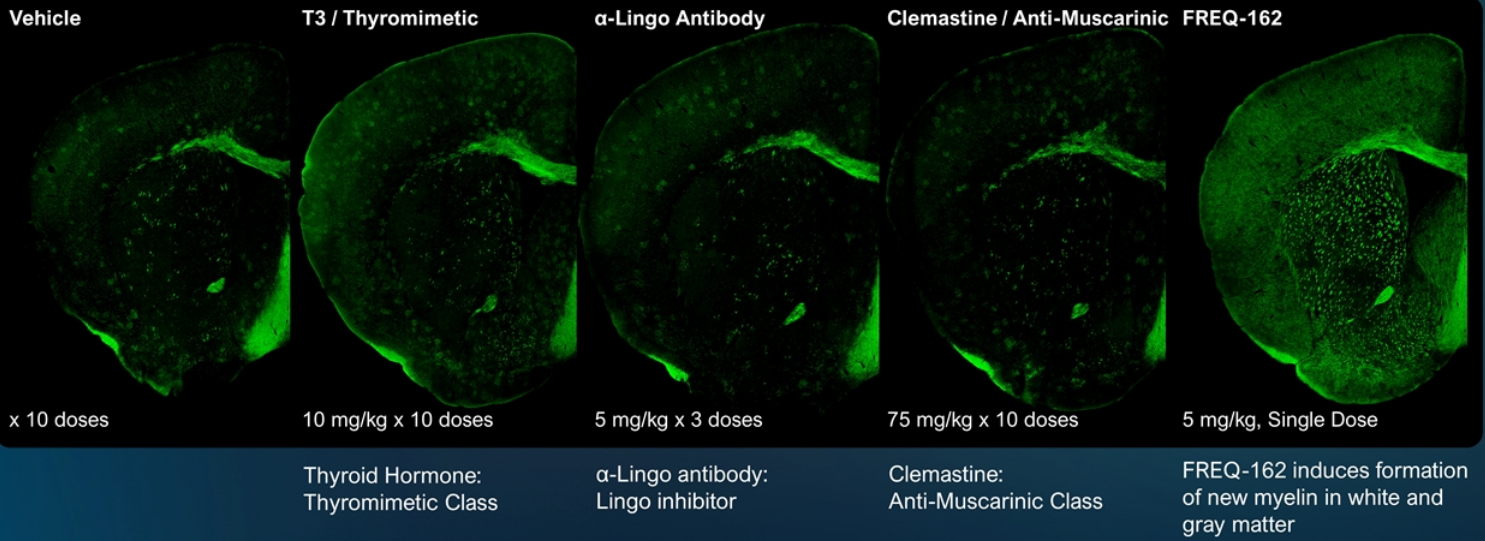
- Elderly mice with long term demyelination

FREQ-162 Outperforms Published Compounds *In Vivo*

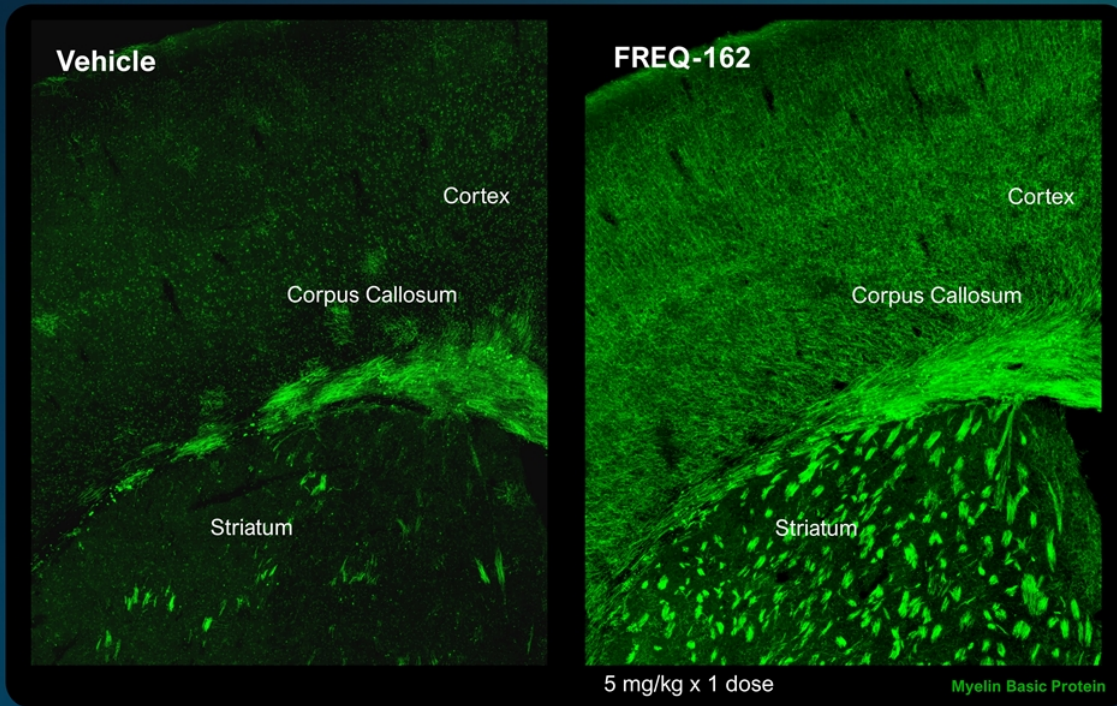
Adult mice received up to 10 daily doses of comparators or a single dose of FREQ-162

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



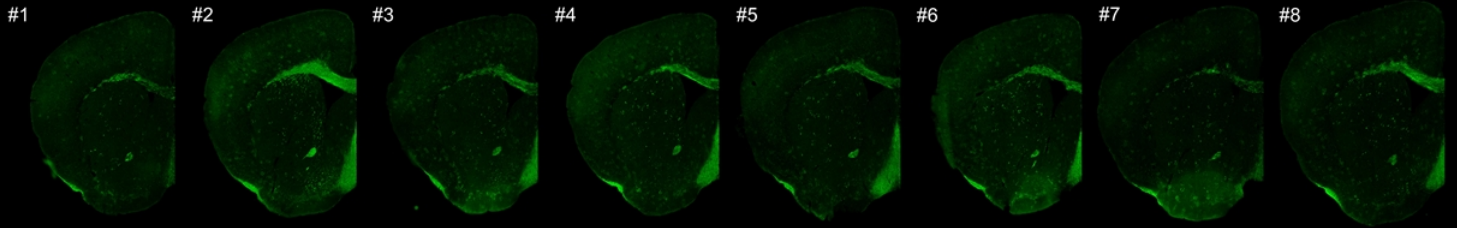
High magnification view reveals that FREQ-162 yields myelination

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

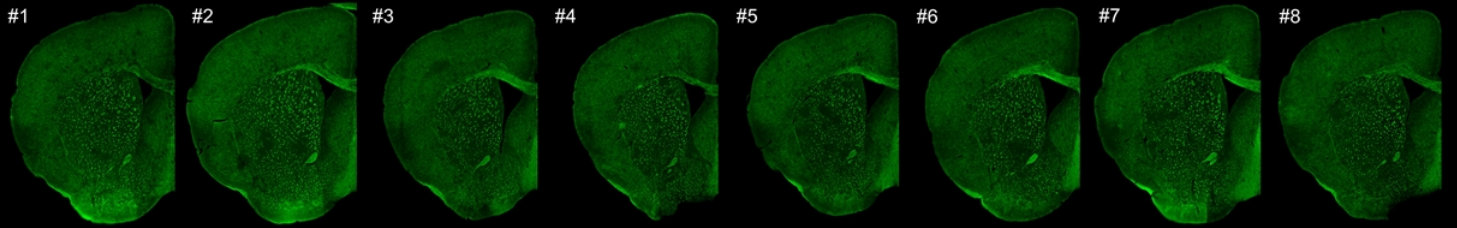
FREQ-162: Highly Reproducible Increases in Myelination

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

Vehicle



FREQ-162

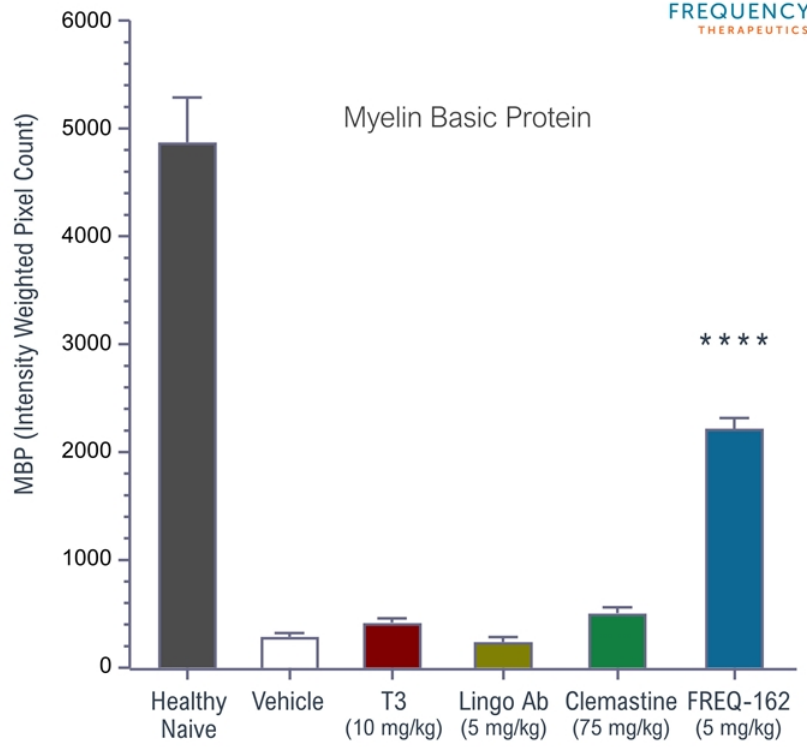


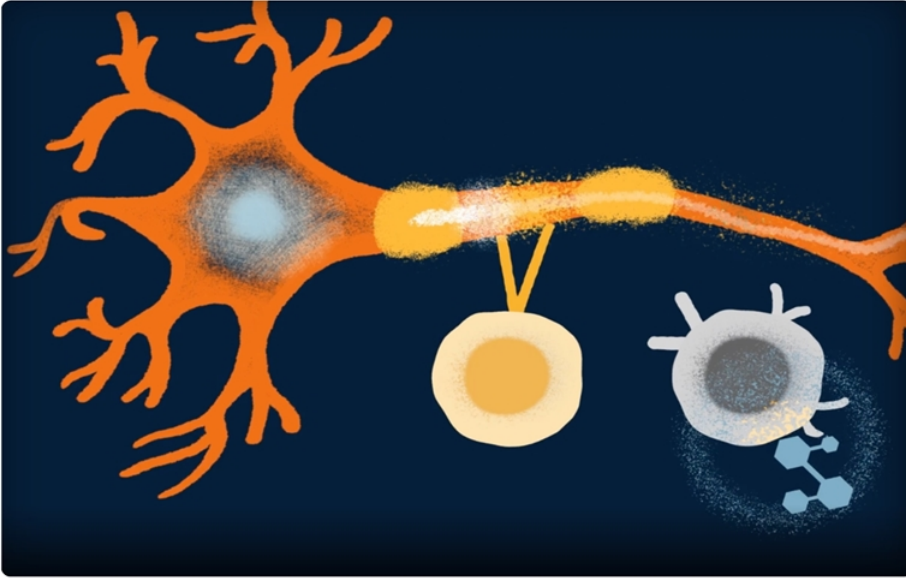
Myelin Basic Protein

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

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

Candidate entering IND-enabling studies

2023: A year of major milestones

- FX-322 phase 2B study read-out in second half of Q1
 - Unique opportunity to advance the first restorative treatment for acquired SNHL
 - Focused on key unmet need of speech perception
 - Clear, pre-defined endpoints
- FX-345 phase 1b study for hearing restoration, H2
- IND for remyelination in MS program, H2

Pipeline programs in key areas of unmet need

- Hearing restoration and remyelination in MS both potential multi-billion-dollar markets addressing great areas of patient needs

Resources to support next set of catalysts

- \$99.3mm cash in hand as of September 30
- Astellas Phase 2b start in Europe/Asia triggers \$90 million in milestones

Appendix

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



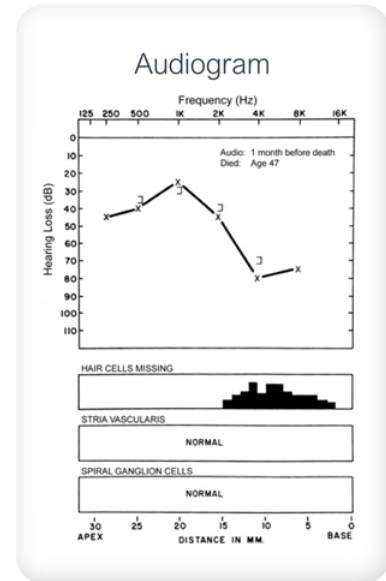
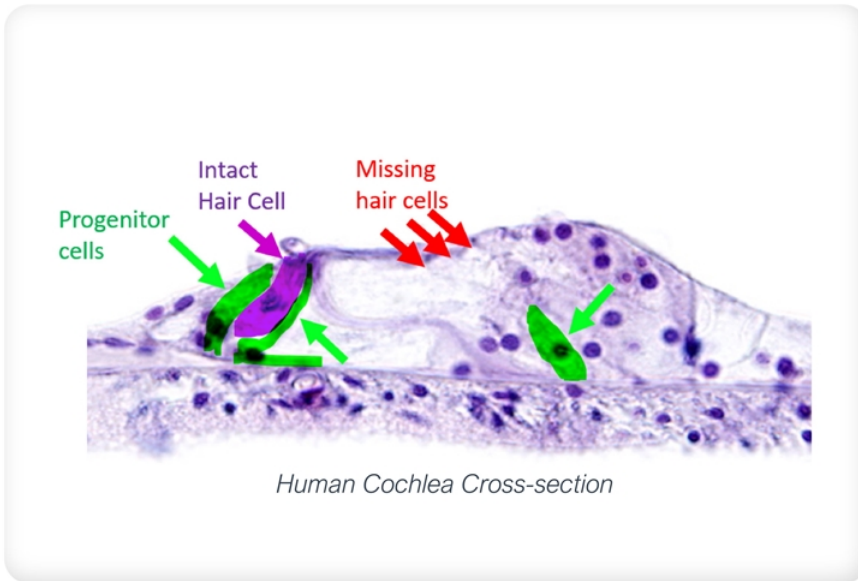
Clonal Expansion of Lgr5-Positive Cells from Mammalian Cochlea and High-Purity Generation of Sensory Hair Cells

Frequency Therapeutics

Small molecule therapeutics show clinical proof of concept



Despite Hair Cell Loss, Progenitor Cells Remain

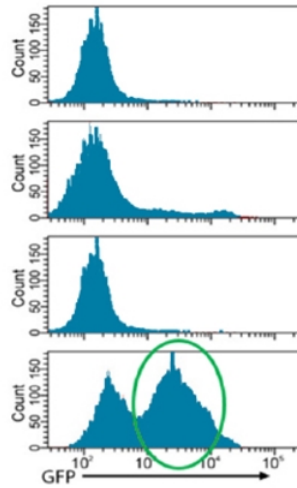


47 Year Old Male with Occupational Noise Deafness

Combination of Pathways to Activate Progenitor Cells

Cochlear Progenitor Proliferation (Lgr5+ – GFP)

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



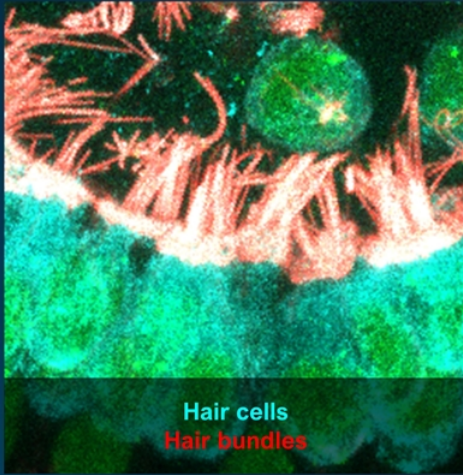
Culture Media

Glycogen synthase kinase-3
(GSK3) Inhibitor; (Iaduviglusib)

HDAC Inhibition
(sodium valproate)

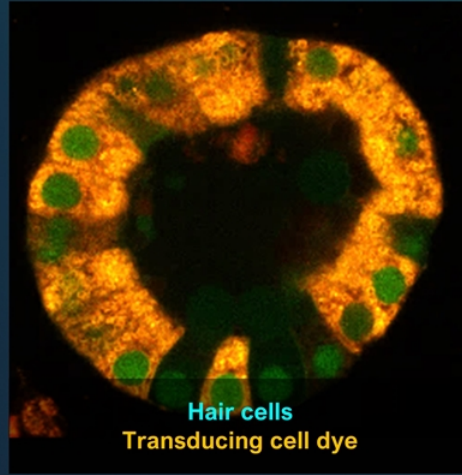
GSK3 + HDAC inhibition

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



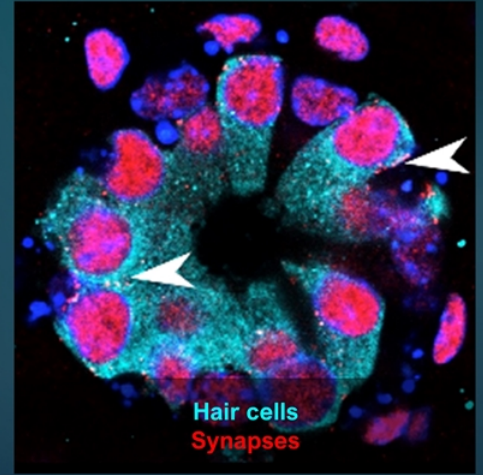
Hair cells
Hair bundles

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

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

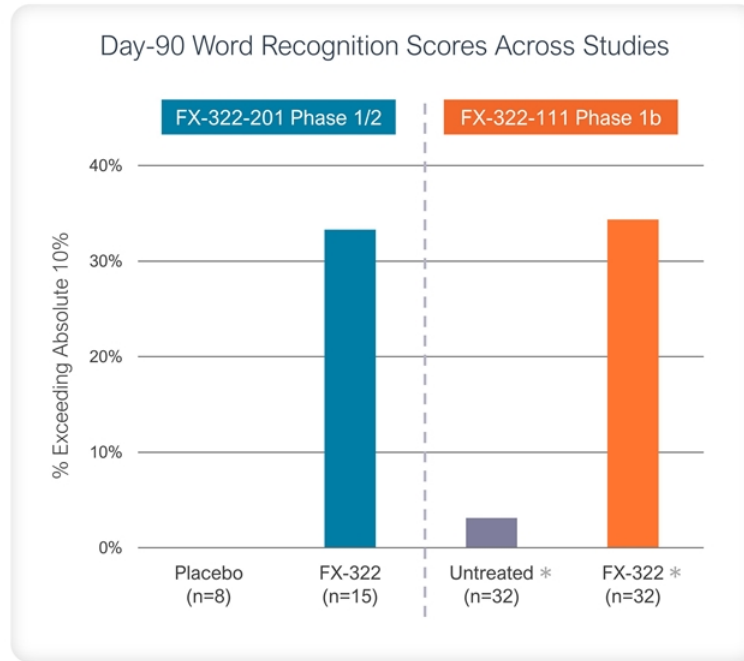
Improvement Shown in Speech Perception in Quiet with Single Dose

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



*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)

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
- Three 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

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.



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.



Dana Hilt, M.D.
Chief Medical Officer

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



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



**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



**Sheng Ding,
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Senior Investigator, Gladstone Institute of Cardiovascular Disease



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



**Siddhartha Mukherjee,
M.D., D.Phil.**

Assistant Professor of Medicine, Columbia University Medical Center



**Amy Wagers,
Ph.D.**

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

Clinical Advisory Board



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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
December 2022

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