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): August 12, 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 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 August 12, 2021, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2021 and provided operational updates. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report").

The information in this Item 2.02 of this Current Report, including Exhibit 99.1, 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 provided by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

On August 12, 2021, 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 99.2 to this Current Report.

The information in this Item 7.01 of this Current Report, including Exhibit 99.2, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of 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, 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 Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibits relate to Items 2.02 and 7.01, which shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on August 12, 2021
99.2	Frequency Therapeutics, Inc. Corporate Slide Presentation as of August 12, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

FREQUENCY THERAPEUTICS, INC.

Date: August 12, 2021

By: /s/ David L. Lucchino

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

Exhibit 99.1

Frequency Therapeutics Provides Business Updates and Second Quarter 2021 Financial Results

Company Plans to Commence New FX-322 Phase 2 Study in Q4 2021 in a Refined Population of Individuals with Sensorineural Hearing Loss (SNHL)

Will Host R&D Event on November 9th to Provide Detailed Insights into FX-322 Clinical Data, Plans for Continued FX-322 Development and New Pipeline Advancements for Hearing Loss and Multiple Sclerosis

LEXINGTON, Mass., Aug. 12, 2021 – Frequency Therapeutics, Inc. (Nasdaq: FREQ), a clinical-stage biotechnology company focused on harnessing the body's innate biology to repair or reverse damage caused by a broad range of degenerative diseases, today announced business updates and financial results for the second quarter ended June 30, 2021.

"We have made important progress in our efforts to advance FX-322, our lead program for SNHL, toward its next step in clinical development. We are now completing a thorough analysis of our FX-322 exploratory clincial studies, which has served to increase our understanding of the etiologies and severities where hearing benefits have been observed in study subjects. Based on the overall learnings from multiple completed studies, we plan to initiate a randomized and well-controlled Phase 2 trial in the fourth quarter of this year, using a single administration of FX-322 in a refined population of subjects with SNHL. In addition, this trial will incorporate several novel study design elements that we believe will help address previously observed study bias," said David L. Lucchino, Frequency's Chief Executive Officer. "In the fourth quarter, we also intend to share topline data from our FX-322 Phase 1b learning study of subjects with severe SNHL (FX-322-113). Our plan is to maintain flexibility in the design of the new Phase 2 trial so we may also incorporate insights from the study of severe SNHL subjects."

"This November, we will host an R&D event for investors where we will detail findings from all of our FX-322 clinical studies. These insights have provided the basis for our enthusiasm in the program and have informed the design of our upcoming Phase 2 clinical trial. In addition, we plan to discuss other potential near-term and longer-term areas of pipeline expansion, including continued advancements in hair cell regeneration, as well as the progress we have made in our preclinical program for remyelination in multiple sclerosis (MS), our scientific approach toward compound selection and the *in vivo* data that we believe supports our MS program," Mr. Lucchino concluded.

Clinical Study Overview and Recent Corporate Highlights

Sensorineural hearing loss is the most common form of hearing loss, typically resulting from damage to auditory sensory hair cells in the inner ear. These cells convert sound waves to signals sent to the brain. Sensory hair cells may be lost due to noise exposure, aging, certain viral infections or exposure to drugs that are toxic to the ear.

Frequency's lead clinical development program has included numerous learning studies that have examined different SNHL severities and etiologies, as well as durability of benefit and the impact of various delivery approaches to best understand target populations and administration approaches for continued FX-322 development. In a Phase 1/2 study of subjects with mild to moderately severe SNHL (FX-322-201) the Company observed statistically significant and clinically meaningful improvements in key measures of hearing loss. In March 2021, the Company shared data from an open-label study of FX-322 (FX-322-111), that, similar to the Phase 1/2 study, showed an improvement in word recognition scores, including a near doubling of these scores in certain patients with stable SNHL.

FX-322-113 Phase 1b Study in Severe SNHL: In November 2020, Frequency commenced a Phase 1b study in patients aged 18-65 with severe SNHL (FX-322-113). The study is fully enrolled with 31 subjects. The primary objectives of the study are to assess the local and systemic safety of a single dose of FX-322 and evaluate hearing responses in a more severe adult cohort. Study participants are randomized 4:1 to receive either FX-322 or placebo in one ear. Validated measures of hearing function including speech perception and pure tone audiometry are utilized in the study. Safety, otologic and audiologic assessments are being conducted at days 30 and 90 following administration of FX-322 or placebo. Frequency expects to share topline results from this study in Q4 2021.

Remyelination in Multiple Sclerosis: Frequency continues to advance its preclinical research efforts designed to repair neurological damage in patients with MS. Research efforts are underway to optimize lead compounds with potent remyelination activity that have favorable brain penetration and pharmacokinetic properties. The Company plans to provide additional details on its MS preclinical program at its November 2021 R&D event.

Support for Patient-Focused Drug Development Event on Sensorineural Hearing Loss: In May 2021, the Company issued a statement of support for the Hearing Loss Association of America's externally led Patient-Focused Drug Development (PFDD) meeting held to address the patient experience in sensorineural hearing loss. The meeting was designed to provide the U.S. Food and Drug Administration (FDA) with an opportunity to hear directly from patients, their families and caregivers, and advocates on the impact of hearing loss on daily life and their experiences with currently available interventions in order to inform the FDA's decisions and oversight both during drug development and review of marketing applications for new drugs.

Second Quarter 2021 Financial Results

Cash Position: Cash, cash equivalents and marketable securites as of June 30, 2021 were $175.5 million, as compared to $220.3 million as of December 31, 2020. Based on current plans and assumptions, the Company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into 2023. This guidance does not include potential future milestones which could be received from Astellas for continued FX-322 development.

Revenue: Revenue was $9.4 million and $14.1 million for the three and six month periods ended June 30, 2021, respectively. The Company had revenue of $8.5 million and $15.8 million in the comparable periods of 2020.

Research & Development Expenses: Research and development expenses were $17.4 million and $32.5 million for the three and six month periods ended June 30, 2021, respectively, as compared to $8.8 million and $15.4 million for the comparable periods of 2020. The increase was due to increased costs

related to the Company's lead product candidate, FX-322, including external development costs related to the Company's ongoing trials for FX-322, as well as increased personnel-related costs due to additional headcount to support the growth of Frequency's research and development organization. Excluding stock-based compensation expense of $3.1 million for the three months ended June 30, 2021 and $4.6 million for the six months ended June 30, 2021, research and development expenses for the three and six months ended June 30, 2021 were $14.3 million and $27.9 million, respectively.

General and Administrative Expenses: General and administrative expenses were $9.5 million and $19.2 million for the three and six months ended June 30, 2021, respectively, as compared to $6.0 million and $12.2 million for the comparable periods of 2020. The increase was primarily due to an increase in personnel-related costs, including stock-based compensation, for additional headcount required to support the growth of the Company as well as costs associated with being a public company, primarily comprised of professional fees. Excluding stock-based compensation expense of $3.0 million for the three months ended June 30, 2021 and $6.1 million for the six months ended June 30, 2021, general and administrative expenses for the three and six months ended June 30, 2021 were $6.5 million and $13.1 million, respectively.

Net Loss: Net loss was $17.7 million and $38.0 million for the three and six months ended June 30, 2021, respectively, as compared to $6.0 million and $10.9 million for the comparable periods of 2020. The increase in net loss reflects the increase in research and development costs associated with the growth of Frequency's research and development organization as well as the increase in general and administrative expenses required to support the growth of Frequency as a public company.

About Frequency Therapeutics

Frequency Therapeutics is a leader in the development of medicines designed to activate progenitor cells within the body to treat degenerative diseases. The Company's progenitor cell activation (PCA) approach stimulates progenitor cells to create functional tissue with the aim of developing disease modifying therapies. The Company's lead product candidate, FX-322, is designed to regenerate auditory hair cells to restore hearing function. FX-322 is being evaluated in multiple ongoing clinical studies in patients with sensorineural hearing loss. The Company also is evaluating additional diseases where its PCA approach could create functional tissue, including in a pre-clinical program in multiple sclerosis.

Headquartered in Lexington, Mass., Frequency has an ex-U.S. license and collaboration agreement with Astellas Pharma Inc. for FX-322, as well as additional collaboration and licensing agreements with academic and nonprofit research organizations including Massachusetts Eye and Ear, Mass General Brigham, the Massachusetts Institute of Technology, The Scripps Research Institute and Cambridge Enterprises Limited. For more information, visit www.frequencytx.com and follow Frequency on Twitter @Frequencytx.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the initiation, timing and design of the new Phase 2 trial of FX-322, including the ability of study design to address study bias, the interpretation and implications of the results of the Phase 2a, FX-322-111, FX-322-201 and FX-322-112 data, the timing and results of top-line data from the

Phase 1b study (FX-322-113) in severe SNHL, the design and timing of future studies of and clinical development path of FX-322, the treatment potential of FX-322, and our program to develop a product candidate for the treatment of multiple sclerosis; the ability of our technology platform to provide patient benefit, the ability to continue to develop our PCA platform and identify additional product candidates, the timing of and content to be disclosed during the R&D event, the timing and progress of the Company's remyelination program, the sufficiency of the Company's capital resources, the implementation of our strategic plans for our business, product candidates and technology, the license and collaboration agreements, including with Astellas Pharma Inc., 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; 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 press release. Any such forward-looking statements represent management's estimates as of the date of this press release. 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 press release.

###

Frequency Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	$ 9,417	$ 8,523	$ 14,068	$ 15,787
Operating expenses:				
Research and development	17,401	8,764	32,507	15,434
General and administrative	9,499	5,959	19,243	12,208
Total operating expenses	26,900	14,723	51,750	27,642
Loss from operations	(17,483)	(6,200)	(37,682)	(11,855)
Interest income	118	178	143	888
Interest (expense)	(182)	—	(400)	—
Realized (loss) gain on investments	(10)	(4)	(14)	65
Foreign exchange (loss) gain	(1)	8	20	9
Other (expense), net	(88)	—	(88)	—
Loss before income taxes	(17,646)	(6,018)	(38,021)	(10,893)
Income taxes	(10)	(7)	(10)	(45)
Net loss	$ (17,656)	$ (6,025)	$ (38,031)	$ (10,938)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.52)	$ (0.19)	$ (1.11)	$ (0.35)
Weighted-average shares of common stock outstanding-basic and diluted	34,238,394	31,066,686	34,177,262	30,967,453

Frequency Therapeutics, Inc.
Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	June 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 175,524	$ 220,341
Working capital	163,333	198,430
Total assets	220,213	264,722
Total liabilities	54,173	72,231
Accumulated deficit	(133,430)	(95,399)
Total stockholders' equity	166,040	192,491

Contacts:

Investor Contact:
Carlo Tanzi, Ph.D.
Kendall Investor Relations
ctanzi@kendallir.com
617-914-0008

Media Contact:
Suzanne Day
Frequency Therapeutics
Tel: 781-496-2211
Email: sday@frequencytx.com


Exhibit 99.2
REIMAGINING THE TREATMENT OF HEARING LOSS
FREQUENCY THERAPEUTICS
Corporate Overview
August 2021

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 interpretation and implications of the results of the Phase 2a study as well as the FX-322-112 and the FX-322-111 studies, the timing and results of top-line data from the Phase 1b study in severe SNHL, the initiation, timing and design of the new Phase 2 trial of FX-322, including the ability of study design to address study bias, the design and timing of future studies of and clinical development path for FX-322, the results and implications of the Phase 1/2 durability of response data, the ability of our technology platform to provide patient benefit, the impact of COVID-19 on the Company's on-going and planned clinical trials and business, future milestone and royalty payments under the license and collaboration agreement with Astellas Pharma Inc. ("Astellas"), the sufficiency of the Company's cash, cash equivalents and short-term investments, estimates of the size of the hearing loss population and population at risk for hearing loss, estimates of the commercial opportunity of FX-322 and the impact on existing treatment paradigms, the timing and progress of the remyelination program, and the potential application of the PCA platform to other diseases.

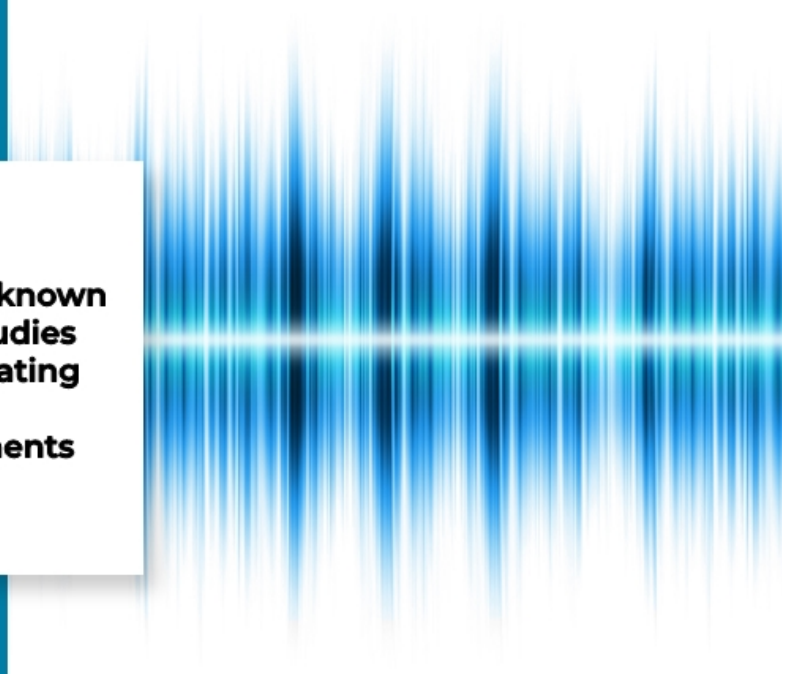
These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from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

Frequency Today: Guided by a Clear Signal

Leading the field of hearing restoration

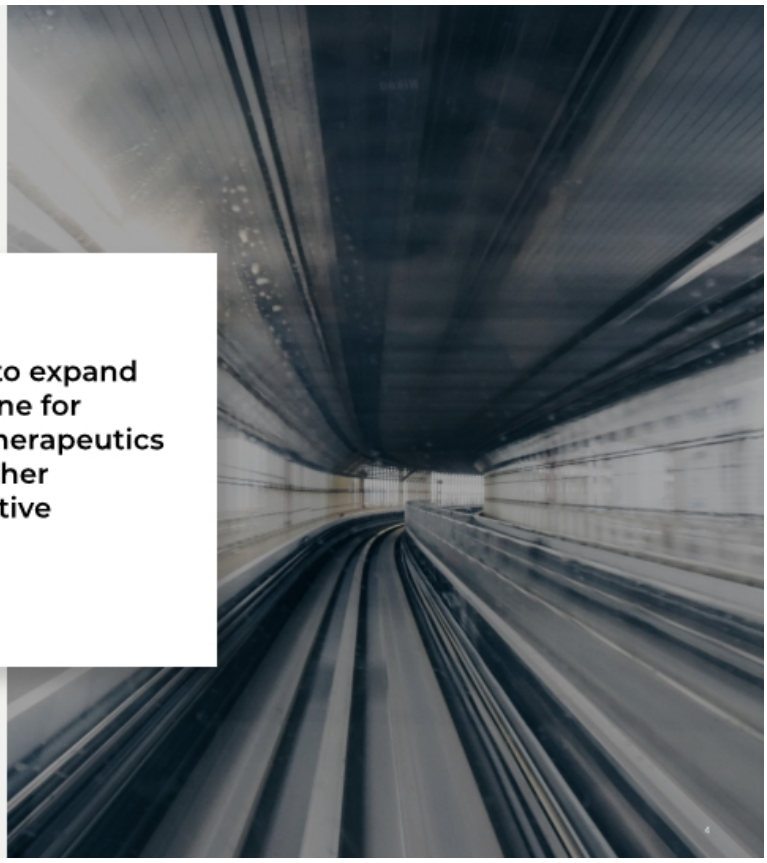
First ever known clinical studies demonstrating hearing improvements



Defining the Target, Expanding the Pipeline

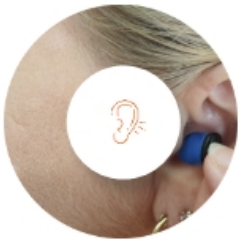
Learnings from exploratory studies support new Phase 2 trials and help define path forward

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



Today's Hearing Loss Market Has No Restorative Treatments

Only 20% market penetration for Hearing Aids



~$10 Billion

US hearing aid market annual sales

~41 Million

Individuals with SNHL in U.S.

$980 Billion

Lost annually due to untreated hearing loss globally*

*Source: World Health Organization


Hearing Loss Can Have a Significant Impact on Overall Health
"Hearing loss is the largest potentially modifiable risk factor for developing dementia"
July, 2020
THE LANCET
Increased risks with untreated hearing loss
50%
41%
DEMENTIA
DEPRESSION
JAMA
JAMA Nov 8, 2018
Deal J, et al. Incident Hearing Loss and Comorbidity: A Longitudinal Administrative Claims Study.

Frequency Therapeutics: A Vision Built on Regeneration

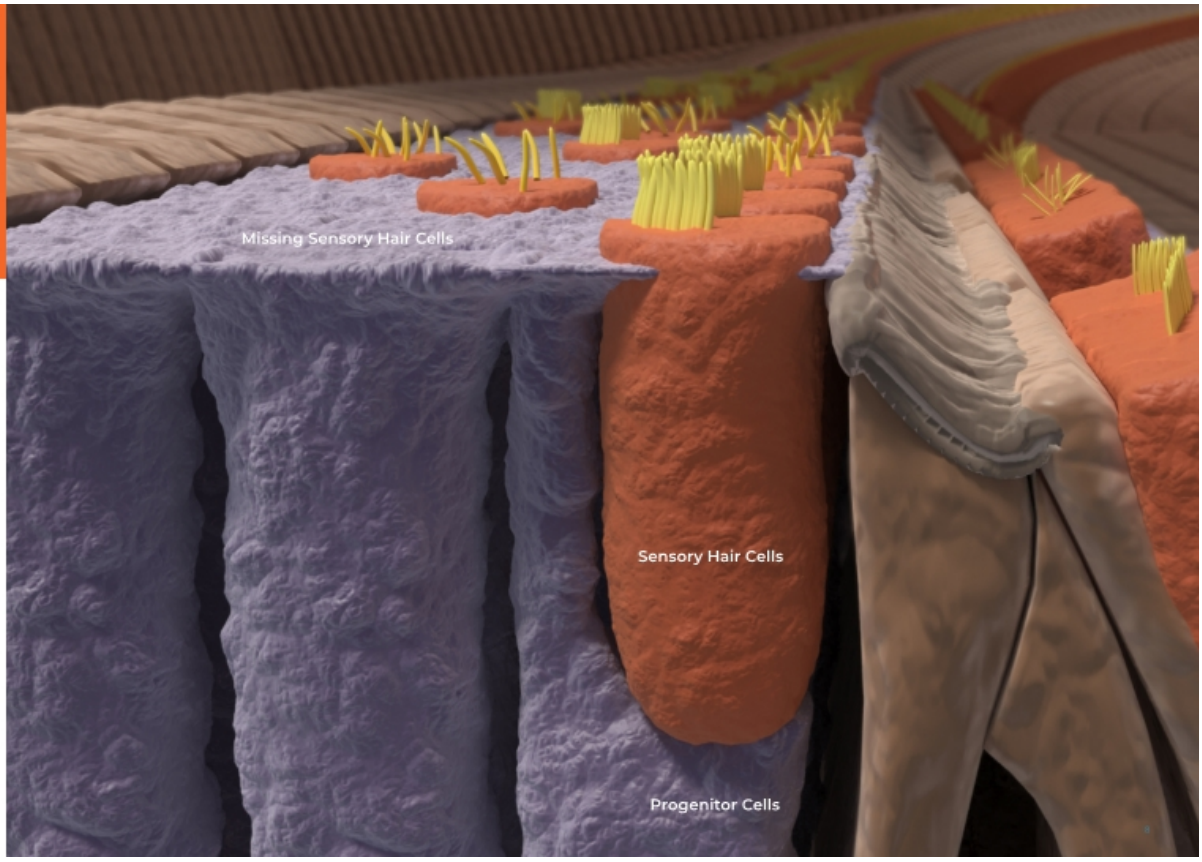
Since 2014 Frequency has been driving a powerful new approach to tissue and cellular regeneration aimed at developing new therapeutics for conditions where there are no treatment options.

The Problem: Missing Sensory Hair Cells in the Cochlea

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

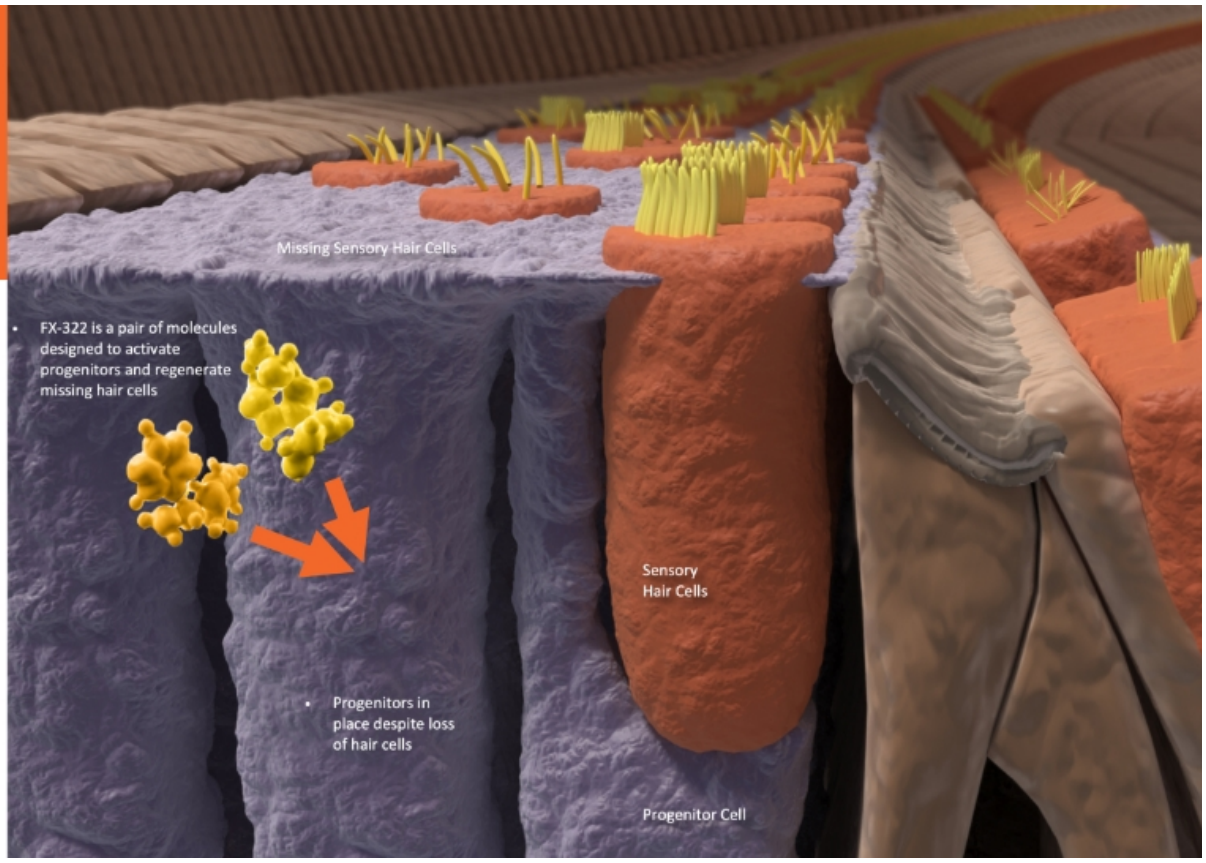
- Journal of Neuroscience

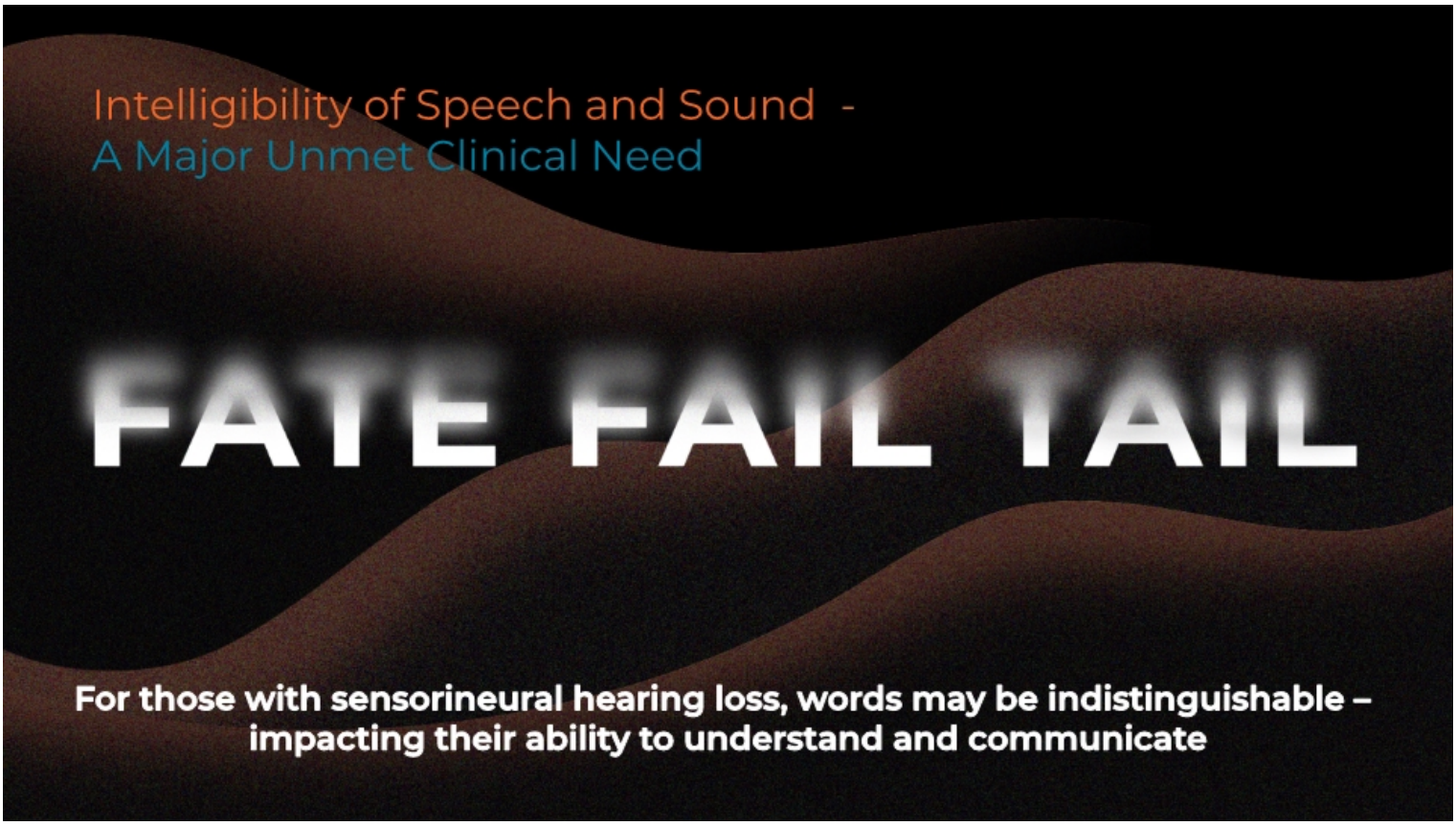
July 2020



Solution: A Therapy to Address the Underlying Pathology

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




Intelligibility of Speech and Sound -
A Major Unmet Clinical Need
FATE FAIL TAIL
For those with sensorineural hearing loss, words may be indistinguishable –
impacting their ability to understand and communicate

40%

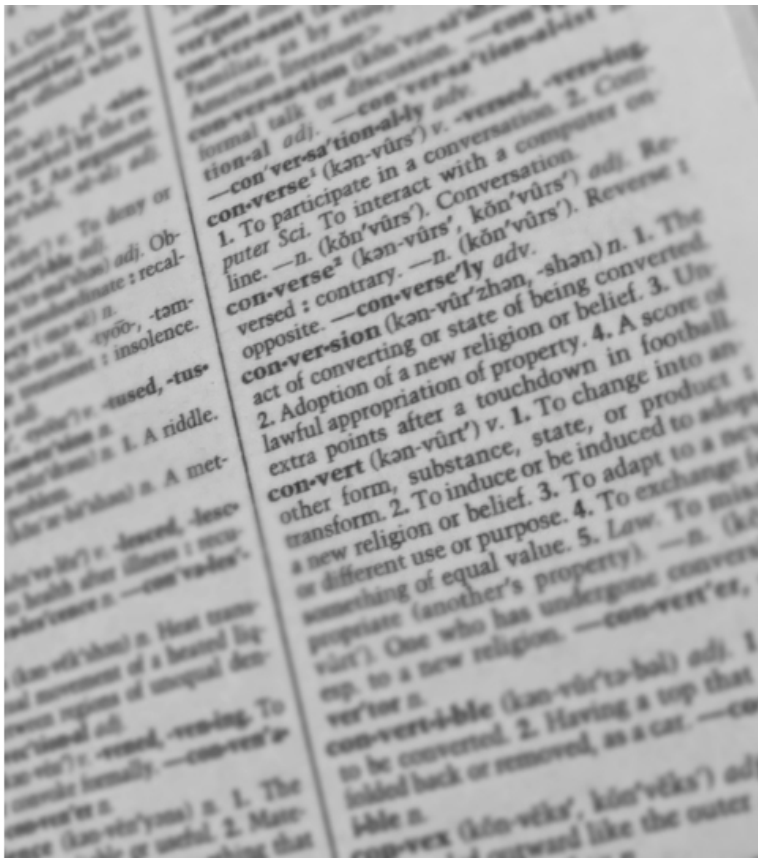
of words in English
rely on the use of fricative
consonants

42%

of words in Mandarin

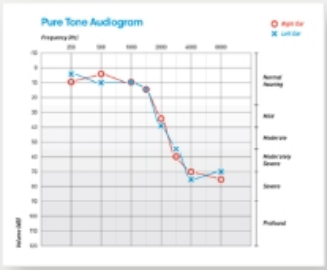
55%

of words in Spanish



Increasing Focus on Hearing Clarity

Audibility (Loudness) **measured with pure tone test**



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

Word Recognition Test

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

Words-in-Noise Test

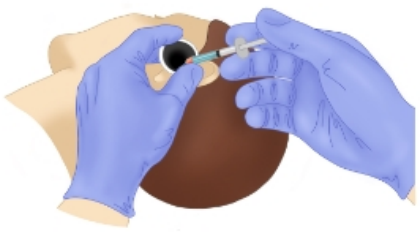
- Background noise from multiple voices
- Played at different signal-to-noise ratios

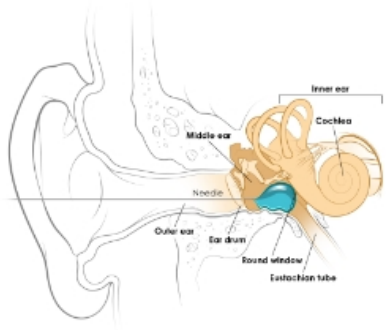
"When you develop SNHL, the issue is not just that you can't hear soft sounds. That's why if you ever talked to anyone who has a hearing loss, what they'll say is ***it's not that I can't hear you...it's I can't understand you."***

- Dr. Frank Lin from Externally-Led Patient Focused Drug Development program on SNHL, June 2021

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

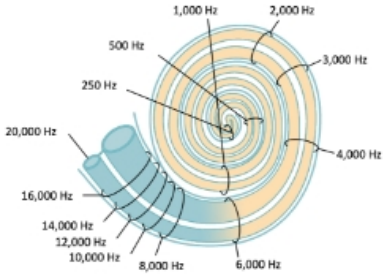
FX-322 is administered via a standard intratympanic injection,, a routine procedure performed by ENTs





Not to scale- for illustrative purposes only

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



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

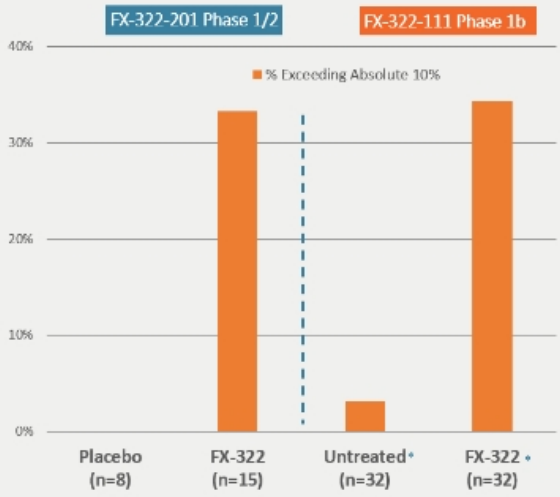
Phase 1/2 Study FX-322-201 Overview

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

Study Results

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

Day 90 Word Recognition Scores Across Studies



Phase 1b Study FX-322-111 Overview

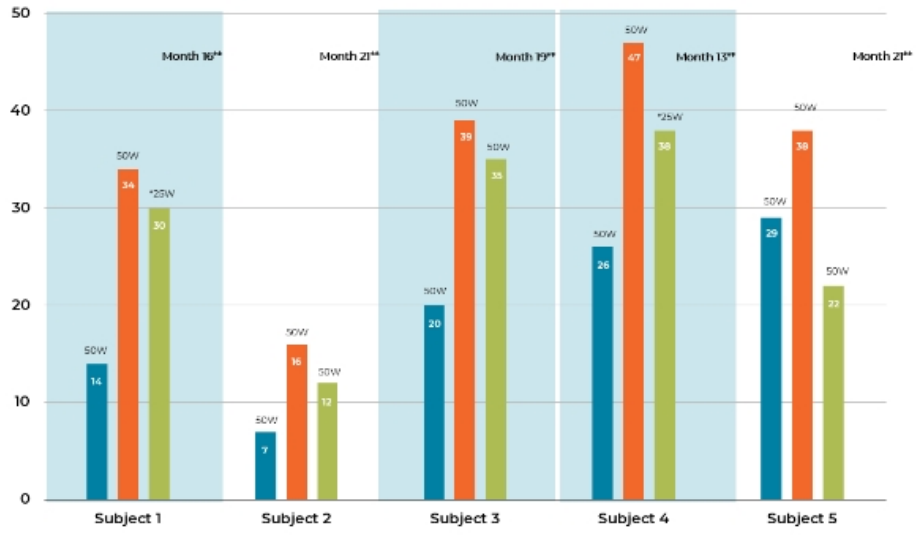
- Compared different FX-322 administration conditions
- Open-label, multi-center, randomized study
- Mild to severe subjects, age 18-65 (n=33)

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

FX-322 Clinical Data Recently Published in Leading Journal

DOI: 10.1097/MAO.0000000000003120

FX-322 Phase 1/2 and drug delivery studies

- *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)
- Pre-eminent, peer-reviewed journal in the field

FX-322 Clinical Profile Informed by Broad Range of Learning Studies

Phase 1/2 (FX-322-201)	Phase 1b (FX-322-111)	Phase 1b (FX-322-112)	Phase 2a (FX-322-202)	*Enrolled* Phase 1b (FX-322-113)
Subjects with mild-to-moderately severe SNHL	Subjects with mild-to-severe SNHL	Subjects with presbycusis (age-related hearing loss) mild-to-mod. severe	Subjects with mild-to-moderately severe SNHL	Severe sensorineural hearing loss
Subjects with Noise-Induced or Sudden SNHL	Subjects with Noise-Induced or Sudden SNHL	*NO SUBJECTS* with Noise-Induced or Sudden SNHL	Subjects with Noise-Induced or Sudden SNHL	Subjects with severe SNHL
Age 18-65; *N=23*	Age 18-65; *N=33*	Age 66-85; *N=30*	Age 18-65; *N=95*	Age 18-65; N=31
Single administration	Single administration	Single administration	Four administration regimen	Single Administration
• Double-blind, placebo **controlled,** multi-center, randomized study	• Open-label, multi-center, randomized study • FX-322 injected in one ear – contra lateral ear acted as control	• Placebo controlled • Multi-center, randomized	Double-blind, placebo controlled, multi-center, randomized study	• Single administration • Placebo controlled • Multi-center, randomized
• **Clinically meaningful and statistically significant improvements in word recognition scores** in patients with measurable word recognition deficits	• **Clinically meaningful and statistically significant improvements in word recognition scores** In patients with measurable word recognition deficits	• No significant treatment effect observed with FX-322 compared to placebo • No response in placebo groups or in untreated ears	• Unexpected increase in word rec (WR) scores in placebo group suggests bias due to trial design. • Lack of reliable baseline scores, left company unable to evaluate hearing improvements across cohorts	• Study enrolled • Data anticipated in Q4 2021
Favorable safety and tolerability profile	Favorable safety and tolerability profile	Favorable safety and tolerability profile	Favorable safety and tolerability profile	

[Detail from subjects *across all single-dose studies* will provide key insights into potential responders]

Next Steps for Continued FX-322 Clinical Development

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

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

Important learnings informing continued FX-322 development

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

Plan to commence an additional FX-322 Phase 2 placebo-controlled study in Q4 2021

- Continuum of data will further inform understanding of the patients and conditions where FX-322 may have the greatest impact

Remyelination Program for Multiple Sclerosis

Repair of neurological damage is the major unmet need in MS

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

Using PCA approach to address restoration in MS patients

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

Frequency: Developing a Platform Approach that Reduces the Complexity of Regenerative Medicine

FREQUENCY THERAPEUTICS

Harnessing Innate Biology
Progenitors already located within target tissue

No Change to Genome
Activating native programs, reducing safety concerns

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

Summary and Financial Profile

Two Single Dose FX-322 Studies Show Hearing Improvements

Statistical significance in key measures of hearing clarity

Defining FX-322 Development Path and Advancing New Studies

Continued clinical validation and development progress

$175.5 Million in Cash and Cash Equivalents*

Runway into 2023

Ex-US Partnership with Strong Potential Milestones and Royalties

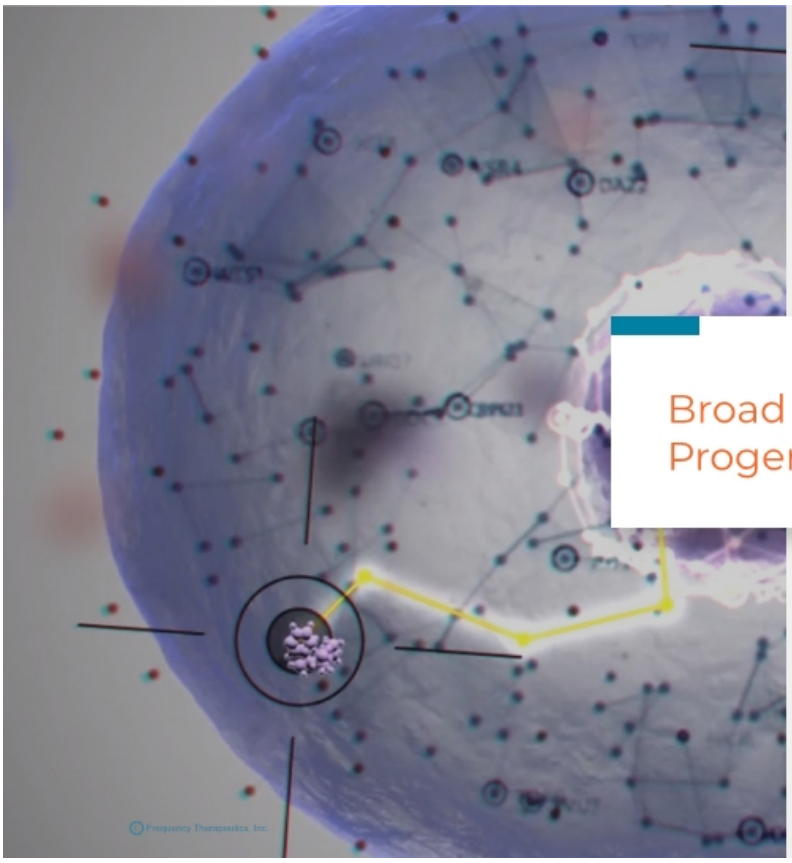
astellas

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


REIMAGINING THE TREATMENT OF HEARING LOSS
FREQUENCY THERAPEUTICS
Corporate Overview
August 2021

APPENDIX

FREQUENCY THERAPEUTICS



FREQUENCY THERAPEUTICS

Broad Potential of Progenitor Cell Activation Approach

Origin of Frequency Therapeutics

Decoding Intestinal Regeneration

Langer and Karp publish small molecules activate intestinal progenitors

nature methods

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

Enabling Cochlear Regeneration

Same cues reactivate normally inactive progenitors in the cochlea

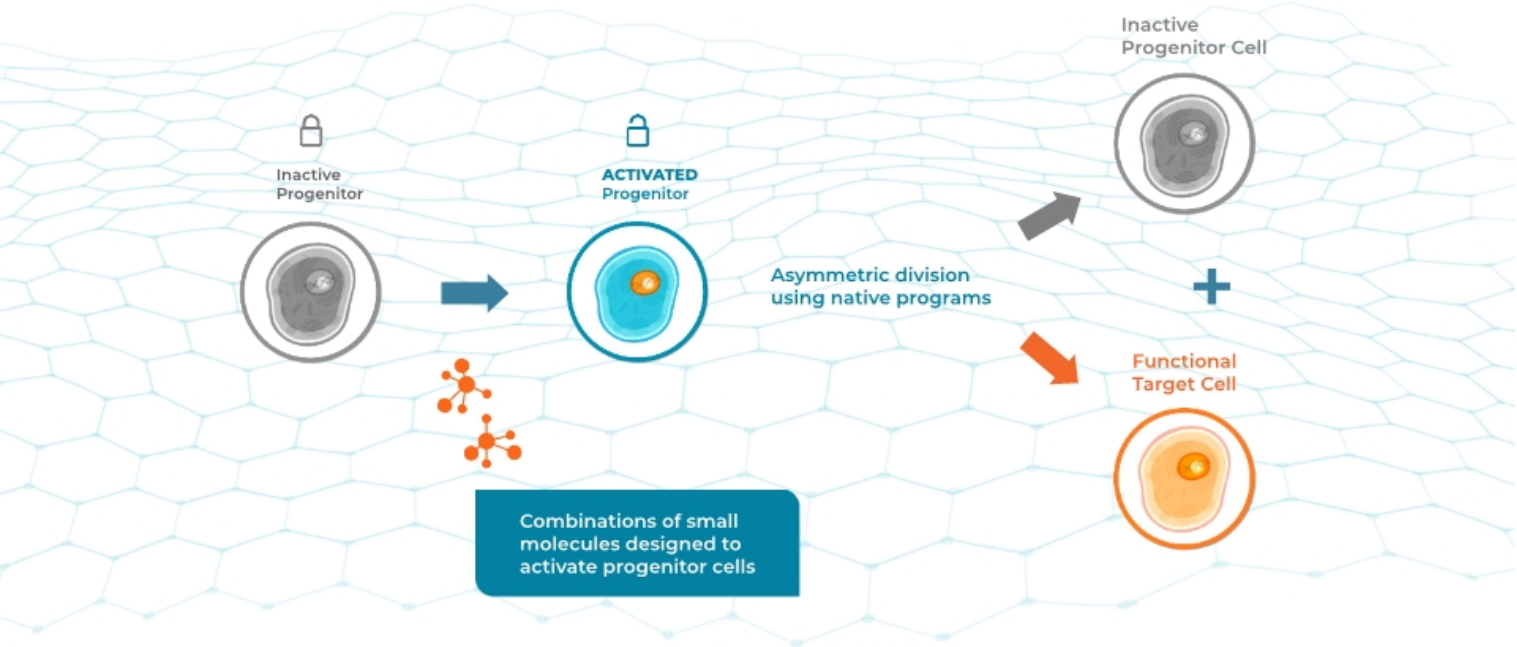
Cell Reports

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

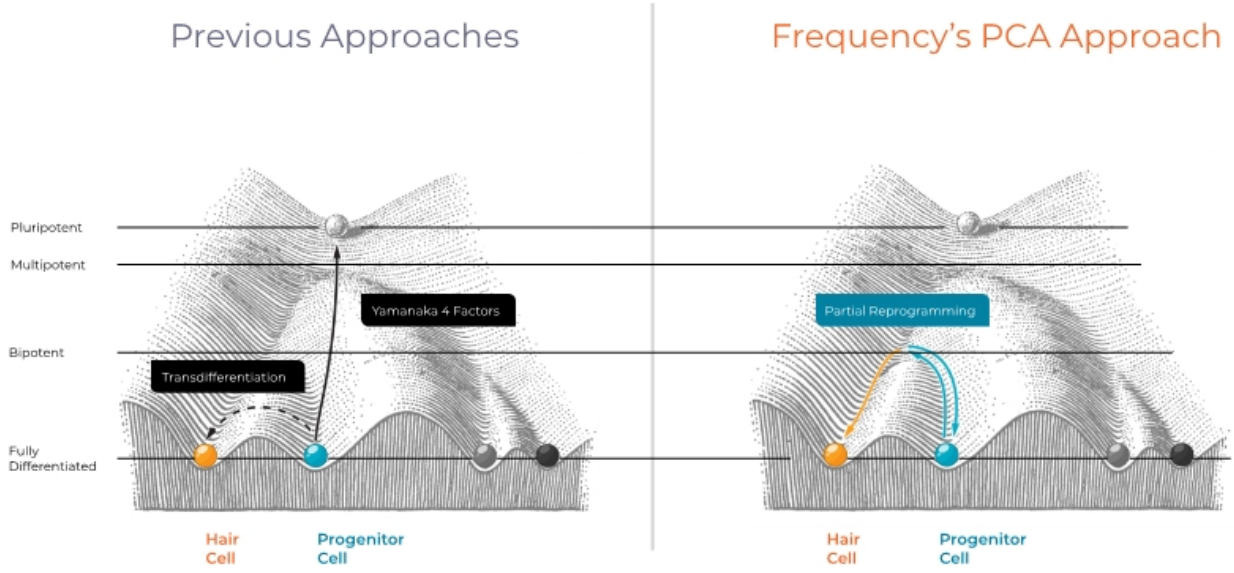
Frequency Therapeutics

Small molecule therapeutics show clinical proof of concept

Frequency Progenitor Cell Activation (PCA) Approach



Uniqueness of Our PCA approach

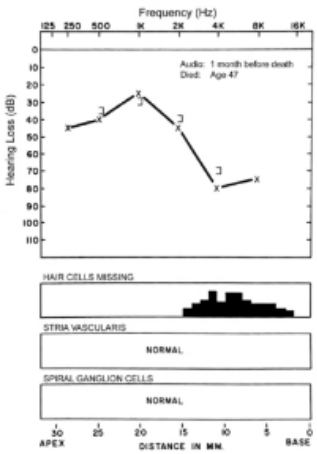


Our Approach: Activation of Progenitors to Replace Hair Cell Loss

Despite Hair Cell Loss, Progenitor Cells Remain

Human Cochlea Cross-section

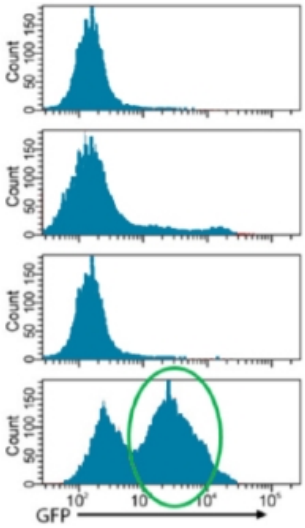
Audiogram



47 Year Old Male with Occupational Noise Deafness

Profound Synergy Between Pathways to Regenerate Cells

Cochlear Progenitor Proliferation (Lgr5-GFP)



Culture Media

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

HDAC Inhibition (sodium valproate)

Wnt Activation + HDAC inhibition

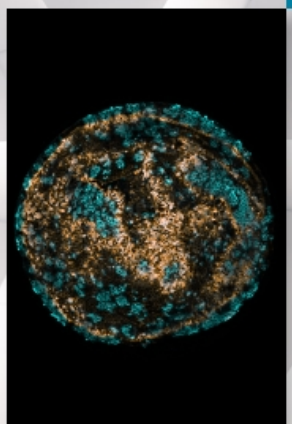
PROFOUND SYNERGY

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

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

FX-322 Program Advances and Global Opportunity



FREQUENCY THERAPEUTICS

FX-322: Robust Clinical Phase 1/2 Design

Study Overview

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

Screening NIHL/SSNHL
Mild to Moderately Severe

FX-322
N = 15

Placebo
N = 8

Day 1 | Dose

Follow-up Visits
Days 15, 30, 60, 90

Single Injection	No Injection
15 drug, 8 placebo	All 23 patients

Injection only in one ear creating an additional control

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

Study Design

Single Injection
15 drug,
8 placebo

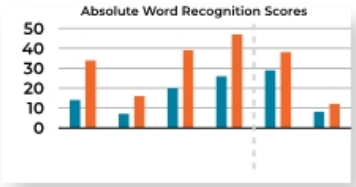
No Injection
All 23 patients

Injection only in one ear creating an additional control

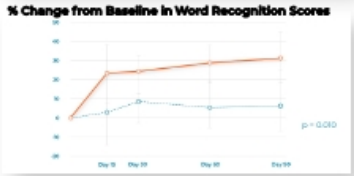
- Safety study
- Patients with mild to moderate SNHL; permanent NIHL/SSNHL for at least 6 months
- Majority of patients did not have measurable impairment in WR

Key Findings

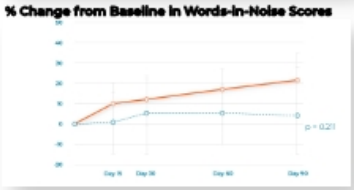
- FX-322 shown to have a favorable safety profile – no serious AEs



- **Clinically meaningful improvement in word recognition scores** in patients with measurable word recognition deficits



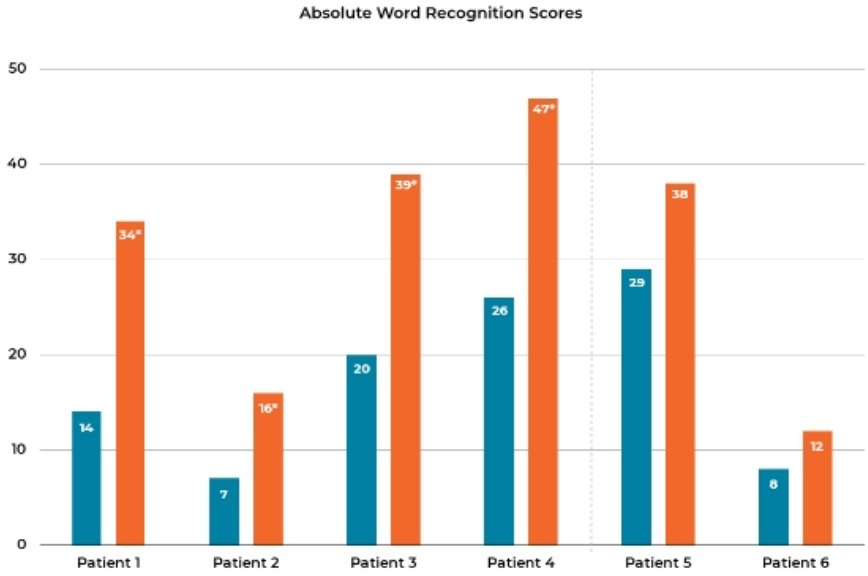
- **Statistically significant improvement in word recognition scores** (words in quiet/sound clarity)



- **Improvement trend in** words-in-noise (statistically significant WIN improvement shown in SNR)

FX-322 Placebo

First Drug Candidate to Show Clinically Meaningful Improvements in Word Recognition



Clarity of Sound

Used word tests in a quiet background

Baseline - Correct words out of 50

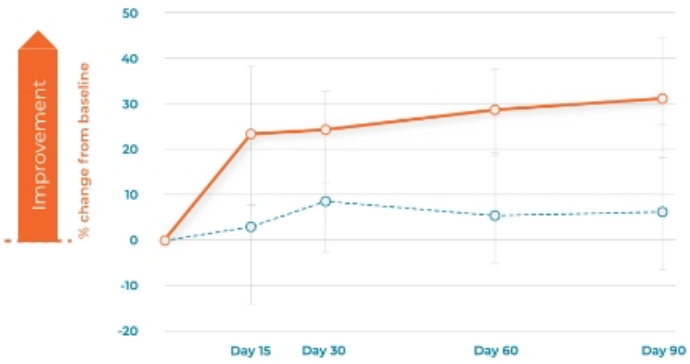
Day 90 - Correct words out of 50

Test/retest variability is one standard deviation, which for a 50-word list is ~ 3 words

***Statistically significant and clinically meaningful improvements in word recognition**

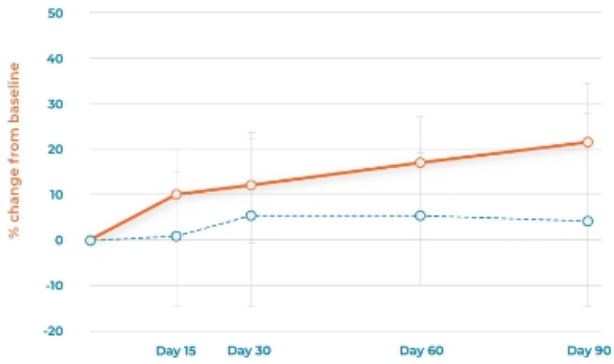
Phase 1/2 Study Results: Sustained Improvements in Sound Clarity

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



p = 0.010

Clear Improvement Trend in Words-in-Noise



p = 0.211

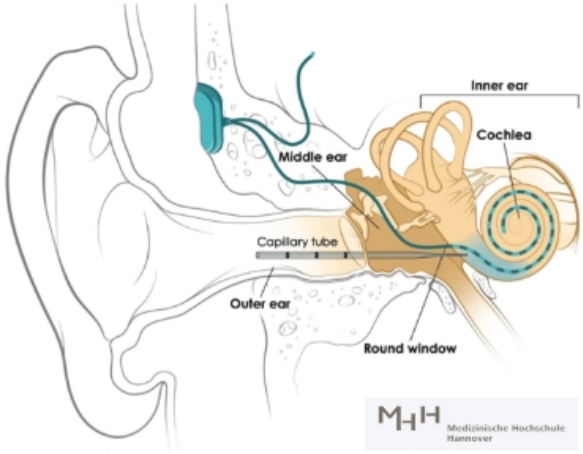
FX-322 Placebo

Clinical Data Confirms FX-322 Delivery to Cochlea

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

Key Findings:

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



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

End of Phase 2a Study Conclusions*

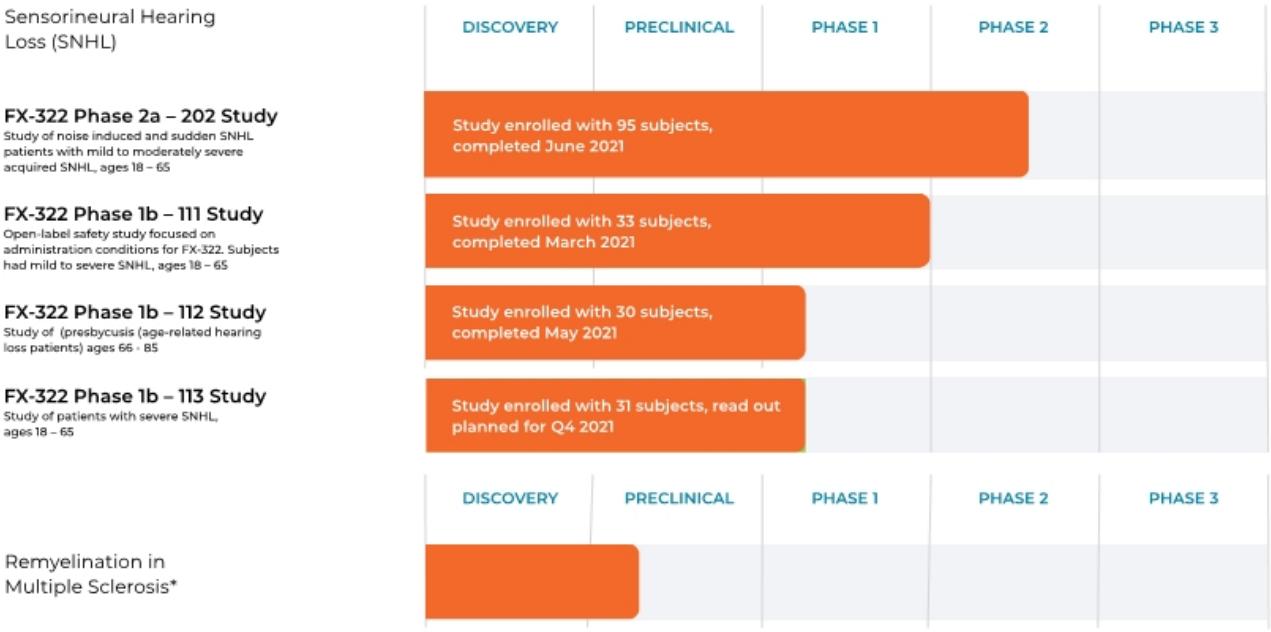
There was an unexpected increase in WR scores in the placebo group, which did not occur in previous FX-322 trials and exceeded well-established published standards.
Potentially suggesting bias due to trial design

As a result of unreliable baseline WR scores in the placebo group due to potential trial design bias, the Company was unable to evaluate hearing improvements in WR scores for FX-322 dosing regimens versus placebo.
Four weekly injections of FX-322 did not demonstrate improvements in any other hearing measures versus placebo

FX-322 continues to have a favorable safety and tolerability profile.
Although there was a higher rate of AEs noted in this 4x dosing trial, there were no treatment-associated serious adverse events observed and no patients withdrew from the study due to treatment-associated AEs.

*Additional study detail and data tables provided in SEC Form 8k dated June 30, 2021

Pipeline



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

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

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

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

LEADERSHIP

FREQUENCY
THERAPEUTICS

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 Consultant

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

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

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

Dan Lee, M.D.

Director, Pediatric Otology and Neurotology, Mass Eye and Ear

Rene Gifford, Ph.D.

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

Ruth Litovsky, Ph.D.

Professor, Communications Sciences and Disorders and Surgery Division of Otolaryngology, University of Wisconsin

Chris Runge, Ph.D.

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


REIMAGINING THE TREATMENT OF HEARING LOSS
FREQUENCY THERAPEUTICS
Corporate Overview
August 2021