Sound Pharmaceuticals (SPI) was founded in 2002 and is developing SPI-1005, the first drug to treat hearing loss and tinnitus under 6 active INDs. We are completing a pivotal Phase 3 in Meniere's Disease (MD), have positive Phase 2 data in three other indications, have raised $65M (equity/grants), and will raise $100M (Series D) to fund our first NDA filing in 2025.

SPI-1005 Key Highlights:

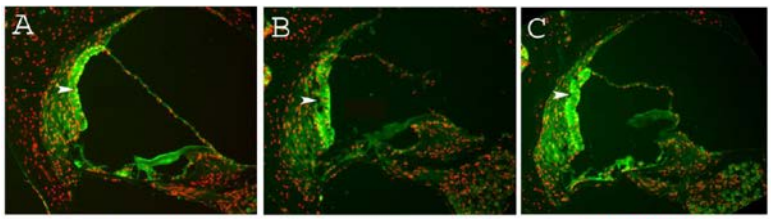
- **Lead indication in MD has completed Phase 3 RCT with OLE ongoing through August 2024**
- **Phase 1b/2b showed improvements in hearing, speech discrimination, & tinnitus after 21-28 days**
- **Oral NCE with unique MOA (GPx1 mimic-inducer)**
- **Good safety profile >1100 adults under 6 INDs involving 13 RCTs (9 completed & 4 active)**
- **Neuropsychiatry indications (BPD and SZ)**
- **Strong IP protection through 2037-2041**

Company and Product Overview

Sound Pharmaceuticals is a late-stage biopharmaceutical company focusing on developing the first therapeutics for neurotologic diseases. The company's lead product, SPI-1005, is an oral small molecule (ebselen) with unique anti-inflammatory and neuroprotective properties and is not immunosuppressive. SPI-1005 acts as a mimic of glutathione peroxidase I (GPx1) and induces GPx1 under redox stress.

Mechanism of Action

SPI-1005 is a seleno-organic compound that catalyzes the redox of glutathione like GPx1, an enzyme highly expressed in the cochlea. GPx1 repairs mitochondrial and cellular membranes injured by redox stress. SPI-1005 also induces GPx1 expression by activating Nrf2, a cytoprotective transcription factor sensitive to oxidative stress. Noise, ototoxins, and aging result in decreased GPx1 expression in the cochlea. This loss of GPx1 activity is reversed by SPI-1005. SPI-1005 also inhibits the swelling of the endolymphatic duct due to intense noise (endolymphatic hydrops). These results suggest that SPI-1005 may be effective in treating idiopathic endolymphatic hydrops or MD.



Investment and Strategic Partnering

Sound Pharmaceuticals is seeking a strategic partner to co-develop and commercialize SPI-1005 in Asia and Europe for Meniere's Disease and other neurotologic (hearing loss, tinnitus, ototoxicity) and neuropsychiatric (bipolar mania and schizophrenia) indications.

Meniere's Disease Symptoms Reduce QoL

MD is diagnosed by episodic vertigo or dizziness, fluctuating hearing loss, and intermittent or constant tinnitus, and is thought to be due to a swelling or inflammation of the inner ear. The auditory symptoms of hearing loss and tinnitus often involve only one ear. Patients are typically diagnosed between 40-65 years of age. In addition, some patients experience aural fullness or pressure that can also contribute to dizziness. As patients age, the hearing loss and/or tinnitus become progressively worse, resulting in profound hearing loss or intractable tinnitus. For the diagnosis of definite MD, the American Academy of Otolaryngology-Head & Neck Surgery guidance requires audiometric documentation of low frequency (250, 500, or 1000 Hz) hearing loss (≥30 dB) in at least one ear. MD can be unilateral or bilateral.

Market Opportunity

1. **Treatment of hearing loss & tinnitus are poorly addressed**

Some interventional therapies have demonstrated modest efficacy in treating vertigo severity and frequency. However, these treatments also showed poor efficacy in treating hearing loss, tinnitus, or aural fullness. Some such as intratympanic gentamycin can worsen hearing loss and tinnitus.

2. **Oral NCE with unparalleled safety across multiple studies**

SPI-1005 has shown safety and efficacy in multiple Phase 2 RCTs in treating hearing loss and tinnitus and the only active Phase 3 RCT for definite MD. SPI-1005's unique MOA cannot be replicated with any other drugs in development.

U.S. Peak Opportunity in Meniere's Disease			
2020 Diagnosed Prevalence	**~630 K Patients**		
Patient Segmentation	*No to Mild*	*Mod.*	*Severe*
	10 – 20%	40 – 50%	20 – 40%
Uptake	~20%	~80%	~80%
Impact of Response Rate	~50%	~70%	~75%
Avg. Therapy Months per Year	~7.5 mos.	~8.5 mos.	~9.5 mos.
Compliance	~50%	~60%	~60%
Net Price per Month	$550		
Market Access	~65%	~75%	~75%
Peak Net Sales	**~$13 M**	**~$334 M**	**~$267 M**
	~$615 M		

Asia & EU represent another $615M–720M in peak net sales

SOUND PHARMACEUTICALS

SPI-1005: Phase 1b (N=40) and 2b (N=126) RCTs showed improvements in low frequency hearing loss and tinnitus loudness after 21 and 28 days of treatment in probable and definite MD patients

Key Clinical Trials for SPI-1005 in MD

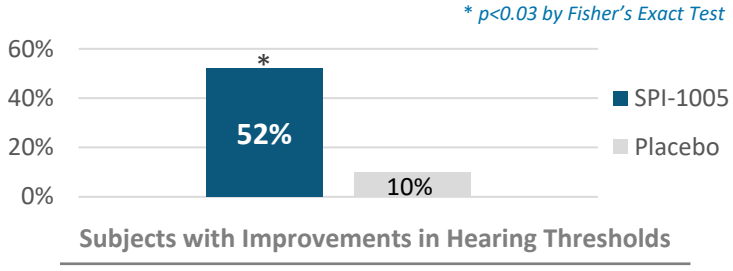
1. SPI-1005-151 Phase 1b (completed)

Study design:

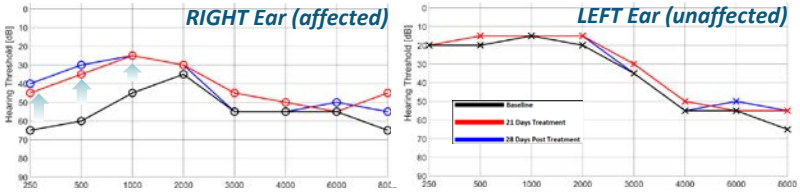
A randomized, double-blind, placebo-controlled study in adults with MD (n=39). Oral dosing of 0, 200, 400 or 600 mg twice daily for 21 days, and 49 days of follow-up.

Results:

- Safety analysis showed that SPI-1005 was well tolerated with no reported drug-related Serious Adverse Events.
- Exploratory efficacy analysis showed 52% of ebselen treated subjects had clinically relevant improvements in hearing threshold from baseline (≥10 dB) in low frequency (250, 500, or 1000 Hz) hearing in at least one ear.



Dramatic response to treatment in a 64 yo male (below), following 400 mg of SPI-1005 twice daily for 21 days. The right ear is affected, with low frequency hearing loss (≥30 dB) at baseline (black). Clinically relevant improvements (≥10 dB) across all low frequencies (250, 500 and 1000 Hz) are observed at 21 (red) and 49 (blue) days of follow-up.



"SPI-1005 seems to work for not only low frequency but also middle frequency hearing loss. One of the problems of MD is poor prognosis in hearing loss as the disease progresses. Having efficacy toward advanced hearing loss is meaningful" – MD specialist

2. SPI-1005-251 Phase 2b (completed)

Study design:

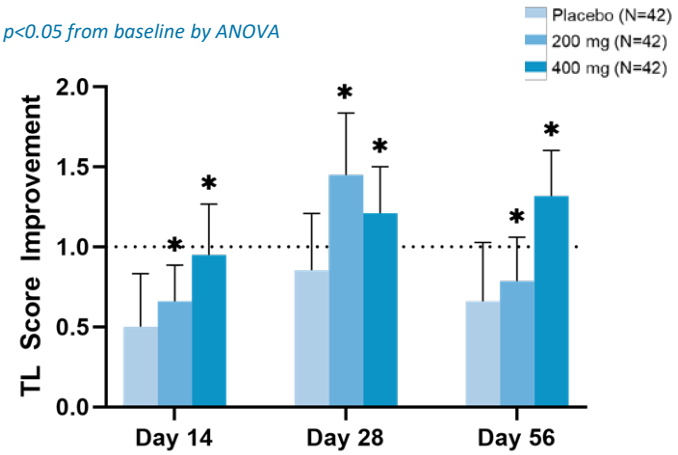
A randomized, double-blind, placebo-controlled study in adults with MD (n=126). Oral dosing of 0, 200, or 400 mg twice daily for 28 days, and 56 days of follow-up.

Primary endpoints:

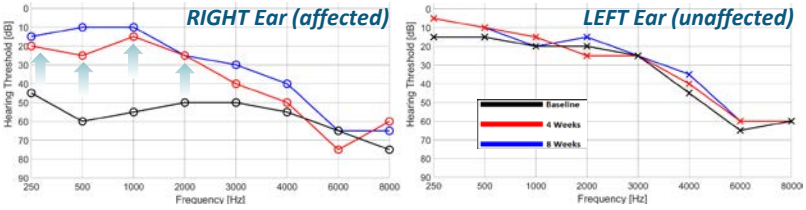
- Improvements in hearing thresholds (≥10 dB) in low frequency (250, 500, or 1000 Hz) from baseline
- Improvements in Words-in-Noise (WIN) score (≥10% increase in the number of words correct) from baseline

Results:

- Safety analysis showed that SPI-1005 was well tolerated with no reported drug-related Serious Adverse Events.
- Efficacy analysis showed primary endpoints were met. 400 mg BID treatment resulted in improvements in hearing loss that were 65% higher than placebo (p<0.03), and improvements in WIN score that were 34% higher than placebo (p<0.06).
- Efficacy analysis also showed improvements in tinnitus loudness (TL) using a visual analog scale (0-10). 400 mg BID treatment resulted in a 30% reduction in TL from baseline vs a 10% reduction in placebo (p<0.02).



Dramatic response to treatment in a 55 yo male (below), following 400 mg of SPI-1005 twice daily for 28 days. The right ear is the affected ear and shows clinically relevant improvements (≥10 dB) across all low and middle frequencies (250, 500, 1000 and 2000 Hz) at 4 (red) and 8 (blue) weeks of follow-up. These 25-50 dB improvements result in hearing thresholds that are considered normal (no longer affected).



Improvements in WIN scores (0-35) at 4 and 8 weeks show the right affected ear has improved 255% from baseline making it very similar to the left unaffected ear.

WIN test score (# words correct)	Baseline	4 weeks	8 weeks
Right ear (affected)	9	20	23
Left ear (unaffected)	23	21	24

Improvements in TL (0-10) at 4 and 8 weeks are significant.

Tinnitus Loudness	Baseline	4 weeks	8 weeks
VAS (0-10)	9	4	3

SOUND PHARMACEUTICALS

SPI-1005: Phase 3 (STOPMD-3) enrolled the RCT (N=221) in 9 months across 12 US sites with >150+ completing Open Label Extension (OLE of 6 and 12-months), received Fast Track Designation, ex-US RCTs planned

Pivotal Clinical Trials for SPI-1005 in MD

3. SPI-1005-351 Phase 3 (US ongoing)

Study design: **RCT completed Sep 2023**

A randomized, double-blind, placebo-controlled study in adults (18-75) with definite MD (n=221) abbreviated as STOPMD-3**.** Oral dosing of 0 or 400 mg twice daily for 28 days, and 84 days of follow-up comprise the 3-month RCT. All compliant patients were allowed to immediately roll-over into 400 mg twice daily to participate in an OLE safety study of 6-month or 12-month duration. Every 3 months during the OLE, patients will have their auditory and vestibular function re-assessed as they did during the RCT.

Anticipated Results/Outcomes in STOPMD-3:

- Sufficient safety and efficacy data to support the Treatment of Meniere's Disease based on RCT.
- Sufficient safety data to support intermittent chronic dosing based on OLE 6-month (N=200).
- Sufficient safety data to support chronic dosing based on OLE 12-month (N=100).
- Sufficient OLE improvement data to support future chronic studies in age-related hearing loss and other tinnitus indications.

STOPMD-3 is registered at:

https://clinicaltrials.gov/ct2/show/NCT04677972

SPI-1005-352 Phase 3 (ex-US) planned for Dec 2024

Study design:

A randomized, double-blind, placebo-controlled study in adults with definite MD (n=200) that is almost identical to the US-based STOPMD-3 RCT**.** Oral dosing of 0 or 400 mg twice daily for 28 days, and 84 days of follow-up. All compliant RCT patients will be allowed to immediately roll-over into an OLE study for safety of 6-month duration. Every 3 months during the OLE, patients will have their auditory and vestibular function re-assessed.

Anticipated Results/Outcomes:

- Sufficient safety and efficacy data to support the Treatment of Meniere's Disease based on RCT.
- Additional pivotal study data to support the US pivotal study data in STOPMD-3.
- Sufficient safety data to support intermittent chronic dosing based on OLE 6-month.
- Sufficient improvement data to support chronic or age-related hearing loss and tinnitus indications.
- Ex-US partnering opportunities in Europe and Asia.

SPI-1005-401 Expanded Access Program (EAP) planned for July 2024

Study design:

An open label study in adults with MD (n=100+) who do not satisfy all the inclusion/exclusion criteria of the STOPMD-3 RCT, such as patients with probable Meniere's**.** Oral dosing of 400 mg twice daily for up to 6 and potentially 12 months. At the start and every 3 months, patients will have their auditory and vestibular function assessed. Very similar to the OLE 6 and 12-month study for safety in the STOPMD-3 trial.

Anticipated Results/Outcomes in EAP:

- Sufficient safety data to support the FDA requirement for treating N=300 patients for 6 months and N=100 patients for 12 months prior to NDA filing.
- Sufficient EAP improvement data (auditory/vestibular) to support the treatment of probable MD patients.

Projected Development Timeline to first NDA filing

The Phase 3 RCT of STOPMD-3 was completed (FPI to LPO) in 14 months across 12 US sites. Anticipated LPO from the OLE 12-mo study is **Aug 2024**. An interim analysis of the initial safety and efficacy data in N=200 RCT patients and safety data in N=150+ OLE 6-month patients will be in **May 2024**. Additional nonclinical studies (DART, mice/rat CARC, 26wk rat & 39wk minipig chronic toxicology) should be completed by **December 2025**. Fast Track Designation allows the filing of the NDA in parts and should begin by **Mar 2025**.

Projected Additional Development Costs 2024-2025

SPI-1005-401 (EAP) **$5M**
SPI-1005-352 (Ex-US) **$15M**
Other ongoing neurotologic indications **$15M**
Additional nonclinical studies to support NDA **$15M**

Projected First Commercial Launch Costs 2026-2027

Manufacturing/Distribution (favorable COGS) **$50M**
Approvals/Marketing (6+ national meetings) **$25M**
Sales (20 FTEs for 400 Rx neurotologists & 500 ENTs) **$25M**

US Sales projection of $1,950M in MD 2026-2031

First Year 2026-2027 $130M

Second Year 2027-2028 $260M

Third Year 2028-2029 $390M

Fourth Year 2029-2030 $520M

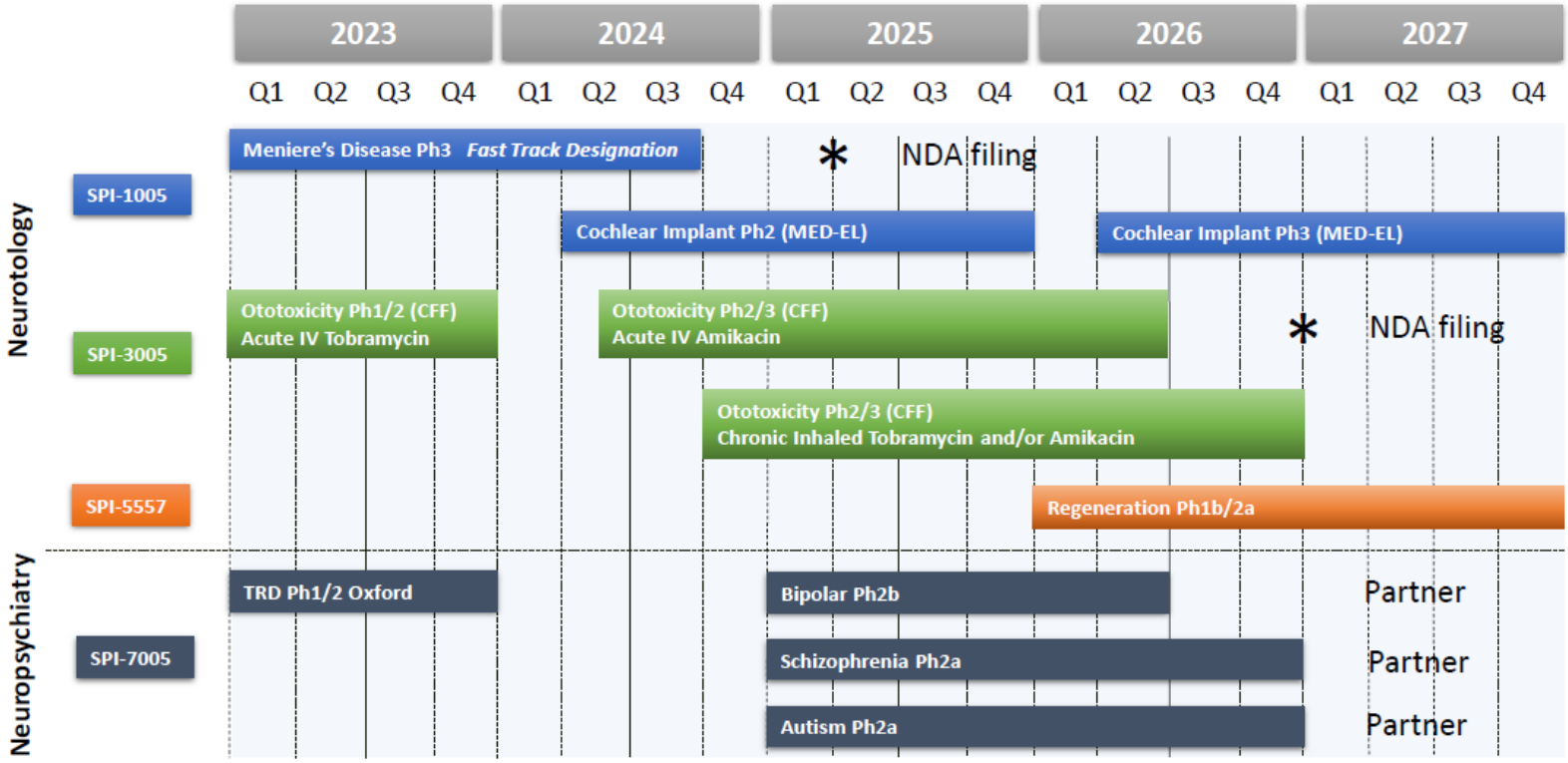
Fifth Year 2030-2031 $650M

SOUND PHARMACEUTICALS

SPI-1005: Development and Regulatory timeline for multiple neurotology and neuropsychiatry indications and their respective partnering and NDA filings

SPI-1005 is the **only** interventional drug in **active Phase 3** clinical trials for the treatment of hearing loss or tinnitus indication registered on clinicaltrials.gov as of **April 01, 2024**

PROGRAM DEVELOPMENT AND REGULATORY MILESTONES



All current SPI-1005 clinical trials are registered at:
[Search of: spi-1005 - List Results - ClinicalTrials.gov]

For further information, contact:

Jonathan Kil, MD
CEO and CMO
jkil@soundpharma.com
US 206-769-4820

Nadia Dac
VP Business Development
ndac@soundpharma.com
US 908-514-9092

John Sullivan
CFO
jsullivan@soundpharma.com
US 206-731-7884