

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE  
ACT OF 1934

For the month of February, 2015

Commission File Number: 001-36582

**Auris Medical Holding AG**

(Exact name of registrant as specified in its charter)

**Bahnhofstrasse 21**  
**6300 Zug, Switzerland**  
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes  No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes  No

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**SIGNATURE**

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, thereunto duly authorized.

**Auris Medical Holding AG**

By: /s/ Thomas Meyer

Name: Thomas Meyer

Title: Chief Executive Officer

Date: February 11, 2015

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EXHIBIT INDEX

**Exhibit Number**

**Description**

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99.1 Company Presentation

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 **Auris Medical**  
Cochlear therapies

## Innovative Treatments for Inner Ear Disorders

### Company Presentation

February 2015



# Forward Looking Statements / Safe Harbor

- This presentation and the accompanying oral commentary contain “forward-looking” statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation and the accompanying oral commentary, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward looking statements. In some cases, you can identify forward-looking statements by terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “might,” “approximately,” “expect,” “predict,” “could,” “potentially” or the negative of these terms or other similar expressions. Forward looking statements appear in a number of places throughout this presentation and the accompanying oral commentary and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates AM-101 and AM-111, our intellectual property position, our ability to develop commercial functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.
- Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These include, but are not limited to, the timing and conduct of clinical trials of our product candidates, the clinical utility of our product candidates, the timing or likelihood of regulatory filings and approvals, our intellectual property position and our financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions or changes to our capital structure, including future securities offerings. Forward-looking statements represent our management’s beliefs and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

## Corporate Overview

- Auris Medical is a clinical late stage company dedicated to developing inner ear therapeutics
- Headquartered in Zug/Basel, Switzerland
- Founded in 2003
- IPO completed in August 2014
- Nasdaq Global Market: EARS
- 28.9M shares
- Market cap \$152M\*



 SOFINOVA VENTURES

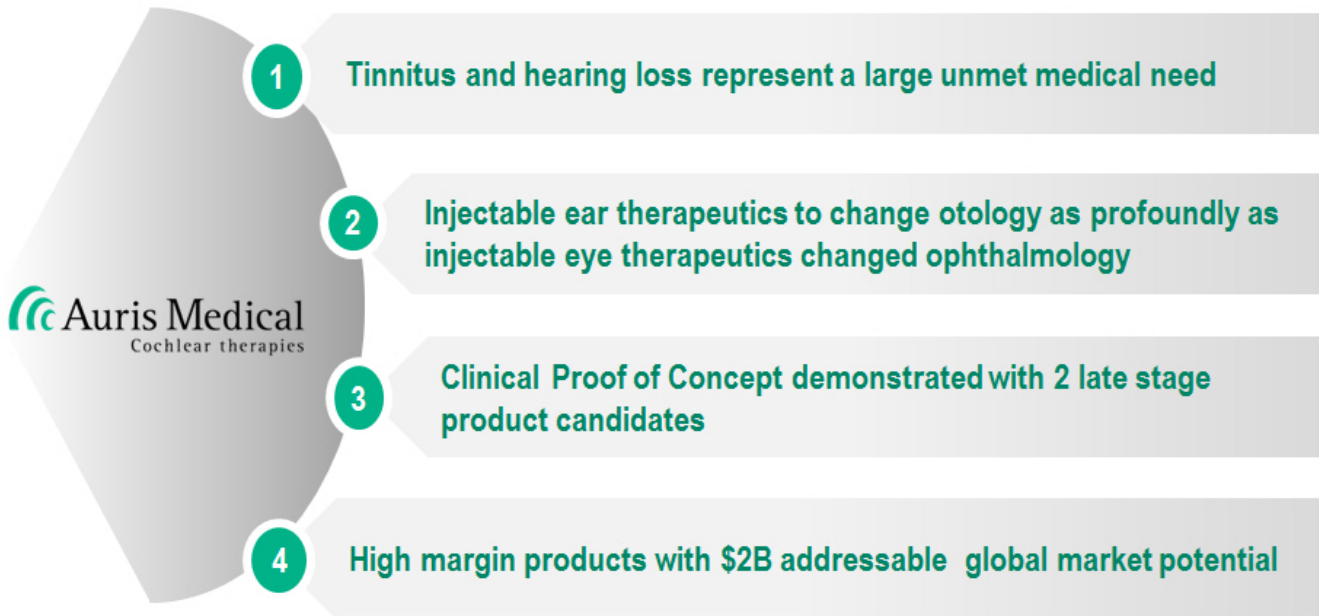
SOFINNOVA  
PARTNERS

 ADAMANT  
Biomedical  
Investments AG

idinvest  
PARTNERS

\* As at February 6, 2015

# Investment Highlights



## Leadership Team



### **Thomas Meyer, PhD**

*Founder, Chairman and CEO*

- Former CEO and BoD member of Disetronic (diabetes care)
- Instrumental in Disetronic's IPO and managing >20% sales CAGR over many years
- > 3 bn CHF market cap



### **Bettina Stubinski, MD, MBA**

*Chief Medical Officer*

- Former Global Head Clinical Development Multiple Sclerosis at Merck Serono
- Former Head Clinical Research at Berlin Chemie (Menarini Group)



### **Sven Zimmermann, PhD**

*Chief Financial Officer*

- Former CFO of PregLem (women's health)
- Key role in company's sale to Gedeon Richter
- Former health care research analyst with UBS

**Highly qualified management team with significant experience in the biotech industry**

# Development Pipeline

Product	Indication	Preclin.	Phase 1	Phase 2	Phase 3	Next Key Milestones <sup>1)</sup>	
<b>AM-101</b> Esketamine	<i>Acute inner ear tinnitus</i>					Data TACTT2	Early 2016
	<i>Post-acute inner ear tinnitus</i>					Data TACTT3	
<b>AM-111</b> D-JNK1-1	<i>Acute inner ear hearing loss</i>					TACTT3 interim	Early 2015
	<i>Menière's disease</i>					Trial start	
<b>AM-102</b> Undisclosed	<i>Tinnitus</i>					Lead compound selected	Early 2015
	<i>Rhinology</i>					Lead compound selected	

*Dates of key milestones are indicative and subject to change*

**Focus on acute inner ear injury with known biology and acute medical needs**



## Inner Ear Disorders – Great Unmet Medical Need

### Tinnitus

- About 16M patients in the US have tinnitus symptoms severe enough to seek medical attention
- About 2M patients cannot function on a normal day-to-day basis
- Tinnitus is now the #1 service related disability for all veterans
- Annual service-related disability payments for tinnitus to veterans from all periods of service are expected to exceed \$2.75B by the end of 2016

Source: American Tinnitus Association

### Hearing Loss

- 17% of US adults have some degree of hearing loss<sup>1)</sup>
- More than 30M Americans are exposed to hazardous sound levels on a regular basis<sup>1)</sup>
- Hearing loss is the #2 service related disability for all veterans
- Only 1 out of 5 people who could benefit from a hearing aid actually wears one<sup>1)</sup>
- 60,000 people in the US are affected by sudden deafness p.a.<sup>2)</sup>

Sources: <sup>1)</sup> American Tinnitus Association, <sup>2)</sup> Rauch and Geller, 2012

**No effective Standard of Care, no FDA or EMA approved drugs available**

## Some Patient Testimonials

"I have been suffering with tinnitus for 4 months. I will admit my life has turned for the worse since this occurred. Lost interest in all things and really don't go out much anymore...You don't know how I would like to get back to the way I was."

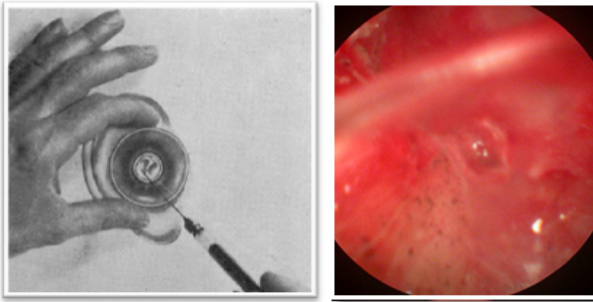
"You really need to hurry with this new drug. There are millions of people who are suffering intensely. How would you like it if your baby daughter of only 27 years old called you all day long crying and saying life isn't worth living if you have tinnitus."

"Sometimes I get a rumble, most of the time it's just a high pitch that gets progressively worse at night time and really bad when I'm sick... I really don't want to as I'm always barely getting by but if I had to take on a loan to get rid of this I would."

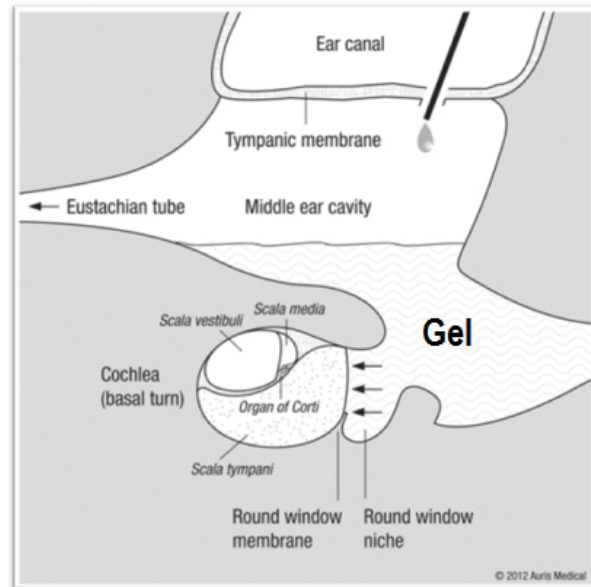
"I feel shattered, I am suffering from tinnitus, violent, invalidating since 4 years and a half, 24 hours a day. Sometimes I look at my box with sleeping pills and a funny desire is creeping up."

"I have got tinnitus for one month. I have taken glucocorticoids and vasodilators since the beginning but it didn't improve anything... Would it be possible to be enrolled for the trial? I'm willing to pay anything if it is necessary."

# Intratympanic Drug Delivery



- Short office based ENT procedure
- Biocompatible, biodegradable sodium hyaluronate gel
- 0.25 mL injected from pre-filled syringe under local anesthesia
- 20-30' resting period for diffusion across round window membrane
- Site specific delivery with minimal systemic exposure



- Proprietary gel formulation
- IP broadly directed to polymer-based formulations





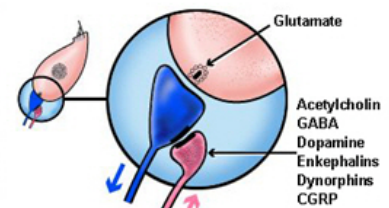
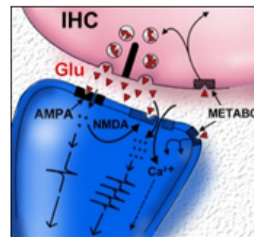
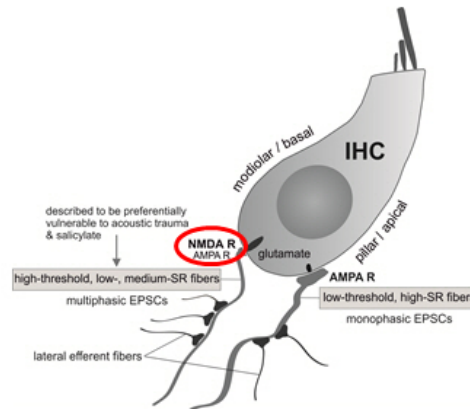
## AM-101 for the Treatment of Acute Inner Ear Tinnitus

# AM-101 for Acute Inner Ear Tinnitus

<b>Significant Unmet Medical Need</b>	<ul style="list-style-type: none"> <li>• Similar to pain, tinnitus is an unpleasant, unwanted sensation</li> <li>• Significant impact on sleep, ability to concentrate or relax</li> <li>• Substantial emotional distress and reduced quality of life</li> </ul>
<b>Attractive Product Profile</b>	<ul style="list-style-type: none"> <li>• Treat tinnitus within first 3 months (= acute) to prevent chronic suffering</li> <li>• One single treatment cycle comprising 3 i.t. injections over 3-5 days</li> <li>• Persistent improvement in tinnitus symptom and impact</li> </ul>
<b>Favorable Market Dynamics</b>	<ul style="list-style-type: none"> <li>• No effective SoC, no FDA or EMA approved drugs available</li> <li>• Specialty care market / significant interest by ENTs</li> <li>• Attractive price reference points (e.g. Tinnitus Retraining Therapy)</li> </ul>
<b>Low Risk Regulatory Pathway</b>	<ul style="list-style-type: none"> <li>• Esketamine is a well-known API</li> <li>• Extensive interactions with FDA and EMA</li> <li>• Agreement on endpoint model</li> </ul>

## AM-101 Mechanism of Action

- Cochlear NMDA receptors
  - Regulate surface expression of AMPA receptors
  - Neurotrophic role post acute insult
- Not involved in normal hearing
- Acute injury leads to NMDA mediated glutamate excitotoxicity
  - Pathologic  $\text{Ca}^{2+}$  influx into postsynapse
  - Similar e.g. to stroke
- Aberrant excitation of auditory nerve perceived as tinnitus
  - May become permanent
- AM-101 / Esketamine is a potent NMDA receptor antagonist



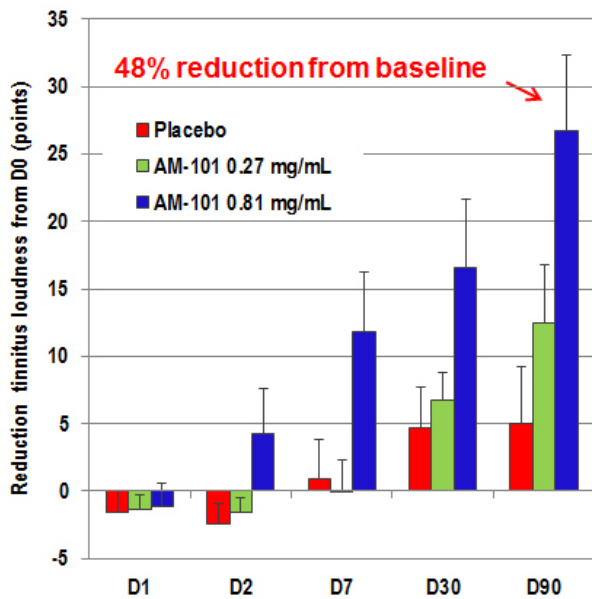
# AM-101 Clinical Development

	Tinnitus Etiology			AM-101 (mg/mL)
	Traumatic insult	Otitis media	Idiopathic	
<b>Phase 1</b> N=24	Well tolerated Trend for efficacy			1 x 0.03, 0.09, 0.27, 0.81
<b>Phase 2</b> <i>TACTT0</i> N=248	Dose dependent reduction in various tinnitus PROs Statistically significant and clinically meaningful Well tolerated		Heterogeneous Efficacy only in subgroup Development stopped	3 x 0.27 or 0.81 over 3 days
<i>TACTT1</i> N=84	Meta-analysis with <i>TACTT0</i> showing best results with 3 x AM-101 over 3 days			1 x 0.81 or 3 x 0.81 over 2 weeks
<b>Phase 3</b> <i>TACTT2</i> N=330 <i>TACTT3</i> N=300	Δ tinnitus loudness as primary efficacy outcome accepted by both FDA and EMA SPA in place			3 x 0.87 over 3-5 days

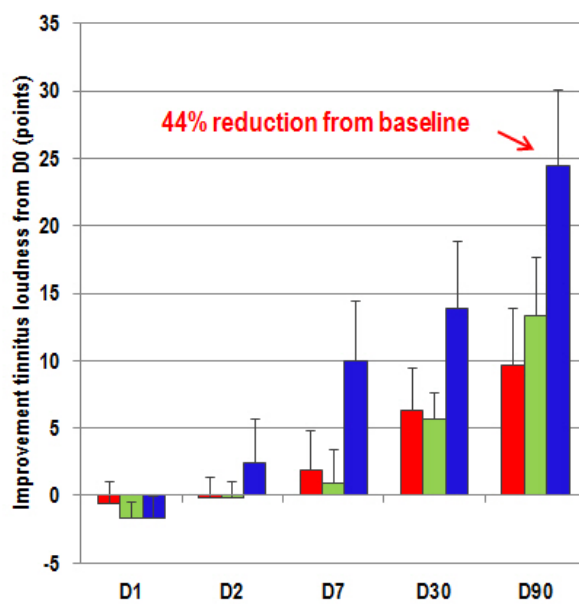
**Consistent signals in traumatic and otitis media tinnitus throughout clinical trials**

# Proof of Concept in Phase 2 (TACTT0)

## Tinnitus Loudness (Unilaterals)



## Tinnitus Loudness (Uni- & Bilaterals)



Baseline (on 0-100 scale): 50-55 points  
 Clinically relevant change = 20 points  
 56% responders high dose vs. 23% placebo group  
 N=78 (only unilateral tinnitus patients)

Baseline (on 0-100 scale): 50-55 points  
 Clinically relevant change = 20 points  
 56% responders high dose vs. 32% placebo group  
 N=118 (note: bilateral tinnitus treated only unilaterally)

*Patients with acute tinnitus following acute acoustic trauma or otitis media.*

## Proof of Concept in Phase 2 (Cont'd)

### Key Outcomes Day 90

Outcome variable	Placebo	AM-101 0.27 g/mL	AM-101 0.81 g/mL
ANCOVA Least Square Mean Change from Baseline			
Δ Tinnitus loudness, 0-100 pts.	1.4	16.0 <i>0.0308*</i>	24.1 <i>0.0005***</i>
Δ Tinnitus annoyance, 0-100 pts.	10.8	21.7 <i>0.0805</i>	27.8 <i>0.0047***</i>
Δ Sleep difficulties, 0-100 pts.	11.8	29.8 <i>0.0234*</i>	38.7 <i>0.0003***</i>
Δ Tinnitus Impact (THI-12), 0-24 pts.	2.5	5.5 <i>0.0400*</i>	5.9 <i>0.0124*</i>
Global Patient Impression of Change in Tinnitus Severity			
„Much“ or „very much improved“	35%	44%	64%

Significant at 5% level, \*\*\* 0.5% compared with placebo  
Patients with unilateral tinnitus following acute acoustic trauma or otitis media, n= 78.

Primary endpoint tinnitus loudness incl. bilaterals (n=111):  
22.4 pts. AM-101 0.81 mg/mL vs. 7.1 pts. placebo, p=0.0033

### Patient Testimonial (Tinnitus Forum)

“I found a quality of quasi-optimal sleep, I am now sleeping well (I insist because it was the main discomfort before...) Some days, I didn't hear it anymore, and over long periods of time (especially at work where I work in a very quiet office), and I really needed to pay attention to hear it again.”

*TACTTO participant, receiving AM-101 0.81 mg/mL*

# AM-101 Phase 3 Program – Pivotal Studies

	TACTT2	TACTT3
Region/countries	USA, Canada, CZ	8 European countries
Population	Tinnitus following acute traumatic cochlear insults or otitis media (<3 months from onset)	
# Patients	330	300
# Sites	~60	~60
Treatment	AM-101 0.87 mg/mL or placebo (ratio 3:2), 3 x over 3-5 days	
Primary endpoint	Δ Tinnitus Loudness (TLQ) Day 84 (0-10 scale)	
Treatment effect <sup>1)</sup> Effect size <sup>1)</sup>	ΔTLQ 1.25 (2.2) points 0.5 (0.8)	ΔTLQ 1.5 (2.2) points 0.6 (0.8)
Co-primary endpoint	Δ Tinnitus Functional Index Day 84	-
Treatment effect Effect size <sup>2)</sup>	Δ TFI 10 points 0.4 (0.6)	-
Readout	Q1 2016	Q1 2016

Assumptions for 90% statistical power. <sup>1)</sup> TACTT0 values in brackets for reference, <sup>2)</sup> THI-12 values from TACTT0 in brackets for reference



## AM-101 Phase 3 Program – Further Studies

### Post-Acute Stage

- Multiple regression analysis of TACTT0 suggests efficacy beyond 3-month acute stage
- Exploring extension of therapeutic time window up to 12 months in a second stratum in TACTT3 (300 patients)
- Interim analysis for futility at enrolment midpoint: Q1 2015

### Follow-On Open Label Trials

- Open label follow-on trials
- AMPACT1 (TACTT2)
- AMPACT2 (TACTT3)
- Objectives:
  - Motivate patients
  - Generate safety data for FDA
- Up to 3 additional R<sub>x</sub> cycles / replications of TACTT studies
- All patients receive AM-101 0.87 mg/mL
- Read-out during NDA



# AM-101 Market Potential

## Primary Market Research

- 53 US ENT doctors surveyed<sup>1)</sup>
  - 41 general ENTs
  - 12 otologists
- See an average of 43.5 tinnitus patients in an average month
- 37.7% of their tinnitus patients seek treatment during the acute stage (up to 3 months from onset)
- 73.6% of respondents expect their monthly tinnitus patient volume to increase if an approved i.t. treatment were available
- 42.6% of their tinnitus patients considered as candidates for AM-101 type of product

<sup>1)</sup> Online survey conducted by MedaCorp, Inc. in April 2014

## Market Potential

- Target label = acute peripheral tinnitus following traumatic injury to the cochlea or otitis media
- Onset factors account for approx. 25% of tinnitus cases
- <10% of tinnitus patients seeking treatment would fall within label
- Bilateral patients: ca. 30%
- Estim. 250,000 treatable ears p.a. in US
- US market potential: \$750M
- Upside from
  - Other onset factors
  - Potential extension of time window
  - More and earlier GP referrals



## AM-111 for the Treatment of Acute Inner Ear Hearing Loss

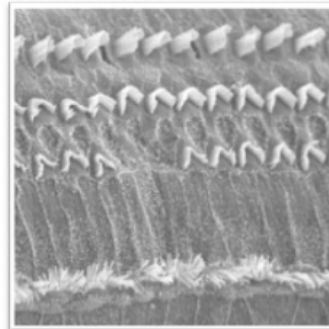
# AM-111 for Acute Inner Ear Hearing Loss

<b>Significant Unmet Medical Need</b>	<ul style="list-style-type: none"><li>• Significant impact on cognitive and auditory function</li><li>• Substantially reduced quality of life</li><li>• Hearing aids cannot replace functional cochlea</li></ul>
<b>Attractive Product Profile</b>	<ul style="list-style-type: none"><li>• Preserve cochlear function before hearing loss becomes irreversible</li><li>• Early, rapid and persistent improvement</li><li>• Single dose intratympanic injection, well tolerated</li></ul>
<b>Favorable Market Dynamics</b>	<ul style="list-style-type: none"><li>• No universal standard of care / no FDA or EMA approved drugs</li><li>• Specialty care market – significant interest by ENTs</li><li>• Attractive price reference points (e.g. hearing aid)</li></ul>
<b>Low Risk Regulatory Pathway</b>	<ul style="list-style-type: none"><li>• 3 x protocol assistance with EMA , Pre-IND meeting with FDA</li><li>• Orphan drug designation (FDA and EMA)</li><li>• Endpoints based on “classic” audiometry</li></ul>

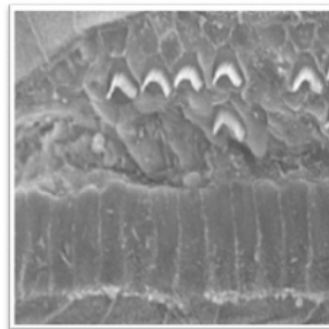
## AM-111's Mechanism of Action

- C-jun N-terminal Kinase (JNK) stress kinase involved in various cochlear insults
- Plays key role in apoptosis and inflammation
- D-JNKI-1 is a 31 amino acid intracellular peptide inhibiting JNK mediated transcription
- Therapeutic time window to preserve sensorineural structures / hearing
- Otoprotection demonstrated in various acute cochlear injury models, e.g.
  - Acute noise trauma
  - Ischemia
  - Infection
  - Inflammation
  - Surgery trauma

### Otoprotection Following Acute Noise Trauma



*Guinea pig hair cells following AAT and treatment with AM-111 4 h post trauma*



*Guinea pig hair cells following AAT and treatment with placebo 4 h post trauma*

## AM-111 Clinical Development

- Two trials completed, including one phase 2 RCT
- Sudden deafness (90%) and acute acoustic trauma (10%) patients
- Favorable safety profile with no systemic side effects
- Proof of concept in severe to profound hearing loss patients
  - Hearing loss of 60 dB or more – highest medical need
  - Mild to moderate cases: High spontaneous recovery preventing demonstration of clinically relevant improvement → no longer pursued
- Audiometric outcomes
  - Rapid and persistent improvement in hearing loss and speech discrimination
  - Results significant and clinically meaningful
- Effect on tinnitus: higher rate of complete remission
- Dose finding to be completed
- Phase 3 program under preparation
  - Protocol assistance from EMA
  - Pre-IND meeting with FDA

# Proof of Concept in Phase 2

## Key Outcomes

Outcome variable	Placebo	AM-111 0.4 mg/mL	AM-111 2.0 mg/mL
ANCOVA Mean Change to Day 7 (Primary Endpoint)			
Δ Hearing threshold (LS mean, dB)	17.9	29.9 <i>0.0174*</i>	22.7 <i>0.3186</i>
Δ Speech discrimination (LS mean, %)	9.1	27.4 <i>0.0186*</i>	23.2 <i>0.0609</i>
Frequency at Day 90			
Δ Complete tinnitus remission (%)	26	56 <i>0.045*</i>	48 <i>0.152</i>

ANCOVA with baseline value as covariate.

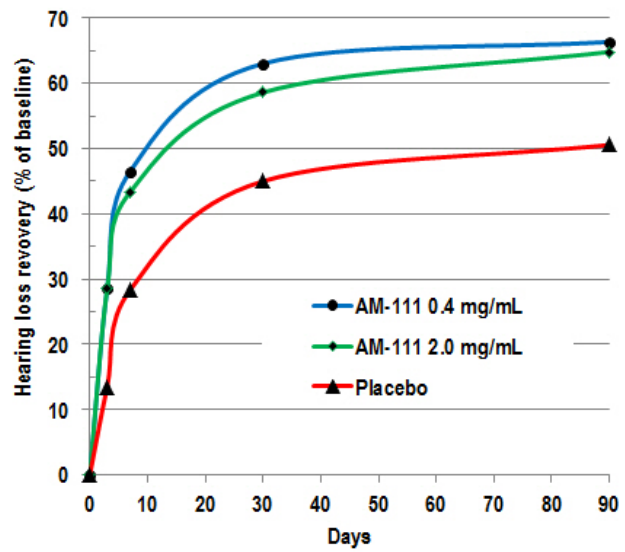
\* significant at 5% level compared with placebo

Improvement at 3 worst affected contiguous hearing thresholds (pure tone average, PTA) in dB, speech discrimination score (20 monosyllabic words) in % at 80 dB stimulus level

Clinically relevant change = 10 dB = twice as loud / half as loud

Patients with severe to profound hearing loss, n = 92 (n = 76 for tinnitus data).

## % Recovery of Hearing Loss



Treatment benefit of AM-111 0.4 mg/mL against placebo clinically relevant at all time points

# AM-111 Phase 3 Program

	HEALOS	US trial
Region	Europe, Asia	US
Population	Severe to profound sudden deafness, within 72 hours from onset	ASNHL (subtype tbd)
# Patients	255	tbd
# Sites	70-80	tbd
Treatment	1 x AM-111 0.4 mg/mL, 0.8 mg/mL or placebo (ratio 1:1:1)	tbd
Primary endpoint	$\Delta$ Hearing threshold Day 28	
Treatment effect <sup>1)</sup> Effect size <sup>1)</sup>	$\Delta$ Hearing threshold 12 (14) dB 0.5 (0.6)	
Readout	Q1 2017	

Assumptions for 90% statistical power. <sup>1)</sup> Phase 2b values in brackets for reference.



# AM-111 Market Potential

## Primary Market Research

- 53 US ENT doctors surveyed<sup>1)</sup>
  - 41 general ENTs
  - 12 otologists
- See an average of 11.2 patients with ISSNHL and 6.3 patients with AAT in an average month
- 39.9% seek treatment within first 3 days and 43.3% have severe to profound hearing loss
- 64.2% of respondents expect their monthly ASNHL patient volume to increase if an approved i.t. treatment were available
- 59.9% of their ASNHL patients considered as candidates for AM-111 type of product

<sup>1)</sup> Online survey conducted by MedaCorp, Inc. in April 2014

## Market Potential

- Target label = severe to profound ASNHL
  - Sudden deafness (ISSNHL)
  - Acute noise trauma
  - Surgery trauma
- Bilateral patients: ca. 10%
- Estim. 105,000 treatable ears p.a. in US
- US market potential: \$500M
- Upside from
  - Other onset factors
  - More and earlier GP referrals





## IP, Financial Position & Commercialization Strategy

## Strong Intellectual Property Portfolio

1

### AM-101

- Use patents issued in 40 countries – 2024 to 2028 (US)
- Controlled substance in major markets (schedule III in US)
- Esketamine currently not marketed in US

2

### AM-111

- Substance of matter patents issued/allowed in 54 countries – 2020 to 2027 (US)
- Use patents (hearing loss) issued/allowed in 54 countries – 2022 to 2027 (US)
- Additional filings related to tinnitus and Menière's

3

### Polymer Formulations

- Patents related to AM-101 issued/allowed in 15 countries – 2025
- Continuation filed for other polymers + other active substances

## Market Strategy

### Commercialization

- Retain full rights in US and key EU markets to commercialize AM-101 and AM-111
- Targeting about 5,000 otologists, neurotologists and general ENTs in US
  - Specialist sales force to call on ENTs
  - 40-50 reps in US
  - Smaller number needed than in ophthalmology
- Selectively partnering in ROW

### Further Expansion

- Product life cycle management
  - Formulation
  - Dosing
- Indication expansion
  - Additional tinnitus or hearing loss triggers
  - Extension of therapeutic time window
- Additional ENT products
  - In-house development
  - Partnering

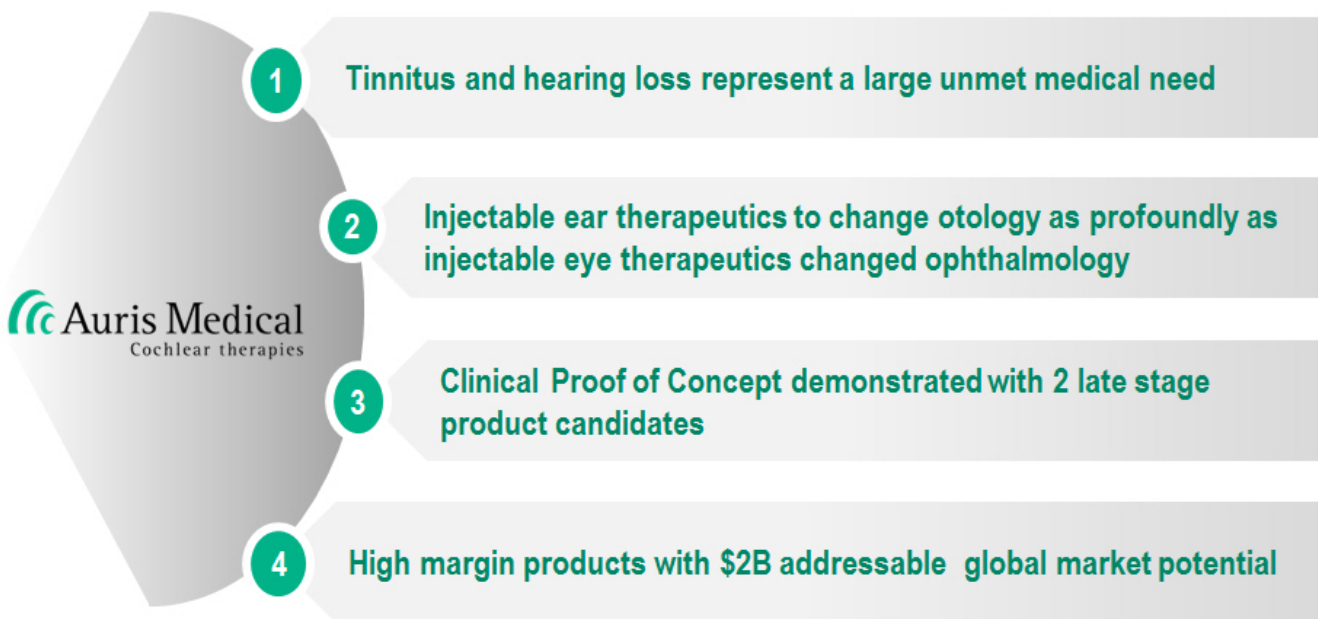
# Financial Overview

Key figures (CHF)	Nine months ended Sep 30, 2014	Nine months ended Sep 30, 2013
Research and development	-13,036,450	-10,327,366
General and administrative	-3,552,021	-1,010,096
Operating loss	-16,588,471	-11,337,462
Net loss for the period attributable to owners of the Company	-14,212,011	-11,505,722
Basic and diluted loss per share	-0.69	-0.79
Cash and cash equivalents	61,892,660	23,865,842

- \$60.7M raised through IPO in August 2014
- Fund R&D expenses for
  - AM-101 clinical program beyond phase 3 read-out
  - Part of AM-111 phase 3 program and early stage programs

**Cash runway until mid 2016**

# Investment Highlights





Take care of your ears!

 **Auris Medical**  
Cochlear therapies  
Innovative Treatments for Inner Ear  
Disorders