# 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 mo	nth of	f Septe	ember	; 20	16
Comr	nission	File I	Numb	er: 00	— )1-3	6582

# **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	X	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	X	
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	$\boxtimes$	

#### 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/ Anne Sabine Zoller
Name: Anne Sabine Zoller Title: General Counsel

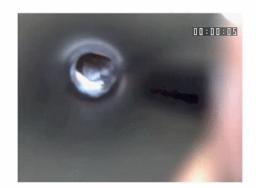
Date: September 19, 2016

#### EXHIBIT INDEX

Exhibit Number	er Description
99.1	Excerpt of AM-101 Safety Profile Presentation presented at AAO-HNSF San Diego 2016.

### What is the safety profile of Intratympanic Injections?

- Common procedure in ENT offices
- Procedure is generally considered safe and routine; Some old literature suggests increased risk of TM perforation
- Commonly used for local, off-label administration of corticosteroids or gentamicin
- Until recently, no drug approved for this route of administration
- Limited data on safety available especially when repeat administrations are performed



#### Safety Data Collected in TACTT2 Trial

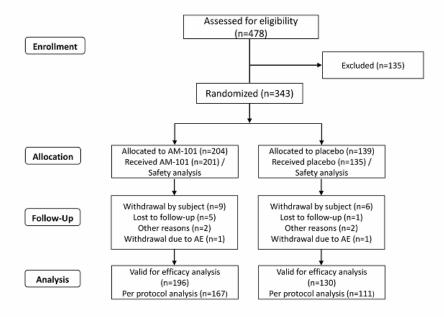
- Efficacy and Safety of AM-101 in the Treatment of Acute Peripheral Tinnitus 2 (TACTT2)
  - AM-101 is a small molecule NMDA receptor antagonist formulated in hyaluronic acid and delivered via an intratympanic injection
- Systematic collection of safety data on repeated intratympanic injections
  - Approximately 1,000 intratympanic injection procedures
  - >60 secondary and tertiary sites in six countries
    - US, Canada, Czech Republic, South Korea, Turkey, Israel
  - Enrollment phase between March 2014 and March 2016

# TACTT2 Trial Design Overview

N = 336 (Safety Analysis Set) Primary efficacy endpoint Primary safety endpoint Placebo (n=135) Randomized 3:2 active/placebo AM-101 (n=201) Screening Treatment Follow-Up FUV1 FUV2 FUV3 SV D-14 D0 - D4 D10 D35 D84

- Acute peripheral tinnitus following traumatic cochlear insult (acute noise trauma, barotrauma, surgery trauma) or otitis media
- Up to 3 months from onset
- Documented tinnitus history

### Patient Enrollment



# Demographics and Baseline Characteristics

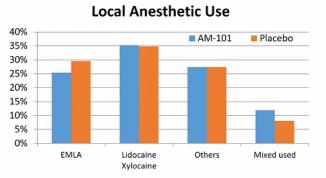
Safety Population	AM-101 (n=201)	Placebo (n=135)	Total (n=336)
Age (mean)	43.4	44.2	43.7
Age (range)	18 to 74	20 to 73	18 to 74
Time from tinnitus onset (mean in days)	64.8	64.6	64.7
Average hearing threshold (4, 6 and 8 kHz)	27.4	28.7	28.0
Tinnitus treatment laterality			
Unilateral	119	76	195
Bilateral	82	59	141

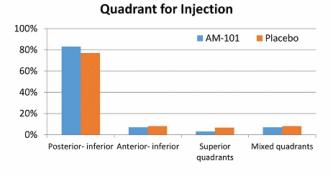
### Safety Endpoints

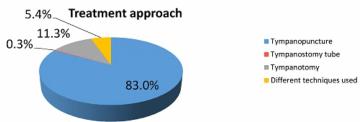
- Primary: Average hearing deterioration of ≥15 dB from baseline to Day 35 in two contiguous frequencies
  - · 15 dB considered as clinically relevant
  - Permanent threshold shift from intervention, if any, expected to show at Day 35
- Secondary:
  - Clinically relevant hearing deterioration from baseline to Day 10 and Day 84
  - Difference in occurrence of clinically relevant hearing deterioration from baseline to all postbaseline visits between treated and untreated contralateral ear (unilaterally treated patients only)
  - · Adverse events
- Exploratory:
  - · Hematology and biochemistry
  - Vital signs

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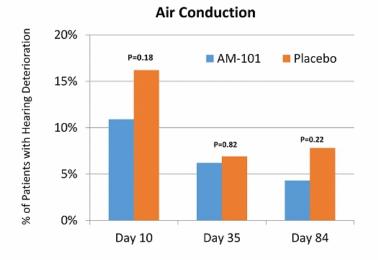
# Injection Procedure (Safety Population)

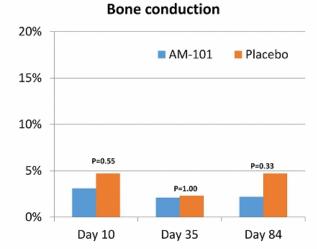






## Clinically Relevant Hearing Deterioration





- · No difference between treated and untreated ear in unilateral cases, except for placebo at Day 10
- Essentially no change from baseline to Day 84 at average of 4, 6 and 8 kHz:
  - +0.56 dB for AM-101 and +0.23 dB for placebo

#### Adverse Events

Number of Patients n(%)	AM-101 (n=201)	Placebo (n=135)	Total (n=336)
Any AEs	97 (48.3%)	50 (37.0%)	147 (43.8%)
TEAEs	90 (44.8%)	46 (34.1%)	136 (40.5%)
Drug-related AEs	14 (7.0%)	6 (4.4%)	20 (6.0%)
Procedure-related AEs	34 (16.9%)	22 (16.3%)	56 (16.7%)
SAEs	5 (2.5%)	1 (0.7%)	6 (1.8%)
AEs leading to withdrawal	1 (0.5%)	1 (0.7%)	2 (0.6%)
AEs leading to death	0	0	0

- All drug-related AEs were mild to moderate
- Procedure-related AEs were predominantly transient and mild to moderate
- All SAEs were isolated cases and not related to study drug or procedure
- Low rate of procedure-related infections
- AEs leading to withdrawal:
  - AM-101: Subjective worsening of hearing (procedure related)
  - Placebo: Blockage and discomfort (drug related)

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# Tympanic Membrane Closure

- Rapid closure of tympanic membrane perforation following injection
- Data confirmed results from previous Phase 2 trial

Closure observed at follow-up visit on:	AM-101	Placebo
Day 10	91.7%	93.1%
Day 35	99.0%	99.2%
Day 84	100.0%	100.0%

### Summary of TACTT2 Safety Results

- AM-101 and intratympanic injection procedure were well tolerated
  - Over course of ~1,000 injections, no drug or procedure-related SAEs observed
  - Comparable drug- and procedure-related AE rate between AM-101 and placebo
  - Low occurence of transient procedure-related effects
  - Closure of tympanic membrane within one week in almost all patients
- Primary safety endpoint at Day 35 achieved
  - Occurrence of clinically relevant hearing deterioration low and not different between treatment groups
  - · Normal variation since no difference to untreated contralateral ear
- Repeated intratympanic injections with AM-101 over 3-5 day period are safe and well tolerated

# Acknowledgements

The authors would like to thank all investigators, study staff and patients who participated in the TACTT2 trial