# 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

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

	For th	e montl	of October, 2016			
	Commiss	ion File	Number: 001-36	582		
Au			al Holdir	$\mathbf{\circ}$	G	
	(Addr	6300 Zu	nofstrasse 21 g, Switzerland ncipal executive office)			
Indicate by check mark whe	ther the registran	t files or w	ill file annual reports unde	r cover of F	orm 20-F or Form	n 40-F:
	Form 20-F	$\boxtimes$	Form 40-F	0		
Indicate by check mark if the re	egistrant is submi	tting the F	orm 6-K in paper as permi	tted by Reg	ulation S-T Rule	101(b)(1)
	Yes	0	No	$\boxtimes$		

No

X

### **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: October 11, 2016

## EXHIBIT INDEX

<b>Exhibit Numbe</b>	er Description
99.1	Press Release dated October 11, 2016
99.2	Keyzilen <sup>TM</sup> Program Update Presentation dated October 11, 2016



Auris Medical News Release

# Auris Medical Provides Update on Development of Keyzilen<sup>TM</sup> for the Treatment of Acute Inner Ear Tinnitus

- · TACTT3 Phase 3 trial protocol amended based on analysis of TACTT2 trial outcomes
- · TACTT3 enrollment to be expanded with top-line results expected in early 2018
- · Conference call scheduled for today to discuss development update

Zug, Switzerland, October 11, 2016 – Auris Medical Holding AG (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in otolaryngology, today announced additional clinical data as well as updates to its development plan for Keyzilen<sup>TM</sup> (AM-101) in acute inner ear tinnitus.

Based on insights from the recently completed TACTT2 trial, the Company is submitting a protocol amendment to regulatory agencies in Europe for TACTT3, the ongoing second Phase 3 clinical trial. In the amended trial protocol, the change in Tinnitus Functional Index (TFI) score will be elevated from a key secondary endpoint to an alternate primary efficacy endpoint. Certain patient subgroups will be included in confirmatory statistical testing, and the trial size will be increased to enhance statistical sensitivity to the effects of treatment. Top-line results from the expanded TACTT3 trial are now expected in early 2018. The outcomes from TACTT2 and the regulatory path forward will be reviewed with the US Food and Drug Administration in early December 2016.

TACTT2 was a randomized, double-blind, placebo-controlled trial conducted primarily in North America, enrolling 343 patients suffering from acute inner ear tinnitus following traumatic cochlear injury or otitis media. As previously announced, the trial failed to meet its two co-primary endpoints: the change in subjective tinnitus loudness (tinnitus loudness question; TLQ) and the change in tinnitus burden measured by the TFI from baseline to Day 84 over placebo. However, the TACTT2 trial data show treatment effects on TFI in favor of Keyzilen<sup>TM</sup> for specific subgroups. In the pre-specified subgroup of patients suffering from tinnitus following otitis media, treatment with Keyzilen<sup>TM</sup> resulted in a clinically meaningful and statistically significant reduction of 14.8 points in the TFI from baseline, as compared to 6.2 points for placebo (p=0.048). A reduction of 13 points was defined as clinically meaningful by the developers of the TFI. A trend for improvement was also observed in active-treated patients who suffered from severe or extreme tinnitus at baseline with a clinically meaningful reduction in TFI of 15.5 points as compared to 11.5 points in the placebo group (p=0.238). Unexpectedly, the TLQ showed a lower sensitivity to change than the TFI, which the Company believes to be related to the frequent (daily) rating of tinnitus loudness over an extended period of time.

"Although we are disappointed that the TACTT2 trial failed to confirm the efficacy of Keyzilen<sup>TM</sup> in the overall study population, we feel very encouraged by the clinically meaningful reductions in tinnitus burden in two relevant subgroups," commented Thomas Meyer, founder, Chairman and Chief Executive Officer of Auris Medical. "New knowledge gained from the TACTT2 trial allows us to make appropriate adjustments to the TACTT3 trial while we are still fully blinded to its outcomes. We believe that the measures outlined today will improve the probability of success of the TACTT3 trial for the entire study population as well as for key patient subgroups."

TACTT3, which is being conducted in Europe, is a randomized, double-blind, placebo-controlled trial in acute and post-acute inner ear tinnitus following traumatic cochlear injury or otitis media. So far, the trial enrolled more than 300 patients during the acute tinnitus stage (Stratum A) and approximately 330 patients during the post-acute tinnitus stage (Stratum B). Under the amended trial protocol, the change in tinnitus loudness and in the TFI from baseline to Day 84 will both be alternate primary efficacy endpoints. Applying the Hochberg procedure, the two endpoints will be tested for the overall study population as well as for the subpopulations of patients with otitis media-related tinnitus or with severe tinnitus at baseline. In order to enhance the trial's statistical power, 60 additional patients will be recruited in TACTT3 in each of Stratum A and Stratum B. The Company expects enrollment to resume in early 2017.

For more information on tinnitus symptoms and the patient experience, please click on this video link: [https://www.youtube.com/watch? v=Cii3SKpe1B0&list=PLNCzVwOupyyiEgXvv71H4M8807HwY65eQ&index=1]

Auris Medical Holding AG · Bahnhofstrasse 21 · CH-6300 Zug · Tel. +41 41 729 71 94 · www.aurismedical.com

#### Conference Call & Webcast Information

Auris Medical will host a conference call and webcast to discuss the Keyzilen<sup>TM</sup> program update today, October 11, 2016, at 8:00 am Eastern Time (2:00 pm Central European Time). To participate in this conference call, dial 1-855-217-7942 (USA) or +1-646-254-3376 (International), and enter passcode 2939516. A live webcast of the conference call will be available in the Investor Relations section of the Auris Medical website at www.aurismedical.com and a replay of the conference call will be available following the live call.

#### About Acute Inner Ear Tinnitus

Tinnitus, the perception of sound without external acoustic stimulation, is a symptom common to various ear or other diseases. Inner ear tinnitus may be provoked by various injuries to the cochlea, the organ of hearing, such as overexposure to noise or inflammation. Tinnitus may be transitory; however, it may also become permanent. Tinnitus of less than three months of duration is considered acute, while older tinnitus is considered chronic. Inner ear tinnitus often has a serious impact on the ability to sleep, relax, or concentrate, and it may lead to tiredness, irritation, nervousness, despair, frustration, or even depression. As of today, neither a universal standard of care for acute inner ear tinnitus, nor a truly proven and effective treatment method is available.

#### About Keyzilen<sup>TM</sup> (AM-101)

Keyzilen<sup>TM</sup> is a small molecule N-methyl-D-aspartate (NMDA) receptor antagonist formulated in a biocompatible gel for intratympanic injection. Emerging evidence suggests that NMDA receptors in the cochlea play a major role in the occurrence of tinnitus following acute injury to the inner ear, e.g. from exposure to excessive noise, infections, disturbances in inner ear blood supply, or the administration of certain ototoxic drugs. Persistent overexpression of NMDA receptors may lead to pathologic excitation of auditory nerve fibers, which in the brain is perceived as tinnitus. Keyzilen<sup>TM</sup> has received fast track designation from the FDA for the treatment of acute peripheral (inner ear) tinnitus following traumatic cochlear injury or otitis media in adults. The development of Keyzilen<sup>TM</sup> is based on research conducted at the INSERM Institute for Neurosciences, and patents have been granted in more than 40 countries worldwide so far.

#### **About Auris Medical**

Auris Medical is a Swiss biopharmaceutical company dedicated to developing therapeutics that address important unmet medical needs in otolaryngology. The Company is currently focusing on the Phase 3 development of treatments for acute inner ear tinnitus (Keyzilen<sup>TM</sup>; AM-101) and for acute inner ear hearing loss (AM-111) by way of intratympanic administration with biocompatible gel formulations. In addition, Auris Medical is pursuing early-stage research and development projects. The Company was founded in 2003 and is headquartered in Zug, Switzerland. The shares of the parent company Auris Medical Holding AG trade on the NASDAQ Global Market under the symbol "EARS."

#### Forward-looking Statements

This press release may contain statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical fact and may include statements that address future operating, financial or business performance or Auris Medical's strategies or expectations. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "outlook" or "continue," and other comparable terminology. Forward-looking statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include, but are not limited to, the timing and conduct of clinical trials of Auris Medical's product candidates, the clinical utility of Auris Medical's product candidates, including the likelihood that the TACTT3 trial may not meet its endpoints, the timing or likelihood of regulatory filings and approvals, Auris Medical's intellectual property position and Auris Medical's financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions or changes to Auris Medical's capital structure, including future securities offerings. These risks and uncertainties also include, but are not limited to, those described under the caption "Risk Factors" in Auris Medical's Annual Report on Form 20-F and future filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they are made, and Auris Medical does not undertake any obligation to

update them in light of new information, future developments or otherwise, except as may be required under applicable law. All forward-looking statements are qualified in their entirety by this cautionary statement.

Contact: Cindy McGee, Head of Investor Relations and Corporate Communications, +41 61 201 1350, investors@aurismedical.com

Media contact: David Schull, Russo Partners, 1-858-717-2310, <a href="mailto:david.schull@russopartnersllc.com">david.schull@russopartnersllc.com</a>

Page 3 of 3





# **Keyzilen**<sup>™</sup> **Program Update**

October 11, 2016

## **Forward-looking Statements**



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, including the likelihood that the TACTT3 trial may not meet its endpoints, the timing or likelihood of regulatory filings and approvals, the timing or likelihood of regulatory filings and approvals, 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. These risks and uncertainties also include, but are not limited to, those described under the caption "Risk Factors" in our Annual Report on Form 20-F and future filings with the Securities and Exchange Commission. 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.



# **Keyzilen**<sup>™</sup> **Development Plan Update**

www.aurismedical.com

# Today's Agenda

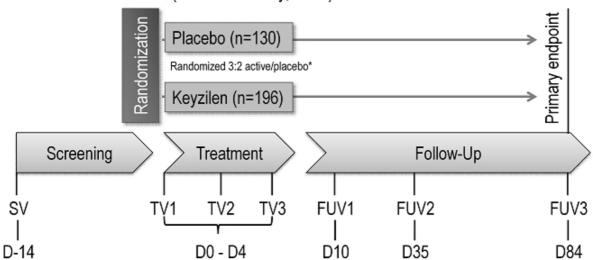


- TACTT2 trial: Additional results and learnings
- TACTT3 trial: Protocol amendment
- Planned discussions with FDA regarding US regulatory pathway

# **TACTT2 Trial Design Overview**



N = 326 (Valid for Efficacy; mITT)



- \* Stratified for etiology (traumatic cochlear injury / otitis media) and laterality (unilateral, bilateral)
- · Acute peripheral tinnitus following traumatic cochlear insult or otitis media
  - Traumatic cochlear insult includes acute noise trauma, barotrauma, surgery trauma
- · Up to 3 months from onset
- · Conducted primarily in North America

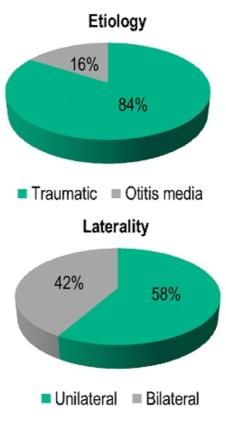
4

# **TACTT2 Trial – Baseline and Demographics**



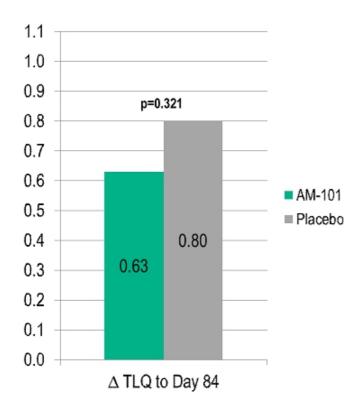
# Co-primary endpoints, measured from baseline to Day 84:

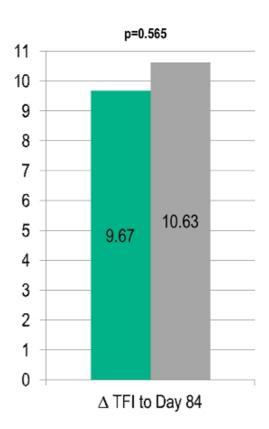
- Change in subjective tinnitus loudness (TLQ; 0-10)
  - Baseline values: 6.44 points for Keyzilen, 6.47 points for placebo
- Change in tinnitus burden (TFI; 0-100)
  - Baseline values: 52.4 points for Keyzilen, 50.2 points for placebo



# **Co-Primary Efficacy Endpoints**







O

# **TACTT2 Trial – Outcome Analysis**



Two principal sources for disappointing outcome:

## Trial design

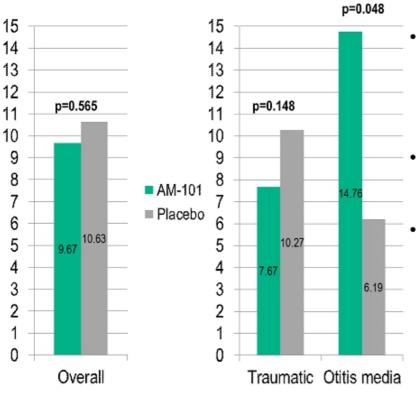
- High frequency (daily) of tinnitus loudness ratings over extended time period
- TLQ showed lower sensitivity to change than the TFI

## Trial administration

- High variability in outcomes between study sites
- Positive outcomes at numerous sites, including many high enrollment centers

# **Subgroup – Otitis Media-Related Tinnitus**



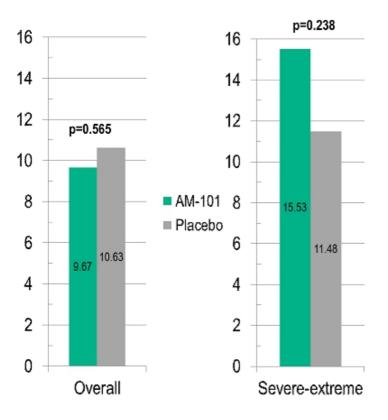


- Clinically meaningful and statistically significant TFI results in subgroup with otitis media-related tinnitus
  - Δ TFI ≥ 13 defined as clinically meaningful by TFI developers
  - Pre-specified subgroup

8

# **Subgroup – Severe or Extreme Tinnitus**





- Post-hoc analysis showing trend for improvement in subgroup with severe or extreme tinnitus at baseline
- Based on self-rated global severity and TFI definition
- Clinically meaningful improvement in TFI for severe or extreme tinnnitus subgroup

9

## **TACTT2 Trial – Safety Outcomes**



- Data show that Keyzilen was well tolerated and confirm favorable safety profile
- · Low incidence of clinically meaningful hearing deterioration
  - Primary safety endpoint did not show a significant difference between treatment groups (p=0.82)
- No drug- or procedure-related SAEs observed and rates of drug- or procedurerelated AEs were similar
- · Occurrence of procedure-related effects low and mostly transient
  - Approximately 1,000 intratympanic administrations performed
- Safety data recently presented at AAO-HNSF meeting

# TACTT2 – Summary



- TACTT2 failure to confirm efficacy of Keyzilen in overall trial population clearly disappointing
- Clinically meaningful reductions in tinnitus burden in relevant subgroups very encouraging
- New knowledge gained from TACTT2 allows appropriate adjustments to TACTT3 while outcomes remain fully blinded



# **TACTT3 Development Plan Update**

www.aurismedical.com

12

# **Original TACTT3 Trial Design / Enrollment**



	TACTT3 – A	TACTT3 – B		
Patients	Acute inner ear tinnitus, within 3 months from onset	Post-acute inner ear tinnitus, 3-6 months from onset		
Dosing	Single treatment cycle of three intratympanic injections over 3-5 days, randomized 3:2 to 0.87 mg/mL or placebo			
Enrollment	<ul> <li>~300 enrolled</li> <li>38% of patients suffering from tinnitus following otitis media as compared to 16% in TACTT2</li> <li>Last patient completed last study visit in late September 2016</li> </ul>			
Primary endpoint	Δ Tinnitus Loudness to Day 84			
Key secondary endpoint	Δ Tinnitus Functional Index to Day 84			

## **TACTT3 Trial – Protocol Amendments**



- 1. TFI elevated from key secondary endpoint to alternate primary efficacy endpoint
  - TFI has ability to directly measure the clinically relevant tinnitus burden
  - TFI showed higher sensitivity than TLQ in TACTT2
  - Study can be considered successful if one of the two endpoints is achieved
  - Alpha level for significance testing will be 4% for TFI and 1% for TLQ
- Otitis media and severity subgroups included in confirmatory statistical testing along with overall study population
  - Allows for further corroboration of TACTT2 findings
  - Testing performed according to Hochberg procedure, which avoids need for prespecification of hierarchy and enhances chance of achieving subgroup success
- 3. Enhance statistical power by enrolling 120 additional patients
  - 60 additional patients in each of Stratum A and Stratum B

TLQ: Endpoint unchanged but reduced rating frequency between study visits

## **TACTT3 Trial – Statistical Powering**



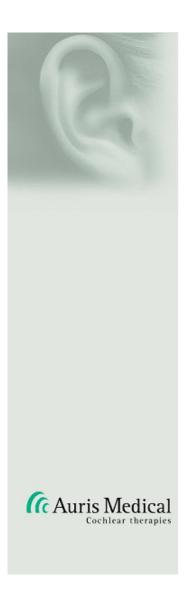
Amended TACTT3 trial, including additional patients, to have statistical power of:

- 87% to show significance for the TFI on at least one of the three patient populations: overall, otitis media tinnitus, severe tinnitus
  - Assumptions:
    - Standard deviations equivalent to 80% confidence level in TACTT2
    - Treatment effect of 5-7 points for change in TFI for Keyzilen group compared to placebo
- Overall, at least 87% and up to 94% to show significance for either the TFI or the TLQ on at least one of the three patient populations
  - Assumptions:
    - As above, plus treatment effect of 0.5 for change in TLQ for Keyzilen group compared to placebo

# **TACTT3 Trial – Summary**



- Favorable differences in patient demographics and trial conduct compared to TACTT2
- Measures implemented under amendment will enhance assay sensitivity and shift focus to the TFI
- Increased likelihood of positive trial that successfully detects true treatment effects of Keyzilen



# Keyzilen Regulatory Update

www.aurismedical.com 17

# **Keyzilen Regulatory Update**

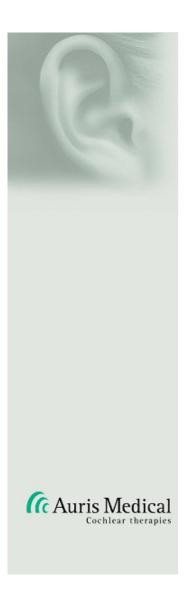


- TACTT3 protocol amendment to be submitted to regulatory agencies and ethics committees in Europe
- Anticipate approvals around the end of 2016
- Plan to resume trial enrollment in January 2017
- Expect top-line results from expanded TACTT3 trial in early 2018

# **Keyzilen Regulatory Update**



- Type C meeting with FDA scheduled for early December
- · Written responses
- · Plan to seek feedback on:
  - TACTT2 outcomes
  - TACTT3 protocol modifications
  - US regulatory path forward



# **Corporate Overview**

www.aurismedical.com 20

# **AM-111 for Acute Inner Ear Hearing Loss**



- Potential to become first specific therapeutic for acute inner ear hearing loss
- Launched HEALOS in November 2015: Over 50% of patients enrolled
- Launched ASSENT in June 2016: Trial ramping up
- Top-line results expected in second half of 2017
- Objective outcomes based on audiometry
- Orphan drug designation from both FDA and EMA



# **Keyzilen Program Update**



- Positive signals in three previous randomized and controlled trials
- Corroborated positive results in two specific subgroups in TACTT2
- TACTT3 provides solid and timely opportunity to apply learnings from TACTT2
- TACTT3 protocol amendments increase probability of success
- Every reason to continue to believe in Keyzilen, its mechanism of action and the therapeutic concept



# **Questions & Answers**

www.aurismedical.com 23



# Take care of your ears!

www.aurismedical.com 24