

---

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 April, 2020

Commission File Number: 001-36582

**Auris Medical Holding Ltd.**  
(Exact name of registrant as specified in its charter)

**Clarendon House, 2 Church Street**  
**Hamilton HM 11, Bermuda**  
(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

---

---

**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: April 16, 2020

EXHIBIT INDEX

Exhibit Number	Description
99.1	<a href="#">Press Release dated April 16, 2020</a>

## Auris Medical Provides Business Update and Reports Second Half and Full Year 2019 Financial Results

- Phase 1b trial with intranasal betahistine for prevention of antipsychotic-induced weight gain progressing towards final read-out
- Phase 2 trial with intranasal betahistine for treatment of acute vertigo progressing towards interim analysis, but temporarily slowed down by COVID-19 impact
- Notice of allowance granted for NKCC1 modulators for oral treatment of tinnitus
- Set-up of subsidiary to bundle tinnitus and hearing loss development projects for potential partnering

Hamilton, Bermuda, April 16, 2020 – Auris Medical Holding AG (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in neurotology, today provided a business update and announced financial results for the second half and full year ended December 31, 2019.

“We made substantial progress with our intranasal betahistine development programs in 2019,” stated Thomas Meyer, Auris Medical’s founder, Chairman and CEO. “We extended our patent coverage both in the US and the EU to 2038, initiated our Phase 2 trial with AM-125 in acute peripheral vertigo and obtained positive interim results from our Phase 1b trial with AM-201 in antipsychotic-induced weight gain. We expect to receive top-line data from the completed AM-201 trial in early May and interim data from the AM-125 trial in the third quarter, provided that COVID-19 restrictions are lifted. As for our late-stage programs in tinnitus and hearing loss, we’ve positioned them for partnering by setting up a dedicated subsidiary, Zilentin Ltd.”

### Development Program Updates

#### *AM-125 for Treatment of Acute Peripheral Vertigo*

- Progressed with dose escalation in TRAVERS Phase 2 trial. Since July 2019, the TRAVERS trial has been enrolling patients suffering from acute vertigo following certain neurosurgical interventions affecting the vestibular nerve. In Part A of the TRAVERS trial, three ascending doses of AM-125 or placebo, administered three times daily over a total of four weeks, are tested in a total of 30 patients. The results from an interim analysis of Part A will inform the selection of two doses for further testing against placebo in an estimated 72 patients in Part B of the trial. In addition to the ongoing intranasal dose escalation, open label testing of oral betahistine for reference purposes has commenced.
- COVID-19 outbreak causing temporary delay in enrollment. Candidates for participation in the TRAVERS trial undergo certain types of neurosurgery, which are elective procedures. Due to the COVID-19 outbreak, the sites participating in the “TRAVERS” trial have postponed elective procedures and temporarily reduced or suspended clinical research activities. As a result, enrollment came to a halt towards the end of March 2020. Although sites are expected to catch up on enrollment once COVID-19 related restrictions are relaxed, the Company expects that the interim analysis following Part A of the trial will be completed only in the third quarter of 2020, at the earliest.

#### *AM-201 for Prevention of Antipsychotic-Induced Weight Gain and Somnolence*

- Positive interim results in Phase 1b trial. In October 2019 an interim analysis of the results from the first 50 participants in the trial showed good safety and tolerability of AM-201 up to a dose of 3 x 20 mg daily for four weeks. Further, it revealed relevant reductions in olanzapine-induced weight gain and daytime sleepiness. In female study participants, who overall showed more pronounced changes than male participants, a reduction in weight gain of 1.1 kg against placebo was observed at the highest tested dose (probability of effectiveness = 90%).
- Progressing towards read-out from Phase 1b trial. Following the interim analysis, the trial proceeded to the next higher and final dose level of 30 mg, which was tested in an additional 30 healthy volunteers, bringing the total for the trial to 80 subjects. The Company expects to report top-line data in May 2020. The primary efficacy outcome for the study will be the reduction in weight gain and the secondary outcome will be the reduction in somnolence.

#### *Other developments related to betahistine*

- Obtained U.S. and European patent applications covering intranasal betahistine. The Company’s intellectual property estate was substantially expanded through the grant of US patent 10,456,386, entitled “Pharmaceutical Composition Comprising Betahistine”, which covers composition of matter and methods of use for formulations of betahistine dihydrochloride for intranasal delivery. In addition, the Company received an “Intention to Grant” notice from the European Patent Office (EPO) for its corresponding European patent application. The new patents are expected to expire no earlier than February 2038.

- Announced independent *in vivo* evidence for betahistine’s anti-epileptic and anti-convulsive activity. In a study published in *Epilepsy & Behavior*, an independent research group reported promising results with pretreatment and repetitive betahistine treatment in a murine model of epilepsy. The results add further to the growing list of potential therapeutic uses for betahistine.

#### *Keyzilen® / AM-101 for Treatment of Acute Inner Ear Tinnitus*

- Received FDA and EMA guidance for Keyzilen® late-stage clinical development program. The Company received feedback from the FDA and EMA regarding the design of a new Phase 2/3 trial for the Keyzilen® program. Both agencies supported the use of the Tinnitus Functional Index (TFI) questionnaire as the primary efficacy outcome measure. The TFI captures the impact of tinnitus on the patient’s day-to-day functioning. Furthermore, the two agencies agreed on a less frequent collection of patient-reported tinnitus loudness than in the previous Keyzilen® trials, where daily ratings had turned out to be problematic. The FDA considers the improvement in tinnitus loudness as a co-primary efficacy endpoint, whereas the EMA endorsed it as a secondary efficacy endpoint. In addition, the two agencies endorsed the planned sample size for the trial.

#### *Other developments related to tinnitus*

- Established scientific advisory board for tinnitus programs. The Company established a Scientific Advisory Board comprising four internationally renowned experts to support its research and development programs in the field of tinnitus.
- Received notice of allowance for NKCC1 tinnitus patent. The US Patent and Trademark Office issued a “Notice of Allowance” and the European Patent Office a notice of “Intention to Grant” for the Company’s patent application covering compounds modulating the sodium potassium chloride co-transporter 1 (NKCC1) for use in the oral treatment or prevention of tinnitus. As demonstrated in an animal model of acute noise trauma, administration of an NKCC1 inhibitor resulted in a significant reduction of a biomarker for the presence of tinnitus ( $p < 0.02$ ).

#### **Corporate Developments**

- Appointed Elmar Schaerli as new Chief Financial Officer. Effective November 1, 2019, Elmar Schaerli, CPA, was appointed the Company’s new CFO. He succeeds Hernan Levett. On the other hand, Raoul Dias, General Counsel, left the Company effective March 20, 2020 in order to pursue a new career opportunity.
- Set up new subsidiary for development projects in tinnitus and hearing loss. In late 2019, the Company formed a new subsidiary, Zilentin Ltd., to bundle its development projects for the treatment of tinnitus and hearing loss in a separate entity. These include Keyzilen® / AM-101 as well as early stage projects in tinnitus as well as Sonsuvi® / AM-111 in hearing loss. Zilentin Ltd. is currently a 100% subsidiary and is domiciled in Zug, Switzerland.

#### **Second Half 2019 Financial Results**

- Total operating expenses for the second half of 2019 were CHF 3.2 million compared to CHF 3.5 million for the second half of 2018.
- Research and development expenses for the second half of 2019 were CHF 2.0 million compared to CHF 1.7 million for the second half of 2018.<sup>1</sup>
- General and administrative expenses for the second half of 2019 were CHF 1.1 million compared to CHF 1.8 million for the second half of 2018.
- Net loss for the second half of 2019 was CHF 3.0 million, or CHF 0.83 per share, compared to CHF 6.7 million, or CHF 5.17 per share, for the second half of 2018.
- Cash and cash equivalents at December 31, 2019, totaled CHF 1.4 million.

#### **Full Year 2019 Financial Results**

- Total operating expenses for 2019 were CHF 7.3 million compared to CHF 11.0 million for 2018.
- Research and development expenses for 2019 were CHF 3.3 million compared to CHF 6.7 million for 2018.<sup>1</sup>
- General and administrative expenses for 2019 were CHF 3.9 million compared to CHF 4.3 million for 2018.
- Net loss attributable to owners of the Company for 2019 was CHF 6.6 million, or CHF 2.28 per share, compared to CHF 11.5 million, or CHF 14.46 per share, for 2018.

The Company expects its total cash need in 2020 to be in the range of CHF 7.5 to 10.0 million for expected total operating expenses of CHF 3.5 to 4.5 million and expected capitalized research and development expenses of CHF 4.0 to 5.5 million.

---

<sup>1</sup> Does not include capitalized costs related to expenses for the AM-125 program in accordance with IAS38.

## Conference Call & Webcast Information

Auris Medical will host a conference call and webcast to present the second half and full year 2019 financial results and to provide a business update today, April 16, 2020, at 8:00 am Eastern Time (2:00 pm Central European Time). To participate in this conference call, dial +1-866-966-1396 (toll free) or +44 2071 928011 (International), and enter passcode **8599310**. A live webcast of the conference call is available via this link and also in the Investor Relations section of the Auris Medical website at [www.aurismedical.com](http://www.aurismedical.com). A replay of the conference call will be available approximately two hours following the live call.

## About Auris Medical

Auris Medical is a biopharmaceutical company dedicated to developing therapeutics that address important unmet medical needs in neurotology and CNS disorders. The company is focused on the development of intranasal betahistine for the treatment of vertigo (AM-125) and for the prevention of antipsychotic-induced weight gain and somnolence (AM-201). These projects have gone through two Phase 1 trials and moved into proof-of-concept studies in 2019. In addition Auris Medical has two Phase 3 programs under development: Sonsuvi<sup>®</sup> (AM-111) for acute inner ear hearing loss and Keyzilen<sup>®</sup> (AM-101) for acute inner ear tinnitus. The Company was founded in 2003 and is headquartered in Hamilton, Bermuda with its main operations in Basel, Switzerland. The shares of Auris Medical Holding Ltd. trade on the NASDAQ Capital 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 facts 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", or the negative of these terms or 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 delays and other impacts on Auris Medical's business and clinical trials that may be caused by the COVID-19 pandemic, Auris Medical's need for and ability to raise substantial additional funding to continue the development of its product candidates, the ability to pursue strategic partnering and non-dilutive funding for its Phase 3 programs, the results of Auris Medical's review of strategic options and the outcome of any action taken as a result of such review, the timing and conduct of clinical trials of Auris Medical's product candidates, the clinical utility of Auris Medical's product candidates, 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 for the year ended December 31, 2019, and in Auris Medical's other filings with the SEC, which are available free of charge on the Securities Exchange Commission's website at: [www.sec.gov](http://www.sec.gov). Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated. All forward-looking statements and all subsequent written and oral forward-looking statements attributable to Auris Medical or to persons acting on behalf of Auris Medical are expressly qualified in their entirety by reference to these risks and uncertainties. You should not place undue reliance on forward-looking statements. 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.*

## Investor contact:

Joseph Green  
Edison Advisors for Auris Medical  
646-653-7030 / 7719  
[jgreen@edisongroup.com](mailto:jgreen@edisongroup.com)

Or

[investors@aurismedical.com](mailto:investors@aurismedical.com)

**AURIS MEDICAL HOLDING Ltd.**  
**Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Loss**  
For the Six and Twelve Months Ended December 31, 2019 and 2018 (in CHF)

	<b>SIX MONTHS</b>		<b>TWELVE MONTHS</b>	
	<b>ENDED DECEMBER 31</b>		<b>ENDED DECEMBER 31</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Research and development	(2,020,990)	(1,731,968)	(3,325,281)	(6,689,589)
General and administrative	(1,130,596)	(1,805,113)	(3,933,863)	(4,264,534)
<b>Operating loss</b>	<b>(3,151,586)</b>	<b>(3,537,081)</b>	<b>(7,259,144)</b>	<b>(10,954,123)</b>
Interest income	17,882	—	17,882	—
Interest expense	(3,367)	(214,020)	(28,628)	(1,070,177)
Foreign currency exchange gain/(loss), net	44,548	(73,956)	(219,573)	(139,870)
Revaluation gain / (loss) from derivative financial instruments	132,480	(2,557,887)	663,725	1,350,071
Transaction costs	—	(108,809)	—	(520,125)
<b>Loss before tax</b>	<b>(2,960,043)</b>	<b>(6,491,753)</b>	<b>(6,825,738)</b>	<b>(11,334,224)</b>
Income tax gain/(loss)	(67,557)	(179,630)	193,837	(162,177)
<b>Net loss attributable to owners of the Company</b>	<b>(3,027,600)</b>	<b>(6,671,383)</b>	<b>(6,631,901)</b>	<b>(11,496,401)</b>
<b>Other comprehensive income/(loss):</b>				
<b>Items that will never be reclassified to profit or loss</b>				
Remeasurement of defined benefit liability, net of taxes of CHF 0	43,356	192,090	(72,010)	1,277,192
<b>Items that are or may be reclassified to profit or loss</b>				
Foreign currency translation differences, net of taxes of CHF 0	9,780	8,065	16,446	(10,964)
<b>Other comprehensive income/(loss)</b>	<b>53,136</b>	<b>200,155</b>	<b>(55,564)</b>	<b>1,266,228</b>
<b>Total comprehensive loss attributable to owners of the Company</b>	<b>(2,974,464)</b>	<b>(6,471,228)</b>	<b>(6,687,465)</b>	<b>(10,230,173)</b>
Basic and diluted loss per share	(0.83)	(5.17)	(2.28)	(14.46)
Average weighted number of shares outstanding, adjusted for effect of reverse stock split	3,628,614	1,289,639	2,909,056	795,043

**AURIS MEDICAL HOLDING Ltd.**  
**Condensed Consolidated Statement of Financial Position**  
(in CHF)

	<b>DECEMBER 31,</b> <b>2019</b>	<b>DECEMBER 31,</b> <b>2018</b>
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property and equipment	66,672	33,895
Intangible assets	6,765,613	3,535,240
Derivative financial instruments	—	226,865
Other non-current financial receivables	20,001	16,001
<b>Total non-current assets</b>	<b>6,852,286</b>	<b>3,812,001</b>
<b>Current assets</b>		
Other receivables	335,299	320,374
Prepayments	434,231	351,283
Derivative financial instruments	219,615	—
Cash and cash equivalents	1,384,720	5,393,207
<b>Total current assets</b>	<b>2,373,865</b>	<b>6,064,864</b>
<b>Total assets</b>	<b>9,226,151</b>	<b>9,876,865</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Share capital	1,650,380	710,336
Share premium	157,191,707	149,286,723
Foreign currency translation reserve	(27,565)	(44,011)
Accumulated deficit	(152,778,389)	(146,303,398)
<b>Total shareholders (deficit)/equity attributable to owners of the Company</b>	<b>6,036,133</b>	<b>3,649,650</b>
<b>Non-current liabilities</b>		
Derivative financial instruments	4,353	675,328
Employee benefit liability	760,447	648,287
Deferred tax liabilities	147,149	340,986
<b>Total non-current liabilities</b>	<b>911,949</b>	<b>1,664,601</b>
<b>Current liabilities</b>		
Loan	—	1,435,400
Trade and other payables	938,247	1,836,335
Accrued expenses	1,339,822	1,290,879
<b>Total current liabilities</b>	<b>2,278,069</b>	<b>4,562,614</b>
<b>Total liabilities</b>	<b>3,190,018</b>	<b>6,227,215</b>
<b>Total equity and liabilities</b>	<b>9,226,151</b>	<b>9,876,865</b>