
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 September, 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

AM-125 Results

On September 3, 2020, Auris Medical Holding Ltd. (the “Company”) issued a press release announcing positive interim data from its TRAVERS Phase 2 Study with AM-125 in Vertigo, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

AM-201 Results

On May 26, 2020, the Company issued a press release announcing positive top-line data from AM-201 Phase 1b Study in antipsychotic-induced weight gain, a copy of which is attached hereto as Exhibit 99.2 and is incorporated herein in its entirety by reference.

INCORPORATION BY REFERENCE

This Report on Form 6-K, including Exhibits 99.1 and 99.2 to this Report on Form 6-K, shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number [333-228121](#)) and Form S-8 (Registration Number [333-232735](#)) of Auris Medical Holding Ltd. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

| Exhibit Number | Description |
|-----------------------|---|
| 99.1 | Press Release, dated September 3, 2020, of Auris Medical Holding Ltd. |
| 99.2 | Press Release, dated May 26, 2020, of Auris Medical Holding Ltd. |

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 Ltd.

Date: September 11, 2020

By: /s/ Thomas Meyer

Name: Thomas Meyer

Title: Chief Executive Officer



Auris Medical Announces Positive Interim Data from TRAVERS Phase 2 Study with AM-125 in Vertigo

- Dose dependent improvement in balance tests over placebo in Part A of TRAVERS trial
- Improvement 1.9 to 2.4 times greater with highest dose than with placebo
- Trial to proceed with Part B to test AM-125 10 and 20 mg vs. placebo

Hamilton, Bermuda, September 3, 2020 – Auris Medical Holding Ltd. (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in neurotology and central nervous system disorders, today announced positive top-line data from the interim analysis of its Phase 2 “TRAVERS” trial with intranasal betahistine in vertigo (AM-125).

The interim analysis was based on Part A of the trial, which enrolled 33 patients suffering from vertigo following neurosurgery who were treated with AM-125 1, 10 or 20 mg or placebo (3 x daily) for four weeks. It demonstrated a dose-dependent improvement in balance as well as good safety and tolerability of ascending doses of AM-125. At the highest dose of 20 mg (3 x daily), AM-125-treated patients improved their performance of the “Tandem Romberg” and the “Standing on Foam” balance tests from baseline to 14 days post-surgery (primary endpoint) on average 1.9 to 2.4 times more than placebo-treated patients (6.0 vs. 3.1 and 10.5 vs. 4.3 seconds, respectively). In contrast to placebo, the improvement from baseline was statistically significant for AM-125 20 mg and for all active dose groups, respectively ($p < 0.02$ and $p < 0.01$ to $p < 0.05$, respectively). These positive results were supported by similar improvements in additional efficacy measures, including additional objective as well as clinician- and patient-reported outcomes.

“We are very excited and encouraged by the good safety and tolerability as well as the strong and consistent signals of AM-125’s clinical efficacy observed in this first part of the TRAVERS trial,” commented Thomas Meyer, Auris Medical’s founder, Chairman and CEO. “For patients suffering from vertigo, regaining balance as quickly as possible is of utmost importance. Unlike other vertigo drugs that suppress the vestibular function to treat just short-term symptoms such as nausea, AM-125 acts as a vestibular stimulant to enhance and accelerate vestibular compensation and help patients to ‘get back on their feet’. There is a strong medical need for a novel drug in this area, with e.g. 35.4% of the US population aged 40 years and older suffering from vestibular dysfunction (i.e. failing the “Standing on Foam” test).¹ We look forward to advancing the AM-125 program further in order to bring this innovative nasal spray to patients.”

Based on the results from the interim analysis, the two highest doses, 10 and 20 mg, were selected by the Company to be tested against placebo in 72 patients in Part B of the trial. As the Company remained blinded to treatment allocation during the interim analysis, the corresponding data from Part A will be pooled with those from Part B. The improvement in the “Standing on Foam” test will become the sole primary efficacy endpoint. This test measures how long patients are able to maintain balance on a foam mat (to obscure proprioceptive input) with their eyes closed (to eliminate visual input), relying primarily on vestibular input from their inner ears. The improvement in the more challenging “Tandem Romberg” test, which is performed with eyes closed and the two feet to aligned one after the other, will become the key secondary efficacy endpoint. Prior to starting Part B of the trial, open label testing of oral betahistine for reference purposes will be completed (n=16).

¹ Agrawal Y et al. (2009), Disorders of Balance and Vestibular Function in US Adults - Data From the National Health and Nutrition Examination Survey, 2001-2004, Arch Intern Med. 169(10):938-944.

About Betahistine

Betahistine is a small molecule structural analog of histamine, which acts as an agonist at the H1 and as an antagonist at the H3 histamine receptors. Unlike histamine, it crosses the blood-brain barrier. It is known to enhance inner ear and cerebral blood flow, increase histamine turnover and enhance histamine release in the brain, increase release of acetylcholine, dopamine and norepinephrine in the brain and to result in general brain arousal. The compound has a very good safety profile, yet it is also known that its clinical utility is held back by poor bioavailability. Intranasal administration of betahistine has been shown to result in 5 to 29 times higher bioavailability.

About AM-125

Intranasal betahistine is being developed under project code AM-125 for the treatment of acute vertigo. Betahistine has been shown to increase cochlear, vestibular and cerebral blood flow, facilitate vestibular compensation and inhibit neuronal firing in the vestibular nuclei. Betahistine for oral administration is approved in about 115 countries, with the US being a notable exception, for the treatment of vertigo and Meniere's disease.

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, in Phase 2) and for the prevention of antipsychotic-induced weight gain and somnolence (AM-201, post Phase 1b). In addition Auris Medical has two Phase 3 programs under development: Sonsuvi® (AM-111) for acute inner ear hearing loss and Keyzilen® (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, 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. 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.

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Auris Medical Announces Positive Top-Line Data from AM-201 Phase 1b Study in Antipsychotic-Induced Weight Gain and Provides Update on TRAVERS Phase 2 Study

- Administration of intranasal betahistine 30 mg shows statistically significant reduction in olanzapine-induced weight gain
- Treatment well tolerated and safe with no adverse effects
- Enrollment into Phase 2 TRAVERS trial with AM-125 resumed following break due to COVID-19 pandemic

Hamilton, Bermuda, May 26, 2020 – Auris Medical Holding Ltd. (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in neurotology and central nervous system disorders, today announced positive top-line data from its Phase 1b trial with AM-201 in antipsychotic-induced weight gain and provided an update on the enrollment into its Phase 2 trial with AM-125 in vertigo.

The Phase 1b trial demonstrated good safety and tolerability of ascending doses of AM-201 as well as a dose-dependent reduction in weight gain in healthy volunteers treated with oral olanzapine (10 mg) for four weeks. At the highest AM-201 dose of 30 mg administered three times daily, the mean weight gain from baseline to the end of the treatment period was 2.8 kg compared against 3.7 kg in control subjects; the primary efficacy endpoint of mean reduction in weight gain was 0.9 kg and statistically significant ($p < 0.02$; $n = 81$ with pre-specified Bayesian augmented controls). As expected, intranasal delivery of betahistine allowed for substantially higher concentrations in blood plasma compared with levels previously reported for oral betahistine.

“We are very pleased with the positive safety, efficacy and pharmacokinetic outcomes achieved with intranasal betahistine in our first clinical trial for the prevention of antipsychotic-induced weight gain“, commented Thomas Meyer, Auris Medical’s founder, Chairman and CEO. “Weight gain and related metabolic or cardiovascular problems are major side effects of olanzapine and other antipsychotic medications, which often results in a major burden on the health and quality of life of patients. We are delighted to see the positive efficacy signals with AM-201 as well as the excellent tolerability of the nasal spray application in the Phase 1b trial.” Following completion of the data analysis, the Company intends to prepare a Phase 2 clinical trial and to disclose detailed results from the study in a scientific journal.

In addition, the Company announced that the Phase 2 TRAVERS trial with AM-125 in acute peripheral vertigo has resumed enrollment. The COVID-19 outbreak had led to a standstill of recruitment towards the end of March 2020 as trial sites postponed elective surgeries, including those generating the type of acute vertigo required for study participation, and temporarily reduced or suspended clinical research activities. As the COVID-19 outbreak has started to subside in several European countries, a small number of trial sites have resumed recruitment in the past few weeks. Barring the reintroduction of COVID-19 related restrictions, the Company expects further sites to reopen in the coming weeks and the interim analysis following Part A of the trial to be completed in the third quarter of 2020.

About Betahistine

Betahistine is a small molecule structural analog of histamine, which acts as an agonist at the H₁ and as an antagonist at the H₃ histamine receptors. Unlike histamine, it crosses the blood-brain-barrier. It is known to enhance inner ear and cerebral blood flow, increase histamine turnover and enhance histamine release in the brain, increase release of acetylcholine, dopamine and norepinephrine in the brain and to result in general brain arousal. The compound has a very good safety profile, yet it is also known that its clinical utility is held back by poor bioavailability. Intranasal administration of betahistine has been shown to result in 5 to 29 times higher bioavailability.

Auris Medical Holding Ltd., Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda www.aurismedical.com

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About AM-201

Intranasal betahistine is being developed under project code AM-201 for the prevention of antipsychotic-induced weight gain and somnolence. Many antipsychotic drugs are known to block the H₁ histamine receptor, which is involved in the control of appetite and wakefulness, resulting in weight gain and somnolence as side effects. As an H₁ receptor agonist, betahistine is thought to counteract the antipsychotics' inhibitory effects; in addition, betahistine blocks presynaptic H₃ histamine autoreceptors, thus increasing histamine release and in turn augmenting betahistine's direct agonistic effects on H₁ receptors.

About Auris Medical

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