
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, 2021

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

INCORPORATION BY REFERENCE

This Report on Form 6-K, including Exhibit 99.1 to this Report on Form 6-K, shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Numbers [333-228121](#) and [333-249347](#)) and Form S-8 (Registration Numbers [333-232735](#) and [333-252141](#)) 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 and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

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.

By: /s/ Thomas Meyer

Name: Thomas Meyer

Title: Chief Executive Officer

Date: April 13, 2021

EXHIBIT INDEX

Exhibit Number	Description
99.1	<u>Press Release dated April 13, 2021</u>



Auris Medical Announces Positive Preclinical and Clinical Outcomes with AM-301 and Details Plans for Market Launch

- Clinical evaluation of AM-301 nasal spray in allergic rhinitis meets primary endpoint
- Extended protection achieved over several hours
- Preliminary preclinical data suggest therapeutic utility post SARS-CoV-2 infection
- Product launch under Bentrío™ brand in selected European countries towards end of Q2 2021

Hamilton, Bermuda, April 13, 2021 – Auris Medical Holding Ltd. (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in neurotology, rhinology and allergy and CNS disorders, and its affiliate Altamira Medica Ltd. today provided an update on its AM-301 program for protection against airborne viruses and allergens.

“We are very pleased to report on major progress with our AM-301 nasal spray program, which is moving in large steps forward towards the start of commercialization”, commented Thomas Meyer, Auris Medical’s founder, Chairman and CEO. “AM-301 has been designed to provide a triple protective effect by acting as a protective layer on the nasal mucosa, trapping and helping to remove airborne particles and humidification of the mucosa. Fresh preclinical and clinical data confirm AM-301’s protective effects in case of exposure to airborne allergens and suggest potential utility of the product also in case of ongoing infection from SARS-CoV-2. We have numerous additional studies ongoing or planned and look forward to sharing further outcomes, including through scientific communications.”

AM-301 effectively alleviates allergy symptoms in clinical pollen challenge

Altamira Medica recently completed the treatment phase of its open-label randomized cross-over clinical investigation of AM-301 in 36 patients with allergic rhinitis to grass pollen. Study participants were administered a single dose of AM-301 nasal spray or a comparator product prior to controlled pollen exposure for four hours in an allergen challenge chamber. The challenge was repeated with the alternate treatment following a wash-out period. Preliminary analyses show that AM-301 met the primary endpoint of non-inferiority in the Total Nasal Symptom Score (TNSS) relative to the marketed comparator product, which serves as the predicate device for the planned 510(k) submission to the US Food and Drug Administration (FDA). In addition, the treatment was well tolerated. Proof of substantial equivalence to the predicate device is a key requirement for market clearance under the 510(k) regulatory pathway.

Furthermore, the allergen challenge study demonstrated a rapid onset and long durability of AM-301’s protective effect, as measured by a clinically relevant 1-point reduction in the TNSS compared to unprotected pollen exposure. On average, the protective effect was maintained for at least three hours. These clinical observations are in line with the results from a new *in vitro* study based on a barrier diffusion model. The assay, which was performed at 35°C and 90% relative humidity to mimic conditions within the nasal cavity, showed that a thin layer of AM-301 prevented Timothy grass pollen from diffusing into an agar block for up to 6 hours, the maximum duration of the experiment.

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www.aurismedical.com

AM-301 helps to reduce growth in infectious titer in ongoing SARS-CoV-2 infection

In parallel with the outcomes from the allergy studies, Altamira Medica obtained first data from testing AM-301 *after* the start of infection of human nasal epithelium cells with SARS-CoV-2. In a previous study in the same type of assay, AM-301 had been shown to be highly effective in reducing the infectious viral titer when daily treatment was started right before inoculation of the cells, i.e. in a preventative fashion. In the new experiment, daily treatment with AM-301 started 24 or 30 hours post inoculation. Saline- and vehicle-treated and untreated cell cultures served as controls.

In control cultures, SARS-CoV-2 replicated efficiently over four days, resulting in a rapid increase in viral titer (as measured by the Median Tissue Culture Infectious Dose, TCID50, in Vero cells). Daily treatment with AM-301 resulted in a statistically significant deceleration of the viral titer growth compared to controls (p-value <0.01, linear mixed-effects model). At Day 4 of the experiment, viral titers were 73.7 to 94.5% lower compared to controls.

Selection of Bentrío™ brand name for commercialization

With the ongoing progress in the development and testing of AM-301, the Company expects to meet the essential requirements for marketing the product in Europe under the CE mark shortly. Altamira Medica intends to launch the commercialization of AM-301 under the brand name *Bentrío™* in selected European countries starting in June 2021, employing various on- and offline distribution channels. The Company expects to expand market coverage rapidly during the second half of 2021, including collaborations with future licensing partners. The expansion will be supported by significant, scalable production capacity of the Company's contract manufacturing partner.

Upon readiness for CE mark conformity, Altamira Medica expects to submit a 510(k) pre-market notification application to the FDA requesting regulatory clearance for AM-301 for the intended use in allergy. Regarding the intended use in viral infections, the Company continues to be engaged in a dialogue with the FDA on the applicable regulatory pathway.

Conference Call & Webcast

Auris Medical's management team will host a live conference call and webcast to present a business update on the AM-301 program at 8:00 am Eastern Time (2:00 pm Central European Time). To participate in this conference call, dial +1-877-870-9135 (US, toll free) or +44-2071-928-338 (international), and enter passcode 5649276. A live webcast of the conference call can be accessed in the Investor Relations section of the Auris Medical website at www.aurismedical.com. A replay will be available approximately two hours following the live call.

About AM-301

AM-301 is a drug-free nasal spray for personal protection against airborne viruses and allergens. Upon application into the nose, AM-301 forms a protective gel layer on the nasal mucosa. This thin film is designed to prevent the contact of viruses or allergens with cells; in addition, the composition serves to bind such particles and help with their discharge and to humidify the nasal mucosa. Together, this is designed to reduce the risk of upper respiratory tract viral infections and promote alleviation of allergic symptoms.

About Auris Medical

Auris Medical is a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in neurotology, rhinology and allergy 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). Through its affiliate Altamira Medica, the Company is developing a nasal spray for protection against airborne viruses and allergens (AM-301). 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, the approval and timing of commercialization of AM-301, Auris Medical's need for and ability to raise substantial additional funding to continue the development of its product candidates, 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, 2020, 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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