
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 March, 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

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: March 31, 2021

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated March 31, 2021

Auris Medical Provides Business Update and Reports Second Half and Full Year 2020 Financial Results

- Clinical evaluation of AM-301 nasal spray in allergen protection progressing
- Launch of AM-301 expected in selected markets towards the end of second quarter 2021
- Phase 2 trial with AM-125 in acute vertigo expected to complete enrollment in third quarter 2021
- Equity and cash position significantly strengthened
- Strategy review ongoing

Hamilton, Bermuda, March 31, 2021 – Auris Medical Holding AG (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in neurotology, rhinology and allergy and CNS disorders, today provided a business update and announced second half and full year 2020 financial results.

“The 2020 business year has been quite transformative for our company as we initiated the development of AM-301, a nasal spray designated for self-protection against airborne viruses and allergens,” stated Thomas Meyer, Auris Medical’s founder, Chairman and CEO. “With a highly dedicated team, we managed to develop in less than six months a drug-free nasal spray that reduced the SARS-CoV-2 viral titer in a model representative of the human nasal mucosa by more than 99%. The project has taken on strong momentum, and we look forward to making AM-301 available to consumers, starting towards the end of the second quarter 2021 in selected markets. With this, we expect to become a commercial stage company quite shortly.” He continued: “The project benefited greatly from our experience acquired with AM-125, our nasal spray for the treatment of acute vertigo. Here, we obtained last year promising interim data in our Phase 2 trial and expect the trial to read out in 2021. Last, but not least, we entered the new business year with a significantly stronger balance sheet, and strengthened our cash position further in the first quarter of 2021.”

Development Program Updates

AM-125 for Treating Acute Vertigo

- Initiated Part B of TRAVERS trial. Following the positive results from the interim analysis in the Phase 2 trial with AM-125, including a dose dependent improvement in patients’ performance of the “Tandem Romberg” and the “Standing on Foam” balance tests, 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. Enrollment into Part B started in October 2020.
- COVID-19 pandemic causing temporary delay in enrollment. Recruitment into the TRAVERS trial slowed down considerably in early 2021 as several study sites postponed elective procedures and temporarily reduced or suspended clinical research activities. Candidates for participation in the TRAVERS trial undergo certain types of neurosurgery, which are elective procedures. Recruitment rates recovered somewhat in March, but they may continue to be impacted for some time. Although sites are expected to catch up on enrollment once COVID-19 related restrictions are relaxed, the Company expects that results from the trial will become only available in the third quarter of 2021, at the earliest.

AM-301 for Protecting Against Airborne Viruses and Allergens

- Initiated clinical investigation of AM-301 in allergic rhinitis. In January 2021, the Company announced the initiation of an open-label randomized cross-over study that will enroll 36 patients with allergic rhinitis to grass pollen. Study participants are administered a single dose of AM-301 nasal spray or a comparator product (one puff into each nostril) prior to controlled pollen exposure for four hours in an allergen challenge chamber. The challenge is repeated with the alternate treatment following a wash-out period. The difference in the Total Nasal Symptom Score (TNSS) between the two treatments over the 4-hour exposure will serve as the primary efficacy endpoint; the investigation shall demonstrate clinical non-inferiority of AM-301 to the comparator product. Results from the clinical investigation are expected to become available in a few weeks.

- Continued preclinical testing program. The Company has initiated or planned several *in vitro* and *in vivo* tests to generate additional data for the intended use in allergies and viral infection. These will assess, among others, the potential capacity of AM-301 reduce the viral titer *post* infection with SARS-CoV-2, the effects of AM-301 on some of the new virus strains as well as on other types of virus, and the durability of its barrier function against pollen.
- Advanced preparations for launch in selected markets late in the second quarter 2021. The Company expects to meet the requirements for CE marking, a prerequisite for commercializing AM-301 in Europe, in the second quarter of 2021 and is currently scaling up the manufacturing process for launch of the product in selected European markets towards the end of the quarter. In the US, the Company is engaged in a dialogue with the FDA on the proposed product development plan and the applicable regulatory pathway. The Company continues to expect that AM-301 will be eligible for clearance through the 510(k) pathway for the intended use in allergy.

Corporate Developments

- Retained full control over Altamira Medica affiliate. The Company increased the share capital of Altamira Medica Ltd. (“Altamira”), its affiliate dedicated to developing and commercializing AM-301, from CHF 0.5 to 3 million to accommodate the progress of the program. A convertible loan of CHF 1.5 million to Altamira was converted in two steps in shares of Auris Medical Holding Ltd., allowing the Company to retain full control of its affiliate.
- Raised CHF 16.6 million (gross) in equity. The Company significantly strengthened its balance sheet and cash position through several transactions in December 2020 and March 2021. These included the placement of 2,000,000 common shares with certain institutional investors at an offering price of \$4.00 per share as well as the exercise of 2,161,280 warrants held by the investors in the May 2019 offering at an exercise price of CHF 4.34. All warrants issued through the May 2019 Offering have been exercised by now.
- Continued strategy review. In September 2020, the Company’s Board of Directors started a process to explore, review and evaluate a broad range of potential strategic alternatives with the aim of unlocking the potential of the Company’s assets and maximize shareholder value. In this context, the Board has been holding discussions with several parties about certain potential transactions. At this point, there can be no assurance the Company’s strategy review will result in the completion of any particular course of action, and there is no defined timeline for completion of the review process.

Second Half 2020 Financial Results

- Total operating expenses for the second half of 2020 were CHF 2.9 million compared to CHF 3.2 million for the second half of 2019.
- Research and development expenses for the second half of 2020 were CHF 2.0 million compared to CHF 2.0 million for the second half of 2019.¹
- General and administrative expenses for the second half of 2020 were CHF 1.1 million compared to CHF 1.1 million for the second half of 2019.
- Net loss for the second half of 2020 was CHF 5.5 million, or CHF 0.75 per share, compared to CHF 3.0 million, or CHF 0.83 per share, for the second half of 2019.
- Cash and cash equivalents at December 31, 2020, totaled to CHF 11.3 million.

Full Year 2020 Financial Results

- Total operating expenses for 2020 were CHF 5.3 million compared to CHF 7.3 million for 2019.
- Research and development expenses for 2020 were CHF 2.9 million compared to CHF 3.3 million for 2019.¹
- General and administrative expenses for 2020 were CHF 2.6 million compared to CHF 3.9 million for 2019.
- Net loss attributable to owners of the Company for 2020 was CHF 8.2 million, or CHF 1.36 per share, compared to CHF 6.6 million, or CHF 2.28 per share, for 2019.

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

The Company expects its total cash needs in 2021 to be in the range of CHF 11.5 to 13 million for expected total operating expenses of CHF 7 to 7.5 million and expected capitalized research and development costs of CHF 4.5 to 5.5 million. Further cash needs may arise in 2021 related to the manufacture of AM-301 as well as marketing and sale activities as the Company intends to commercialize the product in selected markets; these cash needs may initially not be covered by cash flows from product revenues.

Conference Call & Webcast - Rescheduled

Please note that Auris Medical will host a conference call and webcast to present a business update on Tuesday, April 13, 2021, at 8:00 am Eastern Time (2:00 pm Central European Time). This event will be dedicated in full to the AM-301 program and replace the conference call and webcast which was initially scheduled for today, March 31, 2021. Further details will be provided shortly before the event.

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, 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.

Investor contact:

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AURIS MEDICAL HOLDING Ltd.
Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Loss
For the Six and Twelve Months Ended December 31, 2020 and 2019 (in CHF)

	SIX MONTHS ENDED DECEMBER 31		TWELVE MONTHS ENDED DECEMBER 31	
	2020	2019	2020	2019
Other operating income	174,475	—	174,475	—
Research and development	(1,978,232)	(2,020,990)	(2,862,979)	(3,325,281)
General and administrative	(1,058,702)	(1,130,596)	(2,594,662)	(3,933,863)
Operating loss	(2,862,459)	(3,151,586)	(5,283,166)	(7,259,144)
Interest income	258	17,882	258	17,882
Interest expense	(131,999)	(3,367)	(135,151)	(28,628)
Foreign currency exchange gain/(loss), net	(303,531)	44,548	(333,553)	(219,573)
Revaluation gain / (loss) from derivative financial instruments	(2,254,575)	132,480	(2,250,222)	663,725
Transaction costs	—	—	(219,615)	—
Loss before tax	(5,552,306)	(2,960,043)	(8,221,449)	(6,825,738)
Income tax gain/(loss)	10,642	(67,557)	21,284	193,837
Net loss attributable to owners of the Company	(5,541,664)	(3,027,600)	(8,200,165)	(6,631,901)
Other comprehensive income/(loss):				
Items that will never be reclassified to profit or loss				
Remeasurement of defined benefit liability, net of taxes of CHF = 0	51,892	43,356	(26,118)	(72,010)
Items that are or may be reclassified to profit or loss				
Foreign currency translation differences, net of taxes of CHF = 0	72,466	9,780	88,862	16,446
Other comprehensive income/(loss)	124,358	53,136	62,744	(55,564)
Total comprehensive loss attributable to owners of the Company	(5,417,306)	(2,974,464)	(8,137,421)	(6,687,465)
Basic and diluted loss per share	(0.75)	(0.83)	(1.36)	(2.28)
Average weighted number of shares outstanding	7,432,839	3,628,614	6,014,146	2,909,056

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

	DECEMBER 31, 2020	DECEMBER 31, 2019
ASSETS		
Non-current assets		
Property and equipment	46,636	66,672
Intangible assets	9,115,410	6,765,613
Other non-current receivables	20,001	20,001
Total non-current assets	9,182,047	6,852,286
Current assets		
Other receivables	80,861	335,299
Prepayments	277,589	434,231
Derivative financial instruments	—	219,615
Cash and cash equivalents	11,258,870	1,384,720
Total current assets	11,617,320	2,373,865
Total assets	20,799,367	9,226,151
EQUITY AND LIABILITIES		
Equity		
Share capital	114,172	1,650,380
Share premium	177,230,300	157,191,707
Foreign currency translation reserve	61,297	(27,565)
Accumulated deficit	(160,635,879)	(152,778,389)
Total shareholders' (deficit)/equity attributable to owners of the Company	16,769,890	6,036,133
Non-current liabilities		
Derivative financial instruments	6,318	4,353
Employee benefit liability	867,376	760,447
Deferred tax liabilities	125,865	147,149
Total non-current liabilities	999,559	911,949
Current liabilities		
Loan	523,920	—
Derivative financial instruments	310,439	—
Trade and other payables	762,453	938,247
Accrued expenses	1,433,106	1,339,822
Total current liabilities	3,029,918	2,278,069
Total liabilities	4,029,477	3,190,018
Total equity and liabilities	20,799,367	9,226,151