U.S. Securities & Exchange Commission
Division of Corporate Finance
100 F Street, NE
Washington, D.C. 20549

June 19, 2020

Re: Auris Medical Holding Ltd.
Form 20-F for the Fiscal Year ended December 31, 2019
Filed April 16, 2020
File No. 001-36582

Dear Sir, Madam,

On behalf of Auris Medical Holding Ltd (the "Company"), this letter responds to the comment received from the Staff of the Division of Corporation Finance (the "Staff") of the Securities and Exchange Commission (the "Commission") in a letter dated June 8, 2020 (the "Comment Letter") pertaining to the captioned report on Form 20-F. For ease of reference in this letter, the Staff's comment contained in the Comment Letter is reproduced in bold in this letter, and the corresponding response of the Company is shown below the comment.

1. **We reference the disclosure that direct expenditures related to AM-125 are capitalized because the criteria discussed in Note 3 have been met. We also note the discussion on page F-9 that the development is primarily focused on the delivery route and formulation and not the drug itself. Since you have not received regulatory approval for AM-125 please provide us with your analysis of paragraph 57 of IAS 38 in determining that the expenditures meet the criteria for capitalization.**

As requested, we are pleased to provide you below with our analysis of paragraph 57 of IAS 38 Intangible Assets ("IAS 38") in determining that the AM-125 project (the "Project") expenditures meet the criteria for capitalization:

According to IAS 38.57 *"… an intangible asset arising from development (or from the development phase of an internal project) shall be recognised if, and only if, an entity can demonstrate all of the following:*

a. the technical feasibility of completing the intangible asset so that it will be available for use or sale.

b. its intention to complete the intangible asset and use or sell it.

c. its ability to use or sell the intangible asset.

d. how the intangible asset will generate probable future economic benefits. Among other things, the entity can demonstrate the existence of a market for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset

e. the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.

f. its ability to measure reliably the expenditure attributable to the intangible asset during its development."

We have outlined below our consideration of each of the criteria specified in IAS 38.57 above in relation to the Project:

a) Technical feasibility of completing the intangible asset so that it will be available for use or sale.

The Project is a reformulation of betahistine dihydrochloride for intranasal delivery, a generic compound that has been approved and marketed in an oral formulation for several decades for the treatment of vertigo in 115 countries worldwide. Betahistine is recognized as a safe drug, and there exists a large body of data on the pharmacology, pharmacokinetics and toxicology of the compound. However, poor bioavailability of orally administered betahistine due to a strong "first pass effect" is limiting its efficacy, whereas higher bioavailability has been demonstrated to increase betahistine's therapeutic effects on vertigo (for a description of the Project, please refer to item 4, section B, page 50 et seq. in the Company's 20-F for the 2019 fiscal year).

As betahistine dihydrochloride is already approved by regulatory authorities as a generic compound and we are not altering the indication to which it relates, our analysis of the technical feasibility for purposes of capitalization of development costs is focused on the level of uncertainties, technical complexities and judgements remaining for reformulation of the compound for intranasal delivery. We note that those levels are significantly reduced due to the extensive pharmacology, pharmacokinetics and toxicology data available from studies conducted by third parties in support of the approval of oral betahistine that would not typically be available for a Phase 1 product under development. E.g. these data include information about the long-term safety or the clinical efficacy of the compound. Further, uncertainties are reduced through the availability of extensive post-marketing safety data from decades of use by a large number of patients as well as additional efficacy data from numerous additional clinical trials with oral betahistine.

The key substantive milestone as to the Project relates to the ability to demonstrate the tolerability and safety of repeated intranasal dosing as well as the superiority in bioavailability compared to oral administration. Once the active substance is present in the bloodstream, reference can be made to the available / known data generated for / with oral betahistine administration, where the active substance is taken into the bloodstream as well, just through a different route. Regardless of the drug administration route, betahistine is distributed via the bloodstream to the pharmacologic target site, and therefore the same set of general pharmacology, pharmacokinetics and toxicology data can be used in a reformulation project like the present one.

As noted above, the key factor underlying the technical feasibility of the Project relates to the ability to demonstrate the tolerability and safety of repeated intranasal dosing as well as the superiority in bioavailability compared to oral administration. Before Q4 2018, the Company disposed of certain preclinical and clinical data acquired from Otifex Therapeutics Ltd., an Australian company, which suggested that intranasal betahistine might be tolerable and safe and result in higher concentrations in the bloodstream than oral betahistine. However, these data were based on a small phase 1 clinical trial in healthy volunteers who had received just one single dose of intranasal betahistine, and on a toxicology study in six dogs that had received intranasal betahistine for two weeks only. These data had not been subjected to independent verification and were insufficient in duration to support the development and approval of a treatment for vertigo extending over several weeks. Also, there was no head to head study comparing betahistine concentrations in the bloodstream.

In early Q4 2018, the Company reached a major milestone in the Project's development as the results from its own phase 1 trial became available. This trial enrolled more subjects than the previous study (72 vs. 50), included also an oral treatment arm for comparison, explored higher doses and, most importantly, evaluated a clinically relevant dose regimen rather than only a single dose. The study demonstrated that betahistine, when administered intranasally, could achieve significantly higher plasma concentrations than with oral administration. Further, it showed good safety and tolerability of the treatment even when administered three times daily (the targeted frequency in clinical use) over three days. At around the same time, the results from a toxicology study as well as a separate biodistribution study in dogs became available, which showed good safety and tolerability with 3 x administration over one month (the targeted duration in clinical use), and provided further insights into the pharmacokinetics of intranasal betahistine. Taken together, the study results established and confirmed the technical / clinical feasibility of intranasal betahistine therapy for vertigo in accordance with the target product profile defined by the Company.

The data obtained in Q4 2018 will be a cornerstone for the Project's regulatory approval process. They will be complemented by the existing body of pharmacology, pharmacokinetics and toxicology data from the marketed generic drug (oral betahistine). This approach is common with reformulation projects. Given the available data from third party sources as well as the proprietary data generated so far, the Company is confident about its ability to obtain regulatory approval in key markets. Although data from further studies will be required to complete the regulatory submission dossiers – the scope of which has been discussed with key regulatory agencies, including the FDA and the EMA – the Company considers them feasible based on available data. These will include preclinical studies (long-term toxicology study in dogs with intranasal administration, developmental and reproductive toxicology in rats) and clinical efficacy studies. As mentioned before, extensive post-marketing pharmacovigilance data show good safety in humans, and it is highly likely that the efficacy of intranasal betahistine will exceed that of oral betahistine in the treatment of vertigo, considering that intranasal betahistine allows for achieving higher concentrations in the bloodstream than oral betahistine, and therapeutic effects are a function of betahistine blood concentrations.

Based on the positive key pharmacokinetic, safety and tolerability outcomes obtained through our studies as well as the availability of a common regulatory pathway for reformulated generic drug products, we judged the technical feasibility including future regulatory approval of the Project as probable.

b) Intention to complete the intangible asset and use or sell it.

As disclosed in the 20-F, we intend to develop the Project for commercialization either through our own resources and/or partnering with other companies. To this end, we have a defined development plan for the Project, which is regularly reviewed by our leadership team and updated as needed. Under the development plan, we initiated in 2019 a phase 2 clinical trial that is expected to complete in 2021, as well as additional preclinical and development work. We plan to initiate one phase 3 clinical trial with AM-125 in 2021, which we expect to complete in 2022. This would allow for marketing approval in the EU in 2024. We plan to conduct one additional phase 3 trial for the US with expected marketing approval in 2024/25.

c) Ability to use or sell the intangible asset.

In assessing whether the Company will have the ability to use or sell the intangible asset, we performed an assessment to determine that there is no restriction or prohibition for the use or sale of the intangible asset. In particular, we undertook a "Freedom to operate" assessment by a patent lawyer which concluded that there are no potentially conflicting intellectual property rights by third parties. In addition, we also considered any other restrictions and noted that we were not restricted in our ability to use or sell the intangible asset by any contractual obligations to third parties (notably our asset purchase agreement with Otifex).

d) How the intangible asset will generate probable future economic benefits.

As mentioned above, oral betahistine is already available in 115 countries around the world. Current annual sales at manufacturer prices are ca. $450 million. We expect to capture part of the existing market primarily based on increased bioavailability / efficacy and secondarily fewer side effects compared to oral betahistine. In addition, we expect the market potential to expand considerably through the introduction of intranasal betahistine in the US market where oral betahistine currently is available only from compounding pharmacies. Our internal financial projections as well as independent research analyst estimates suggest considerable economic benefits of the Project, which are exceeding capitalized development expenditures to a very large degree.

Last, but not least, we consider that the intellectual property generated from the Project can also be monetized through licensing or a sale to a third party. In 2019 we obtained a patent with claims covering composition of matter and methods of use for formulations of betahistine dihydrochloride for intranasal delivery in both the US and Europe. The availability of IP protection has increased the economic value of a license to market Project-derived products. Since 2018, we have already received several unsolicited expressions of interest from third parties in licensing rights to the Project.

Based on the factors noted above, we believe that it is probable that the Project will provide future economic benefits.

e) Availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.

Since its inception, we have funded our development programs, including the Project, through private placements as well public offerings, raising capital in excess of $185 million through 2019. In accordance with IAS 38.61, we expect to raise additional capital through existing financing instruments (ATM, equity line), other share offerings and/or partnering transactions. Our development team has the required expertise in developing drug products and can draw on external expertise and resources from existing or additional external service providers.

As mentioned above, the Project is managed based on a business plan, which outlines the expected costs up to market launch.

f) Ability to measure reliably the expenditure attributable to the intangible asset during its development.

As disclosed in the 20-F, we capitalize only direct Project costs that arise from contracts with our vendors as well as third party expenditures for obtaining Project related intellectual property rights. Such costs are separately tracked by individual projects and thus can be directly attributed to the Project. Accordingly, the measure of these costs is considered straightforward and reliable.

Conclusion

In conclusion, we believe that all the requirements under IAS 38.57 for capitalizing the Project are met. As noted above, the main uncertainty on the Project was related to our ability to demonstrate the tolerability and safety of repeated intranasal dosing as well as the superiority in bioavailability compared to oral administration, which was resolved in Q4, 2018. The remaining development pathway is common in the industry and benefits from the existing body of pharmacology, pharmacokinetics and toxicology data available from the marketed generic drug.

We hope that we could answer your question satisfactorily, and remain at your disposal for any further questions you may have in this matter.

Sincerely yours,

/s/ Elmar Schaerli

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