

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

April 14, 2014

Via E-mail
Thomas Meyer
Chief Executive Officer
Auris Medical AG
Falknerstrasse 4
4001 Basel, Switzerland

Re: Auris Medical AG

Draft Registration Statement on Form F-1

Submitted March 18, 2014

CIK No. 0001601936

Dear Mr. Meyer:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

General

- 1. We note that there are a number of additional exhibits that still need to be filed. Please provide these exhibits as promptly as possible. Please note that we may have comments on these materials once they are provided.
- 2. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
- 3. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please

supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

Prospectus Summary Our Business, page 1

- 4. Please expand your discussion to define the following terms at your first reference in the prospectus summary:
 - "statistically significant"
 - "clinically relevant"
 - "favorable safety profile"
- 5. We note that your product development table indicates that one of the indications for AM-111 is undisclosed. Please revise your table to identify this undisclosed indication if it remains a material part of your product development program for AM-111. Otherwise, please remove reference to product development for this indication form the table.
- 6. Please disclose whether you have applied for an IND for AM-101 and AM-111 and if so, the date the application was filed with the FDA.
- 7. We note that AM-101 is in Phase 3 clinical development for acute inner ear tinnitus under a special protocol assessment, or SPA, from the FDA. Please provide the meaning of a "special protocol assessment, or SPA" the first time you refer to it.
- 8. Please revise your disclosure in this section to indicate the benefits conveyed by orphan drug designation. In addition, please clarify that the granting of a request for orphan designation does not alter the standard regulatory requirements and process for obtaining marketing approval.
- 9. Please explain what you mean by the term "system exposure" and describe why intratympanic injection allows for minimal system exposure.

Risks Associated with Our Business, page 3

10. Please revise your summary of material risks to disclose your accumulated deficit to date.

<u>Implications of being an "Emerging Growth Company," page 3</u>

11. Please expand your disclosure to discuss your status as a foreign private issuer and the exemptions available to you as a foreign private issuer. In this regard, please identify those exemptions which overlap with the ones available to you as an emerging growth

company and to what extent you will continue to enjoy any exemptions as a result of your status as a foreign private issuer once you no longer qualify as an emerging growth company.

Risk Factors

<u>Risks Related to the Development and Clinical Testing of our Product Candidates</u>

If serious adverse, undesirable or unacceptable side effects are identified during the..., page 13

12. We note your disclosure that that a limited number of serious adverse events have occurred in clinical trials of AM-101 and AM-111 and that such events were considered unrelated or unlikely related. Please specify whether such events were determined to be related to the administration of the product candidate or the conduct of the trials. If so, please revise your risk factor to identify the specific serious adverse events, the frequency with which they occurred, and the product candidate being evaluated when the event occurred. Please also include any information regarding serious adverse events in your respective discussions of the clinical trials for AM-101 and AM-111 elsewhere in the prospectus.

We may become exposed to costly and damaging liability claims..., page 14

13. Please quantify the amount of product liability insurance that you carry. Similarly, for any other type of insurance coverage discussed in your prospectus, please quantify the amount of insurance coverage you maintain.

Our special protocol assessment agreement with the FDA for our Phase 3 study...page 18

14. Please include a separate risk factor which discusses the FDA's request for safety data regarding the chronic intermittent use of AM-101 and how a failure to evaluate a sufficient number of patients in underlying safety trials would impact the FDA's review of your NDA submission. Please also specifically highlight the number of patients for which the FDA has requested safety data and any specific safety concerns expressed in the FDA's correspondence.

<u>Risks Related to Regulatory Approval of our Product Candidates</u>
Enacted and future legislation may increase the difficulty and cost..., page 19

15. We note that your risk factor discussion references legislative and regulatory changes in the United States, the European Union and other foreign jurisdictions. However, your risk factor only provides a discussion of such changes in the United States. Please expand your disclosure to discuss the legislative and regulatory changes in the European Union and other foreign jurisdictions which may increase the difficulty and cost for you to obtain marketing approval and to commercialize your product candidates and which may affect the prices you set.

If we fail to maintain our current strategic relationships with INSERM and Xigen..., page 24

16. Please revise your risk factor to provide a summary of the material rights and obligations under your agreements with INSERM and Xigen.

We may not have sufficient patent terms to effectively protect our products and..., page 28

17. Please revise your risk factor discussion to highlight the current expected expiration date for the patents underlying your most advanced product candidates, AM-101 and AM-111.

<u>Risks Related to the Offering and our Common Shares</u> As a foreign private issuer and as permitted by the listing requirements... page 39

18. Please state or list the corporate governance provisions for which you will rely on certain stock exchange exemptions that allow you to follow your home country corporate governance requirements.

Market and Industry Data, page 41

19. We note your statements, "While we believe that each of these publications and third party studies is reliable, we have not independently verified the market and industry data obtained from these third-party sources. While we believe our internal research is reliable and the definition of our market and industry are appropriate, neither such research nor these definitions have been verified by any independent source." It is not appropriate to disclaim liability for information contained in your prospectus. Please revise your disclosure to delete these statements or, alternatively, state that you are liable for this information.

Use of Proceeds, page 43

20. Please quantify the amount of your cash and cash equivalents in this section.

Dilution, page 47

21. Please add a line item to your Dilution table to start with the assumed initial public offering price per common share.

<u>Management's Discussion and Analysis of Financial Condition and Results of Operations Financial Operations Overview</u>

Research and development expense, page 52

22. Please expand your disclosures to include the total costs incurred during each period presented and to date for AM-101 and AM-111 separately.

Significant accounting policies and use of estimates and judgment

Share-based compensation

Valuation of share options, page 61

- 23. Please expand your disclosures to state that the estimates are highly complex and subjective. In addition, please disclose that estimates will not be necessary to determine fair value of new awards once underlying shares begin trading.
- 24. We may have additional comments on your accounting for stock compensation or any beneficial conversion features once you have disclosed an estimated offering price. Please provide us with a quantitative and qualitative analysis explaining the difference between the estimated offering price and the fair value of each equity issuance through the date of effectiveness for the preceding twelve months.

<u>Business</u>

Market, page 65

25. Please expand your disclosure to describe "Meniere's disease."

Our Solution – AM-101, page 68

26. Please identify the academic partner with which you developed a more clinically relevant model of tinnitus induced by acute acoustic trauma, or AAT.

AM-101 Clinical Development

Phase 1/2, page 69

27. Please explain what the term "p-value" refers to and what it indicates about the statistical significance of results obtained from the clinical trials.

AM-111 Clinical Development

Phase 2 Clinical Trial, page 76

28. Please describe the transient procedure related effects which occurred in less than 5% of cases.

Intellectual Property

Patents, page 81

29. We note that your patents and patent applications for AM-101 and AM-111 have foreign counterparts in various jurisdictions. Please expand your disclosure to identify these foreign jurisdictions.

Collaboration and License Agreements INSERM, page 82

30. Please expand your disclosure regarding your co-ownership/exploitation agreement with INSERM to describe the material terms of the agreement, including, but not limited to the parties' rights and obligations under the agreement, duration of the agreement, including any royalty term, termination provisions and payment provisions, including aggregate future potential milestones, royalty rates or profit/revenue sharing provisions. Also, please file the agreement as an exhibit pursuant to Item 601(b)(10) of Regulations S-K.

Xigen, page 82

31. Please expand your disclosure regarding your collaboration and license agreement with Xigen to describe the material terms of the agreement, including, but not limited to the specific compounds which Xigen licensed to you, the parties' rights and obligations under the agreement, duration of the agreement, including any royalty term, termination provisions and payment provisions, aggregate future potential milestones, royalty rates or profit/revenue sharing provisions. Also, please file the agreement as an exhibit pursuant to Item 601(b)(10) of Regulations S-K.

Manufacturing, page 82

32. We note that you currently rely on Lifecore to manufacture the hyaluronic acid component of AM-101 and AM-111. Please disclose whether you have an underlying agreement with Lifecore, and if so, please provide the material terms of the agreement, including, but not limited to the parties' rights and obligations under the agreement, duration of the agreement, termination provisions and any material payment provisions. Also, please file the agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K or provide an analysis as to why you are not required to file this agreement as an exhibit.

Properties, page 90

33. Please file the lease agreement for your headquarters in Basel, Switzerland as an exhibit.

Management

Employment Agreements, page 94

34. We note that certain of your executive officers have entered into employment agreements with the company. Please identify these executive officers and provide the material terms of the employment agreements with these executive officers. Also, please file the employment agreements with your executive officers as exhibits.

Stock Options Plans, page 94

35. Please file Plan A, Plan B and Plan C as exhibits.

Principal and Selling Shareholders, page 95

36. Please state the number of record holders in the United States and the corresponding percentage of your outstanding stock currently held in the United States. See Item 7.A.2 of Form 20-F.

<u>Indemnification Agreements</u>, page 97

37. Once you have entered into indemnification agreements with your managing directors and supervisory directors, please file the form of indemnification agreement as an exhibit.

Description of Share Capital and Articles of Association, page 98

38. Please revise your disclosure to include the information required by Item 10.B of Form 20-F.

Lock-Up Agreements, page 100

39. Please confirm that the lock-up agreement will be filed as part of the underwriting agreement. If not, please file the form of lock-up agreement as an exhibit.

Taxation, page 101

40. Please delete the term "certain" here and in your introductory paragraph under "Swiss Tax Considerations, page 101" and make clear that you discuss all material consequences and considerations. Additionally, to the extent practicable, you should replace the vague term "certain" in your discussion under "Swiss Federal Withholding Tax on Dividends and Distributions, page 101" with substantive disclosure.

Enforcement of Judgments, page 118

41. We note that you have included information related to this section in the risk factor entitled "U.S. shareholders may not be able to obtain judgments or enforce civil liabilities against us or our executive officers or members of our board of directors" on page 38. Please expand your disclosure in this section to also provide the substantive information discussed in the referenced risk factor on page 38.

Notes to the Consolidated Financial Statements

12. Capital and reserves

Issue of preferred shares, page F-20

42. Please expand your disclosures to clarify that in the event of an initial public offering, all of the outstanding preferred shares will convert into common shares.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Vanessa Robertson at (202) 551-3649 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Johnny Gharib at (202) 551-3170, Bryan Pitko at (202) 551-3203 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Bryan J. Pitko for

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-mail</u> Richard D. Truesdell, Esq.

Davis Polk & Wardwell LLP