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FOIA Confidential Treatment Request Pursuant to Rule 83 by Auris Medical AG

April 18, 2014

Re: Auris Medical AG

Amendment No. 1 to Draft Registration Statement on Form F-1

**Confidentially Submitted March 18, 2014** 

CONFIDENTIAL

Mr. John Gharib Division of Corporation Finance U.S. Securities and Exchange Commission 100 F Street, N.E. Mail Stop 4720 Washington, DC 20549-3628

Dear Mr. Gharib,

On behalf of our client, Auris Medical AG, a private company organized under the laws of Switzerland (the "Company"), we are responding to the comments from the Staff (the "Staff") of the Securities and Exchange Commission (the "Commission") relating to the Company's confidential draft Registration Statement on Form F-1 (the "Registration Statement") contained in the Staff's letter dated April 14, 2014 (the "Comment Letter"). In response to the comments set forth in the Comment Letter, the Company has revised the Registration Statement and is confidentially submitting a revised draft of the Registration Statement together with this response letter. The revised draft of the Registration Statement also contains certain additional updates and revisions. We are also sending, under separate cover, a copy of the revised draft of the Registration Statement (including exhibits) and three marked copies of the Registration Statement showing the changes to the Registration Statement confidentially submitted on March 18, 2014.

Set forth below are the Company's responses to the Staff's comments. For convenience, the Staff's comments are repeated below in italics, followed by the Company's response to the comments as well as a summary of the responsive actions taken. We have included page numbers to refer to the location in the revised draft of the Registration Statement submitted herewith where the revised language addressing a particular comment appears.

# 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.

# Response:

The Company will file all exhibits as soon as practicable and acknowledges that the Staff may have further 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.

#### Response:

The Company does not currently intend to include any additional graphic, visual or photographic information in the printed prospectus. However, if and to the extent that additional artwork or graphics are to be included, the Company will promptly provide such material to the Staff on a supplemental basis.

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.

## Response:

The Company acknowledges the Staff's request and undertakes to comply with it as applicable. The Company will supplementally provide the Staff with written materials provided during presentations to potential investors in reliance on Section 5(d) of the Securities Act.

To the Company's knowledge, to date, no broker or dealer that is participating or will participate in the Company's initial public offering has published or distributed a research report in reliance upon Section 2(a)(3) of the Securities Act.

# 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"

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 1 and 2 of the revised draft of the Registration Statement.

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.

**Response:** In response to the Staff's comment, the Company has revised the product development table on pages 2 and 69 of the revised draft of the Registration Statement to remove the reference to product development for this indication.

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 2 and 78 of the revised draft of the Registration Statement.

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 1 of the revised draft of the Registration Statement.

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 1 of the revised draft of the Registration Statement.

9. Please explain what you mean by the term "system exposure" and describe why intratympanic injection allows for minimal system exposure.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 1 of the revised draft of the Registration Statement.

#### Risks Associated with Our Business, page 3

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

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 3 of the revised draft of the Registration Statement.

# <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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 4 of the revised draft of the Registration Statement.

#### Risk Factors

Risks Related to the Development and Clinical Testing of our Product Candidates

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 14, 72, 74 and 79 of the revised draft of the Registration Statement.

#### 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.

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 16 of the revised draft of the Registration Statement to reflect that the Company purchases insurance for each of its clinical trials.

## 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.

Response:

In response to the Staff's comment, the Company has revised the disclosure pages 19 and 20 of the revised draft of the Registration Statement. The Company respectfully advises the Staff that the FDA has not expressed any specific safety concerns in its correspondence with the Company.

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

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.

**Response:** In resp

In response to the Staff's comment, the Company has revised the disclosure on pages 20 and 21 of the revised draft of the Registration Statement.

#### 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.

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Response:

In response to the Staff's comment, the Company has revised the disclosure pages 25 and 26 of the revised draft of the Registration Statement. The Company will update its disclosure to include the material rights and obligations under its agreement with Xigen in a future filing.

#### 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 30 of the revised draft of the Registration Statement.

## Risks Related to the Offering and our Common Shares

# 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.

Response:

In response to the Staff's comment, the Company has revised the disclosure on pages 40 and 41 of the revised draft of the Registration Statement.

## 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.

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 43 of the revised draft of the Registration Statement by deleting these statements.

# Use of Proceeds, page 43

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

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**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 45 of the revised draft of the Registration Statement.

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.

**Response:** In response to the Staff's comment, the Company has revised the table on page 49 of the revised draft of the Registration Statement.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Financial Operations Overview

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.

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 54 of the revised draft of the Registration Statement. The Company respectfully advises the Staff that project costs prior to 2012 were not classified as research and development expense in accordance with IFRS and hence are not available since inception on a candidate by candidate basis in a consistent manner.

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 63 of the revised draft of the Registration Statement.

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.

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Response:

The Company respectfully acknowledges that the Staff may have further comments on our accounting for stock compensation or any beneficial conversion features once we have disclosed an estimated offering price. The Company will disclose the information requested by the Staff when the estimated offering price is determined.

#### **Business**

# Market, page 65

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

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 68 of the revised draft of the Registration Statement.

# 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 71 of the revised draft of the Registration Statement.

#### 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 73 of the revised draft of the Registration Statement.

# **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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 79 of the revised draft of the Registration Statement.

#### **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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 84 and 85 of the revised draft of the Registration Statement.

## 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.

**Response:** The Company

The Company respectfully acknowledges the Staff's comment and will disclose the material rights and obligations under the INSERM agreement in a future filing. The Company will submit a copy of this agreement with the revised draft of the Registration Statement. We are also submitting to the Staff a request for confidential treatment with regard to certain terms in the agreement.

# 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.

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Response:

The Company respectfully acknowledges the Staff's comment and will disclose the material rights and obligations under the Xigen agreement in a future filing. The Company will submit a copy of this agreement in a future filing.

# 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.

# Response:

The Company respectfully submits that it is not required to file its agreement with Lifecore. Item 601(b)(10)(i) states that "material" contracts, if not in the ordinary course, must be filed. Accordingly, for contracts outside the ordinary course, the appropriate standard is whether the contract is material. However, under Item 601(b)(10)(ii), registrants need not file a contract if "the contract is such as ordinarily accompanies the kind of business conducted by the registrant," unless it falls into one or more of the categories specified therein.

We would note that the Lifecore agreement is one that ordinarily accompanies the business of the Company, and thus only needs to be filed if within one of the specified categories referred to in Item 601(b)(10)(ii). The only potentially relevant category is (B), which requires the filing of any contract "upon which the registrant's business is substantially dependent."

The Company's business is not "substantially dependent" on the Lifecore agreement as evidenced by the fact that, while the Company currently has a supply contract only with Lifecore, there are other suppliers of hyaluronic acid with which the Company has had, and may in the future have, agreements to procure such material. For example, the Company has sourced hyaluronic acid from other manufacturers, such as Genzyme, in the past [\*\*\*Redacted\*\*\*]. Accordingly, because the Company is not "substantially dependent" on the Lifecore agreement, such agreement is not required to be filed pursuant to Item 601(b)(10)(ii) We have revised the disclosure on pages 28 and 86 to remove the references to Lifecore.

#### Properties, page 90

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

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Response:

In response to the Staff's comment, the Company will submit a translated copy of the lease agreement with the revised draft of the Registration Statement.

#### <u>Management</u>

#### 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.

**Response:** 

In response to the Staff's comment, the Company has revised the disclosure on page 97 of the revised draft of the Registration Statement.

The Company respectfully does not believe that it is required to file its employment agreements with Thomas Meyer, Jürgen Heitmann, Bettina Stubinski and Sven Zimmermann ("Management Employment Agreements").

Item 601(b)(10)(iii)(A) of Regulation S-K generally requires to be filed any management contract or equity compensation plan in which any director or any of the named executive officers participates and any other management contract or any other compensatory plan in which any other executive officer of the registrant participates unless immaterial in amount or significance.

Although Item 601(b)(10)(iii)(A) would cover the Management Employment Agreements, pursuant to Item 601(b)(10)(iii)(C)(5), this requirement does not apply to a registrant that is a foreign private issuer that furnishes compensatory information under Item 402(a)(1), and the public filing of the plan, contract or arrangement is not required in the registrant's home country and is not otherwise publicly disclosed by the registrant. The Company is relying on the compensatory disclosure requirements of Item 402(a)(1) and has been advised by Swiss counsel that no public filing of these agreements is required in Switzerland and has not otherwise publicly disclosed these agreements. Therefore the Management Employment Agreements are not required to be filed under Item 601(b)(10)(iii)(A).

# Stock Options Plans, page 94

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

Response:

The Company will submit the Plan A and Plan C stock option plans with the revised draft of the Registration Statement.

The Company respectfully does not believe that it is required to file Stock Option Plan B ("Plan B").

Under Item 601 of Regulation S-K, stock option plans must be filed if they fall under either of the two following categories:

- Item 601(b)(10)(iii)(A) generally requires to be filed any equity compensation plan in which any director or any of the named
  executive officers participates and any other compensatory plan in which any other executive officer of the registrant participates
  unless immaterial in amount or significance; or
- Item 601(b)(10)(iii)(B) generally requires to be filed any equity compensation plan adopted without the approval of security holders unless the plan is immaterial in amount or significance.

Pursuant to Item 601(b)(10)(iii)(C)(5), the requirement of Item 601(b)(10)(iii)(A) does not apply to a registrant that is a foreign private issuer that furnishes compensatory information under Item 402(a)(1), and the public filing of the plan is not required in the registrant's home country and is not otherwise publicly disclosed by the registrant. The Company is relying on the compensatory disclosure requirements of Item 402(a) (1) and has been advised by Swiss counsel that no public filing of its stock option plans is required in Switzerland and has not otherwise publicly disclosed these plans. Therefore, the Company's stock option plans are not required to be filed under Item 601(b)(10)(iii)(A).

The Company believes that Plan B need not to be filed pursuant to Item 601(b)(10)(iii)(B) because it is immaterial in amount and significance. Under Plan B, only 72,350 options were granted, the last of which were granted in 2009, and there are no outstanding options.

# 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 99 of the revised draft of the Registration Statement.

# Indemnification Agreements, page 97

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

**Response:** The Company confirms that it will file the form of the indemnification agreement with a future submission of the Registration Statement.

#### 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.

**Response:** In response to the Staff's comment, the Company respectfully informs the Staff that it will revise its disclosure to include the information required by Item 10.B of Form 20-F in a future submission of the Registration Statement.

#### 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

**Response:** The Company confirms the lock-up agreement will be filed as part of the underwriting agreement with a future submission of the Registration Statement.

# 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 112 of the revised draft of the Registration Statement.

# 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.

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**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 129 of the revised draft of the Registration Statement.

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page F-20 of the revised draft of the Registration Statement.

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Please do not hesitate to contact me at (212) 450-4674, (212) 701-5674 (fax) or richard.truesdell@davispolk.com if you have any questions regarding the foregoing or if I can provide any additional information.

Very truly yours,

/s/ Richard D. Truesdell, Jr.

Richard D. Truesdell, Jr.

cc: <u>Via E-mail</u>

Mr. Thomas Meyer, Chief Executive Officer Mr. Sven Zimmermann, Chief Financial Officer Auris Medical AG